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APPLICATION NO.	ISSUE DATE	PATENT NO.
17/865,266	11-Jul-2023	11697012

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,266	07/11/2023	11697012	111552-8016.US04	6816

25096 7590 06/21/2023

PERKINS COIE LLP - SEA General
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P.O. BOX 1247
SEATTLE, WA 98111-1247

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

Benjamin E. Merritt, San Clemente, CA;
John C. Thress, Capistrano Beach, CA;
Paul Lubock, Monarch Beach, CA;

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Inari Medical, Inc., Irvine, CA;

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8016.US4

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	229.	20160262790	09-15-2016	Rosenbluth et al.	
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	232.	20170014560	01-19-2017	Minskoff et al.	
	233.	20170037548	02-09-2017	Lee	
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	235.	20170058623	03-02-2017	Jaffrey et al.	
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Change(s) applied to document, /C.L./ 11/30/2022

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	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8016.US4

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	196.	20150088190	03-26-2015	Jensen	
	197.	20150127035	05-07-2015	Trapp et al.	
	198.	20150133990	05-14-2015	Davidson	
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	204.	20150196380	07-16-2015	Berrada et al.	
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	217.	20160022293	01-28-2016	Dubrul et al.	
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Change(s) ~~applied~~ to document, /C.L./ 11/30/2022

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	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8016.US4

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	162.	20130345739	12-26-2013	Brady et al.	
	163.	20140005712	01-02-2014	Martin	
	164.	20140005713	01-02-2014	Bowman	
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	166.	20140005717	01-02-2014	Martin et al.	
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	174.	20140155980	06-05-2014	Turjman	
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	178.	20140243882	08-28-2014	Ma	
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	180.	20140276403	09-18-2014	Follmer et al.	
	181.	20140318354	10-30-2014	Thompson et al.	
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	183.	20140330286	11-06-2014	Wallace et al.	
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Change(s) applied to document,
/C.L/
11/30/2022

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Doc code: IDS
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	First Named Inventor	Benjamin E. Merritt
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8016.US4

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	135.	20120089216	04-12-2012	Rapaport et al.	
	136.	20120101480	04-26-2012	Ingle et al.	
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	138.	20120138832	06-07-2012	Townsend	
	139.	20120143239	06-07-2012	Aklog et al.	
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	146.	20120277788	11-01-2012	Cattaneo	
	147.	20120310166	12-06-2012	Huff	
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	153.	20130102996	04-25-2013	Strauss	
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Change(s) applied to document,
/C.L/
11/30/2022

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Q.N.V./

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Benjamin E. Merritt et al.

Application No.: 17/865,266	Confirmation No.: 6816
Filed: July 14, 2022	Art Unit: 3783
For: HEMOSTASIS VALVES AND METHODS OF USE	Examiner: Quynh-Nhu Hoang Vu

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In the Notice of Allowability mailed April 27, 2023, the Examiner allowed claims 1–9. The Applicant acknowledges Examiner's statements of Reasons for Allowance of the above-referenced patent application and agrees that the claimed subject matter is patentable. However, the Applicant takes no position regarding the Reasons for Allowance presented by the Examiner other than the positions the Applicant may have previously taken during prosecution. Therefore, the Examiner's Reasons for Allowance should not be attributed to the Applicant as an indication of the basis for Applicant's belief that the claims are patentable. Furthermore, the Applicant respectfully asserts that there may also be additional reasons for patentability of the claimed subject matter not explicitly stated in this record and the Applicant does not waive its rights to such arguments by not further addressing such reasons herein.

Dated: ___May 25, 2023_____

Respectfully submitted,

By _/Matthew S. Williams/_____
Matthew S. Williams
Registration No.: 77,516

Perkins Coie LLP
P.O. Box 1247
Seattle, WA 98111-1247
Phone: (206) 359-3343
Fax: (206) 359-7198

Attorney for Applicant

UNITED STATES
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Alexandria, VA 22313 - 1450
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/865,266	05/25/2023 03:01:13 PM ET	111552-8016.US04

Title of Invention

HEMOSTASIS VALVES AND METHODS OF USE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6816	FILED BY	JiYoung Anderson
PATENT CENTER #	62156143	AUTHORIZED BY	Matthew Williams
CUSTOMER #	25096	FILING DATE	07/14/2022
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Benjamin E. Merritt

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 3369	E20235OF02288624	JiYoung Anderson

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1501	UTILITY ISSUE FEE	1200.00	1	1200.00
			TOTAL AMOUNT:	$1,200.00

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If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage

submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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Alexandria, VA 22313-1450

By fax, send to: (571) 273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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25096
Perkins Coie LLP
P.O. Box 1247
PATENT - SEA
Seattle, WA, 98111-1247
US

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

JiYoung Anderson	(Typed or printed name)
/JiYoung Anderson/	(Signature)
2023-05-25	(Date)

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
17/865,266	July 14, 2022	Benjamin E. Merritt	111552-8016.US04	6816

TITLE OF INVENTION: HEMOSTASIS VALVES AND METHODS OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
UTILITY	LARGE	1200	0	0	1200	2023-07-27

EXAMINER	ART UNIT	CLASS-SUBCLASS
Quynh-Nhu Vu		-

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363)

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. Perkins Coie LLP
2.
3.

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Inari Medical, Inc.

(B) RESIDENCE: (CITY and STATE or COUNTRY): Irvine, CA

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☑ Corporation or other private group entity ☐ Government

4a. Fees Submitted: ☑ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment (*Please first reapply any previously paid fee shown above*):

☑ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 50-0665

5. Change of Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29. NOTE: Absent a valid Certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

☐ Applicant asserting small entity status. See 37 CFR 1.27. NOTE: If the application was previously under micro entity status, checking this box will be taken as a notification of loss of entitlement to micro entity status.

☐ Applicant changing to regular undiscounted fee status. NOTE: Checking this box will be taken as a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Matthew S. Williams/ Date 2023-05-25

Typed or printed name Matthew S. Williams Registration No. 77,516

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The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/865,266	**05/25/2023 03:01:13 PM ET**	**111552-8016.US04**

Title of Invention

HEMOSTASIS VALVES AND METHODS OF USE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6816	FILED BY	JiYoung Anderson
PATENT CENTER #	62156143	FILING DATE	07/14/2022
CUSTOMER #	25096	FIRST NAMED INVENTOR	Benjamin E. Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-5-25 Issue Fee Trans - 111552-8016US4.PDF	2	Issue Fee Payment (PTO-85B)	252 KB
2023-5-25 Comment - 111552-8016US4.PDF	2	Miscellaneous Incoming Letter	74 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-5-25 Issue Fee Trans - 111552-8016US4.PDF	19EF3673DCD752BDDFBE26D9314770E4FE4A26DD3E73587B59E041789565B28D8DB114AF01D8A140B02D63E1AAD5ADAA

B5BABA1022EB591E62669010C1868566

2023-5-25 Comment - 111552-8016US4.PDF	3100B0EE1715349FADEAD35D04C010E709D1CE36F4D5D32A9C7A874977F3EE41C1D3305816D7FDA3BBB51B1091AFFBF8BE125F7E2E40534C1D8EFB388AD789AA

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,266	07/14/2022	Benjamin E. Merritt	111552-8016.US04	6816

25096 7590 05/12/2023

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER
VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
05/12/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentprocurement@perkinscoie.com

Response to Rule 312 Communication	Application No.	Applicant(s)	
	17/865,266	Merritt et al.	
	Examiner	Art Unit	AIA (FITF) Status
	QUYNH-NHU H VU	3783	Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☑ The amendment filed on 02 May 2023 under 37 CFR 1.312 has been considered, and has been:

a) ☐ entered.

b) ☑ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.

Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

f) ☐ not entered because the supplemental or corrected Application Data sheet (ADS)

☐ was not accompanied by a petition to accept an unintentionally delayed claim under 37 CFR 1.55 or 27 CFR 1.78;

☐ did not identify the information being changed in accordance with 37 CFR 1.76(c)(2);

☐ was not properly signed in accordance with 37 CFR 1.76(e) (or 37 CFR 1.33(b) for applications filed prior to September 16, 2012).

———

/QUYNH-NHU H. VU/
Primary Examiner, Art Unit 3783

OK TO ENTER: /Q.N.V./ 05/04/2023

Docket No. 111552.8016.US04
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Benjamin E. Merritt et al.

Application No.: 17/865,266 | Confirmation No.: 6816

Filed: July 14, 2022 | Art Unit: 3783

For: HEMOSTASIS VALVES AND METHODS OF USE | Examiner: Quynh-Nhu Hoang Vu

AMENDMENT AFTER ALLOWANCE UNDER 37 C.F.R. § 1.312

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

The Applicant respectfully requests entry of this amendment under 37 C.F.R. § 1.312 for the above-identified U.S. patent application prior to issuance of the patent.

Amendments to the Specification begin on page 2.

Remarks begin on page 3.

AMENDMENTS TO THE SPECIFICATION

Please amend the specification as follows:

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 17/705,189, filed on March 25, 2022, entitled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. Patent Application No. 17/226,318, filed on April 9, 2021, entitled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. Patent Application No. 16/117,519, filed on August 30, 2018, now issued as U.S. Patent No. 11,000,682, and entitled "HEMOSTASIS VALVES AND METHODS OF USE," which claims the benefit of U.S. Provisional Patent Application No. 62/554,931, filed on September 6, 2017, and entitled "HEMOSTASIS VALVES AND METHODS OF USE," each of which is herein incorporated by reference in its entirety.

REMARKS

In this Amendment, the specification has been amended to correct the priority claim information. The continuity information was missing in the Cross-Reference to Related Applications filed on July 14, 2022. The Applicant confirms that the Application Data Sheet on file is correct which corresponds with this amendment. No new matter has been added.

Please charge any underpayment or credit any overpayment to our Deposit Account No. 50-0665, under Order No. 111552-8016.US04 from which the undersigned is authorized to draw.

Dated: May 2, 2023

Respectfully submitted,

By __/Matthew S. Williams/____
Matthew S. Williams
Registration No.: 77,516

Perkins Coie LLP
P.O. Box 1247
Seattle, WA 98111-1247
Phone: (206) 359-3258
Fax: (206) 359-7198

Attorney for Applicant

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Benjamin E. Merritt et al.	
Application No.: 17/865,266	Confirmation No.: 6816
Filed: July 14, 2022	Art Unit: 3783
For: HEMOSTASIS VALVES AND METHODS OF USE	Examiner: Quynh-Nhu Hoang Vu

AMENDMENT AFTER ALLOWANCE UNDER 37 C.F.R. § 1.312

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

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Dated: May 2, 2023

Respectfully submitted,

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Matthew S. Williams
Registration No.: 77,516

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P.O. Box 1247
Seattle, WA 98111-1247
Phone: (206) 359-3258
Fax: (206) 359-7198

Attorney for Applicant

UNITED STATES
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/865,266	**05/02/2023 06:45:39 PM ET**	**111552-8016.US04**

Title of Invention

HEMOSTASIS VALVES AND METHODS OF USE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6816	FILED BY	JiYoung Anderson
PATENT CENTER #	62026102	FILING DATE	07/14/2022
CUSTOMER #	25096	FIRST NAMED INVENTOR	Benjamin E. Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-5-2 Amendment After Allowance - 111552-8016US4.PDF	3	Amendment after Notice of Allowance (Rule 312)	82 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-5-2 Amendment After Allowance - 111552-8016US4.PDF	FCD059AFED7FA1E5538D2EF826A66E8930E445CEBE57D3705 0EF45F57138D019C59AC416B8DBBDD3FE20095E4D2928DB61 E4617B4F1F44F806C83A2584F3AF76

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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NOTICE OF ALLOWANCE AND FEE(S) DUE

25096 7590 04/27/2023

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER
VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
3783	

DATE MAILED: 04/27/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,266	07/14/2022	Benjamin E. Merritt	111552-8016.US04	6816

TITLE OF INVENTION: HEMOSTASIS VALVES AND METHODS OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	07/27/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

25096 7590 04/27/2023
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,266	07/14/2022	Benjamin E. Merritt	111552-8016.US04	6816

TITLE OF INVENTION: HEMOSTASIS VALVES AND METHODS OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	07/27/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
VU, QUYNH-NHU HOANG	3783	604-167030

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via Patent Center or EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,266	07/14/2022	Benjamin E. Merritt	111552-8016.US04	6816

25096 7590 04/27/2023

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	**PAPER NUMBER**
3783	

DATE MAILED: 04/27/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/865,266	Applicant(s) Merritt et al.	
	Examiner QUYNH-NHU H VU	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to IDS 01/31/23 & 03/28/23.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-9 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/QUYNH-NHU H. VU/
Primary Examiner, Art Unit 3783

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/865,266	Merritt et al.
	Examiner	Art Unit
	QUYNH-NHU H VU	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	08/30/2022	11/08/2022							
	1	÷	=							
	2	÷	=							
	3	÷	=							
	4	÷	=							
	5	÷	=							
	6	÷	=							
	7	÷	=							
	8	÷	=							
	9	÷	=							

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/865,266	Merritt et al.
	Examiner	**Art Unit**
	QUYNH-NHU H VU	3783

CPC							
Symbol						**Type**	**Version**
A61M	/	39	/	0613		F	2013-01-01
A61B	/	17	/	3207		A	2013-01-01
A61M	/	2039	/	0673		A	2013-01-01
A61M	/	2039	/	062		A	2013-01-01

CPC Combination Sets								
Symbol						**Type**	**Set**	**Ranking**	**Version**
	/		/						

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	9	
/QUYNH-NHU H. VU/ Primary Examiner, Art Unit 3783	23 April 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20230410

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/865,266	Merritt et al.
	Examiner	**Art Unit**
	QUYNH-NHU H VU	3783

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61M	/	39	/	06

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	9	
/QUYNH-NHU H. VU/ Primary Examiner, Art Unit 3783	23 April 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

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☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1														
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	3														
	4														
	5														
	6														
	7														
	8														
	9														

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	9	
/QUYNH-NHU H. VU/ Primary Examiner, Art Unit 3783	23 April 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office Part of Paper No.: 20230410

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/865,266	Merritt et al.
	Examiner	Art Unit
	QUYNH-NHU H VU	3783

CPC - Searched*		
Symbol	Date	Examiner
A61M2039/0673 OR A61M39/0613 OR A61M2039/062 OR A61M2039/0626	11/07/2022	QNV

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
PE2E, Inventor, IDS, forward/backward searches	11/07/2022	QNV
updated search, IDS search	04/10/2023	QNV

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	all the above	11/08/2022	QNV

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	3783
	Examiner Name	Quynh-Nhu Hoang Vu
	Attorney Docket Number	111552-8016.US4

U.S. PATENTS and PUBLICATIONS

Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	20220346800	11-03-2022	Merritt et al.	
	2.	20220346813	11-03-2022	Quick	
	3.	20220346814	11-03-2022	Quick	
	4.	20220346801	11-03-2022	Merritt et al.	
	5.	6451036	09-17-2002	Heitzmann et al.	
	6.	20080234715	09-25-2008	Pesce et al.	
	7.	20110034986	02-10-2011	Chou et al.	
	8.	20190336142	11-07-2019	Torrie et al.	
	9.	20190239910	08-08-2019	Brady et al.	
	10.	20060217664	09-28-2006	Hattler et al.	
	11.	20170252057	09-07-2017	Bonnette et al.	
	12.	20170340867	11-30-2017	Accisano, II	
	13.	11457936	10-04-2022	Buck et al.	
	14.	11259821	03-01-2022	Buck et al.	
	15.	11439799	09-13-2022	Buck et al.	
	16.	20210315598	10-14-2021	Buck et al.	
	17.	11529158	12-20-2022	Hauser	
	18.	20220362512	11-17-2022	Quick et al.	
	19.	20220142638	05-12-2022	Enright et al.	
	20.	20220151647	05-19-2022	Dolendo et al.	
	21.	20220152355	05-19-2022	Dolendo et al.	
	22.	5653684	08-05-1997	Laptewicz et al.	
	23.	5908435	06-01-1999	Samuels	
	24.	4611594	09-16-1986	Grayhack et al.	
	25.	9827084	11-28-2017	Bonnette et al.	
	26.	20210137667	05-13-2021	Sonnette et al.	
	27.	20180256177	09-13-2018	Cooper et al.	
	28.	11013523	05-25-2021	Arad Hadar	
	29.	11406801	08-09-2022	Fojtik et al.	
	30.	11554005	01-17-2023	Merritt et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Q.N.V./

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	Examiner Name	Quynh-Nhu Hoang Vu
	Attorney Docket Number	111552-8016.US4

	31.	11559382	01-24-2023	Merritt et al.	
	32.	6818006	11-16-2004	Douk et al.	
	33.	9078682	07-14-2015	Lenker et al.	
	34.	20140052161	02-20-2014	Cully et al.	
	35.	20180042623	02-15-2018	Batiste	
	36.				

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.					
	2.					
	3.					
	4.					
	5.					
	6.					

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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	Attorney Docket Number	111552-8016.US4

EXAMINER SIGNATURE			
Examiner Signature	/QUYNH-NHU H. VU/	Date Considered	04/10/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

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	First Named Inventor	Benjamin E. Merritt
	Art Unit	3783
	Examiner Name	Quynh-Nhu Hoang Vu
	Attorney Docket Number	111552-8016.US4

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-01-31
Name/Print	Matthew S. Williams	Registration Number	77,516

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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U.S. PATENTS and PUBLICATIONS

Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	20180184912	07-05-2018	Al-Ali	
	2.	20160262774	09-15-2016	HONDA	
	3.	20120172918	07-05-2012	Fifer et al.	
	4.	20050054995	03-10-2005	Barzell et al.	
	5.	5421824	06-06-1995	Clement et al.	
	6.	20210236148	08-05-2021	Marchand et al.	
	7.	5158533	10-27-1992	Strauss et al.	
	8.	20230046775	02-16-2023	Quick	
	9.	20140188127	07-03-2014	Dubrul et al.	
	10.	20140074144	03-13-2014	Shrivastava et al.	
	11.	8535283	09-17-2013	Heaton et al.	
	12.	8753322	06-17-2014	Hu et al.	
	13.	8808259	08-19-2014	Walton et al.	
	14.	20230062809	03-02-2023	Merritt et al.	
	15.	20230070120	03-09-2023	Cox et al.	
	16.	20010031981	10-18-2001	Evans et al.	
	17.	20040102807	05-27-2004	Kusleika et al.	
	18.	6059814	05-09-2000	Ladd	
	19.				
	20.				
	21.				
	22.				
	23.				

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.	WO2006124307	11-23-2006	KERBEROS PROXIMAL SOLUTIONS, INC.		
	2.					

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Q.N.V./

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	13.		

EXAMINER SIGNATURE

Examiner Signature	/QUYNH-NHU H. VU/	Date Considered	04/10/2023

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[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	3783
	Examiner Name	Quynh-Nhu Hoang Vu
	Attorney Docket Number	111552-8016.US4

OR

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SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-03-28
Name/Print	Matthew S. Williams	Registration Number	77,516

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U.S. PATENTS and PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS						
Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.	WO2006124307	11-23-2006	KERBEROS PROXIMAL SOLUTIONS, INC.		
	2.					

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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CERTIFICATION STATEMENT

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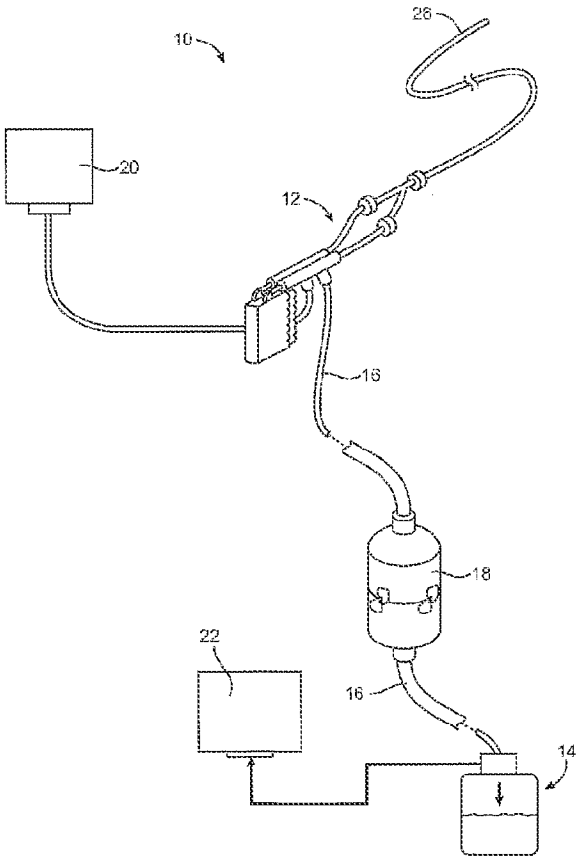
(54) Title: METHODS AND SYSTEMS FOR FILTERING ASPIRATED MATERIALS



(57) Abstract: Solid materials are separated from hollow body structure aspirates using a filter assembly disposed between an aspiration catheter and an aspirate receptacle. Filter elements having different pore or mesh sizes may be used to size classify the separated solid materials. Multiple filter assemblies may be disposed in parallel or series between the aspiration catheter and aspirate receptacle to provide for different levels of size classification.

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

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METHODS AND SYSTEMS FOR FILTERING ASPIRATED MATERIALS

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention. The present invention relates generally to medical apparatus and methods. More particularly, the present invention relates to a method and system for separating and optionally classifying solids removed from a patient in a fluid aspirate.

[0002] Aspiration is a part of many surgical procedures performed in various body structures and lumens. Blood and/or other natural body fluids may be aspirated from various hollow body structures, such as blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts, lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, the gastrointestinal tract, and the like. In some instances, aspiration is performed on a natural body fluid(s) only, while in many other instances, a liquid irrigant will be introduced which will form at least part of the aspirated fluid. Such irrigants may comprise saline or other biologically inert fluids. Alternatively, such irrigants may comprise biologically active agents, such as thrombolytic agents introduced to occluded blood vessels, antiseptic or antibiotic agents introduced to infected body locations, or the like.

[0003] Of particular interest to the present invention, fluids aspirated from any of these hollow body structures will often contain solid materials, such as cellular debris, damaged tissue, thrombus, or the like, which is aspirated together with the fluid. In many instances, such removed solid materials will have diagnostic or other value to a treating physician. For example, during aspiration, it may be desirable to monitor the solid materials which are being removed in order to decide when to terminate or alter or adjust the aspiration protocol. Additionally, the identification of the aspirated material may serve as a diagnostic tool to direct further intervention or other therapies.

[0004] While the collected materials may be observed in the aspirate collection bags which are commonly employed in such procedures, it will usually be difficult to remove the materials while additional aspirate is entering the collection bags and the solids will frequently remain suspended and difficult to separate from the collected materials.

[0005] For these reasons, it would be desirable to provide improved and additional systems and protocols for separating solid materials from liquid and fluid aspirates removed from a hollow body structure. It would be particularly desirable if the methods and protocols permitted direct observation and/or removal of the separated solid materials while an aspiration protocol was continuing. It would be further desirable if the separated solid materials were collected in a form substantially separated from a liquid fraction of the materials removed from the hollow body structure and further that the separated solid materials be in a convenient structure or assembly to permit easy removal and observation. In some instances, it would also be desirable to provide for classification of the solid materials, i.e. separation based on size, while the aspiration protocol was being performed. At least some of these objectives will be met by the inventions described and claimed hereinbelow.

[0006] 2. Description of the Background Art. Patient irrigation and aspiration systems which may employ the separation technology of the present application are described in commonly assigned U.S. Patent Nos. 6,827,701 and 6,878,128, the full disclosures of which are incorporated herein by reference.

BRIEF SUMMARY OF THE INVENTION

[0007] In a first aspect of the present invention, methods are provided for separating materials in fluid aspirates removed from a hollow body structure. The fluid is aspirated from the hollow body structure, where the fluid carries entrained solid materials in the aspirate. The solid materials are filtered from the fluid to produce both a filtrate and a fluid stream. The fluid stream is collected separately from the filtrate. In this way, the filtrate may be easily observed and optionally removed from the aspiration circuit even while the aspiration protocol continues.

[0008] The fluid may be aspirated from a variety of hollow body organs and other structures, including blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts, lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, joint capsules, the gastrointestinal tract, and the like. Thus, natural body fluids which may be aspirated according to the present invention include blood, bile, urine, synovial fluid, and the like. In addition to such natural body fluids, the hollow body structures may optionally be irrigated prior to and/or during aspiration. The introduction of irrigation fluid may improve debris capture through the aspiration channel by creating localized mixing / turbulence and possibly

decreasing the viscosity of the aspirant. Thus, the aspirated fluids may comprise or consist of a variety of irrigant fluids introduced to the hollow body structure. Suitable irrigant fluids include saline, lactated ringers, and the like. The irrigant fluids may further comprise active agents intended for therapeutic or diagnostic purposes. For example, in the case of occluded blood vessels, thrombolytic agents may be introduced as part of an irrigant stream. Alternatively, in the case of infected hollow body structures, the irrigant may include antibiotics, antiseptics, or the like.

[0009] Most typically, aspiration will be performed by introducing an aspiration catheter, cannula, or other tubular or needle-like device into the hollow body structure. By applying a vacuum to a proximal end of the aspiration device, the fluid may be withdrawn through a port or ports at or near the distal end of the device which has been placed within an interior region of the hollow body structure. For convenience, as used hereinafter and in the claims, the aspiration structure will be referred to as a "catheter," but it will be appreciated that this term is intended to be broad enough to encompass needles, cannulas, tubular structures, conduits, and other aspiration structures known in the medical art.

[0010] The aspirated fluids will usually be collected in an aspirate receptacle, such as a conventional fluid collection bag. A syringe, vacuum connection, or other conventional vacuum source may be connected at or through the catheter and/or the aspiration receptacle in order to aspirate the fluid from the hollow body structure, through the aspiration catheter, and into the aspirate receptacle. The filter(s) may be positioned before or after the aspiration source.

[0011] In a preferred aspect of the present invention, at least one filter assembly including a filter housing and a removable (and replaceable) filter element is placed between the aspiration catheter and the aspirate receptacle in order to remove solid materials from the aspirate before the remaining liquid phase of the aspirate flows to the aspirate receptacle. The filter element may be any conventional filter element, such as a paper, polymer, a woven filter membrane, a screen, other porous member, or the like. The filter element may have any one of a variety of geometries including cup-shaped, conical and the filter could be inclined or slanted in the filter-housing to spread the filtrate over the filter to permit differentiation of the filtrate material. Additionally, the filter element could be coated or otherwise combined with a chemical, biological, or other indication or marker to facilitate identification of different analytes or markers present in the filtrate, typically using colormetric indicating

systems. Preferably, the filter element will allow the separated solid materials to collect on an exposed surface so that the solid materials will be easily removed and/or absorbed. The filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff. For example, suitable filter membranes may have a pore size in the range from 1 μm to 1000 μm, usually from 5 μm to 240 μm, and preferably from 20 μm to 120 μm. For separation of larger particles, screens having mesh sizes in the range from 0.1mm to 5mm, and preferably from 0.2mm to 1mm may be used.

[0012] In a specific aspect of the methods of the present invention, at least two filter assemblies may be provided between the aspiration catheter and the aspirate receptacle. The two or more filter assemblies may be disposed in parallel, in series, or in a combination of parallel and series arrangements. Typically, valving will be provided so that the multiple filter assemblies may be isolated from the flowing stream of aspirate so that the filter elements may be removed and the collected solids observed even while the aspiration protocol continues. In some cases, an unfiltered bypass path will be provided with valving so that a single filter assembly or group of filter assemblies may be isolated while the aspirate is directed or shunted to the aspirate receptacle without any filtration.

[0013] In a further specific aspect of the methods of the present invention, two or more filter elements may be employed in series or in parallel in order to size classify the materials being removed. Most simply, two, three, or more filter elements having progressively smaller pore or mesh sizes may be provided in series in a single filter housing. Alternatively, such a series of progressively smaller filtering elements could be provided in separate filter assemblies which are disposed in series between the aspiration catheter and the aspirate receptacle. Alternatively, separate filter assemblies having filter elements with differing particle size cutoffs could be provided in parallel or in a series-parallel arrangement in order to separately collect and classify particles having different sizes. In any of these ways, the solid materials may be filtered and separated into at least two size groups, often at least three size groups, and into virtually any number of different sized collection groups desired.

[0014] In a second aspect of the present invention, systems for aspirating a hollow body structure comprise an aspiration catheter, an aspirate receptacle connectable to receive aspirate from the aspiration catheter, and at least one filter assembly disposed between the aspiration catheter and the aspirate receptacle. Typically, the aspirate receptacle will be a fluid collection bag, although any other conventional medical receptacle would be suitable.

The aspirate receptacle will typically be connected by a flexible tube between the aspiration catheter and the aspirate receptacle. Usually, a syringe, vacuum connector, or other conventional vacuum source will be provided in order to effect the system aspiration.

[0015] The filter assembly usually comprises at least one filter housing having at least one filter element removably disposed in an interior thereof. The filter element, as described above, may comprise a filter membrane, a mesh, link, or the like, having a pore or mesh size selected to collect and separate solids having a target threshold size or sizes. The filter housing and optionally filter element may be at least partially transparent to permit observation of the solid materials as they collect. In an exemplary embodiment, the filter housing has an upper shell and a lower shell which may be taken apart to permit introduction, removal, and replacement of the filter element in the interior of the housing. The housing will further have conventional connectors to permit connection at an upper end to the aspiration catheter and at a lower end to the aspirate receptacle.

[0016] The system may further comprise at least a second filter assembly, a third filter assembly, or even greater number of filter assemblies which may be disposed in parallel or series to the first filter assembly. Additionally, at least one unfiltered flow path may be provided in parallel to the filter assembly(ies), and valving will be provided to permit selective flow through any one or more of the filter assemblies as well as through the unfiltered flow path. The different filter assemblies may each have a filter element with a different pore or mesh size. Alternatively, two or more filter elements may be provided within a single filter assembly, where the individual filter elements within the individual assembly may optionally have different pore or mesh sizes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Fig. 1 illustrates an exemplary system including an irrigant source, an aspiration and irrigation catheter, a filter assembly, an aspirate receptacle, and a vacuum source, constructed in accordance with the principles of the present invention.

[0018] Fig. 2 illustrates an exemplary filter housing constructed in accordance with the principles of the present invention.

[0019] Figs. 3 and 4 illustrate two exemplary filter assembly connection patterns which may be employed in the apparatus and methods of the present invention.

[0020] Fig. 5 illustrates use of filter elements having different pore or mesh sizes disposed in series for classifying solid materials in accordance with the principles of the present invention.

[0021] Fig. 6 illustrates the use of filter elements having different pore or mesh sizes disposed in parallel for classifying solid material sizes in accordance with the principles of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0022] The present invention provides systems and methods for separating solid materials, typically particulate materials, from aspirated body fluids, including both natural body fluids and introduced fluids. As shown in Fig. 1, an exemplary system 10 comprises catheter 12 (move the arrow for 12 distal to the 2-line section) which is connected to an aspirate receptacle 14 by tubing 16. The catheter 12 is illustrated as an irrigation/aspiration catheter which is connectable to a source of irrigant fluid 20. Exemplary irrigation/aspiration catheters are described in commonly assigned U.S. Patent Nos. 6,827,701 and 6,878,128, both of which have been previously incorporated herein by reference. It will be appreciated, however, that the present invention does not require that the catheters 12 provide for irrigation, but rather only that they provide for aspiration and the ability to discharge a fluid aspirate stream to an aspirate collection receptacle.

[0023] The irrigation/aspiration catheter 12 illustrated in Fig. 1 and described in the copending U.S. patents incorporated above, provides for a pair of syringe elements for both introducing the irrigant fluid from the irrigant source 20 and discharging the aspirate stream to the aspirate receptacle 14. In other cases and for other aspiration catheters, it may be desirable to provide a separate vacuum source 22 which may be connected to or through the catheter 12 and/or aspirate receptacle 14 in order to draw the aspirate stream through the tubing 16 or other discharge connections. The present invention, of course, does not depend on what particular mechanism is provided for generating the aspirate stream or the location of the said mechanism with respect to the filter(s).

[0024] The catheter 12 has a distal end or portion 26 which is introducible into a target hollow body structure in order to withdraw fluid therefrom to produce the aspirate stream. In the preferred example of the irrigation aspiration catheter, described in the previously incorporated commonly owned U.S. patents, the catheter 12 will be intended for introduction

to a blood vessel for introducing a thrombolytic agent in order to disrupt clot. In this exemplary use, the solid material aspirated by the catheter will frequently comprise disrupted clot, thrombus, and/or plaque, which is then discharged through the aspirate line 16 to the aspirate receptacle. It will be appreciated, however, that the present invention is not limited to vascular use, clot disruption, or any other particular treatment protocol, and may instead extend to the different hollow body structures and body fluids described above.

[0025] In the simplest embodiment of the present invention, a single filter housing 18 is disposed between the aspiration catheter 12 and the aspirate receptacle 14, as illustrated in Fig. 1. As shown in Fig. 2, the filter assembly 18 typically comprises an upper shell 30, a lower shell 32, and a filter element 34 which may be disposed within the interior of the shells. The upper shell 30 is removable from the lower shell 32, typically including mating connectors 36 disposed about the open peripheries of each shell. All or a portion of the shells 30 and 32, as well as optionally the filter element 34, may be composed of transparent materials in order to permit observation of the collection of solids within the filter element 34 as the aspiration progresses. While the particular structure of filter assembly 18 shown in Fig. 2) is suitable and presently preferred, a variety of other specific filter assembly constructions could also be used.

[0026] The filter elements 34 may comprise any one of a variety of conventional filtering materials, as generally described above in the Summary of the Invention. The geometries in which the filter elements 34 are arranged will depend in large part on the construction of the remainder of the filter assembly. In the embodiment of Fig. 18, the filter element 34 is constructed so that it nests within the lower shell 32 of the filter assembly. A wide variety of other geometries would also be suitable.

[0027] In many instances, it will be desirable to provide two or more filter assemblies 18 between the aspiration catheter 12 and the aspirate receptacle 14. As illustrated in Fig. 3, a pair of filter assemblies 18 are disposed in parallel to receive the aspirate through an upper portion of tubing 16 and discharge the aspirate through a lower portion of tubing 16. Isolation valves 40 are provided so that either of the filter assemblies 18 may be taken off-line to permit access even while the aspiration continues. Optionally, as shown in broken line, a third filter assembly 18 may also be provided in parallel. It is clear that any number of such filter assemblies may be provided in parallel, although the valving may have to be

modified in order to permit any single one of the assemblies to be isolated while all others remain on line.

[0028] The filter assembly arrangement of Fig. 4 illustrates another arrangement within the scope of the present invention. A first filter assembly 18 may be provided and isolated by valves 40 in parallel with an unfiltered flow path 50 having a valve 52 therein. With this embodiment, all flow could be directed through the filter assembly 18 with valve 52 being closed. Should it be desired to gain access to filter 18, the isolation valves 40 could be closed and the flow path valve 52 open.

[0029] As a still further option, as shown in broken line in Fig. 4, additional filter assemblies 18 could be provided, with individual assemblies 18 being disposed in series, where the two series assemblies may be together placed in parallel with first filter assembly 18. It will be appreciated that a wide variety of different parallel and/or series arrangements of filter assemblies and unfiltered flow paths may be provided within the scope of the present invention.

[0030] Referring now to Figs. 5 and 6, it should also be appreciated that filter elements having different pore or mesh sizes may also be provided in series and/or in parallel in order to permit separation and classification of the particulate solid materials which are being separated from the flowing aspirate. For example, as shown in Fig. 5, three filter elements 70, 72, and 74 may be placed in series, with progressively smaller pore or mesh sizes in the direction of flow. Thus, all particles having a size greater than a first threshold would collect on top of the first filter element 70, while intermediate particle sizes having a smaller threshold size would collect on the second filter element 72. Still smaller particles would collect on the third filter element having the smallest pore or mesh sizes, while still smaller particles would pass into the aspirate receptacle without separation. The three filter elements 70, 72, and 74 could be arranged within a single filter housing or alternately within a series of three filter housings.

[0031] The filter elements 70, 72, and 74 could also be arranged in parallel, as shown in Fig. 6. Each of the screens would collect particles having a size greater than the threshold pore or mesh size of the filter element. Such a parallel arrangement of the different sized filter elements, however, would not result in true size classification, since each of the filters would collect the larger elements and would only allow smaller elements to selectively pass. This configuration would allow the use of indicator media which would be placed in the

filter(s). This indicator(s) could detect the presence of a certain biological or chemical components in the aspirant or filtered solids for the diagnostic purposes.

[0032] The collected elements could be used for a variety of therapeutic purposes. For example, when collecting aspirated thrombus in thrombolytic procedures,

[0033] The collected material could be used to diagnose certain disease states or conditions. These diagnostic findings could then be used to direct further interventions and/or treatments.

[0034] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. A method for separating materials removed from a hollow body structure, said method comprising:

aspirating a fluid from the hollow body structure, wherein solid materials from the hollow body structure are entrained in the aspirate;

filtering solids from the aspirate to produce a filtrate and a fluid stream; and

collecting the fluid stream separately from the filtrate.

2. A method as in claim 1, wherein aspirating the fluid comprises introducing an aspiration catheter in the hollow body structure.

3. A method as in claim 1, wherein filtering comprises interposing at least one filter assembly including a filter housing and a removable filter element between the aspiration catheter and an aspirate receptacle.

4. A method as in claim 3, further comprising removing the filter element from the housing to permit inspection of solids collect by the filter element.

5. A method as in claim 4, wherein the filter element is removed while aspirate continues to flow from the aspiration catheter to the aspirate receptacle.

6. A method as in claim 5, wherein the aspirate flow is directed past the filter assembly while the filter element is removed.

7. A method as in claim 6, wherein the aspirate is directed past the filter assembly through at least a second filter assembly disposed in parallel to the first filter assembly.

8. A method as in claim 6, wherein the aspirate is directed past the filter assembly through an unfiltered flow path disposed in parallel to the filter assembly.

9. A method as in claim 1, wherein filtering comprises separating the solids into at least two size groups.

10. A method as in claim 1, wherein filtering comprises separating the solids into at least three size groups.

11. A method as in claim 1, wherein filtering comprises passing the fluid through at least two filter elements, wherein said filter elements have different pore sizes.

12. A method as in claim 11, wherein the at least two filter elements are arranged in series.

13. A method as in claim 11, wherein the at least two filter elements are arranged in parallel.

14. A method as in claim 1, wherein the hollow body structure is selected from the group consisting of blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts, lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, and gastrointestinal tracts.

15. A method as in claim 14, wherein the hollow body structure is an artery.

16. A method as in claim 15, wherein the artery is a coronary artery, a peripheral artery, or a cerebral artery.

17. A method as in claim 14, wherein the hollow body structure is a vein.

18. A method as in claim 17, wherein the vein is a peripheral vein.

19. A method as in claim 1, further comprising introducing an irrigation fluid to the hollow body structure, wherein at least a portion of the aspirated fluid comprises the irrigation fluid.

20. A method as in claim 19, wherein aspirating and introducing the irrigation fluid are performed with an irrigation and aspiration catheter positioned in the hollow body structure.

21. A method as in claim 19, wherein the irrigation fluid comprises saline.

22. A method as in claim 1, wherein the irrigation fluid comprises a biologically active agent.

23. A method as in claim 22, wherein the biologically active agent comprises a thrombolytic agent.

24. A system for aspirating a hollow body structure, said system comprising:

an aspiration catheter;

an aspirate receptacle connectable to receive aspirate from the aspiration catheter;

at least one filter assembly disposed between the aspiration catheter and the aspirate receptacle.

25. A system as in claim 24, wherein the aspirate receptacle is a fluid collection bag.

26. A system as in claim 24, further comprising a flexible tube connecting the aspiration catheter to the aspirate receptacle, wherein the filter housing is connected to the flexible tube between the catheter and the receptacle.

27. A system as in claim 24, wherein the filter assembly comprises:

at least one filter housing; and

at least one filter element removably disposed in the filter housing to separate solids from aspirate flowing from the irrigation and aspiration catheter to the aspirate receptacle.

28. A system as in claim 26, wherein the filter housing is at least partly transparent to allow observation of the filter contents.

29. A system as in claim 26, wherein the filter housing comprises an upper shell and a lower shell, wherein the upper shell and lower shell are separable to provide access to the filter element in an interior of the filter housing.

30. A system as in claim 27, further comprising at least a second filter assembly disposed in parallel and/or series to the first filter assembly between the irrigation and aspiration catheter and the aspirate receptacle, and valving to permit selective diversion of aspirate flow through either filter assembly.

31. A system as in claim 30, wherein the second filter assembly has a filter element with a pore size different from that of the first filter assembly.

32. A system as in claim 27, wherein the filter assembly includes at least two filter elements, wherein at least one of said filter elements has a different pore size than that of another filter element.

33. A system as in claim 27, further comprising at least one flow path in parallel to the filter assembly, and valving to permit selective bypass of the filter assembly.

34. A system as in claim 24, wherein the aspiration catheter comprises a catheter shaft having at least one irrigation lumen, at least one aspiration lumen, at least one irrigation port near a distal end of the shaft, and at least one aspiration port near said distal end.

35. A system as in claim 34, wherein the distal end of the shaft is free from isolation balloons.

36. A system as in claim 35, wherein the distal end of the shaft includes at least one isolation balloon disposed proximally of the irrigation and aspiration ports.

37. A system as in claim 34, wherein the distal end of the shaft includes at least a second isolation balloon disposed proximally of the irrigation and aspiration ports.

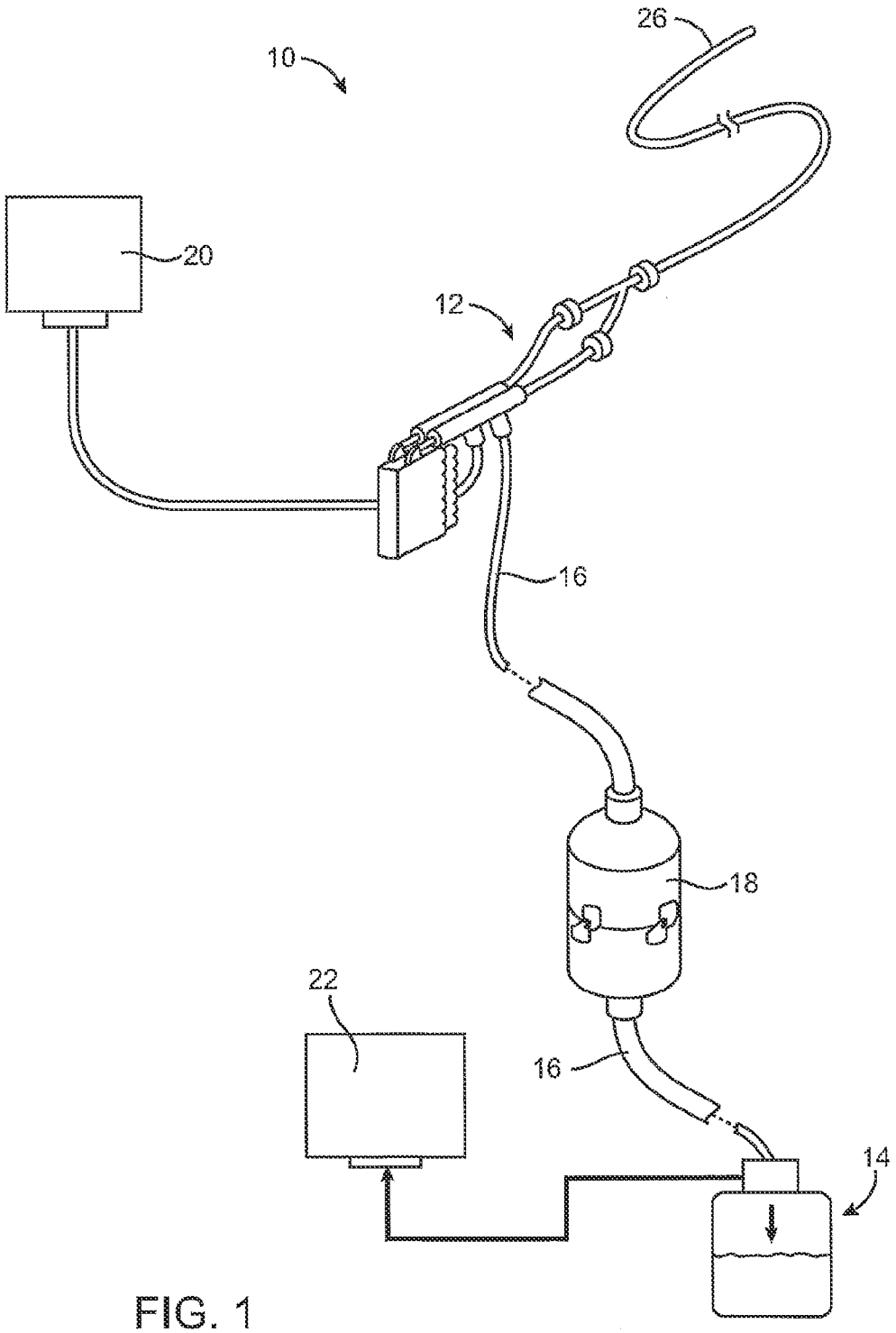

FIG. 1

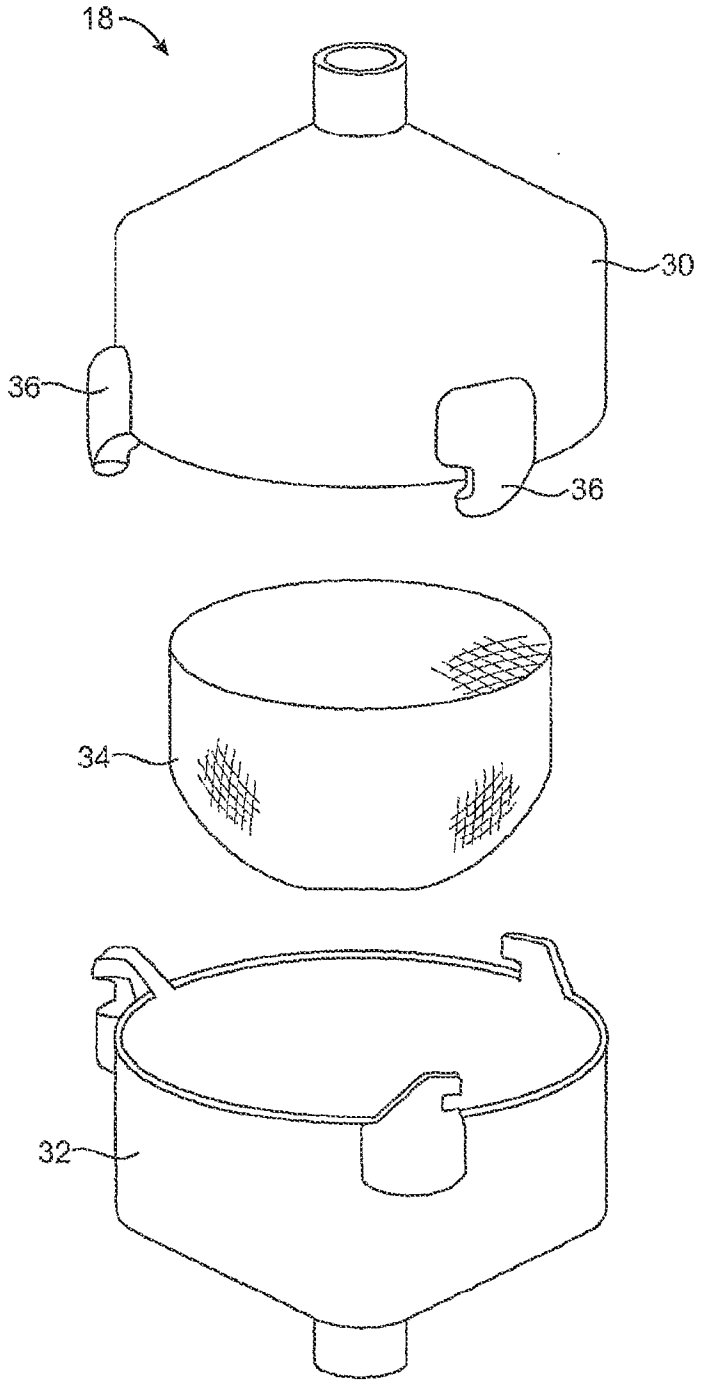

FIG. 2

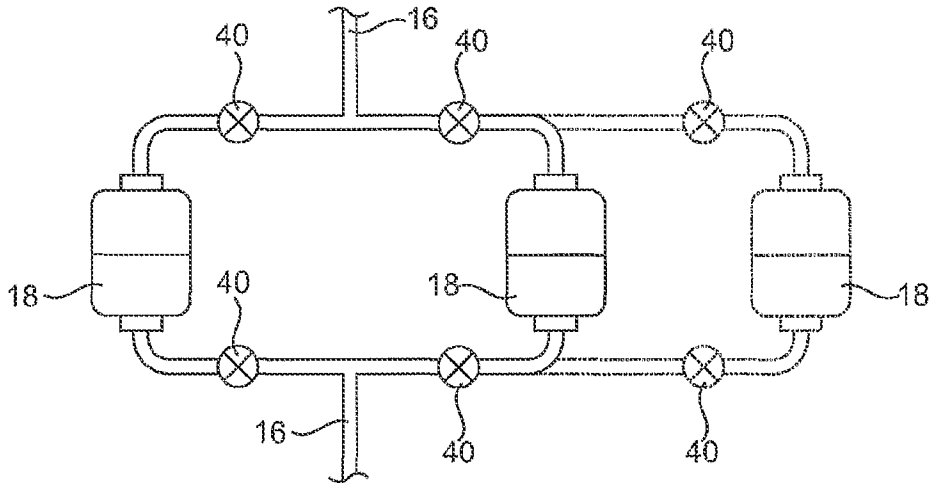

FIG. 3

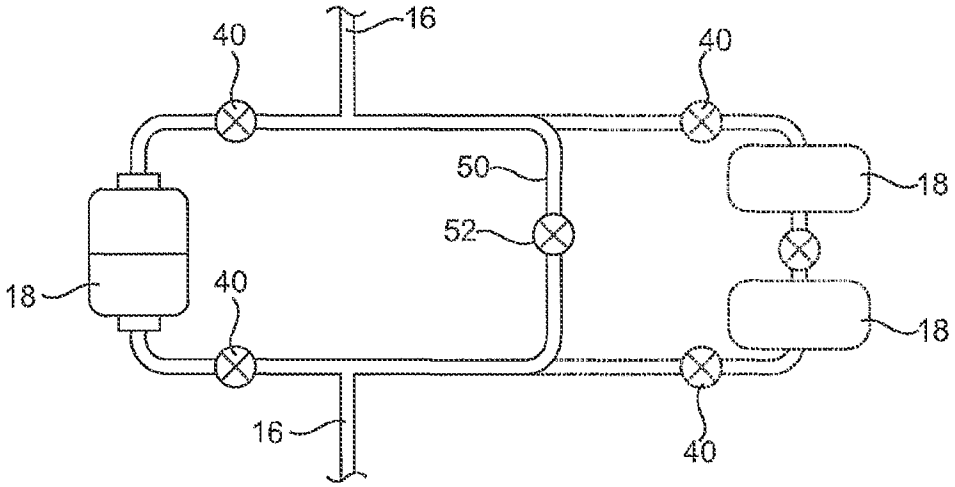

FIG. 4

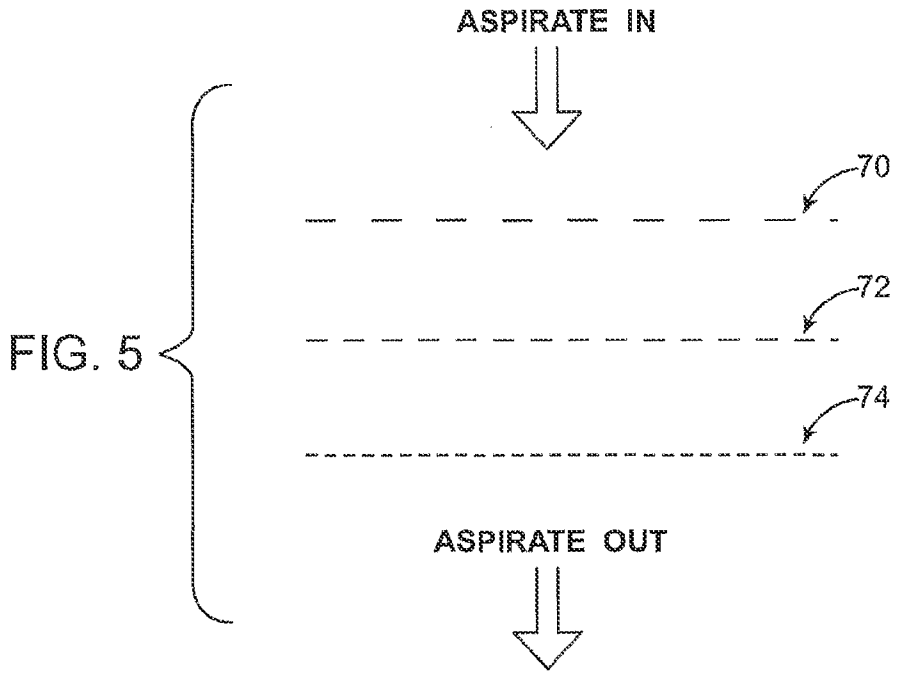
ASPIRATE IN
70
72
74
ASPIRATE OUT

FIG. 5

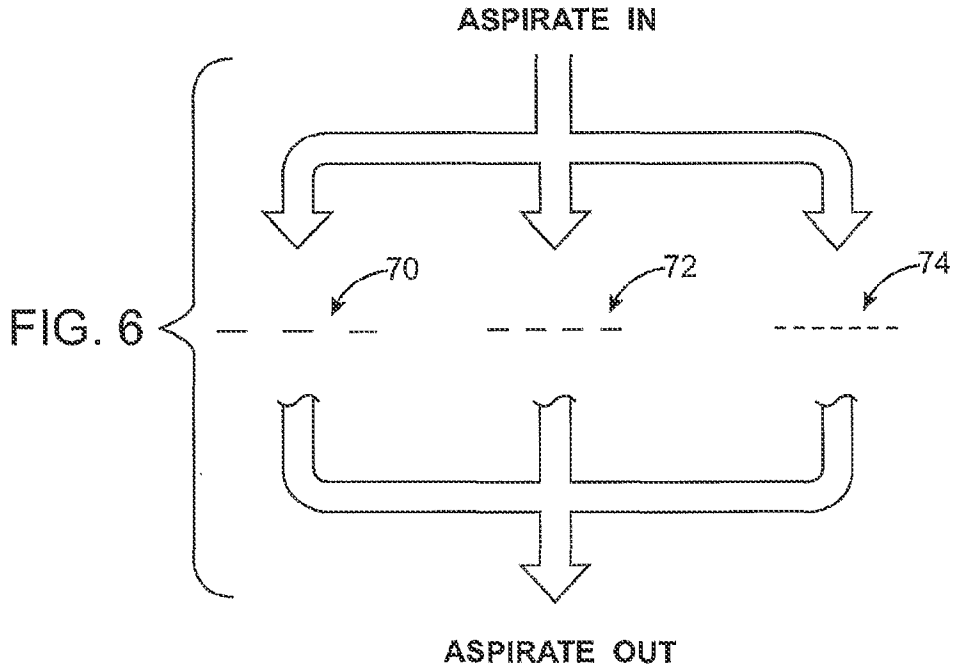
ASPIRATE IN
70
72
74
ASPIRATE OUT

FIG. 6

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/865,266	**03/28/2023 04:44:34 PM ET**	**111552-8016.US04**

Title of Invention

HEMOSTASIS VALVES AND METHODS OF USE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6816	FILED BY	JiYoung Anderson
PATENT CENTER #	61827428	FILING DATE	07/14/2022
CUSTOMER #	25096	FIRST NAMED INVENTOR	Benjamin E. Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-3-28 IDS SB08 - 111552-8016US4.PDF	3	Information Disclosure Statement (IDS) Form (SB08)	128 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
FOR-WO2006124307.PDF	19	Foreign Reference	2080 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)

2023-3-28 IDS SB08 - 111552-8016US4.PDF	0F5C9146C567502BBCA39265912A19AA13786C4F2F62080A6765EAFC6B9BBF3B14CAA8C3CAE9AF372D1B0DCF51317AD2919408BB4FE9FA07D4A40E5C58800253
FOR-WO2006124307.PDF	4CA9E275B28C639DF92082C698747D391EB4FEFEEA1BB6C9B742A1F4DE7964B77944A82E842650ED0069421D200988267A5E6CE83FEC33F777AC3CCFF6120555

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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Approved for use through 05/31/2024. OMB 0651-0031
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	17/865,266	Filing Date	2022-07-14	Docket Number (if applicable)	111552-8016.US04	Art Unit	3783
First Named Inventor	Benjamin E. Merritt			Examiner Name	Quynh-Nhu Vu		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☐ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☐ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No _____

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

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Signature of Registered U.S. Patent Practitioner			
Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-01-31
Name	Matthew S. Williams	Registration Number	77516

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/865,266	01/31/2023 06:53:20 PM ET	111552-8016.US04

Title of Invention

HEMOSTASIS VALVES AND METHODS OF USE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6816	FILED BY	JiYoung Anderson
PATENT CENTER #	61523791	AUTHORIZED BY	Matthew Williams
CUSTOMER #	25096	FILING DATE	07/14/2022
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Benjamin E. Merritt

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 3369	E20231UI54173737	JiYoung Anderson

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1801	REQUEST FOR CONTINUED EXAMINATION (RCE) - 1ST REQUEST (SEE 37 CFR 1.114)	1360.00	1	1360.00
			TOTAL AMOUNT:	$1,360.00

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	3783
	Examiner Name	Quynh-Nhu Hoang Vu
	Attorney Docket Number	111552-8016.US4

U.S. PATENTS and PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	3783
	Examiner Name	Quynh-Nhu Hoang Vu
	Attorney Docket Number	111552-8016.US4

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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.					
	2.					
	3.					
	4.					
	5.					
	6.					

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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PTO/SB/08a (01-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	3783
	Examiner Name	Quynh-Nhu Hoang Vu
	Attorney Docket Number	111552-8016.US4

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

PTO/SB/08a (01-10)
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	Attorney Docket Number	111552-8016.US4

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2023-01-31
Name/Print	Matthew S. Williams	Registration Number	77,516

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/865,266	**01/31/2023 06:53:20 PM ET**	**111552-8016.US04**

Title of Invention

HEMOSTASIS VALVES AND METHODS OF USE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	6816	FILED BY	JiYoung Anderson
PATENT CENTER #	61523791	FILING DATE	07/14/2022
CUSTOMER #	25096	FIRST NAMED INVENTOR	Benjamin E. Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-1-31 IDS SB08 - 111552-8016US4.PDF	4	Information Disclosure Statement (IDS) Form (SB08)	134 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
RCE - 111552-8016US4.PDF	3	Request for Continued Examination (RCE)	1628 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)

2023-1-31 IDS SB08 - 111552-8016US4.PDF	CC0FA4CC77E0EDE129F39BACFB8252372BA3800718E99A1B57A38B8508AF273B0120C783E7BC6F6B596D7221792906F4EE3DBC798F3A764B65D4CC6D0BAD3F25
RCE - 111552-8016US4.PDF	5084633358AB202F21AE0A90DB78FD39422781154A69972C40F2FF2FF16351099B5A3211C2EC5EF467913BFAD0B1A74F4BCEE144B93EB38F11E2F57C1CE1689A

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

25096 7590 11/23/2022

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER
VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
3783	

DATE MAILED: 11/23/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,266	07/14/2022	Benjamin E. Merritt	111552-8016.US04	6816

TITLE OF INVENTION: HEMOSTASIS VALVES AND METHODS OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	02/23/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

25096 7590 11/23/2022
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,266	07/14/2022	Benjamin E. Merritt	111552-8016.US04	6816

TITLE OF INVENTION: HEMOSTASIS VALVES AND METHODS OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	02/23/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
VU, QUYNH-NHU HOANG	3783	604-167030

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,266	07/14/2022	Benjamin E. Merritt	111552-8016.US04	6816

25096 7590 11/23/2022

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	**PAPER NUMBER**
3783	

DATE MAILED: 11/23/2022

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/865,266	Applicant(s) Merritt et al.	
	Examiner QUYNH-NHU H VU	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 10/28/22.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-9 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☑ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. 20221107.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/QUYNH-NHU H. VU/
Primary Examiner, Art Unit 3783

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an interview with Matthew Williams on 11/08/2022.

The application has been amended as follows:

1. (Currently Amended) An aspiration catheter, comprising:

an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen;

a hemostasis valve on the proximal end of the catheter, the hemostasis valve comprising

(a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and

(b) a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that ~~the~~ a diameter of the valve lumen decreases in response to reducing a diameter of the loop.

Allowable Subject Matter

Claims 1-9 are allowed.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The claims in this application have been allowed because the prior art of record fails to disclose either single or in combination the claimed an aspiration catheter including: a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that the diameter of the valve lumen decreases in response to reducing a diameter of the loop..

The closet prior art of record is Hartley (US 2003/0116731), Wong et al. (US 2011/0144592), Myers (US 9,216,277), however these references do not disclose the device as claimed or described above.

a) Hartley discloses a catheter is capable for aspiration therefore, it can be called as an aspiration catheter, comprising: an elongate, flexible tubular body 4, having a proximal end (adjacent to element 7), a distal end (opposite end of the proximal end, the distal end being inserted into a patient) and a central lumen (catheter lumen); a hemostasis valve 8 on the proximal end of the catheter, the hemostasis valve 8 comprising - (a) a collapsible tubular sidewall 22 defining a valve lumen 3 in communication with the central lumen; and (b) a constricting mechanism 12 & 20 having at least a first actuator 12, a first filament 14 formed into a loop around the collapsible tubular sidewall 8, see Figs. 3-4, the filament 14 having at least a first end portion 16 extending away from the loop and connected to the first actuator 12.

Harley fails to disclose that and a first spring configured to move the first actuator in a direction that pulls the first end portion such that the diameter of the valve lumen decreases in response to reducing a diameter of the loop.

b) Wong discloses a catheter (being connected to a hemostatic valve) and capable of using for aspiration. Therefore, it can be called as an aspiration catheter, comprising:

an elongate, flexible tubular body (being connected to element 7, in Figs. 1-2), having a proximal end (directly connected to the element 7), a distal end (opposite end to the proximal end and being

inserted into a patient) and a central/catheter lumen; a hemostasis valve 19 on the proximal end of the catheter, the hemostasis valve comprising - (a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and a first actuator 15a/15b; a spring 20a/20b configured to move the first actuator 15a/15b such that the diameter of the valve lumen decreases in response to the spring, see Figs. 11 & 14. **Note**: The Fig. 11 shows that the valve lumen decreases; and the Fig. 14 shows that the valve lumen increase when the actuator being depressed.

Wong fails to disclose that a constricting mechanism having a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that the diameter of the valve lumen decreases in response to reducing a diameter of the loop.

c) Myers discloses a catheter (being connected to a hemostatic valve) and capable of using for aspiration. Therefore, it can be called as an aspiration catheter, comprising: a elongate, flexible tubular body 20 having a proximal end (directly connected to the element 12), a distal end (opposite end to the proximal end and being inserted into a patient) and a central/catheter lumen; (a) a collapsible tubular sidewall 38 defining a valve lumen 14 in communication with the central lumen; and

(b) a constricting mechanism 32 having at least a first actuator 54, and a first spring 56 configured to move the first actuator in a direction that a diameter of the valve lumen decreases (Fig. 6) and the diameter of the valve lumen increase (Fig. 5).

Myers fails to disclose a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator. Myers fails to disclose that a first spring 56 configured to move the first actuator in a direction that pulls the first end portion such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop.

Although Wong or Myers discloses a missing limitation of Hartley (i.e. a spring), however, the spring in Wong or Myers is inapplicable to add into the device of Harley.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU HOANG VU whose telephone number is (571)272-3228. The examiner can normally be reached on M-F 7:30 am-4:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhisma Mehta can be reached on 571-272-3383. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Quynh-Nhu H. Vu/
Quynh-Nhu H Vu
Primary Examiner, Art Unit 3783

Examiner-Initiated Interview Summary	**Application No.** 17/865,266	**Applicant(s)** Merritt et al.		
	Examiner QUYNH-NHU H VU	**Art Unit** 3783	**AIA (First Inventor to File) Status** Yes	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
QUYNH-NHU H VU	Primary Examiner	Telephonic
Matthew Williams	Attorney of Record	

Date of Interview: 08 November 2022

Issues Discussed:

Proposed Amendment(s)

During the interview, the claim 1 was discussed. Examiner stated that the limitation "the diameter" in line 12 of the claim 1 lacks of antecedent basis. Therefore, the limitation "the diameter" suggested to be changed to --- a diameter ---.
Attorney Williams agreed to change the suggested language above. Please see Examiner's Amendment for more detail.

/QUYNH-NHU H. VU/ Primary Examiner, Art Unit 3783	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Notice of References Cited	Application/Control No. 17/865,266	Applicant(s)/Patent Under Reexamination Merritt et al.	
	Examiner QUYNH-NHU H VU	Art Unit 3783	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
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	P					
	Q					
	R					
	S					
	T					

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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/865,266	Merritt et al.
	Examiner	Art Unit
	QUYNH-NHU H VU	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	08/30/2022	11/08/2022							
	1	÷	=							
	2	÷	=							
	3	÷	=							
	4	÷	=							
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	7	÷	=							
	8	÷	=							
	9	÷	=							

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/865,266	Merritt et al.
	Examiner	**Art Unit**
	QUYNH-NHU H VU	3783

CPC								
Symbol							**Type**	**Version**
A61M	/	39	/	0613			F	2013-01-01
A61B	/	17	/	3207			A	2013-01-01
A61M	/	2039	/	0673			A	2013-01-01
A61M	/	2039	/	062			A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	9	
/QUYNH-NHU H. VU/ Primary Examiner, Art Unit 3783	08 November 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20221107

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/865,266	Merritt et al.
	Examiner	**Art Unit**
	QUYNH-NHU H VU	3783

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61M	/	39	/	06	

NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	9	
/QUYNH-NHU H. VU/ Primary Examiner, Art Unit 3783	08 November 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

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☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1														
	2														
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	9														

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	9	
/QUYNH-NHU H. VU/ Primary Examiner, Art Unit 3783	08 November 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/865,266	Merritt et al.
	Examiner	Art Unit
	QUYNH-NHU H VU	3783

CPC - Searched*		
Symbol	Date	Examiner
A61M2039/0673 OR A61M39/0613 OR A61M2039/062 OR A61M2039/0626	11/07/2022	QNV

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
PE2E, Inventor, IDS, forward/backward searches	11/07/2022	QNV

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	all the above	11/08/2022	QNV

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8016.US4

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

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PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8016.US4

Those documents which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application number **16/117,519** and filed on **August 30, 2018** and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2022-09-07
Name/Print	Matthew S. Williams	Registration Number	77,516

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Q.N.V./

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	16/117519 and (pliable) and (reinforcement) and (tensioning adj mechanism)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/10 09:36 AM
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L3	2	("4551862").PN.	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	OFF	OFF	2020/06/10 11:14 AM
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L5	6	(("6824553") or ("7905877") or ("2013184703")).PN.	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	OFF	OFF	2020/06/10 11:16 AM
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L13	3470	L12 and (seal or valve)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/10 02:11 PM
L14	2235	L12 and (seal)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/10 02:11 PM
L15	270	L12 and (seal) and (reinforc$5)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/10 02:11 PM
L16	2795	L12 and (valve)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/10 02:43 PM
L17	0	L12 and (hemostic adj valve)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/10 02:43 PM
L18	411	L12 and (hemostatic adj valve)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/10 02:43 PM
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L26	1	16/117519 and (vacuum adj pressure)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/10 06:27 PM
L27	2	16/117519 and (vacuum)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/10 06:27 PM
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L33	14	(compliant adj polymer) with (silicon adj rubber)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/11 11:13 AM
L34	57	(compliant adj polymer) with (silicone adj rubber)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/11 11:14 AM
L35	57	L34 not L33	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/11 11:14 AM
L36	179	((benjamin near Merritt) or (John near Thress) or (Paul near Lubock)).in. and valve	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/11 02:17 PM
L37	2	L36 and (reinforcement) and (filament)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/11 02:18 PM
L38	4	L36 and (reinforcement) and (tension$4)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/06/11 02:18 PM
L39	1	16/117519 and uniform	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/11/19 01:13 PM
L40	1	("20180193043").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2020/11/19

			FPRS; EPO; JPO)				01:16 PM
L41	1114	(hemostatic adj valve) and (filament or thread or string) and (bias or spring)	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/11/19 04:38 PM
L42	943	L41 and (@ad<"20170906")	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/11/19 04:38 PM
L43	1305	((pinch adj valve) or (hemestatic with seal)) and (filament or thread or string) and (bias or spring) and (@ad<"20170906")	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/11/19 04:59 PM
L44	1304	L43 not L42	(US-PGPUB; USPAT; FPRS; EPO; JPO)	OR	ON	ON	2020/11/19 05:00 PM
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L56	3	16/117519 AND	(US-PGPUB; USPAT;	OR	ON	ON	2022/05/22

		(constricting ADJ mechanism)	FPRS; EPO; JPO)				07:06 PM
L57	21	("1100682").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/05 04:00 PM
L58	2	("11000682").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/05 04:01 PM
L59	0	("201403717779").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/05 05:26 PM
L60	1	("20140371779").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/05 05:26 PM
L61	333	("2846179" | "3088363" | "3197173" | "3435826" | "3892161" | "3923065" | "4030503" | "4034642" | "4287808" | "4393872" | "4523738" | "4551862" | "4650466" | "4873978" | "4883458" | "4890611" | "4960259" | "4978341" | "5011488" | "5059178" | "5102415" | "5127626" | "5129910" | "5192286" | "5192290" | "5360417" | "5370653" | "5476450" | "5490859" | "5591137" | "5746758" | "5749858" | "5766191" | "5782817" | "5827229" | "5827304" | "5868708" | "5873866" | "5873882" | "5876414" | "5882329" | "5911710" | "5972019" | "5974938" | "5989233" | "5993483" | "6066149" | "6221006" | "6228060" | "6238412" | "6254571" | "6258115" | "6306163" | "6350271" | "6364895" | "6368339" | "6383205" | "6413235" | "6423032" | "6440148"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/08/05 05:28 PM

		| "6454741" | "6454775" | "6458103" | "6458139" | "6511492" | "6514273" | "6530935" | "6530939" | "6544279" | "6551342" | "6589263" | "6596011" | "6602271" | "6605074" | "6605102" | "6623460" | "6635070" | "6645222" | "6660013" | "6663650" | "6685722" | "6692504" | "6699260" | "6755847" | "6767353" | "6800080" | "6824553" | "6939361" | "6960222" | "7004954" | "7036707" | "7041084" | "7052500" | "7056328" | "7069835" | "7094249" | "7179273" | "7220269" | "7232432" | "7244243" | "7285126" | "7306618" | "7320698" | "7323002" | "7331980" | "7534234" | "7578830" | "7621870" | "7674247" | "7691121" | "7695458" | "7763010" | "7766934" | "7775501" | "7905877" | "7905896" | "7938809" | "7938820" | "7967790" | "7976511" | "7993302" | "7993363" | "8043313" | "8052640" | "8066757" | "8070791" | "8075510" | "8088140" | "8100935" | "8109962" | "8118829" | "8197493" | "8246641" | "8261648" | "8267897" | "8298257" | "8317748" | "8337450" | "RE43902" | "8357178" | "8361104" | "8409215" | "8486105" | "8491539" | "8512352" | "8535334" | "8545526" | "8568432" | "8574262" | "8579915" | "8585713" | "8696622" | "8715314" | "8771289" | "8777893" | "8784434" | "8784441" | "8795305" | "8795345" | "8801748" | "8814927" | "8820207" | "8826791" | "8828044" | "8833224" | "8845621" | "8852205" | "8852226" | "8932319" | "8939991" | "8945143" | "8945172" | "8968330" | "8992504" | "9005172" |				

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L62	105	("1170208" | "1741526" | "2217718" | "2269401" | "3675657" | "4118805" | "4256094" | "4399809" | "4401107").pn. OR ("4551862").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/08/05 05:29 PM
L63	19	("2003/0116731").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/08/05 05:43 PM
L64	1	17/705189	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 11:02 AM
L65	1	("20110144592").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 01:12 PM
L66	12	"7775501"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO);	OR	ON	ON	2022/08/08 01:22 PM

			FPRS; EPO; JPO)				
L67	5183	((A61M2039/062 OR A61M2039/0673 OR A61M39/0613).cpc.) AND (@ad<"20170906")	(US-PGPUB; USPAT; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 01:55 PM
L68	4288	L67 AND (valve OR seal)	(US-PGPUB; USPAT; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 01:55 PM
L69	1185	L68 AND (string OR thread OR filament)	(US-PGPUB; USPAT; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 01:55 PM
L70	474	L69 AND (button OR actuator)	(US-PGPUB; USPAT; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 01:56 PM
L72	2	10/309485	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 02:04 PM
L73	1594	((F16K7/02 OR F16K7/08 OR F16K7/04).cpc.) AND (@ad<"20170906")	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 02:05 PM
L74	362	L73 AND (button OR actuator)	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 02:05 PM
L75	24	("3383131" | "4094492" | "4540411" | "4570898" | "5112324" | "5211370" | "5582165" | "5814026" | "6270053" | "6450989" | "6475135" | "7914492" | "7981086" | "8079973" | "8132783" | "8900168" | "20040015177" | "20050131344" | "20070118021" | "20070161956" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/08/08 02:08 PM

		"20110022063" | "20140012235" | "20140330309").pn. OR ("10183159").urpn. AND (PGPB | USPT | USOC).dbnm.					
L76	250	("20010004699" OR "20010041909" OR "20010051810" OR "20020022858" OR "20020026211" OR "20020032455" OR "20020095161" OR "20020095171" OR "20020111648" OR "20020120277" OR "20020147458" OR "20020156457" OR "20030083693" OR "20030100919" OR "20030114875" OR "20030116731" OR "20030125663" OR "20030135230" OR "20030135258" OR "20030153873" OR "20030153973" OR "20030168068" OR "20030176884" OR "20030191516" OR "20030208224" OR "20040039412" OR "20040068288" OR "20040073243" OR "20040098033" OR "20040133232" OR "20040138692" OR "20040167567" OR "20040199201" OR "20040199202" OR "20050033172" OR "20050038468" OR "20050055047" OR "20050085826" OR "20050085849" OR "20050119668" OR "20050177132" OR "20050187570" OR "20050283165" OR "20050283166" OR "20050283186" OR "20060020286" OR "20060042786" OR "20060047286" OR "20060089533" OR "20060100662" OR "20060155305" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/08/08 02:18 PM

		"20060173525" OR "20060195137" OR "20060200221" OR "20060224177" OR "20060229645" OR "20060247500" OR "20060253145" OR "20060276874" OR "20060282111" OR "20060293696" OR "20070038225" OR "20070112374" OR "20070118165" OR "20070149996" OR "20070161963" OR "20070179513" OR "20070191866" OR "20070198028" OR "20070208361" OR "20070208367" OR "20070213753" OR "20070213765" OR "20070255252" OR "20070288054" OR "20080015541" OR "20080088055" OR "20080157017" OR "20080167678" OR "20080183136" OR "20080228209" OR "20080234722" OR "20080262528" OR "20080269798" OR "20080300466" OR "20090018566" OR "20090054918" OR "20090062841" OR "20090069828" OR "20090076417" OR "20090160112" OR "20090163846" OR "20090182362" OR "20090281525" OR "20090292307" OR "20090299393" OR "20100030256" OR "20100042136" OR "20100087844" OR "20100087850" OR "20100114113" OR "20100121312" OR "20100137846" OR "20100190156" OR "20100204712" OR "20100249815" OR "20100268264" OR "20100318178" OR "20110034987" OR					

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L77	32	("20170348014" OR "20180042624" OR "20180042626" OR "20180064453" OR "20180064454" OR "20180070968" OR "20180092652" OR "20180105963" OR "20180125512" OR "20180193043" OR "20180236205" OR "20180256178" OR "20180296240" OR "20180344339" OR "20180361116" OR "20190000492" OR "20190046219" OR "20190070401" OR "20190117244" OR "20190133622" OR "20190133623" OR "20190133624" OR "20190133625" OR "20190133626" OR "20190133627" OR "20190150959" OR "20190231373" OR "20190321071" OR "20190336148" OR "20200046368" OR "20210113224" OR "20210186541").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/08/08 02:18 PM

L78	1263	((Benjamin NEAR Merritt) OR (John NEAR Thress) OR (Paul NEAR Lubock)).in.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 02:19 PM
L79	110	L78 AND (valve AND filament)	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/08 02:19 PM
L81	5	("10309485").pn.	(US-PGPUB; USPAT; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/11 12:16 PM
L82	2	("11000682").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/11 12:17 PM
L83	25	("1840967" | "1977504" | "2434835" | "2846179" | "3329396" | "3572627" | "3897039" | "3994472" | "4007904" | "4095805" | "4310139" | "4372026" | "4447037" | "4449719" | "4452421" | "4458876" | "5116017" | "5273108" | "7845648" | "20140174754").pn. OR ("10648268").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/08/11 12:48 PM
L84	1	17/705189	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/11 01:58 PM
L85	0	17/865266 AND (slide OR slidable OR slidably)	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/30 09:42 AM
L86	0	17/865266	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO);	OR	ON	ON	2022/08/30 09:43 AM

			FPRS; EPO; JPO)				
L87	2	("11000682").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/08/30 10:02 AM
L88	2	17/705189	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 10:32 AM
L89	6	("2016100252").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 10:49 AM
L90	3	("20160100252").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 10:50 AM
L91	7	"20160100252"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 10:51 AM
L92	28	"2016100252"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 10:51 AM
L93	52	(Pattok NEAR Greg).in.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 10:52 AM
L94	92	"2012009675"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 10:54 AM
L95	1524	("10004531"|"10010335"|"10016266"|"10028759"|"10045790"|"10098651"|"10130385"|"10226263"|"10238406"|"1027	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO);	OR	ON	ON	2022/11/07 10:56 AM

		1864"|"10327883"|"103 35186"|"10342571"|"10 349960"|"10383644"|"1 0524811"|"10588655"|" 10695159"|"10709471"| "10799331"|"10912577" |"11000682"|"11058445 "|"11058451"|"1114757 1"|"11154314"|"200100 04699"|"20010041909"| "20010051810"|"20020 022858"|"20020022859 "|"20020026211"|"2002 0032455"|"2002004945 2"|"20020095161"|"200 20095171"|"200201116 48"|"20020120277"|"20 020147458"|"20020151 918"|"20020156457"|"2 0020161392"|"2002016 9474"|"20020173819"|" 20020188276"|"200300 83693"|"20030100919"| "20030114875"|"20030 116731"|"20030125663 "|"20030135230"|"2003 0135258"|"2003015387 3"|"20030153973"|"200 30168068"|"200301768 84"|"20030191516"|"20 030208224"|"20030216 774"|"20040039412"|"2 0040068288"|"2004007 3243"|"20040098033"|" 20040122359"|"200401 33232"|"20040138525"| "20040138692"|"20040 167567"|"20040199201 "|"20040199202"|"2004 0260344"|"2004026727 2"|"20050033172"|"200 50038468"|"200500550 47"|"20050085769"|"20 050085826"|"20050085 846"|"20050085849"|"2 0050119668"|"2005017 7132"|"20050187570"|" 20050283165"|"200502 83166"|"20050283186"| "20060020286"|"20060 042786"|"20060047286 "|"20060074401"|"2006 0089533"|"2006010066 2"|"20060155305"|"200 60173525"|"200601951 37"|"20060200221"|"20 060224177"|"20060229 645"|"20060247500"|"2	FPRS; EPO; JPO)				

		0060253145"|"2006027 6874"|"20060282111"|" 20060293696"|"200700 38225"|"20070093744"| "20070112374"|"20070 118165"|"20070149996 "|"20070161963"|"2007 0179513"|"2007019186 6"|"20070198028"|"200 70208361"|"200702083 67"|"20070213753"|"20 070213765"|"20070255 252"|"20070288054"|"2 0080015541"|"2008008 8055"|"20080157017"|" 20080167678"|"200801 83136"|"20080228209"| "20080234722"|"20080 262528"|"20080269798 "|"20080300466"|"2009 0018566"|"2009005491 8"|"20090062841"|"200 90069828"|"200900764 17"|"20090160112"|"20 090163846"|"20090182 362"|"20090192495"|"2 0090281525"|"2009029 2307"|"20090299393"|" 20100016837"|"201000 30256"|"20100042136"| "20100087844"|"20100 087850"|"20100114113 "|"20100121312"|"2010 0137846"|"2010019015 6"|"20100204712"|"201 00249815"|"201002682 64"|"20100318178"|"20 110034987"|"20110054 405"|"20110060212"|"2 0110118817"|"2011012 5181"|"20110144592"|" 20110152823"|"201101 52993"|"20110160742"| "20110160763"|"20110 190806"|"20110196414 "|"20110213290"|"2011 0213403"|"2011022470 7"|"20110245807"|"201 10251629"|"201102641 33"|"20110265681"|"20 110288529"|"20110288 572"|"20110319917"|"2 0120059309"|"2012005 9356"|"20120083824"|" 20120083868"|"201200 89216"|"20120101480"| "20120101510"|"20120 138832"|"20120143239					

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		2161"|"3923065"|"4030 503"|"4034642"|"42223 80"|"4243040"|"428780 8"|"4324262"|"4393872" |"4469100"|"4523738"|" 4551862"|"4604094"|"4 643184"|"4646736"|"46 50466"|"4776337"|"479 0812"|"4863440"|"4870 953"|"4883458"|"48860 62"|"4890611"|"489857 5"|"4946440"|"4960259" |"4978341"|"5059178"|" 5100423"|"5127626"|"5 129910"|"5135484"|"51 54724"|"5192274"|"519 2286"|"5192290"|"5329 923"|"5360417"|"53643 45"|"5376101"|"538388 7"|"5389100"|"5419774" |"5443443"|"5456667"|" 5476450"|"5490859"|"5 496365"|"5527326"|"55 49626"|"5591137"|"566 2703"|"5746758"|"5749 858"|"5769816"|"57828 17"|"5800457"|"582722 9"|"5846251"|"5860938" |"5873866"|"5873882"|" 5876414"|"5895406"|"5 911710"|"5911733"|"59 11754"|"5941869"|"594 7985"|"5954737"|"5971 938"|"5972019"|"59749 38"|"5989233"|"599348 3"|"6030397"|"6066158" |"6068645"|"6126635"|" 6142987"|"6146396"|"6 146403"|"6152946"|"61 56055"|"6159230"|"616 5196"|"6168579"|"6179 859"|"6221006"|"62280 60"|"6238412"|"624507 8"|"6245089"|"6254571" |"6258115"|"6264663"|" 6306163"|"6322572"|"6 350271"|"6361545"|"63 64895"|"6368339"|"638 3205"|"6402771"|"6413 235"|"6423032"|"64321 22"|"6458103"|"647523 6"|"6485502"|"6508782" |"6511492"|"6514273"|" 6530923"|"6530935"|"6 544276"|"6544278"|"65 44279"|"6551342"|"656 9181"|"6575995"|"6589 263"|"6596011"|"66022					

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L96	435	L95 AND (valve OR seal)	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 11:10 AM
L97	1	17/865266	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 11:53 AM
L98	5994	((A61M2039/0673 OR A61M39/0613 OR A61M2039/062 OR A61M2039/0626).cpc.) AND (@ad<"20170906")	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 11:55 AM
L99	5031	L98 AND (valve OR seal OR elastic)	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 11:55 AM
L100	596	L99 AND (collapse OR collapsible)	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 11:56 AM
L101	1464	L99 AND (bias OR spring)	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 11:56 AM
L102	295	L100 NOT L101	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA,	OR	ON	ON	2022/11/07 01:48 PM

			CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)				
L103	2	("11000682").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 02:18 PM
L104	4	("5376101").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 02:42 PM
L105	4	"2019246240"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 02:55 PM
L106	10	"110652645"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 02:56 PM
L107	9	("5011488," "5800457").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 02:57 PM
L108	28	"2011213403"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 03:02 PM
L109	4	("2017086864").pn.	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 03:07 PM
L110	18	"2017086864"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 03:08 PM
L111	26	"2017086864," "2013226196"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA,	OR	ON	ON	2022/11/07 03:11 PM

			CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)				
L112	7	"20170086864," "20130226196"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 03:11 PM
L113	2	"20140371779"	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 03:16 PM
L114	3958	(hemostasis ADJ valve) AND spring AND (@ad<"20170906")	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 03:32 PM
L115	3684	L114 NOT L101 NOT L100	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/07 03:34 PM
L116	2516	L114 AND (filament OR thread OR string)	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/08 10:09 AM
L117	134	L116 NOT L115	(US-PGPUB; USPAT; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO)	OR	ON	ON	2022/11/08 10:10 AM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N47	1423	(A61B17/3207).CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2020/11/24 03:05 PM
N48	1681	(A61M39/06 OR A61M2039/062 OR A61M2039/0673 OR A61M39/0613).CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2020/11/24 03:05 PM
N49	0	("I1" or N47) and ((hemostatic adj valve) and reinforcement and	(US-PGPUB; USPAT)	OR	ON	ON	2020/11/24 03:06 PM

		filament and biasing).clm.					
N50	2	(N47 or N48) and ((hemostatic adj valve) and reinforcement and filament and biasing).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2020/11/24 03:06 PM
N51	2	((hemostatic adj valve) and reinforcement and filament and biasing).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2020/11/24 03:06 PM
N52	2	(A61M39/06 OR A61M2039/062 OR A61M2039/0673 OR A61M39/0613).CPC. AND ((constricting ADJ mechanism) AND filament AND spring).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/08 10:25 AM
N53	3	((hemostasis ADJ valve) AND (constricting ADJ mechanism) AND filament AND spring).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/08 10:26 AM

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	3783
	Examiner Name	Quynh-Nhu Hoang Vu
	Attorney Docket Number	111552-8016.US4

U.S. PATENTS and PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	6564828	05-20-2003	Ishida	
	2.	5197485	03-30-1993	Grooters	
	3.	20130035628	02-07-2013	Garrison et al.	
	4.	8057497	11-15-2011	Raju et al.	
	5.	20150173782	06-25-2015	Garrison et al.	
	6.	20130281788	10-24-2013	Garrison	
	7.	20170196576	07-13-2017	Long et al.	
	8.	20070010787	01-11-2007	Hackett et al.	
	9.	20170319221	11-09-2017	CHU	
	10.	20110196309	08-11-2011	Wells	
	11.	20140296868	10-02-2014	Garrison et al.	
	12.	20010049486	12-06-2001	Evans et al.	
	13.	20100217276	08-26-2010	Garrison et al.	
	14.	20140257363	09-11-2014	Lippert	
	15.	20170056032	03-02-2017	Look et al.	
	16.	20160220741	08-04-2016	Garrison et al.	
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	19.	10478535	11-19-2019	Ogle	
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	27.	5158564	10-27-1992	Schnepp-Pesch et al.	
	28.				
	29.				
FOREIGN PATENT DOCUMENTS					

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Q.N.V./

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	3783
	Examiner Name	Quynh-Nhu Hoang Vu
	Attorney Docket Number	111552-8016.US4

Examiner Initial*	Cite No	Foreign Document Number[3]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
	1.					
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NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Doc code: IDS
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	Attorney Docket Number	111552-8016.US4

EXAMINER SIGNATURE			
Examiner Signature	/QUYNH-NHU H. VU/	Date Considered	11/08/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Q.N.V./

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2022-10-28
Name/Print	Matthew S. Williams	Registration Number	77,516

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Q.N.V./

Bibliographic Data

Application No: 17/865,266

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /QUYNH-NHU H. VU/ Examiner's Signature | Initials

Title: HEMOSTASIS VALVES AND METHODS OF USE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/14/2022	604	3783	111552-8016.US04
RULE			

APPLICANTS

Inari Medical, Inc., Irvine, CA,

INVENTORS

Benjamin E. Merritt, San Clemente, CA, UNITED STATES

John C. Thress, Capistrano Beach, CA, UNITED STATES

Paul Lubock, Monarch Beach, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 17705189 03/25/2022

17705189 is a CON of 17226318 04/09/2021

17226318 is a CON of 16117519 08/30/2018 PAT 11000682

16117519 has PRO of 62554931 09/06/2017

FOREIGN APPLICATIONS

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07/21/2022

STATE OR COUNTRY

UNITED STATES

ADDRESS

PERKINS COIE LLP - SEA General
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P.O. BOX 1247
SEATTLE, WA 98111-1247
UNITED STATES

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/865,266	07/14/2022	Benjamin E. Merritt	111552-8016.US04

CONFIRMATION NO. 6816

25096
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

PUBLICATION NOTICE

Title:HEMOSTASIS VALVES AND METHODS OF USE

Publication No.US-2022-0347455-A1
Publication Date:11/03/2022

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	3783
	Examiner Name	Quynh-Nhu Hoang Vu
	Attorney Docket Number	111552-8016.US4

U.S. PATENTS and PUBLICATIONS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	2.	5197485	03-30-1993	Grooters	
	3.	20130035628	02-07-2013	Garrison et al.	
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	7.	20170196576	07-13-2017	Long et al.	
	8.	20070010787	01-11-2007	Hackett et al.	
	9.	20170319221	11-09-2017	CHU	
	10.	20110196309	08-11-2011	Wells	
	11.	20140296868	10-02-2014	Garrison et al.	
	12.	20010049486	12-06-2001	Evans et al.	
	13.	20100217276	08-26-2010	Garrison et al.	
	14.	20140257363	09-11-2014	Lippert	
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	18.	6719717	04-13-2004	Johnson et al.	
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NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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EXAMINER SIGNATURE			
Examiner Signature		Date Considered	
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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.			

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OR

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☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

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SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2022-10-28
Name/Print	Matthew S. Williams	Registration Number	77,516

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Acknowledgement Receipt

EFS ID:	46920193
Application Number:	17865266
International Application Number:	
Confirmation Number:	6816
Title of Invention:	HEMOSTASIS VALVES AND METHODS OF USE
First Named Inventor/Applicant Name:	Benjamin E. Merritt
Customer Number:	25096
Filer:	Matthew S. Williams/JiYoung Anderson
Filer Authorized By:	Matthew S. Williams
Attorney Docket Number:	111552-8016.US04
Receipt Date:	28-OCT-2022
Filing Date:	14-JUL-2022
Time Stamp:	19:23:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	2022-10-28-ResponseTo_RR-111552-8016US4.PDF	82646 18aa3aa0cf8f85c7523f98abced5f11667389b97	no	6

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	2022-10-28-IDS-SB08-111552-8016US4.PDF	136423 01748374ca71403968854b1a1aca23ca4bd33d5a	no	4
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
			Total Files Size (in bytes):	219069	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Benjamin E. Merritt et al.

Application No.: 17/865,266	Confirmation No.: 6816
Filed: July 14, 2022	Art Unit: 3783
For: HEMOSTASIS VALVES AND METHODS OF USE	Examiner: Quynh-Nhu Hoang Vu

RESPONSE TO RESTRICTION REQUIREMENT UNDER 37 C.F.R. § 1.142

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

The present communication responds to the Restriction Requirement mailed on September 20, 2022 in the above-identified U.S. patent application. The claims and specification have not been amended in this paper. The pending claims are reflected in the listing of claims beginning on page 2 of this paper, and remarks begin on page 5.

THE CLAIMS

Following is a complete listing of the claims pending in the application:

1. (Original) An aspiration catheter, comprising:

an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen;

a hemostasis valve on the proximal end of the catheter, the hemostasis valve comprising -

(a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and

(b) a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that the diameter of the valve lumen decreases in response to reducing a diameter of the loop.

2. (Original) The aspiration catheter of claim 1 wherein:

the collapsible tubular sidewall comprises a tubular member defining the valve lumen configured to slidably receive the elongate, flexible tubular body;

the constricting mechanism further comprises a second actuator and a second spring coupled to the second actuator; and

the filament further comprises a second end portion extending away from the loop in a different direction than the first end portion and connected to the second actuator, and wherein the first actuator and the second actuator are moveable between (a) a first position wherein the filament circumferentially constricts the valve lumen to

create a seal about the elongate, flexible tubular body and (b) a second position wherein the filament is moved to open the valve lumen at least partially.

3. (Original) The aspiration catheter of claim 2 wherein the tubular member is pliable.

4. (Original) The aspiration catheter of claim 2 wherein the first actuator comprises a first button and the second actuator comprises a second button, wherein the first button and the second button are undepressed in the first position, and wherein the first button and the second button are depressed in the second position.

5. (Original) The aspiration catheter of claim 2 wherein, when the first actuator and the second actuator are in the first position, the valve lumen of the tubular member is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the valve lumen and adjacent to a first end of the tubular member and (b) a second volume outside the central lumen and adjacent to a second end of the tubular member.

6. (Original) The aspiration catheter of claim 2 wherein, when the first actuator and the second actuator are in the first position, the valve lumen of the tubular member is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the valve lumen and adjacent to either a first end or a second end of the tubular member.

7. (Original) The aspiration catheter of claim 2 wherein the valve lumen of the tubular member extends a long a first longitudinal axis, wherein the first actuator and the second actuator are movable between the first and second positions along a second longitudinal axis, and wherein the first longitudinal axis is orthogonal to the second longitudinal axis.

8. (Original) The aspiration catheter of claim 2 wherein the first spring comprises a first compression spring coupled to the first member and the second spring comprises a second compression spring coupled to the second member.

9. (Original) The aspiration catheter of claim 2 wherein, in the first position, the first actuator and the second actuator pull the filament to circumferentially constrict the collapsible tubular member such that the valve lumen is constricted and sealed.

REMARKS

In the September 20, 2022 Restriction Requirement, the Examiner required an election of a single species from the following:

Species I: Fig. 1–5; or

Species II: Fig. 12.

Additionally, if Species I was elected, the Examiner required an election of a single species from the following:

Species IA: Figs. 1–5;

Species IB: Fig. 6;

Species IC: Fig. 7;

Species ID: Fig. 8; or

Species IE: Fig. 9.

In response, the Applicant elects Species I (Figs. 1–5) and Species IB (Figure 6), without traverse. Based on the Applicant's review, claims 1–9 read on Species I and Species IB. The foregoing election is made with the understanding that the Examiner and the U.S. Patent and Trademark Office are bound to the finding of non-obviousness between each of the species. Accordingly, claims 1–9 remain pending.

Please charge any underpayment or credit any overpayment to our Deposit Account No. 50-0665, under Order No. 111552-8016.US04 from which the undersigned is authorized to draw.

Dated: October 28, 2022

Respectfully submitted,

By: /Matthew S. Williams/
Matthew S. Williams
Registration No.: 77,516

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P.O. Box 1247
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Phone: (206) 359-3343
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Attorney for Applicant

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/865,266	Filing Date 07/14/2022	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	10/28/2022	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 9	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/PATIENCE RESPER/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,266	07/14/2022	Benjamin E. Merritt	111552-8016.US04	6816

25096 7590 09/20/2022

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER
VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
09/20/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentprocurement@perkinscoie.com

Office Action Summary	Application No. 17/865,266	Applicant(s) Merritt et al.	
	Examiner QUYNH-NHU H VU	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 07/14/22.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-9 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☐ Claim(s) _____ is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☑ Claim(s) 1-9 are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Election/Restriction

This application contains claims directed to the following patentably distinct species:

I) Figs. 1-5 II) Fig. 12

If elected species I, the application further contains distinct sub-species of filament:

IA) Figs. 1-5 IB) Fig. 6 IC) Fig. 7 ID) Fig. 8 IE) Fig. 9

The species are independent or distinct because these species and sub-species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

(a) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(b) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(c) the prior art applicable to one invention would not likely be applicable to another invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

A telephone call was made to Paul Parker on 08/30/22 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process

invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU HOANG VU whose telephone number is (571)272-3228. The examiner can normally be reached M-F 7:30 am-4:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhisma Mehta can be reached on 571-272-3383. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions,

contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/QUYNH-NHU H. VU/
Primary Examiner, Art Unit 3783

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17/865,266 - Conf# 6816
	Filing Date	July 14, 2022
	First Named Inventor	Benjamin E. Merritt
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8016.US4

U.S. PATENTS					
Examiner Initial*	Cite No	Patent Number	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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PTO/SB/08a (01-10)
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PTO/SB/08a (01-10)
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	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	111552-8016.US4

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

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☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

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Those documents which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application number **16/117,519** and filed on **August 30, 2018** and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Matthew S. Williams/	Date (YYYY-MM-DD)	2022-09-07
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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/865,266	Merritt et al.
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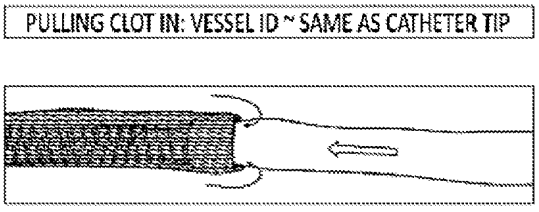


FIG. 8A

(57) Abstract: Mechanical thrombectomy apparatuses that may be configured to prevent or reduce jamming (e.g., "anti-j amming" thrombectomy devices), grab clot, and/or macerate the thrombus, e.g., clot, being removed. These mechanical thrombectomy apparatuses may include a tractor comprising a flexible tube of material that inverts as it rolls over itself while being drawn into a catheter in a conveyor-like motion. In particular, described herein are mechanical thrombectomy apparatuses having tractors selectably extendable projections that may aid in grabbing and/or macerating a clot. Also described herein are seesawing tractors for mechanical thrombectomy apparatuses.

WO 2017/189535 A2

ANTI-JAMMING AND MACERATING THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to U.S. provisional patent application no. 62/327,024, filed on April 25, 2016 and titled "DOZER THROMBECTOMY SYSTEM"; U.S. provisional patent application no. 62/345,152, filed on June 3, 2016, and titled "DOZER THROMBECTOMY SYSTEM 2"; and U.S. provisional patent application no. 62/393,460, filed on September 12, 2016, and titled "DOZER II THROMBECTOMY SYSTEM PROV".

[0002] This patent application may be related to U.S. patent application no 15/291,015, filed on October 11, 2016, titled "MECHANICAL THROMBECTOMY APPARATUSES AND METHODS", which is a continuation of U.S. Patent Application No. 15/043,996, filed February 15, 2016, now U.S. 9,463,035, which claims priority to each of the following provisional patent applications: U.S. Provisional Patent Application No. 62/284,300, filed September 28, 2015; U.S. Provisional Patent Application No. 62/284,752, filed October 8, 2015; and U.S. Provisional Patent Application No. 62/245,560, filed October 23, 2015.

[0003] Each of these patents and patent applications is herein incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

[0004] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0005] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0006] It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue from within a vasculature, such as blood clots, may improve patient conditions and quality of life.

[0007] Many vascular system problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0008] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0009] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, inventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[00010] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to

mechanical retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[00011] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them. These apparatuses may be configured to prevent or reduce jamming and enhance grabbing and/or macerating a thrombus, e.g., clot, being removed. Typically, the mechanical thrombectomy apparatuses described herein are inverting tractor thrombectomy apparatuses that includes a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

[00012] Implementation of a rolling tractor that is sufficiently flexible to easily roll at the distal end (e.g., over a catheter) but sufficiently stiff to prevent jamming at the distal end of the elongate inversion support has proven challenging.

[00013] The elongate inversion support portion of the apparatus described herein may be or may include (particularly at its distal end) any appropriate catheter, e.g., a flexible tube that can be inserted into a body vessel (e.g., blood vessel) into which the more flexible tractor portion can be withdrawn by pulling against the elongate inversion support. The elongate inversion support may, in some variations, also be referred to as outer catheters (e.g., when the puller for the tractor is referred to as an inner catheter) and/or inversion catheters and/or support catheter, as it may support the inversion of the tractor. The elongate inversion support, including a catheter forming the elongate inversion support, may include a braided or woven portion, a spiral or coiled portion, etc. (e.g., having a braided shaft), may have a single layer or multiple layers, and may be formed of biocompatible materials, including polymers, metals, etc. (e.g., PTFE). Examples of vascular catheters that may form the elongate inversion support include micro catheters.

[00014] The mechanical thrombectomy apparatuses described herein include a tractor region and/or elongate inversion support that are configured to prevent jamming, while still able to efficiently "grab" a clot from within a vessel. For example, described herein are mechanical thrombectomy apparatuses that may be configured to grab or grasp and/or macerate a clot as it is mechanically drawn into the apparatus for removal. Although suction may be used in addition to the mechanical grabbing of the clot, in some variations suction is not used.

[00015] The tractor regions described herein may include projections that extend from the tractor region, particularly or exclusively as it bends around during inverting (e.g., at the distal end of the device). These projections may remain flat or non-extending when the tractor is held in parallel with the elongate inversion support. Alternatively, the projections may extend at all times. In general, the tractor may be formed of a woven materials, knitted material, or laser-cut sheet of material. The knitted and/or woven materials may be fibrous materials (including natural fibers, synthetics fibers, etc.), polymeric materials, or the like. For example, the material (e.g., strands) forming the woven or knitted material may be one or more of: monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Cobalt chromium alloy filament, Cobalt chromium alloy tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene. The sheets of material (e.g. a solid sheet of material) formed into the tractor region may be one or more of: polymeric material (e.g., PTFE), silicone materials, polyurethanes, shape memory alloys, stainless steels, etc. The sheets may be extruded, glued, or the like. The sheets may be cut to form pores and/or projections. For example, the sheets may include one or more laser-cut projections. Any of these apparatuses may be coated with a hydrophilic and/or hydrophobic coating, and/or may include pores. The tractor may have a porosity of greater than >60% (greater than 70%, greater than 75%, greater than 80%, greater than 85%, etc., between 60-95, 65-95, 70-95%, etc.).

[00016] For example, described herein are clot-grabbing mechanical thrombectomy apparatuses that include a tractor region. The tractor region may include a plurality of clot-grabbing projections extending from one face of the tractor. In some variations, the clot-grabbing projections may be configured so that they move to extend (e.g., out of the plane of the tractor) when the tractor region bends around, e.g., around the distal end of the catheter of the elongate inversion support, to invert.

[00017] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: a elongate inversion support comprising a catheter having a distal end

and a distal end opening; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire. The proximal end of the tractor may be loose (e.g., may be free to slide over the catheter. The tractor may also be configured so that is it biased to hold itself against outer diameter of the catheter, and simultaneously biased to expand when inverted within the catheter; in this configuration, the inverting distal-facing end of the tractor may be flared outward slightly so that the diameter of the tractor expands slightly near the distal-facing inverting end of the apparatus. This configuration may also maintain the portion of the tractor within the catheter so that it is close to the inner diameter of the catheter; e.g., the inner diameter of the portion of the tractor within the catheter may be greater than 50 % of the inner diameter of the catheter, greater than 55% of the inner diameter of the catheter, greater than 60% of the inner diameter of the catheter, greater than 65% of the inner diameter of the catheter, greater than 70% of the inner diameter of the catheter, greater than 75% of the inner diameter of the catheter, etc.

[00018] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in a second configuration (that is inverted relative to the first configuration) along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; and a plurality of projections that extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, wherein the plurality of projections do not extend from the tractor as it extends proximally in the inverted configuration along the distal end of the catheter.

[00019] As mentioned, in general, the mechanical thrombectomy apparatuses described herein may include a clot-grabbing projection. For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, the flexible tube comprising a tube

wall, wherein the tractor is configured to invert over the distal end opening when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections configured so that the plurality of projections extend out of a plane of the tube wall as the tube wall inverts over the distal end opening, further wherein the plurality of projections remain in the plane of the tube wall as the tube wall extends along the distal end of the catheter; and a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.

[00020] In particular, the tractor may be a tube of woven ribbons, further wherein the plurality of projections is formed from edges of the ribbons. The ribbons may comprise flattened strips or strands of material having at least one (through typically four) elongate edges. For example, the ribbons may have a rectangular cross-section. In some variations the ribbons may have square or triangular or other cross-sections having one or more edges. Ribbons having edges may be woven, e.g., so that they are arranged in a helical pattern as they extend over the distal end of the elongate inversion support. Thus, the edge(s) of the ribbon may extend outward, out of the plane of the tractor, when the tractor inverts. These extending edges may bend up, forming scooping, cutting and/or grabbing projections over the bending region of the tractor. The ribbons may be formed of any appropriate material, including those discussed above, such as a metallic or polymeric material.

[00021] The projections from the tractor regions described herein may be formed by cut-out regions in the tractor material. For example, a sheet or tube of material may be used to form the tractor, such as a tube of steel (e.g., stainless steel), polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric, and projections may be formed, e.g., by cutting, from the tube or sheet. For example, the projections may be cut from the tube wall. In some variations the projections may be cut in addition to openings, slits, slots, or gaps (e.g., forming pores). For example, a tractor may have at least one porous section having a pore pattern having a longitudinal separation between pores of less than about 0.005 inches in width. In some variations, the projections may be cut from the tube wall at an angle of less than 90° tangent to the tube wall. For example, each of the plurality of projections may have a width in a direction transverse to the flexible tube and a length in a direction along a long axis of the flexible tube; the ratio of length to width may be between, e.g., 2 and 100 (e.g., 5 and 100, 10 and 100, 5 and 90, 5 and 80, 5 and 70, 5 and 50, 10 and 90, 10 and 80, 10 and 70, 10 and 60, etc.).

[00022] The projections may be shaped to grab and/or macerate the clot. For example, all or some of the plurality of projections may have one or more of: a paddle shape, a scoop

shape, and spike shape. The projections may extend proud of the plane of the tractor (e.g., at 90° or perpendicular to the tractor surface from which the projection extends, or between about 45-135° from the plane of the tractor surface, etc.). The projections may be sharp (e.g., may have sharp ends). The projections may extend between 0.01 mm to 5mm from the tractor surface (e.g., between 0.01 mm and 2 mm, between 0.05 mm and 1 mm, etc.). The size of the projections may be scaled to the size of the tractor and/or the size of the vessel into which the apparatus is intended to be inserted into.

[00023] In any of the apparatuses described herein, the elongate inversion support (e.g., catheter) may be adapted to enhance rolling of the tractor region (inverting) over the distal end. For example, in any of the apparatuses described herein, the catheter may be configured so that the material hardness of the catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile. The catheter distal end may be stiffer because it is thicker (e.g., it may be formed by inverting the distal end of the catheter back over itself, and/or it may be formed of a stiffer material than the adjacent more proximal region (including by including a reinforcing material).

[00024] The projections configured to help grab clot may be distributed over the entire length of the tractor, or only over a region of the tractor (e.g., the distal end region, e.g., the distal 5 mm, 7mm, 10 mm, 15 mm, 20 mm, etc. or less). In some variations, the distribution of projections may be non-uniform distributed, e.g., the tractor may include a non-uniform density of projections along the length of the tractor. The projections may be oriented relative to the tractor so that the projections extend in the distal direction when the tractor is on the outer diameter of the catheter, which may help them grab clot.

[00025] The projections may be configured (e.g., by laser cutting the tube forming the tractor) as a plurality of slots or openings through the tractor.

[00026] In any of the apparatuses described herein, the tractor may include one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating. In particular the tractor may include a uniform or non-uniform lubricious (e.g., hydrophilic) coating. Such coatings may assist in making the tractor slide more easily to invert (e.g., over the distal end of the catheter), but may make it particularly hard to grab clot. The projections described herein may address this issue.

[00027] Any of the apparatuses described herein may include a releasable attachment between the tractor and an outer surface of the elongate inversion support (e.g., catheter),

configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold. This may prevent premature deployment of the apparatus. The releasable attachment may be a breakable (e.g., frangible) region, e.g., of an adhesive, etc. or a releasable tie, etc. The releasable attachment may be formed by regions of different hydrophobicity/hydrophilicity. Any of these apparatuses may be configured so that the force required to deploy the apparatus is greater than a predetermined threshold, e.g., the releasable force threshold may be greater than 50 g, 100 g, 200 g, 300 g, 400 g, 500 g, 600 g, 700 g, 800 g, 900 g, 1000 g, etc. of force (e.g., greater than 200 g of force). In addition, any of these apparatuses may include a cover, an outer elongate inversion support comprising a catheter, sleeve, sheath, etc., holding the proximal end of the tractor against the catheter until it is ready to be deployed. Deployment may mean releasing the end (e.g., the end on the outer surface of the catheter) from a releasable attachment; once deployed, the force required to pull the tractor proximally in the catheter, including drawing the tractor from along the outer diameter of the catheter, inverting the tractor and pulling the tractor into the catheter distal end opening (without a clot or other material in the tractor) may be substantially less than the initial deployment force. For example, the force required to pull the tractor into the catheter proximally may be 1 gram (g) of force or less (or 2 g, 3 g, 4 g, 5 g, 6 g, 7 g, 8 g, 9 g, 10 g, 20 g, 30 g, 40 g, 50 g, etc., of force or less). Altematively or additionally, any of these apparatuses may include a material between the tractor and the catheter (e.g., a sleeve, coating, etc.) to reduce the amount of force required to invert the catheter over the distal end of the catheter, and/or to prevent jamming of the tractor in the catheter.

[00028] As mentioned, any of these apparatuses may include a puller, e.g., an elongate puller coupled to a distal end of the tractor. Any of these apparatuses may include an elongate puller within the catheter coupled to a distal end of the tractor. The elongate puller may comprise a hypotube having an inner lumen that is continuous with the guidewire lumen though the flexible tube.

[00029] In general, the tractor may be any appropriate length. For example, the tractor may be between 3 to 100 cm long (e.g., between 3 and 50 cm, between 3 and 40 cm, between 3 and 30 cm, between 3 and 20 cm, between 10 and 100 cm, between 10 and 50 cm, between 20 and 100 cm, between 20 and 50 cm, etc.).

[00030] In any of these apparatuses, the apparatus may be configured so that the tractor may be retracted into the catheter by applying less than 300 grams of force (e.g., less than 400 g of force, less than 300 g of force, less than 200 g of force, less than 100 g of force, less than 90 g of force, less 80 g of force, less than 70 g of force, less than 60 g of force, less than

50 g of force, less than 10 g of force, etc.) to a distal end of the flexible tube. For example, as mentioned above, the apparatus may include a hydrophilic coating, a lubricant on the catheter and/or tractor, a sleeve between the tractor and catheter, etc. This force required to retract the tractor into the catheter typically refers to the force required to roll the tractor over the distal end of the tractor; an initial deployment force (e.g., to release the end of the tractor outside of the catheter) may be greater than the force required to retract the catheter (e.g., greater than 100 g of force, 200 g of force, 300 g of force, 400 g of force, 500 g of force, 600 g of force, 700 g of force, 800 g of force, 900 g of force, 1000 g of force, 1500 g of force, 2000 g of force, etc.).

[00031] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first (e.g., "un-inverted") configuration within the catheter, inverts over the distal end opening of the catheter into a second configuration (that is inverted relative to the first configuration) and extends proximally in an inverted configuration along the distal end of the catheter, the flexible tube comprising a plurality of ribbons having a square or rectangular cross-section woven together, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein a plurality of edges of the plurality of ribbons extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, further wherein the projecting edges are not extended from the tractor in a portion of the tractor that extends over the distal end of the catheter; and a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.

[00032] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, the flexible tube comprising a tube wall formed from a plurality of woven ribbons having a square or rectangular cross-section, wherein the tractor is configured to invert over the distal end opening when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections configured so that the plurality of projections extend out of a plane of the tube wall as the tube wall inverts over the distal end opening, further wherein the plurality of projections are

formed from edges of the ribbons and the projections remain in the plane of the tube wall as the tube wall extends along the distal end of the catheter; and a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.

[00033] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending within the catheter and doubling back over the distal end of the catheter, the flexible tube comprising a tube wall, wherein the tractor is configured to invert over the distal end opening when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections formed in the tube wall and configured so that the plurality of projections extend proud of the tractor when the tractor inverts over the distal end opening and otherwise remain in a plane of the tube wall; wherein each of the plurality of projections have a width in a direction transverse to the flexible tube and a length in a direction along a long axis of the flexible tube, further wherein the ratio of length to width is between 10 and 100; and a guidewire lumen through the catheter and the tractor configured to pass a guidewire.

[00034] Any of the apparatuses described herein may be configured so that the tractor is highly soft, and therefore rolls around the distal end of the catheter forming the elongate inversion support easily without jamming and/or requiring a large force to roll the tractor over the distal end opening of the catheter. In particular, tractors having a low axial compression strength, that would, but for the elongate inversion support, typically buckle, have been found to prevent jamming of the elongate inversion support as the tractor inverts. In particular, unsupported tractors (e.g., tractor that are not rolling over a catheter supported annular opening) that are configured to collapse radially under an axial compression of less than about 500g of force (e.g., less than: about 500g force, about 400g force, about 300g force, about 200g force, about 150 g force, about 100 g force, about 50 g force, etc.) may be particularly helpful in preventing jamming. For most knitted, woven, and braided tractors, including those described herein, when the tractor is configured to withstand greater that this amount of axial compression force, the tractor may jam, and/or may require excessive force to invert. Thus, in any of the apparatuses and methods described herein, the tractor maybe sufficiently soft such that without support from the catheter, the tractor collapses radially under an axial compression of less than 200g of force when inverting (and may instead buckle).

[00035] Further, in any of the apparatuses described herein, the tractor may be biased to expand to greater than the outer diameter of the catheter in a second configuration (that is

inverted relative to the first configuration) where the tractor is extending over the outer diameter of the catheter. The same tractor may be biased to expand to greater than the inner diameter of the catheter of the elongate inversion support in the first (e.g., un-inverted), configuration where the tractor is within the catheter of the elongate inversion support. Thus, in relaxed configuration, prior to assembling with the elongate inversion support, the tractor may be oversized compared to the catheter of the elongate inversion support; the portion of the tractor that extends within the catheter of the elongate inversion support, referred to as "un-inverted," may have an inner diameter that is greater than the inner diameter of the catheter, which may tend to drive the tractor toward the walls of the inner diameter of the catheter without collapsing down into the catheter. Further, the inner diameter of the tractor in the "inverted" configuration, e.g., the configuration of the portion that is doubled back over and along the catheter of the elongate inversion support, may be greater than the outer diameter of the catheter of the elongate inversion support. This arrangement may prevent jamming and an increased resistance between the tractor and the outside of the catheter of the elongate inversion support. The catheter may be biased to expand in both the inverted and un-inverted configurations by, e.g., heat setting. The tractor may be inverted to transition between the first and second configurations by rolling over the distal end of the catheter; the terms "inverted" and "un-inverted" are therefore relative terms.

[00036] Also described herein are methods of removing a clot using a mechanical thrombectomy apparatus. For example, a method of removing a clot using a mechanical thrombectomy apparatus may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of an elongate inversion support having a catheter and inverts over a distal end of the catheter so that a distal end of the tractor extends proximally within the catheter; pulling the distal end of the tractor proximally within the catheter to invert the tractor over the distal end of the catheter to extend a plurality of projections from the tractor and grab the clot; and drawing the clot into the catheter.

[00037] Any of these methods may include macerating the clot with the plurality of projections.

[00038] For example, a method of removing a clot using a mechanical thrombectomy apparatus may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of

the catheter so that a first end of the tractor extends proximally within the catheter; pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and extends a plurality of projections from the tractor; grabbing the clot with the plurality of projections; and drawing the clot into the catheter.

[00039] As mentioned above, the tractor may comprises a plurality of woven ribbons having a square or rectangular cross-section, further wherein pulling the distal end of the tractor proximally within the catheter to invert the tractor over the distal end of the catheter to extend a plurality of projections from the tractor comprises extending a plurality of edges of the woven ribbons from out of a plane of the tractor as the tractor is inverted over the distal end of the catheter to grab the clot with the extended edges.

[00040] Alternatively or additionally, the tractor may comprise a plurality of cut-out regions formed in the tractor, further wherein pulling the distal end of the tractor proximally within the catheter to invert the tractor over the distal end of the catheter extends the cut-out regions forming the plurality of projections from the tractor to grab the clot. Any of these methods may include sliding a loose proximal end of the tractor over the catheter as the distal end of the tractor is pulled proximally.

[00041] Any of these methods may include using a guidewire. For example, positioning the distal end of the mechanical thrombectomy apparatus may comprise sliding the mechanical thrombectomy apparatus over a guidewire.

[00042] Similarly, any of these methods may include releasing a releasable attachment between the tractor and an outer surface of the catheter.

[00043] Pulling the distal end of the tractor proximally may comprises maintaining an inner diameter of the tractor within the catheter at greater than 60 % of an inner diameter of the catheter to prevent the tractor from locking over the distal end of the catheter.

[00044] Also described herein are apparatuses having tractor regions with variable stiffness along the length of the tractor. These apparatuses may invert (roll) at their distal-facing end of the tractor with a ratcheting motion. These apparatuses, and methods of using them, may provide a movement that prevents jamming, and may also help grab clot.

[00045] For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that may include: a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower

stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness; an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire.

[00046] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness, further wherein a diameter of the distal-facing end of the tractor oscillates as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter; an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire.

[00047] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening having a radius; a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend along the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness helically arranged around the flexible tube, wherein the regions of higher stiffness have a first length and a stiffness that is greater than the regions of lower stiffness, wherein the first length is between about 0.1 and 1.1 times the radius of the catheter; an inner puller coupled to a distal end of the tractor; and a guidewire lumen extending through the catheter, tractor and the inner puller and configured to pass a guidewire.

[00048] Thus, the regions of higher stiffness may have a longitudinal length along the flexible tube that is between about 0.05 and 1.2 (e.g. between 0.1 and 1.1 between 0.2 and 1 between 0.3 and 1 between 0.5 and 1, between 0.5 and 1.1, etc.) times the radius of the catheter. The the regions of higher and lower stiffness may be helically arranged around the flexible tube. In any of these apparatuses, the ratcheting motion may be seen by an oscillation of the diameter of the distal end-facing end of the tractor as it rolls over the catheter. For example, the diameter of the distal-facing end of the tractor may oscillate as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter.

[00049] As mentioned, the tractor may be formed of a woven and/or knitted material. For example tractor may comprise a knitted material comprising one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), and Nitinol. The tractor may comprise a sheet of one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric. The sheet may comprise a plurality of cut-out regions modifying the stiffness.

[00050] Methods of operating any of the apparatuses described herein (including the apparatuses including a ratcheting or see-saw tractors) are also described herein.

[00051] As mentioned above, any of the apparatuses described herein may be configured to prevent jamming by pre-biasing the tractor region so that it has an inner diameter in a first configuration within the lumen of the catheter (referred to for convenience herein as the "un-inverted" configuration, relative to the configuration of the portion of the tractor that has rolled over the distal end opening of the catheter) has a greater outer diameter than the inner diameter of the catheter. Further, any of the apparatuses described herein may also have an inner diameter in a second configuration over the catheter (referred to herein as the "inverted" configuration, relative to the first configuration) that is greater than the outer diameter of the catheter.

[00052] For example, described herein are mechanical thrombectomy apparatus for removing a clot from a vessel without jamming comprising: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first configuration (e.g., an "un-inverted" configuration) within the catheter, inverts over the distal end opening of the catheter and extends proximally in a second (e.g., "inverted") configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein the tractor is biased to expand to have an inner diameter that is greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to have an inner diameter that is greater than the inner diameter of the catheter in the un-inverted configuration; and an elongate puller coupled to the first end of the tractor.

[00053] A mechanical thrombectomy apparatus for removing a clot from a vessel without jamming may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in a first (an "un-inverted") configuration within the catheter, inverts over the distal end opening

of the catheter and extends proximally in a second (an "inverted") configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration; an elongate puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening; and a guidewire lumen extending through the elongate inversion support, puller, and tractor that is configured to pass a guidewire. The tractor may be any of the tractors described herein, e.g., a woven tube, a braided tube, a knitted material, etc.

[00054] Any of the apparatuses described herein may be used with or may include an outer catheter within which the elongate inversion support extends distally; this outer catheter may be referred to as a sleeve or sheath, or in some variations an "intermediate" catheter, as it may be positioned, e.g., using a guidewire or by itself, first within the vasculature and then the elongate inversion support and tractor may be inserted within it to guide them to the clot to be removed, including after removing the guidewire, or leaving the guidewire in position. Any of these devices may be used with a vacuum to help capture and pull clot. For example, if an outer catheter is used, the outer catheter (within which the elongate inversion support can extend distally) may be proximally coupled to a vacuum source. The elongate inversion support may be configured as described herein to permit drawing the vacuum to the end of the elongate inversion support and/or outer catheter. For example, the elongate inversion support may have a diameter that is leaves sufficient clearance. In particular, the apparatus may be configured so that there is at least about 0.002 inches or greater (e.g., 0.003 inches or greater, 0.004 inches or greater, 0.005 inches or greater, 0.006 inches or greater, etc.) between the outer diameter of the catheter and the inner diameter of the outer catheter. The elongate inversion support may have a catheter with the distal end opening about which the tractor inverts that extends only part ways from the distal end towards the proximal end of the elongate inversion support. For example, the full catheter portion of the elongate inversion support may extend less 0.5 cm or less, 1 cm or less, 2 cm or less, 3 cm or less, 4 cm or less, 5 cm or less, etc. In some variations the elongate inversion support comprises a catheter that is skived at the proximal end. The catheter, and particularly the distal end region of the elongate inversion support, may include one or more openings, slots, holes, windows, cut-out

regions, etc. for allowing vacuum to pass from the outer sleeve and preventing choking of the flow of vacuum from the distal end of the apparatus.

[00055] As mentioned, in any of the variations described herein, the tractor may be configured to collapse radially under an axial compression of less than 200g of force. Thus, the tractor may be sufficiently soft and easy to roll (and invert) over the distal end aperture (distal end opening, e.g. of a catheter of the elongate inversion support). Similarly, the elongate inversion support may be configured to withstand buckling of an axial compression of greater than 500 g of force, sufficient to allow pulling of the tractor over the distal end opening (e.g. aperture) of the elongate inversion support without collapsing, kinking or displacing the elongate inversion support. In some variations, and particularly peripheral vascular variations, the elongate inversion support is configured to withstand buckling of an axial compression of greater than 1500 g of force.

[00056] Any of the apparatuses described herein may include a tractor having one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.

[00057]

BRIEF DESCRIPTION OF THE DRAWINGS

[00058] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00059] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows an example of an elongate inversion support portion of an apparatus, configured as a catheter portion. For example, at least the distal end of the elongate inversion support may be configured as a catheter. FIG. 1B shows an enlarged view of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube) extending from a puller (the puller in this example is configured as a catheter. The tractor is shown in a first (e.g., un-inverted) configuration) and may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with

the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus with the elongate inversion support and the flexible tube forming the tractor is shown. The tractor extends through the catheter of the elongate inversion support and doubles back over the distal end opening of the catheter and extends over the outer diameter of the catheter. The outer portion of the tractor (extending along the outer diameter of the catheter) may be held in a collapsed configuration (as shown in FIG. 1E), or it may be expanded, as shown in FIG. 1F. Thus, the tractor may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. FIGS. 1G and 1H illustrate the use of the apparatus of FIGS. 1E and 1F to remove a clot by drawing the flexible tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00060] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00061] FIGS. 2A and 2B illustrate jamming of a mechanical thrombectomy apparatus. In FIG. 2A the mechanical thrombectomy apparatus includes a tractor region that collapses within the inner diameter (lumen) of the catheter portion of the elongate inversion support, jamming so that the tractor region cannot roll, without applying excessive force, or at all, around the open end of the catheter. Similarly, in FIG. 2B, the tractor region is loose, and also jams on the distal open end of the catheter as it inverts.

[00062] FIG. 2C illustrates an example of an anti-jamming configuration, in which the distal-facing, inverting portion of the tractor is flared outwards at an angle, so that the portion of the tractor on either side of the catheter end approaches at an angle of less than 45 degrees relative to a length of the tractor (e.g., 0.5 mm, 1 mm, 2mm) on either side of the opening. In this example, the portion of the tractor that is around the outer diameter is biased to contract down onto the outer diameter of the catheter, and after inverting the bias is to expand outward slightly, resulting in the trumpet-shaped inverting region. Even in this configuration, the

tractor may be set (e.g., biased) so that the outer diameter of the first configuration (within the catheter of the elongate inversion support) has a greater outer diameter than the inner diameter of the catheter in the relaxed state (e.g., when not compressed and constrained in the catheter inner diameter), and the outer diameter of the tractor in the second configuration (inverted over the outer diameter of the catheter of the elongate inversion support) is greater than the outer diameter of the catheter. In some variations the unconstrained first configuration has a greater OD than the unconstrained OD of the second configuration. Alternatively, the unconstrained OD of the first configuration may be less than the OD of the unconstrained OD of the second configuration.

[00063] FIGS. 3A-3C illustrate the operation of a mechanical thrombectomy apparatus having a tractor region such as that shown in FIG. 2C capturing a clot. In FIG. 3A the apparatus is positioned adjacent to the clot. FIG. 3B shows an alternative variation in which a guidewire is used to position the apparatus; the guidewire may remain in place during capture of the clot, or it may be removed. FIG. 3C shows the apparatus capturing the clot by rolling the tractor portion of the apparatus over the end of the catheter of the elongate inversion support as the tractor portion is drawn proximally; the apparatus may be advanced distally within the lumen of the vessel.

[00064] FIGS. 4A and 4B illustrate another example of a mechanical thrombectomy apparatus having a tractor in which an anti-jamming sleeve portion is included between the catheter outer diameter and the tractor. In FIG. 4A the tractor portion is configured to include a central guidewire lumen and a hypotube (inner catheter) is used to pull the proximal end of the tractor; in FIG. 4B the tractor is configured to collapse down to a puller wire.

[00065] FIGS. 5A-5B illustrate formation of catheter tip having a stiffer distal end adapted to prevent jamming and/or collapse of the catheter distal opening when inverting a tractor over the distal end. In FIG 5A the tip is shown with a slightly proximally-offset from the distal end marker band; in FIG. 5B the tip of the catheter has been folded back over itself, increasing both the diameter of the catheter at the distal end and the stiffness of the distal end.

[00066] FIGS. 6A-6B is an example of a distal tip or end region of a catheter such as that shown in FIG. 5B, over which a tractor is inverting. FIG. 6A is an example of a side perspective view and FIG. 6B shows the distal end face of the apparatus.

[00067] FIGS. 7A-7E illustrate examples of heat set 0.085" ID PET (FIGS. 7A-7C) tractors and nickel titanium heat-set 0.085" ID tractors.

[00068] FIGS. 8A-8D illustrate operation of mechanical thrombectomy apparatus pulling in a clot. FIGS. 8E-8F illustrate reversal of the apparatus of FIGS. 8A-8D, ejecting the clot.

[00069] FIGS. 9A-9C illustrate operation of an apparatus having a 48-end PET (0.002" monofilament) tractor. FIG. 9D illustrates reversing the apparatus of FIGS. 9A-9C.

[00070] FIGS. 9E-9G illustrate operation of an apparatus having a 72-end PET (0.002" 4x0.0008" filament) tractor drawing in a clot.

[00071] FIGS. 10A-10E illustrate examples of knitted tractors.

[00072] FIGS. 11A-11D illustrate patterns that may be used to form a tractor for a mechanical thrombectomy apparatus.

[00073] FIGS. 12A-12I show examples of microstructures that may be included in any of the mechanical thrombectomy apparatuses described herein.

[00074] FIGS. 13A and 13B show side and cross-sectional views, respectively, illustrate an example of a tractor having selectively deployable projections that may extend from the inverting region of the tractor to assist in grabbing and/or macerating a clot.

[00075] FIG. 14 illustrates an example of an apparatus including a plurality of projections extending from the tractor region that may aid in grabbing and/or macerating a clot.

[00076] FIG. 15A shows an example of a distal end of a mechanical thrombectomy apparatus having a tractor formed from a plurality of filaments having a round cross-sectional profile; the tractor of FIG. 15A does not include any projections extending therefrom. FIG. 15B illustrates the outer profile of a filament of the device of FIG. 15A as it inverts over a distal catheter opening of the elongate inversion support. FIG. 15C illustrates the rounded profile of the filaments forming the tractor of FIG. 15A.

[00077] FIG. 15D is a section through a rectangular filament (e.g., ribbon filament) having four edges. FIG. 15E illustrates the projection of a ribbon filament as it inverts over a catheter filament; because it approaches from an angle relative to the catheter opening (and because it is constrained by the adjacent filaments) the edge of the ribbon forming the inverting region may project up and out of the plane of the tractor.

[00078] FIGS. 16A and 16D illustrate an example of a tractor having a plurality of projections formed by rectangular filaments (e.g., ribbon filaments) as schematically illustrated in FIGS. 15D-15E. FIG. 16A shows a top perspective view and FIG. 16B is a side view.

[00079] FIGS. 17A-17D illustrate exemplary tractors formed by cutting (e.g., laser cutting) a tubular material.

[00080] FIGS. 18A-18C illustrate different slotted patterns that may be cut into a tube (or sheet) to form a tractor region.

[00081] FIG. 19 is another example of a pattern that may be use to form a tractor region.

[00082] FIGS. 20A-20B show an example of a pattern that may be use to form a tractor region. FIG. 20B is an enlarged view of the pattern of FIG. 20A.

[00083] FIGS. 21A-21B show an example of a pattern that may be use to form a tractor region. FIG. 21B is an enlarged view of the pattern of FIG. 21A.

[00084] FIGS. 22A-22B show an example of a pattern that may be use to form a tractor region. FIG. 22B is an enlarged view of the pattern of FIG. 22A.

[00085] FIGS. 23A-23B show an example of a pattern that may be use to form a tractor region. FIG. 23B is an enlarged view of the pattern of FIG. 23A.

[00086] FIGS. 24A-24B show an example of a pattern that may be use to form a tractor region. FIG. 24B is an enlarged view of the pattern of FIG. 24A.

[00087] FIGS. 25A-25C illustrate tractor regions having different patterns of slots and openings.

[00088] FIG. 26A illustrates bending of a typical small bore catheter distal tip.

[00089] FIGS. 26B-26C show examples of a catheter comprising a keyed slotted tube extending along the entire length of the catheter.

[00090] FIG. 27 shows an example of a catheter design formed as a slotted tube.

[00091] FIGS. 28A-28B is an example of a catheter design.

[00092] FIGS. 29A-29B is an example of a catheter design.

[00093] FIG. 30A schematically illustrates a portion of a tractor having alternating stiff/less stiff regions. FIGS. 30B-30D illustrate the seesawing motion of a tractor having alternating stiff/less stiff regions.

[00094] FIG., 31A is an example of a knitted tractor having alternating more stiff/less stiff regions extending in a corkscrewing/helical pattern along the length of the tractor.

[00095] FIGS. 31B-31C show side and end views, respectively of an apparatus having a knitted tractor, similar to that shown in FIG. 31A.

[00096] FIGS. 31D and 31E show side and end views, respectively of an apparatus having a knitted tractor.

[00097] FIGS. 32A-32B illustrate jamming in an apparatus having a seesawing tractor region that has alternating stiff regions that are too long for the diameter of the catheter over which it is inverting.

[00098] FIGS. 32C-32D illustrate jamming in an apparatus having a seesawing tractor region that has alternating stiff regions that are too small for the catheter over which it is inverting.

[00099] FIGS. 33A and 33B illustrate another example of an apparatus having a knitted tractor.

[000100] FIG. 34 is a schematic of a knitted tractor.

[000101] FIGS. 35A-35C illustrate movement of the loops of a knitted tractor having loops of a nickel titanium filament forming alternating stiff/less stiff regions (arranged down the long axis of the tractor).

[000102] FIGS. 36A-36B illustrate end perspective and side perspective views, respectively, or an apparatus having a knitted tractor.

[000103] FIGS. 37A-37C illustrate seesawing operation of the apparatus of FIGS. 36A-36B.

[000104] FIGS. 38A-38B show an example of an apparatus having a motor-driven tractor.

[000105] FIGS. 39A-39C illustrate operation of the apparatus of FIGS. 38A-38B.

[000106] FIGS. 40A-40C illustrate apparatuses as described herein including patterned coatings (e.g., hydrophilic and/or hydrophobic coatings).

[000107] FIG. 41A illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus is extended from a distal end of the intermediate catheter to remove a clot.

[000108] FIG. 41B illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus removes a clot that has been drawn into the distal end of the intermediate catheter.

[000109] FIGS. 42A-42B illustrate a variation of a catheter of an elongate inversion support having both different diameters (e.g., a larger-diameter distal catheter connected to a smaller-diameter proximal region extending longitudinally in the proximal-to-distal axis), and a plurality of openings (e.g., cut-out regions, holes, etc.).

[000110] FIGS. 42C-42D illustrate another variation of a catheter of an elongate inversion support having a plurality of opening formed therethrough.

[000111] FIGS. 42E-42F illustrate another variation of a catheter of an elongate inversion support having a distal catheter region and an elongate support member formed by skive cutting the catheter.

[000112] FIGS. 42G-42H illustrate another variation of an elongate inversion support having a distal catheter region and an elongate support member extending from the catheter region.

[000113] FIGS. 42I-42J illustrate another variation of an elongate inversion support having a plurality or openings along the distal-to-proximal length.

[000114] FIGS. 42K-42L illustrate another variation of an elongate inversion support having a minimal catheter region at the distal end forming a distal end opening that is connected to an elongate support (e.g., wire, tube, bar, rod, etc.).

[000115] FIG. 43A is another variation of an elongate inversion support having a minimal catheter region at the distal end. FIGS. 43B-43D illustrate an elongate inversion support such as the one shown in FIG. 43A having additional supports (FIG. 43B) and used as part of a mechanical thrombectomy apparatus (FIG. 43C and 43D).

[000116] FIGS. 44A-44C illustrates an example of the operation of a mechanical thrombectomy apparatus with an expandable distal end region.

DETAILED DESCRIPTION

[000117] In general, described herein are mechanical thrombectomy apparatuses having an inverting tractor that is configured to prevent jamming and grab a blood clot. These apparatuses may include an elongate elongate inversion support support that supports an annulus over which the tractor inverts at the distal end. The tractor may comprise a flexible tube that doubles back over (e.g., inverts) over the distal end of the elongate inverting support (e.g., a catheter) so that it extends into the annuls opening of the elongate inverting support and an inner puller coupled to the inner end of the tractor that the tractor can be pulled proximally to pull and invert the tractor over the annulus at the distal end of the elongate inverting support to roll and capture a clot. The apparatus may include a guidewire lumen extending through the elongate inverting support, and/or tractor puller that is configured to pass a guidewire.

[000118] Any of the apparatuses described herein may be adapted to prevent jamming, e.g., by including a coating (e.g., hydrophilic, lubricious coating, etc.) or the like to enhance the sliding and inverting of the tractor over the distal end. Further, any of these apparatuses may include one or more projections that are configured to enhance grabbing and/or maceration of a clot. Grabbing of a clot may be particularly, but not exclusively, helpful when the tractor is lubricious. Although lubricious tractors may may resist jamming and require less force to operate, e.g., inverting over the distal end of the catheter, it may be more difficult to initially grab or grasp clot when the tractor is more lubricious. It may also be particularly helpful to include projections that are retracted along the length of the tractor adjacent to the outer diameter of the elongate inverting support (e.g., catheter), for example, when positioning the

apparatus within a vessel, but extend the projections outward from the tractor when rolling and inverting to grab a clot.

[000119] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support having a distal end and a distal annulus, and a flexible tractor assembly at least partially inverted and configured to roll and invert over the distal annulus of the elongate inverting support.

[000120] In many of the examples described herein, the elongate inversion support is a catheter (or a portion of a catheter at the distal end) and the annulus is formed by the distal end opening of the catheter; the tractor extends within the catheter and doubles back over the distal end of the catheter to extend over the outer diameter of the catheter at the distal end of the catheter, although it may extend proximal for any appropriate distance (including between 1-30 cm, between 2-20 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). The end of the tractor within the catheter may be coupled to a puller (e.g., at a proximate puller region connected to the distal or inner end of the tractor). The tubular tractor may include an elongate lumen that is configured to allow passage of a guidewire. The tubular tractor may also be configured to slide along the long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor may be referred to herein as a tractor assembly, tractor portion, tractor tube, or simply a tractor, and is typically positioned and longitudinally slideable within the catheter, and arranged so a portion of the tractor (sometimes referred to as the "distal tractor region" or "distal-facing" tractor region) doubles back over itself.

[000121] For example, FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x)

has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[000122] In FIG. 1A, the elongate inversion support is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include a elongate inversion support that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like (as will be described in greater detail below in reference to FIGS. 42A-43D) or may be skived. Thus, any of the apparatuses and methods described herein may be adapted for use with an elongate inversion support that is not limited to catheters, including elongate inversion supports that include a portion of a catheter, or that include a ring or other structure forming the annulus at the distal end. In FIG. 1A the catheter 100 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[000123] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[000124] FIG. 1C shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-

expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1D. In FIG. 1D, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[000125] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor 144 and a less expandable (or non-expandable) proximal portion comprising the puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[000126] In FIG. 1E, the flexible tractor of FIG. 1C is shown with the tractor doubled back over itself an over the the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration, as shown in FIG. 1F, the tractor in this second configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration (shown in FIG. 1F) inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[000127] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter of an elongate

inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be "loose" relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[000128] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[000129] Jamming may occur if the tractor cannot easily invert over the distal end of the catheter, as shown in FIGS. 2A and 2B. In FIG. 2A, pulling the tractor 201 proximally from within the catheter 207 of the elongate inversion support, e.g., by pulling 204 on the inner puller catheter 205, would normally cause the tractor to roll 211 over the distal end of the catheter tip. If the force required to pull the tractor so that it inverts and rolls into the catheter is too great, such as 200 g of force (e.g., greater than 10 g force, greater than 20 g force, greater than 30 g force, greater than 40 g force, greater than 50 g force, greater than 60 g force, greater than 70 g force, greater than 80 g force, greater than 90 g force, greater than 100 g force, etc.), exclusive of any initial deployment force to release the tractor, described herein, then the device is jammed. Typically the tractor may be pulled and inverted over the distal end opening with significantly less force that this jamming force. Jamming may lead to collapse of the elongate inversion support, and device failure. Jamming may occur when, for example, the tractor gets caught on the distal end opening of the catheter of the elongate inversion support. In FIG. 2A, one failure mode leading to jamming results when the portion of the tractor within the catheter 213 collapses inward, as shown. The inventors have found that it is desirable, and may prevent jamming, if the portion of the tractor within the catheter collapses only so that it has a diameter (e.g., inner diameter) of 40% or more of the inner diameter of the catheter (e.g., 45% or more, 50% or more, 55% or more, 60% or more, 65% or more, 70% or more, 75% or more, etc. of the inner diameter of the catheter).

[000130] Similarly, FIG. 2B illustrates another example of an apparatus in which jamming has occurred, as indicate by the "X" through the arrows showing the proximal movement of the tractor within the catheter 204' and rolling 211' of the distal-facing inverting portion of the tractor. In FIG. 2B, the tractor bends sharply around the distal end of the catheter. This sharp bend may result in jamming over the distal end of the catheter, as shown.

[000131] Various features that may be used alone or in any combination to prevent jamming of the tractor on the catheter are described herein. For example, in FIG. 2C, a the tractor may be biased so that the portion of the tractor within the catheter in the first configuration 223 (e.g., extending from the puller in an un-inverted configuration in FIG. 2C) would have a relaxed outer diameter (OD) that is approximately equal to or greater than the ID of the catheter (e.g., the relaxed OD of the tractor is between 0.8x to 3x the ID of the catheter), and the OD of the tractor in a second configuration (inverted relative to the first configuration) 221 is typically greater than or approximately equal to the OD of the catheter (e.g., the relaxed OD of the tractor in the second configuration is between about 0.9x and 5x the OD of the catheter, e.g., >1x the OD of the catheter, etc.). It should be noted that the

tractor may be configured so that the relaxed OD of the first configuration of the tractor is greater than the relaxed OD of the tractor in the second (inverted) configuration, or vice versa. This combination of biasing may result in a distal-facing inverting region that is slightly trumpet-shaped 227, as shown. This trumpet shape may result in an angle of approach between the surface of the tractor and the open end of the catheter that is more close to perpendicular relative to the open end, as can be seen by comparing FIG. 2C with FIGS. 2A and 2B. The outwardly-flaring distal-facing tractor region may therefore prevent jamming. FIGS. 3A-3C illustrate the operation of an apparatus including a tractor region that flares outward at the distal-facing rolling/inverting region as it rolls over the distal end of the catheter. In FIG. 3A, the apparatus 305 is driven down the vessel 160 into proximity with the clot 155. A guidewire 309 may be used to aid in positioning, as shown in the alternative view of FIG. 2B. For example, a guidewire may be first guided to the clot, and the apparatus may then be slid over the guidewire to position adjacent to the clot. The guidewire may be left in place or removed before actuating the apparatus as shown in FIG. 3C to remove the clot. In FIG. 3C, the apparatus is actuated by drawing proximally 309 on the inner portion of the tractor 311 so that it rolls and inverts 182 over the distal end of the catheter, as shown. The inverting tractor grabs and pulls the clot into the catheter, compressing and/or distorting it as it pulls it inside. The apparatus may be advanced distally as the tractor is pulled proximally. In some variations the tractor may be expanded longitudinally (distally-proximally) within the catheter as it is drawn proximally within the catheter, because it may be a woven, knitted or elastic material. This may allow the clot to be drawn in quickly and may secure it within the catheter.

[000132] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions.

[000133] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example

the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[000134] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[000135] In any of the variations described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily side over the catheters distal end and around the tip of the catheter when pulled through the inside of the catheter.

[000136] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[000137] The stiffness of the distal of the catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the catheter tip (e.g., the last 5mm) may be fabricated of

a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inward ward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[000138] As will be described in greater detail below, it may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may be desirable to form a braid structure with texture. One example is to braid 2 or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[000139] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[000140] Reducing the sliding friction of tractor to outer catheter wall, improving tractor to tip rolling, and/or enhancing tractor to inner catheter sliding may also be achieved by including a sliding skin or sleeve. For example, a thin (e.g., ultrathin) sleeve may be used. The sleeve would be made from low friction polymer (PET, PE, PP, PTFE, ePTFE, pebax, urethanes) by braiding, knitting, weaving, extrusion, melt blown, melt spinning, etc. The sleeve could be made from laser slotted tubing, chemical etching, micro machining. The sleeve could be also coated with a lubricious coating such as a hydrophilic coating. Lubricious coatings can be located on the outside and/or inside surfaces. The sleeve may be placed between the dozer element and the catheter wall and attached to the puller element. The sleeve may be less than 0.002" thick, ideally, less than 0.001" wall thickness. The sleeve may decouple the tractor clot grabbing system from the catheter wall, tip rolling and inner catheter dragging friction. The sleeve could be totally free from the tractor, connected to the tractor in discrete locations or connected fully to the tractor. This may allow the tractor to be designed to grab clot (larger wires: 0.001" to 0.002" for neuro, and 0.002" to 0.007" for other applications) and the skin to minimized in thickness and structure to reduce friction and skin bending stiffness.

[000141] FIG. 4A shows one example of a sleeve that may be used. In this example, the sleeve 403, such as those described above, may be positioned between the catheter 401 outer diameter and the tractor 405. The sleeve (or "skin") may be inverted with the tractor, or it may be held on the outer diameter and the tractor moved over it. FIG. 4B is another example in which the tractor is pulled by a pull wire 409; in FIG. 4A the tractor is pulled by a puller catheter 408 within the outer device catheter 401.

[000142] In some variations, the tractor region may be formed of with a mixed or hybrid structure, combining one or more of interwoven or knitted braid polymer filaments with metallic filaments. The mixed structure (hybrid structure) may leverage both metallic elements interwoven with low friction polymer elements. The metallic filaments may create stiffness elements that may grip/grab a clot. The polymer filaments may aid in grabbing clot but may provide surface friction reduction to the outer catheter wall, the catheter tip and the inner catheter wall once around the tip.

[000143] Any of the apparatuses described herein may include a tractor having a hydrophilic/lubricous coating on the inside surface, e.g., for braided/knitted tractors, on the inside surface (contacting the outer and inner diameter of the catheter) of the braid/knit, which is in contact with the outside of the catheter. Examples of lubricous coatings include hydrophilic coatings (e.g.,. hydrogels) and hydrophobic coatings (e.g., fluorine coating such as PTFE & FEP, parylene, silicone, siloxane (silicone additive) added to various polymers including pebax to make any material more lubricious, Polyethylene, polypropylene, FEP)

[000144] As mentioned above, any of these apparatuses may include a distal tip that is less rigid (e.g., 'softer') than the more proximal regions of the distal tip. This may be achieved by having a structural supporting member reinforcing the distal tip, or by modifying the material forming the distal tip. In some variations, the distal tip of the catheter may be stiffened (made more rigid) by inverting over the catheter end. See, e.g., FIGS. 5A-5B showing an inverted soft tip of a catheter. In this example, a 72-end PET braid was used to invert the tip 501 of the 0.071 catheter back over itself 505 as shown in FIG. 5B. Inverting the distal section of the catheter tip, which may include a hydrophilic coating, inside of the catheter and (in this example, though not a necessity) a radiopaque marker band 507. This may crease a larger radius tip which is relatively stiffer than the tip and has a hydrophilic coating around the outer diameter and inner diameter all the way on the last 2-5 mm of the catheter. Optionally, the catheter may be delivered with a tip similar to that show in FIG. 5A, but when the tractor is pulled initially into the catheter, the distal end of the catheter may invert to form the tip as shown in FIG. 5B.

[000145] FIGS. 6A and 6B show another example of an inverted soft-tip catheter over which a tractor 601 (in this example, a PET braid having 72 ends and a 4 x 0.0008" material). The tractor in FIG. 6A is rolled over the hydrophilic coated tip 603 showing a large collapsed radius (e.g., it does not collapse down on itself). The coating of hydrophilic material enhanced the rolling of the material over the catheter. The catheter was loaded with the tractor having a small (2 mm) ID tube, which is very close to the catheter OD. In this example, 23 cm of tractor was pulled easily into the catheter having a rolled tip as shown in FIG. 5B. In this example, the tip did not collapse, however other tractor materials (e.g., metallic, such as Nitinol materials) may collapse the tip, even when inverted as shown.

[000146] FIGS. 7A-7F illustrate examples of braided tractors that may be used. In these examples, FIGS. 7A-7C show PET braids that are heat-set to 0.085" IDs (at 395°F for 10 min). For example, FIG. 7A is a 0.001 inch PET, having 36 ends and a 77° braid angle at 9 mm, and 0.008 OD filaments. This example was highly porous, but was the least stable of all of the examples shown in FIGS. 7A-7F. FIG. 7B is a 72-end 0.001 polyester strand braid of 8 mm, 90° braid angle, with 4 filaments in each strand. FIG. 7C is a 48-end braid tractor of 0.002" polyester, 90° angle over 9 mm mandrel. The braid shown in FIG. 7A collapses 50% of the diameter, while the the braided tractor shown in FIG. 7B collapsed less than 5% of the diameter, and the braided tractor of FIG. 7C collapsed less than 25% of the diameter. FIGS. 7D and 7E show Nitinol braided tractors heat-set to 0.085" ID (at 510 °C for 8 min). These braided tractors were constrained to 0.070 inches to show the pore size when pulling into a 0.071 catheter. Other examples of braided tractors had between 96 or 144 ends of 0.0005"-0.0015" PET mono or 0.0005" - 0.001" filaments with a <35° braid angle.

[000147] FIGS. 8A-8D illustrate the operation of a 72-end 0.001" NiTi tractor capturing clot in a model vessel. In this example showing pulling the clot into the catheter, the ID of the vessel is nearly the same as the OD of the catheter tip. Drawing the tractor into the vessel shows that the tractor region does not collapse down with inverted into the vessel, preventing locking of the end, and leaving space for drawing the clot, as shown. FIGS. 8E and 8F illustrate reversing the rolling movement of the device to eject the clot from the apparatus.

[000148] Similarly, FIGS. 9A-9C illustrate using a 48-end 0.002" PET monofilament braided tractor capturing a clot in a vessel. FIG. 9D shows reversing of the same apparatus to eject the clot. FIGS. 9E-9G show another example of a braided tractor, comprising a 72-end 0.001" PET (4x 0.0008" fil) material drawing clot into the device by rolling the tractor region into the catheter, as shown.

[000149] As discussed above, tractors may also be formed of a knitted material. A knitted material typically includes materials in which the same filament (or a series of filaments connected in tandem) is knitted to itself to form the tractor. It may be particularly advantageous to use a knit to form a tractor as described herein. For example, FIGS. 10A-10F illustrate an example of a 0.002" knitted tractor 26 needle (SN5923) material, which is a circular weft knit of 0.002" PET monofilament 26 needle head Greige (from Secant Medical). In FIGS. 10A-10C, the knit material is not heat set; the tractor regions shown in FIG. 10E is heat set, knot post-heat treated (at 395°F, 10 min on 0.085" mandrel).

[000150] Any of the apparatuses described herein may include a tractor region that is configured to grab a clot. In particular, described herein are apparatuses that may include a tractor region that has a plurality of projections extending from the tractor, particularly when the tractor rolls around the distal end of the catheter and inverts; these projections may help grab and/or macerate the clot.

[000151] For example, described herein are apparatuses including a plurality of projections that are formed as part of the tractor region. For example, any of these apparatuses may be configured to include projections that are formed by cutting (e.g., laser cutting) or forming from the tractor. Cutting and may be used to form projections or protrusions from a tube of material (or a sheet formed into a tube during processing) such as a sheet or tube of NiTi, thin-film NiTi, cobalt chromium, stainless steel, etc. Projections may be formed from a laser cut NiTi hypotube, a NiTi laser cut sheet, or the like. Projections may also be formed on any of these devices by welding. For example, projections may be formed by welding to a thin-film NiTi tube or sheet. The cut or formed tractor regions may be configured to have virtually any pattern or shape. For example a tractor region having projections that extend from an inverting/rolling tractor region may be formed of a metallic or polymeric material that can include any cut or shaped pattern so that the pattern lays flat (e.g., in the plane of the tractor) on outside of catheter and extend from the tractor (e.g., out of the plane of the tractor) as it rolls around the catheter. The projections may comprise portions of the tractor region pattern that extend and may grab and/or cut, e.g., macerate, the clot as they stick into the clot. These same regions of the tractor may then lie relatively flat against the ID of the catheter when fully inverted and pulled into the catheter.

[000152] In general, cut may be made in the tubes or sheets (e.g., sheets to be formed into tubes) in order to enhance flexibility, porosity and/or to add projections that may extend from the tractor as it is rolled over the distal end opening of a flexible tube (e.g., catheter). A

tractor may therefore be formed into any appropriate pattern, so long as it is sufficiently flexible.

[000153] For example, FIGS. 11A-11D illustrate examples of patterns that may be used for a flexible tractor region. These two dimensional (2D) patterns (e.g., textured surfaces) may provide flexibility of the tractor region in rolling and inverting over the catheter distal end; in some variations, such patterns may help grab a clot when the tractor is rolled and pulled into catheter. These patterns or textures could be formed by laser cutting, molding of plastics or thin film metal (e.g., NiTi Technology), stamping, etching, or the like. The patterns shown in FIGS. 11A-11D generally form closed-cell shapes having angled arms forming the cell walls. The angles may allow deformation in one or more directions. The pattern may mimic the patterns of woven, braided and/or knitted materials, or may be different.

[000154] In any of the apparatuses described herein, the tractor region may also include surface micropatterns that may be added or formed onto the tractor. These micropatterns may help with grabbing a clot. For example, FIGS. 12A-12I illustrate micropatterns protrusions, projections, knobs, bumps, spikes, etc. that may extend from the surface of the tractor. In some variations, e.g., in FIGS. 12A-12C, 12E and 12F, the micropatterns may extend from the tractor region at all times, not just when rolling over the end of the catheter. Another example of an apparatus including a tractor having projections that extend from the tractor including the portion of the tractor that is over the catheter is shown in the apparatus of FIG. 14. In FIG. 15, the tractor 1401 includes a plurality of projections 1403 that extend from the tractor at all times, including the portion of the tractor that is rolling over the distal end opening of the catheter (the distal-facing tractor portion) as well as the portion that is over the outer diameter of the catheter, and within the inner diameter of the catheter. Other variations (e.g., FIG. 12D-12I, FIGS. 13A-13B, and 16A-16B) may project only from the portion of the tractor that is rolling over the distal end opening of the catheter.

[000155] For example, FIGS. 13A and 13B illustrate an example of a tractor region having a plurality of projections that extend from the portion of the surface of the tractor only when that portion of the tractor is inverting and rolling. FIG. 13B illustrates the extension of the projections 1105 from the tractor as the tractor is rolling over the distal catheter opening 1109 to invert. In this example, the tractor is a tubular structure 1101 having longitudinally arranged lengths of tractor material 1103 forming a backbone. Spanning between these flat, elongate regions 1103 are regions that extend between adjacent elongate regions first distally in the long axis, then back proximally. As the tractor rolls over the end of the catheter opening, e.g., as shown in cross-section in FIG. 13B, the loops of material 1105 extend out of

the tractor (out of the plane of the tractor that is defined by the long axis of the tractor), and form projections 1105 that, as the tractor rolls over itself (inverting), extend outward, as shown in FIG. 11B. These projections may help grab a clot.

[000156] Projections formed in the tractor may be formed by cutting (e.g., laser cutting, press cutting, etc.), etching, etc., or they may be woven, braided or knitted into the tractor. For example when the tractor is formed of tube or sheet of material, the projections may be formed from the plane of the tractor material by removing material to leave a projection that may extend up and out of the material. When the tractor is not bending (e.g., inverting), the projections may have a low profile that does not substantially impact tracking of the tractor region when positioning the apparatus, e.g., moving it through a vessel in a patient's anatomy, while still enabling and enhancing rolling around the tip of the catheter. A projection that may help grab a clot may extend distally (e.g., towards the distal tip of the catheter when positioned on the outer catheter surface), so that as the tractor is rolled into the catheter, they extend distally (e.g., shown in FIG. 11B). Thus, the projections may create a grabbing effect. In some variations the projections may also cut into the clot and may macerate it. The projections may also help with catheter removal.

[000157] In some variations the tractor is a woven, braided or knitted tractor that may be formed of one or more strands that have one or more (e.g., 2, 3, 4, etc.) edges that may project from the plane of the tractor as it rolls over the distal end of the catheter. When the strand(s) forming the tractor have a rounded profile (see, e.g. FIG. 15C), as the tractor inverts over the catheter, the face of the inverting distal-facing tractor region remains smooth, as shown in FIG. 15A. FIG. 15B shows a single strand inverting over the distal end opening of a catheter.

[000158] If the strand forming the braided or woven tractor region is instead formed of a material having an edge (e.g., a ribbon, such as a ribbon having a rectangular profile, as shown in FIG. 15D), when the tractor rolls over the distal end opening of the catheter, particularly where the strand (e.g., ribbon) is at an angle relative to the distal end opening (and the distal-facing inverting portion of the tractor), as shown in FIG. 15E, the edge of the strand projects upwards and away from the tractor, out of the plane of the tractor. This is schematically shown in FIG. 15E, showing a rectangular strand or ribbon that may be woven, e.g., in a helical weave, and the edge 1505 of the woven strand twists up and out of the plane of the tractor as it inverts over the catheter to form a projection 1507 as shown in FIG. 15E. This projection may act as a scoop or shovel-like element that may help grab the clot, even if the tractor is lubricated and/or lubricious.

[000159] FIGS. 16A-16B illustrate an example of a tractor formed from a plurality of strands having an edge; shown here as strands that are ribbons having an edge (forming a rectangular profile).

[000160] In FIG. 16A and 16B, the apparatus includes a catheter having a distal end and a distal end opening (not visible beneath the distal end-face of the tractor shown), and a tractor 1600 that includes a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter. The tractor forms a tubular wall and is configured to invert by rolling over the distal end opening of the catheter, as shown in FIG. 16A, when a first end of the tractor is pulled proximally within the catheter. The tractor includes a plurality of projections 1603 (in this example, formed by the edges of the ribbon-shaped strands, that extend from the distal-facing portion of the tractor as it is inverted over the distal end opening of the catheter. As the tractor rolls over the distal end opening of the catheter, the ribbon-shaped strands twist up and out 1603 of the tractor. These twisting edges form projections that can help grab a clot. Thus, FIG. 16A shows a distal end-face of the tractor inverting region as it rolls over the distal end opening of the catheter from the outer diameter to the inner diameter of the catheter. The plurality of projection regions 1603 are formed as the strands (ribbons) twist so that the edges of the strands extend up out of the plane of the tractor. As shown in FIG. 16B, when the tractor is over the outer diameter of the catheter, including the catheter distal end and more proximal regions, these strands do not project out of the tractor, but remain flush against the outer diameter, even when the catheter, and therefore the tractor, are bent and positioned in a tortious vessel; only when inverting do they project outward. Thus, the projections are not extended from the tractor in the portion of the tractor that extends over the distal end of the catheter. The center of this apparatus forms a guidewire lumen extending through the catheter and the tractor and may pass a guidewire. When the tractor is extended along the outer diameter of the catheter proximal to the inverting region, the strands, which are helically woven to form the tractor, remain flat, in the flat cylindrical surface ("plane") of the tractor.

[000161] As will be described in greater detail below, in some variations, including knitted tractor variations, the cells of the tractor may extend up and out of the inverting distal-facing region as it rolls around the catheter. These projections may also act as scoops, shovels, etc. and may help grab onto a clot.

[000162] Some variations of the tractors described herein may be formed of a non-woven, non-braided and non-knitted material. The tractor may be formed of a sheet and/or tube of material that may be directly fabricated (e.g., extrusion, etc.). This tractor may be cut,

including laser cut, to form slots. In some variations these cuts may form projections. For example, the tractor may be formed of a solid (including porous) material into which a pattern is formed (e.g., slots, cut-out regions, etc.) including patterns that produce projections as described above. A tractor region may be formed of a tube of material into which slots or cut-out regions are formed. Such apparatuses may include a tractor formed from a tube of material such as ePTFE (which may be relatively soft, strong in tension and radial compression), NiTi (a super elastic and/or thermally settable material), a fabric (which may be a soft, thin walled material having a reasonably high radial/axial strength), or the like. The tractor may have material frictional properties and material surface hardness that are appropriate to grabbing a clot. In general, materials that are softer may be easier to track the apparatus in the anatomy. As mentioned, the tractor may have pores and may therefore have a tube porosity. The pores may be formed by removing material (or shaping into the openings) and may be oriented to aid in flexibility, rolling and/or tissue grabbing. A tube forming a tractor may be laser cut at an angle relative to axial length, or it may be laser cut (e.g., perpendicular versus angled relative to the tube thickness). Angled cuts may create a cutting surface to mince or macerate a clot, whereas perpendicular or rounded cuts through the thickness of the tractor may enhance grabbing of clot. Any of the tractors described herein may have a final shaped cross-section that is heat-set and/or formed on a mandrel (e.g., formed shape as set on heat treatment mandrel). The tractor regions described herein may be self-expanding. For example, in particular, the tractor may be set (e.g., as a shape-memory material) to expand outwards when inverted (e.g., within the catheter) and may therefore collapse inward slightly when inverted over the outside of the catheter. As discussed above in reference to FIGS. 2C and 3A-3C, this may aid in forming a trumpet shaped distal-facing region of the tractor, where the tractor is inverted over itself. Some variations of tractors may not be self-expanding. As mentioned, the tractor may be formed of a polymeric material (e.g., ePTFE, PET, PP, Nylon), metals (including alloys) or combinations of these. The tractor may have a low profile (e.g., minimum thickness), may be highly flexible and able to to navigate through tortuous vessels, may be able to invert around the catheter tip, may have clot grabbing properties (including projections and/or surface roughness) and may provide a column strength in compression (e.g., strut stiffness), and may be partially or completely radiopaque. The tractors described herein may scale from 1mm OD fully formed to 15mm. Any of these tractors may include a lubricious surface on one or both sides (particularly the side that faces outwards when extending over the outer diameter.

[000163] Examples of slotted laser cut tubes forming a tractor are provided herein, including those shown in FIGS. 17A-25B. The starting tubes may be flexible or rigid. For example, a soft flexible tube, strip, or roll of material such as ePTFE or a dense fabric (e.g., knit or weave or braid) may be used. Flexible tubes may provide tractors and/or combinations of tractors and catheters that allow tracking of the apparatus to the treatment site even in tortious vessels. Tracking allows pushing of the apparatus through tortuous vessels of small caliber over long distances from their introduction site to the human body, over length that can exceed 1 meter in some uses. A flexible tube (pre-laser cutting to form the tractor) may have a softness resulting in a low radial crush force, such as a micro-porous, polymer based tube. The tube may be processed (e.g., by cutting or any of the other techniques mentioned herein) to provide flexibility (e.g., the ability to pull the tractor into catheter, invert, and expand over catheter outer diameter) and/or to create a textured/porous surface that may aid in grabbing a clot (e.g., emboli) and may provide free spaces (voids) that may help store and/or masticate emboli, making them easier to store within the apparatus and transport. Prior to forming into the tractors the sheets or tubes (e.g., films, rolls, etc.) may have a smooth surface. Patterns may be formed into the sheet or tube to form the tractor. For example, laser slot patterns may be formed in the material to increase macro-surface roughness. Holes, slots, edges, divots, and bumps may be formed on the material. In addition to helping grab and hold emboli, such holes or slots may create free space in the tube wall to cut the clot and/or carry it away. The patterns used to form any of the tractors described herein may have a shorter strut length to strut width ratios. Short, wider struts may create tractors that are stiffer and may grab clot better. In combination with strut length to width, in some variations, thicker walls may be preferred. Thicker slotted walls may create stiffer struts and more aggressive surface texture to grab clots. Furthermore, thicker walls may enhance clot storage capacity within the slot gaps.

[000164] In some variations, it may be beneficial to provide slot designs which do not foreshorten. For example, if the slotted tube design is pulled axial (e.g., down its length), the tube diameter may not decrease. A decreasing diameter slotted tube may grab the outside of the catheter and cleat, increasing drag force when the tube is pulled.

[000165] In variations in which the initial tube or sheet of material used to form the tractor tube is relatively rigid (e.g., formed of a material such as Steel, Nitinol, Polyester, PTFE, Nylon, etc.), the initial tube stiffness/hardness may enhance the clot-grabbing ability when the tractor is slotted properly, to allow both increased flexibility, expansion and rolling. For example, a rigid tube may include slot designs that focuses in catheter tracking and creates a

flexibly bending tractor with minimal foreshortening, that is able to be pulled into a catheter (inverting) structure. As with the more flexible starting tubes discussed above, tractors formed of more rigid starting materials may grab and transfer a clot, and the number of slots and/or voids may be increased to increase clot grabbing and/or carrying capacity. A slotted tube forming a tractor may include surface grabbing features, such as channels/corrugations (e.g. any of the microstructures such as those shown in FIGS. 12A-12I above. More rigid tubes may create harder or stiffer slotted tractors. For example, when struts are formed into the tractor (e.g., by cutting, etc.), the slot strut length to strut width may be greater than with less rigid starting materials, and may be a function of the rigid tubes elastic modulus. Higher elasticity materials (e.g., Niti, PET, PTFE) may have strut length to width ratios from 10 to 100. Stiffer materials (e.g., steel, MP35N) may have a length to width ratio greater than 50. The wall thickness to strut width for elastic materials may be, for example, between 0.5 to 10; for stiffer materials it may be between 0.25 to 5.

[000166] As mentioned, any of the apparatuses described herein may include a tractor region that is non-foreshortening. The foreshortening of the tractor may depend at least in part on the slot designs for non-woven, non-braided, non-knitted designs (e.g., tractors that are not formed of a strand or strands of material). FIGS. 17A-17D illustrate an example of non-foreshortening design. Also, for both flexible and rigid starting tubes forming a non-woven tractor, the tube inner diameter can be slightly bigger then catheter tube outer diameter pre-slotting. Slotted tube designs which foreshorten may reach their smallest diameter limit when tensioned axially. If the tube is sized to be slightly larger than the catheter outer diameter, then it may jam (preventing any foreshortening) before it cleats to the catheter outer diameter. Tractor regions formed of an initially rigid material may grab clot more efficiently than tractors having an equivalent thickness but formed of a more flexible material. More flexible materials may deform as a function of stiffness.

[000167] FIGS. 17A-17D illustrate an example of tractors that are formed by cutting slots and/or windows into tubes of material. In FIGS. 17A-17D, an initially soft material (e.g., ePTFE) was formed by a subtractive manufacturing technique to from, slots, pores and textures in the soft flexible tube. In FIGS. 17A-17D, a 3mm ID ePTFE tube (configured to be used with a 2.9mm OD catheter) was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall to create textures and bend zones which impart clot grabbing and rolling. The ePTFE itself is highly lubricous. Addition of a lubricant (e.g., hydrophilic coating) may improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately. FIG. 17A shows

a first pattern 1701, having minimal cuts to create a smooth rolling of the tractor around the catheter 1703 portion of the apparatus.

[000168] A second exemplary pattern is shown in FIG. 17B. In this example, the apparatus slightly larger cut-out regions 1709 (removed by laser cutting in this example), which may create better clot grabbing properties and more clot holding capacity. In FIG. 17B, the ePTFE tube forming the tractor region is slotted on the outside of the catheter. Note that the porosity (14 holes around the circumference) may help grab and hold colt. In both FIG. 17A and 17B, the laser pattern may foreshorten, but may jam before it grips/cleats the catheter outer surface.

[000169] Another example of a tractor was made from a 2.9 mm OD ePTFE tube (configured for use with a 3 mm ID catheter). This example was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall in a pattern to create textures and configured to include bend zones which impart clot grabbing and rolling. Similarly, a tractor may be made of, e.g., a 2.9mm OD PET woven fabric tube (for use with a 3mm ID catheter). The tractor may be formed of 30 Denier PET multi-filaments, 0.003" thickness. The resulting tractor may be configured to be soft and have some level of column stiffness and radial/hoop stiffness by laser cutting slot patterns into the tube wall in a patterns providing texture and bend zones which may impart clot grabbing and rolling. As with ePTFE, the PET material may itself be lubricous although additional lubricant may be added to improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately.

[000170] An example of a tractor made from a somewhat rigid starting material was formed from a nickel titanium (NiTi) tube having a 3mm OD (which may be used with, e.g., a 2.9 mm ID catheter). The wall thickness in these examples was between 0.001" and 0.002". Laser slot patterns were cut into the tube wall in various patterns to create textures and purpose-designed bend zones which may help impart clot grabbing and rolling. A lubricant may be applied, e.g., as a coating, to the ID and OD or to either separately. A first pattern similar to that shown in FIG. 17A was made by minimal laser cutting to create a smooth rolling tractor. The strut length to width ratio was between 25-50. A second pattern having larger slots/openings (similar to that shown in FIG. 17B) was formed by laser cutting. These patterns may foreshorten, but typically minimize or stop foreshortening before the tractor grips/cleats the catheter outer surface (which may result in jamming). The Niti design has the additional benefits of radiopacity, thermal shaping and super elasticity.

[000171] Any of these designs or patterns may for projections that may extend from the rolling distal-facing and inverting portion of the tractor, as discussed above. Such projection may be cut out as "teeth" or elongate members. The regions forming the projections may be sharp, e.g., pointy and/or cutting. Sharp projections may be chew and cut a mature clot. These projections regions may be short or long, may extend in one or more directions (e.g., forward or backward or bidirectional), and may be scoop-shaped (e.g., paddle-shaped). The number of projections may be selected based on the desired coarseness, e.g., the number of projections, the size (length/width/thickness), etc. The projections may change density down their length. For example, the laser pattern can be designed to allow tractor rolling (e.g., long struts) more easily initially, then have grabbing teeth at higher density; alternatively the tractor may be configured for greater initially grabbing, having a pattern with more and/or larger projections initially (distally) then transitioning to more slits (and flexibility) toward the proximal end, which may make it easier to pull. Further, the distribution of projections can be uniform around the tube perimeter and/or non-uniform (e.g., forming a spiral pattern, distributed in patches, having open areas, etc.).

[000172] Any of the tractors described herein may include a marker or makers (e.g., radiopaque markers, such as gold, Pt, etc.). When forming the tractor from a tube or sheet, the tubes may be be cut, then shaped to have any profile, such as straight, rolled over the tip, flaring at the proximal end, etc. Any of the microstructure described herein may be included or formed, as mentioned above, e.g., wells on the struts may help carry and grab clot. Tractors formed of tubes from which material was removed (or sheets formed into tubes) may be configured to have less cleating of the tractor onto the outer diameter of the clot, preventing jamming, particularly compared to woven or braided or knitted materials. However any of the slotted tube tractor configurations described herein may be used with, e.g., in combination with, a braid or knit or polymer sleeve, including either in parallel or in series. In general, any of these tractors may be formed as multi-layers, particular these slotted tube tractors.

[000173] For example, a tractor portion of an apparatus may be formed by removing material from a Niti tube that is slightly smaller than the inner diameter of the catheter that it will be used with, or it may be made from a tube that is slightly larger than the outer diameter of the catheters. The tube may be cut with a pattern that increase the coarseness of the outer surface (e.g., to include projections such as struts/scoops/teeth). For example a 0.001" tube wall thickness or smaller may be used.

[000174] FIGS. 17C and 17D illustrate an example of a tractor region cut from paper. In FIG. 17C a rigid paper tube was cut to include slots and the distal end expanded, a shown. It may be inverted over itself and used as a tractor region. This paper prototype was prepared to illustrate the effectiveness of this pattern. Similarly, FIG. 17D is an example of a prototype tractor region.

[000175] FIGS. 18A-18C illustrate examples of patterns that may be formed into a flat sheet or tubular member to form a tractor (e.g., slotted tractor). Similar to those shown in FIGS. 17A-17D. In FIG. 18A, the pattern may be cut to form the tractor. White regions 1801 may represent or form struts, while the lines indicate slots 1803 from which material is removed. This pattern is one of many resulting in a flexible tube having stout struts. FIG. 18B shows a similar example having a higher density of slots forming thinner struts and potentially higher porosity, which may result in a larger clot-carrying capacity. FIG. 18C illustrates an example of a pattern having curves that may produce a slightly more bendable (flexible in bending stiffness) slotted tractor. In FIGS. 18A-18C, the pattern is oriented so that the distal direction of the tractor formed by the pattern is at the right or left of the pattern shown (e.g., the tube is oriented right and left, relative to the figures, so that the tube is formed by rolling up from the bottom of the figure).

[000176] FIG. 19 is an example of a pattern that may be formed into a tube as part of a tractor having a plurality of both slots 1903 and cut-out regions 1901 (holes). Another example of a pattern having a plurality of cut-out holes 2001 formed into it is shown in FIGS. 20A and 20B. FIG. 20B shows an enlarged view.

[000177] An example of a pattern having a plurality of projections is shown in FIGS. 21A-24B. For example in FIGS. 21A and 21B, the pattern includes a plurality of slots 2101 and cut-out regions that leave a projecting strut or tooth 2105 behind. In these examples, the tooth 2105 is pointed and oriented to the left of the page, which may be the distal end direction of the tractor. (e.g., the left side of the image may correspond to the distal end of the tractor); thus when the pattern is formed into a tubular body to form the tractor, and the tractor is inverted over itself (e.g., rolling over the distal end opening of a catheter) the plurality of pointed projections 2105 may extend out of the tractor, and may help grab and draw clot into the catheter.

[000178] Similarly, the pattern shown in FIGS. 22A-22B illustrate another example include a slot 2201, a projection 2203 and a cut-out portion 2205. As in FIGS. 21A and 21B, the projection may extend out of the plane of the tubular tractor (shown here as the plane of the paper, even when rolled up to form the tractor region). FIG. 23A, and enlarged view of FIG.

24B, shows another example of a pattern for a tractor that is similar to that shown in FIG. 21A-21B, but with smaller projecting regions. In this example, the projections 2305 are sharp, and open into an opening 2303 connected to a slot 2301. The pattern shown in FIGS. 24A-24B is similar to that shown in FIG. 23A-23B but with additional openings (cut out regions 2407) which may increase the carrying capacity (e.g., clot carrying capacity) of the tractor region.

[000179] FIGS. 25A-25C are examples of laser-cut tube prototypes of tractor regions. In FIGS. 25B and 25C the tractor region is inverted over the distal end opening of the catheter.

[000180] In any of the tractor regions described herein, the tractor may have sufficient coarseness to grab the clot, yet still roll easily around catheter tip. Coarseness may relate to the thickness profile of the tractor region. For example, knitted tractors may be more course than braided tractors, due to the macro structure (e.g., cells, wire cross overs, shape of cells). The ability of the tractor to capture and transfer (like a conveyor) clot material through the catheter may be aided by coarser macro structures. In addition, as mentioned above, projections may both increase the coarseness and may help aid in grabbing clot. However, projections that extend only when inverting the tractor may be desirable; e.g., the tractor may feel smooth to the touch unless the dozer is rolled around a corner. The act of rolling the tractor may expose or activate the passive grabbing elements (projections). As mentioned, any of these apparatuses may include pores. For example, any of these apparatuses may include pores having a size that is greater than 1/50th of the catheter circumference. For example, the pore size may be 200 μm or greater (e.g., 300 μm or greater, 400 μm or greater, 500 μm or greater, etc.). In some variations the number pores (openings) per circumference may be between 5-20, 5-10, 10-15, 15-20, etc. pores on per catheter circumference on the tractor. As mentioned, the projections may be sharp, or dull, or may have an enlarged surface area (e.g., paddle-shaped). Sharp strut edges may grab and/or cut clots, while projections may also help grab clot. For example, a tractor may have a texture/roughness of at 0.0005" or greater (e.g., 0.0001"-0.0010"). The tractor may be formed of an inherently lubricious material, and/or may be lubricated through the use of hydrophilic coating on the tractor and/or OD of aspiration catheter or construction of lubricious hydrophobic materials such as Polyethylene, Polypropylene, fluoropolymers, FEP, PTFE.

TRACTORS HAVING ALTERNATING STIFFNESS

[000181] Also described herein are tractors having alternating stiffness along their length. For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may

include a elongate inversion support including a catheter and having a distal end and a distal end opening and a tractor that is configured as a flexible tube that extends longitudinally within the catheter and doubles back over the distal end of the catheter to extend over the distal end of the catheter. The tractor may be formed of longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness. In some variations this may allow the lower stiffness regions to act as hinge-regions relative to the stiffer regions, when the tractor is pulled into the catheter. These variations may result in a seesawing motion at the distal end opening of the catheter, as the tractor is inverted and pulled into the catheter. This is illustrated schematically in FIGS. 30A-30D. For example, a portion of a length of tractor may include more stiff regions 3001 and less stiff regions 3003 that are alternating along the long axis of the tractor, as shown schematically in FIG. 30A. As the tractor region is inverted over the distal opening of the catheter (shown in FIG. 30B, in which a portion of the catheter wall is shown 3009), pulling the tractor over the wall 3009 causes the more flexible portions to bend over the wall, while the less flexible regions 3001 bend less or not at all. FIGS. 30B-30D illustrate progression of a tractor portion over the distal end opening, showing the bending of the less stiff/more flexible regions 3003 over the wall, while the more stiff/less flexible regions 3001 do not bend. The result is that, as shown by the arrows on the bottom, the diameter of the distal-facing region changes, and oscillates, as the tractor is pulled into the catheter.

[000182] Thus, the tractor may be configured so that it rolls around the catheter tip opening an inverts in a ratcheting fashion, in which parts of the tractor that are stiffer than other sections alternate with more stiff regions. These differently-stiff sections may cause the tractor rolling around the catheter tip to move in a semi-rigid manor and/or a pivoting/seesawing motion around the distal face of the catheter opening and the regions adjacent to the distal opening.

[000183] Tractors having alternating stiff/less stiff regions down the length of the catheter (including arranged in a helical manner spiraling down the length) may be formed in a variety of different manners, including constructing braids, laser cut tubes, knits, weaves, and laminates. For example, FIGS. 31A-31D illustrate an example of a knitted tractor region having this configuration. As the the variable stiffness tractor rolls around the catheter, sections of the tractor may temporarily dive to towards the center of the catheter ID, which may also aid in grabbing clot or a foreign body to pull into the catheter. The apparatus may be configured so that the tractor includes sections that sea-saw around the catheter tip so the

dozer protrudes into the catheter ID by a distal equivalent to 5%, 10,%, 15%, 20%, 25%, 30%, 40%, 50%, 70%, 80%, 90% of the catheter's inner radius length, or any range of the numbers.

[000184] The tractor shown in FIG. 31A is a knit construct which has sections that are stiffer alternating with others sections that are less stiff. A first region 2401 of FIG. 31A, is stiffer than the adjacent second region 2403, which is also adjacent to another stiffer region 2401'; the stiffer/less stiff regions alternate and spiral in a helix along the length of the tractor. As the knit tractor shown in FIG. 31A rolls around the catheter, the less stiff section 2403 of the knit shown may temporarily bend, diving the stiffer region 2401 towards the center of the catheter inner diameter in a seesawing motion. FIG. 21B shows a side view of an apparatus including a knit tractor such as shown in FIG. 31A, having alternating stiff/less stiff regions extending down the length of the tractor. FIG. 31C illustrates the distal-facing and inverting tractor that is rolling (in a seesawing manner) over the distal end opening in the catheter. FIGS. 31D and 31E show alternative side and end views, respectively, of a mechanical thrombectomy apparatus including a tractor region such as is shown in FIG. 31A.

[000185] In this example, when the tractor rolls over the distal end opening of the catheter, the alternating stiff/less stiff construction causes the stiffer region to moves towards the center of the catheter, which may aid in grabbing clot or a foreign body to pull into the catheter. The tractor may therefore seesaw around the catheter tip opening so that the tractor protrudes into the catheter ID by a distal equivalent to 5%, 10,%, 15%, 20%, 25%, 30%, 40%, 50%, etc. of the catheter's inner radius length, before withdrawing, and then repeating the cycle.

[000186] The alternating stiff and less stiff regions may have a distance (e.g., axial distance, along the long axis of the tractor) that is related to the inner diameter of the catheter. In particular, if the stiff regions are too large relative to the catheter inner diameter, then the tractor may jam in the catheter, as illustrated in FIGS. 32A and 32B. In FIGS. 32A and 32B, for example, the stiff regions are greater than half the diameter of the inner diameter of the catheter. As shown in FIG. 32B, pulling the tractor into the catheter results in locking or jamming the tractor in the end of the catheter. In some variations the stiff region may be slightly larger than half the diameter without jamming, for example, if the adjacent stiff and less stiff regions wind around the tractor at a sufficiently large angle (e.g., greater than 10 degrees, 15 degrees, 20 degrees, etc.) so that only a subset of the stiff regions moving into the inner diameter of the catheter at the same time. Thus, the length of the stiffer regions may be 0.7 times the diameter of the catheter ID or less (e.g., 0.65 times, 0.6 times, 0.55 times, 0.5

time, 0.45 times, 0.4 times, etc., the diameter of the catheter ID or less). This may also be expressed the length of the stiff region being 1.3 times the radius of the catheter ID or less (e.g., 1.2 times, 1.1 times, 1.0 times, 0.9 times, 0.8 times, etc. the radius of the catheter ID or less).

[000187] Similarly, if the length of the stiff regions is too small, it will not see-saw in any appreciable amount and may, in some variations, jam onto the end of the catheter, as illustrated in FIGS. 32C and 32D. In FIGS. 32C and 32D, the length of the stiffer alternating regions is not substantially larger than the thickness of the catheter (e.g., the distance between the ID and OD of the catheter), so that no seesawing motion will occur. For example, the length of the stiff region may be 1.1 times or more than the thickness of the catheter (e.g., 1.2 times, 1.3 times, 1.4 times, 1.5 times, 1.6 times, 1.7 times, 1.8 times, 1.9 times, 2 times, etc. or more than the thickness of the catheter). Alternatively the length of the stiff regions maybe 0.1 times the radius of the catheter or greater (e.g., 0.2 times the radius of the catheter, 0.3 times the radius of the catheter, etc.).

[000188] In FIG. 32A-32B, the tractors formed of knit materials having different sizes post-heat treatment (e.g., 0.002" knit 26 needle (SN5923) heat treated on a 0.085" mandrel) than those shown in FIG. 32C and 32D. In FIGS. 32A-32B, the knit material locked on and could not be rolled over the catheter. Relative to the size of the knit, the ID of the catheter (0.045" ID/0.055" OD) was too small. In contrast, in FIGS. 32C and 32D, the catheter dimensions were too large for the knit (e.g., 0.085" ID 72D Pebax, 0.95" OD); the knit material could not pull around and invert on the tubing of this size.

[000189] FIGS. 33A and 33B illustrate another example of a seesawing tractor formed from a knitted material. FIG. 34 shows an enlarged view of a portion of knitted material forming a tractor. The knitted tractor is formed from a filament (a monofilament or group of fibers collected into a filament) that is knitted to itself. The knit may be a tubular knitted material formed from a filament (monofilament or group of filaments) forming interlocking loops as shown in FIG. 34. In this example, the regions of overlap 3401 between the loops form the stiffer region, while the non-overlapping regions form the less stiff regions 3403. In any of the variations described herein, the loops formed by the knit may also act as protrusions as discussed above, and may aid in drawing the clot into the catheter and/or macerating the clot. For example, the sequence of illustrations in FIGS. 35A-35C show a portion of a knitted tractor having loops of nickel titanium forming alternating stiff/less stiff regions (arranged down the long axis of the tractor) as they roll in a seesawing manner over the distal end opening of the catheter. In this example, a single loop 3501 has been indicated showing it's

progression from flush against the wall of the outer diameter of the catheter as the tractor is pulled into the catheter, until, as it approaches the distal opening of the catheter, it inverts by swinging the loop portion 3501 out of the plane of the tractor and up, where it may help grab clot material, as shown in FIGS. 35B-35C. The seesawing motion of a knitted tractor may also be seen in FIGS. 36A-36B and 37A-37C. An example of a mechanical thrombectomy apparatus is shown in FIGS. 36A-36B from end and side perspective views. FIGS. 37A-37C illustrate a method (e.g., that may be used for grabbing and removing a clot from a vessel) including pulling the distal end of the tractor (in this example, a knitted, seesawing tractor) proximally into the catheter. As shown in FIG. 37A the tractor may initially pull a stiff region 3703 towards the catheter opening. Because it is sufficiently stiff that it does not bend over the edge of the catheter, but is 'hinged to an adjacent stiff region, as the tractor is pulled proximally, the stiff region eventually tilts over the edge (in a seesawing motion), so that one end flips up away from the opening, as shown in FIG. 37B (stiff segment 3703 is indicated); finally it slides forward into the inner diameter of the catheter, as shown in FIG. 37C.

[000190] As discussed above, it may be desirable to have a tractor region that is sufficiently and/or selectively coarse so that it may grab a clot. In some variations a rougher tractor may grab clot despite the lubriciousness of the tractor. Knits may be generally more course than braids due to their macro structure (e.g., cells, wire cross overs, shape of cells). Knits may also have the desired porosity discussed above (e.g., having a porosity that permits the tractor to grab and store clot/clot carrying capacity). The size of the pores may be, e.g., between 5-20, 5-10, 10-15 or 15-20 pores on the tractor per circumference. The knit may be formed of any appropriate material, including, e.g., Nickle titanium (Niti) wire. For example, a knit may be formed of a PET monofilament, a PTFE monofilament, etc. A knitted tractor may also have a surface lubricity based on either material properties (e.g., metal, polymer, etc.) or added lubricant (inside, outside, both), and may be radiopaque (e.g., including an inter weave in Pt., DFT, over braid wires with Pt., etc.)

Patterned Tractors

[000191] Also described herein are tractors having a pattern of lubricious and/or non-lubricious regions on their outward-facing surfaces. These patterned regions may be coatings and/or surface modification, they may be formed by the material properties of the tractor, and/or they may be due to the application of a lubricious material (e.g., lubricant) in the pattern. A pattern of lubrication and/or non-lubricous material may assist in reducing friction while enhancing clot grabbing. A uniform lubricant (e.g., hydrophilic surface) on the outer-

facing surface of the tractor has been found to reduce the ability of the tractor to grab a clot, particularly in the absence of other clot-grabbing features, such as the protrusions and edges discussed and illustrated above. Thus, described herein are patterns of lubricious and/or non-lubricous (including less lubricious, and tacky or adhesive) materials that may be included on the outward-facing surface of the tractor that may enhance pulling the tractor proximally into the device (e.g., the catheter of the elongate inversion support) and inverting the tractor, while still permitting or even enhancing clot grabbing.

[000192] For example, any of the methods and apparatuses described herein may also include a pattern of non-uniform hydrophilic and/or hydrophobic coating (e.g., a patterned lubricious coating) that may assist with the positioning of the apparatus within the tortuous vessels before or during grabbing a clot. Even a partial hydrophilic coating (e.g., lubricious coating) on the outer-facing surface of the tractor element may reduce friction within the vessel ID. These lubricious regions (e.g., coatings) may be arranged in a pattern such as alternating regions (e.g., bands, stripes, checkerboard pattern, grid, spots, etc.). For example, it may be preferred to partially coat the tractor (e.g., braid) with a hydrophilic material such as using, e.g., a 5 mm coated length of braid followed by a 5 mm non-coated section. This coating may be in other patterns, as mentioned, including strips (longitudinal strips), a spiral pattern coating, a random pattern coating, etc. FIGS. 40A-40C illustrate examples of hydrophilic coating options.

[000193] For example, FIG. 40A shows an example of an apparatus including a tractor region and 4001 a catheter of an elongate inversion support 4005 into which the tractor is inverted and drawn proximally at the distal end of the tractor. The tractor 4001 may be attached to a puller 4009 (e.g., pull wire or pull catheter) to pull, or in any of these variations, push and pull, the tractor within the catheter from the distal end of the tractor. The proximal end of the tractor is attached over the outer surface (OD) of the outer catheter 4005. In FIGS. 40A-40C the tractor is shown as a braided tractor, but any of the tractor types (braided, woven, knitted, solid/cut-out, etc.) described herein may be configured to include a pattern of more/less lubricious regions.

[000194] The tractor shown in FIG. 40A includes a pattern of lubricious regions arranged in bands along the distal-to-proximal elongate length of the tractor. For example, regions coated with a lubricious material 4011 and uncoated (less lubricious or even sticky) regions 4013 alternate down the length of the tractor. Alternatively, the pattern may be formed of a grid or checkered pattern, a spiral/helical pattern along the length of the tractor, etc. As the tractor is drawn into the catheter and inverted 4017, the alternating lubricious/non-lubricious

regions may help grab clot, which is particularly or only important when initially pulling the clot material into the inverting tractor and therefore the catheter.

[000195] FIG. 40B illustrates another example of a tractor 4001 in which elongate (in the long axis of the tractor) lengths of lubricious 4021 and non-lubricious 4023 regions altemate to form a stripe pattern down the length of the tractor. These "stripes" may be varying in size (e.g., diameter) and may be curved, zig-zag, wavy, etc.

[000196] In some variations, lubricious regions may be separated by non-lubricious regions by a minimum and/or maximum distance. For example the lubricous regions may be alternated with non-lubricous regions (including less lubricious and/or sticky/adhesive regions) by between 0.05mm and 15 mm (e.g., by greater than at least: 0.005 mm, 0.01 mm, 0.02 mm, 0.03 mm, 0.04 mm, 0.05 mm, 0.06 mm, 0.07 mm, 0.08 mm, 0.09 mm, 0.1 mm 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 0.6 mm, 0.7 mm, 0.8 mm, 0.9 mm, 1mm, 2 mm, 3 mm, 4 mm, 5 mm, etc.). Similarly the maximum separation between lubricious regions may be less than about: 20 mm, 15 mm, 10 mm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, etc.). The minimum and maximum distance may be determined based on the size of the tractor (e.g., diameter), and/or the rate at which the tractor is to be pulled. The minimum distance may also or alternatively be based on the lubriciousness of the coating. More highly lubricious materials may be separated by a greater minimum distance.

[000197] In some variations only a portion of the tractor is coated, either completely or in a pattern, and the proximal end portion (e.g., the last portion be drawn into the catheter) is not lubricious (e.g., uncoated or coated in a tacky/sticky material); the region distal to that (e.g., the region near the initial distal-facing inverting portion of the tractor is lubricious. Alternatively, the proximal end portion is lubricious (e.g., coated with a lubricious material) but the region distal to that (e.g., the region near the initial distal-facing inverting portion of the tractor) is uncoated or is tacky/sticky to help initially grab the clot.

[000198] For example, FIG. 40C shows an example of an apparatus including a sleeve 4035 or cover over the most proximal end of the tractor 4001. This sleeve may itself be lubricious on the outer-facing surface, and may protect or hold the tractor in position until it is drawn distally over the catheter, exposed, and inverted to grab/pull clot 4017. The proximal end of the tractor under the sleeve may be lubricious and/or non-lubricious (e.g., patterned) 4033. The region proximal to the inverting portion, and distal to the sleeve, 4037 may be lubricious or (preferably) non-lubricious and/or a pattern of non-lubricious and lubricous regions.

ELONGATE INVERSION SUPPORTS

[000199] In general, the elongate inversion supports described herein may be or may include catheters that are operated with the tractor and are configured so that the tractor may invert over the distal end opening (aperture) of the elongate inversion support. Any appropriate elongate inversion support may be used and may be configured as a catheter (or micro catheter). Since the tractor region is pulled against the catheter to invert it, the catheter may be configured to have high compression resistance while maintaining superior tip bending (e.g., flexible tip) which may allow it to reach distal vessel segments within the human vasculature.

[000200] Small bore catheters including those for use herein may have braid reinforced segments combined with coil reinforcement. A braid may be used on the proximal end of the catheter to provide column stiffness and medium shaft flexibility, and coils are typically used distally to enhance flexibility while sacrificing column strength. The apparatuses described herein may use a catheter having a slotted tube distal segment element that, when activated, can create a significant axial column compression through the entire catheter shaft. Typically, this column compression may result in some catheter foreshortening and catheter bending (e.g., cork screwing). Described herein are catheters that may reduce this foreshortening and corkscrewing by leveraging slotted tube elements into the catheter distal segment (e.g., the last 8cm or less).

[000201] FIGS. 26A illustrates bending of a typical small bore catheter distal tip. As seen in FIG. 21A, the catheter may bend around a small radius (as compared to the reference dime). The distal segment of this catheter may include a coil, and a low-durometer thin-walled polymer that is relatively soft, flexible and stretchy.

[000202] FIGS. 26B-26C illustrate, for comparison, a catheter comprising a keyed slotted tube extending along the entire length of the catheter. In this variation, the interlocking key segment 2601 of the design provides a axial stiffness when the structure sees compressive loads in the axial direction through the interlocking segments stacking or contacting a one or more point about its circumference. This structure still allows for adequate conformability around a tight radius allowing it to be push-able through a tortuous anatomy (ie neuro tortuous vessel). In order to increase bending flexibility and therefore the ability to make tighter tums, the keys may be shorter or longer and/or nested.

[000203] In general, the bending stiffness of the catheter is a function of the material, material composite structure, wall thickness, strut length, strut width, cell angle, strut shape,

and cell length. FIG. 27 shows an example of a catheter design formed as a slotted tube. The tube includes cut-out regions that provide flexibility while leaving column strength.

[000204] Another example of a catheter configured to have a high column strength and stiffness along its entire length is shown in FIGS. 28A-28B. In FIG. 28A, a hybrid laser-formed coil (spiral) has compaction-resistant features, along the entire continuous length of the catheter. The coil bending stiffness in this design is a function of the material, wall thickness, coil width, helix angle, hinge shape, hinge height, hinge location (e.g., linear axial or out of phase/helix), shape of coil surface and the catheter material stiffness.

[000205] The catheter configuration shown in FIGS. 29A-28B illustrate variations in which individual hoop/ring segments are linked by a polymer wall of the catheter only. The ring bending stiffness is a function of the material, wall thickness, ring width, hinge shape, hinge height, hinge location (linear axial or out of phase/helix), shape of ring surface and the catheter material stiffness.

[000206] Any of the apparatuses described herein may include a catheters having a hard distal tip (e.g., formed of a PTFE, PEEK, stainless steel, etc.) and may be radiused to enhance rolling. The tip opening may be radiused from a middle of catheter wall, without an outer radius. Any of these catheters may include a lubricious coating. Finally, any of these catheters may also be configured to permit aspiration (e.g., drawing suction) through them, which may be helpful.

[000207] FIGS. 42A-43D, described in greater detail below, including examples of elongate inversion supports that may be used in any of the apparatuses described.

[000208] For example, any of the apparatuses described herein may include or be configure for use with a vacuum. The vacuum may aid in initially gasping or grabbing the thrombus. The vacuum may be applied from the distal end of the apparatus and/or of an intermediate or outer catheter or sleeve that is used with the apparatuses (e.g., elongate inversion support and inverting tractor) described herein. Also described herein are apparatuses that are adapted for use with a vacuum, including for use with an intermediate or outer catheter through which the apparatus may be delivered to the clot. The apparatus may grab clot from within the outer catheter, or it may be extended distally out of the intermediate or outer catheter.

[000209] FIG. 41A shows an example of a configuration in which an outer/intermediate catheter or sleeve that is highly flexible may be maneuvered, for example with a guidewire, to a distal end of the device. Thus, the intermediate catheter may be maneuvered near, or adjacent to, the thrombus. As in any of these methods of use described herein, imaging (such as fluoroscopy, contrast imaging, etc.) may be used. Once in positioned, the guidewire may

be removed or left in place, and the apparatus including the elongate inversion support and inverting tractor may be extended within the intermediate catheter/sleeve. In FIG. 41A, the intermediate catheter 4104 is shown positioned within the vessel 4109 distally. As with any of the illustrations here, in the vessel maybe highly tortious and branching, although for convenience it is shown as straight in the figures. The apparatus 4100 is extended distally through the intermediate catheter, and extends out of the distal opening of the intermediate catheter to grab the clot 4111, as shown. The puller 4105 may thus be drawn proximally (to the left in the figure) to pull the tractor 4103 from over the catheter portion of the elongate inversion support 4113, so that it inverts and rolls into the lumen of the elongate inversion support, capturing and drawing the clot in with it. The clot may be compressed.

[000210] Thus, this configuration may be referred to as a vessel cleaner. In addition to the rolling of the tractor to grab and pull the clot, the clot may be pulled by a vacuum applied from one or both of the intermediate catheter 4121 and/or the elongate inversion support 4123. Vacuum may be applied, e.g., within the intermediate catheter, before the apparatus is positioned distally (or even within the intermediate catheter at all) or after it has been extended distally from the intermediate catheter. This configuration shown in FIG. 41A may introduce the tractor through outer catheter to the face of clot. As mentioned, the mechanical thrombectomy apparatus may be extended distally from the intermediate catheter either by pushing it out distally and/or by pulling back the intermediate catheter to deploy all or part of the tractor into vessel, as shown. If vacuum is applied through the catheter, the catheter forming the elongate inversion support may be jacketed or sealed to allow aspiration through this catheter.

[000211] Optionally pull vacuum through outer and/or inner and/or puller. As mentioned, thereafter the tractor may be pulled proximally relative to the the elongate inversion support to pull the clot. The intermediate catheter may then be advanced distally and/or the mechanical thrombectomy apparatus may be withdrawn proximally to remove the apparatus once the clot has been removed. Thereafter an angiogram may be taken to confirm that the clot has been removed.

[000212] Alternatively, in FIG. 41B, a clot may be removed using the intermediate catheter to draw a vacuum with the mechanical thrombectomy apparatus within the lumen (e.g., near the distal end, but not extending fully from the distal end) of the intermediate catheter. As described for FIG. 41A, in FIG. 41B the intermediate catheter may be inserted into the vessel (e.g., using a guidewire) so that the distal end is positioned near the clot. Suction may be

used to draw the clot into the intermediate catheter either before the mechanical thrombectomy device is inserted or after it has been inserted.

[000213] In FIG. 41B, the elongate inversion support 4113' is particularly well suited for use with a vacuum applied through the intermediate catheter 4104 surrounding the apparatus. For example, in FIG. 41B, the elongate inversion support 4113' include a distal catheter region 4125 that extends just a few cm from the distal end opening in which the clot is drawn. The elongate inversion support then tapers down to an elongate support, which may be formed by a wire, hypotube or skived region. This configuration may prevent the catheter from blocking the lumen of the intermediate catheter and and therefore increasing the resistance of the vacuum before it can reach the open distal end and apply suction to drawn the clot. Alternatively or additionally, the outer diameter of the catheter portion of the elongate inversion support may be sized to allow more of the vacuum to pass. For example, the apparatus may be sized such that there is at least about 0.002 inches or greater (e.g., 0.003, 0.004, 0.005, 0.006, etc., inches) between the outer diameter of the catheter and the inner diameter of the intermediate catheter ("outer catheter"). This may also permit unimpeded rolling of the tractor over the distal end opening of the elongate inversion support.

[000214] In operation, the method of removing clot such as shown in FIG. 41B may include pulling at least the tip of a clot into the intermediate catheter through the use of a vacuum 4121. Typically the clot may clog within the intermediate catheter; the mechanical thrombectomy apparatuses described herein may be used to remove the clot from within the intermediate catheter. For example, while maintaining vacuum, the mechanical thrombectomy apparatus may be inserted (or it may be preloaded in intermediate catheter as mentioned) and the tractor puller 4105 may be pulled to pull the clot out of the intermediate catheter and the vessel, compress and/or macerate it and pull it into the apparatus and therefore the intermediate catheter, where it can be withdrawn proximally, e.g., by removing the mechanical thrombectomy apparatus. As mentioned, an angiogram may be taken through intermediate catheter (e.g., leaving it in place in case the mechanical thrombectomy apparatus needs to be re-inserted and used to remove more clot) to confirm clot has been removed.

[000215] As mentioned, a full catheter such as shown in FIG. 41A may block or prevent the vacuum from reaching the distal end of the intermediate vessel. Therefore it may be beneficial to adapt the mechanical thrombectomy apparatus so that it can be used with vacuum within an intermediate catheter or sleeve, as shown in FIG. 41B. This may be achieved as mentioned above, by minimizing the larger-diameter catheter portion of the elongate inversion support forming the distal end opening over which the tractor inverts. In

FIG. 42A for example, the elongate inversion support 700 has a distal catheter portion 701 having a larger diameter than the more proximal region 703, and also includes a plurality of openings, holes, gaps, cut-out regions, slots, etc. 709 that may allow the flow of vacuum through the elongate inversion support more easily. The elongate inversion support shown also includes a distal end 707 into which a tractor 711 inverts, as shown in FIG. 42B. IN FIG. 42B, the elongate inversion support is shown transparent so that the puller 713 and tractor within the elongate inversion support is visible.

[000216] Similarly, in FIGS. 42B and 42C, the entire length of the elongate inversion support includes a plurality of cut-out regions 713 which may increase the ability to allow the flow of a vacuum or other fluid within the apparatus, but may still allow the elongate inversion support to provide column strength to resist collapsing up to at least 500 g of compressive longitudinal force applied by, e.g., pulling on the tractor. Similarly, the elongate inversion support of FIGS. 42E and 42F show a skived catheter that also includes openings 709 along its length. The puller and tractor 412 are shown within the elongate inversion support in FIG. 42F. FIGS. 42G and 42H illustrate an example in which rather than a skived portion of the catheter, the distal catheter region of the elongate inversion support is formed by a wire, bar, tube, 721 etc., that is attached to the catheter at the distal end. The catheter may also optionally include openings 709. The elongate inversion support of FIGS. 42I and 42J includes openings 709' along all or much of its length (particularly near the distal end region) as shown.

[000217] Finally, the variation of the elongate inversion support shown in FIG. 42K includes a minimal catheter portion 732 that is connected to a wire, bar, tube, hypotube, skived region, etc.

[000218] FIGS. 43A-43D illustrate the operation of a similar minimal elongate inversion support 800. In this example, the apparatus includes a distal aperture 743 bonded securely to a wire, bar, tube, hypotube, skived region, etc. 746 forming an elongate support. The elongate support may be hollow (e.g., may include a lumen for a guidewire) or solid. The elongate support may also include one or more additional support guides 750 as shown in FIG. 43B. These supports may help contain the puller and/or tractor within the elongate inversion support. Any of the elongate inversion supports described herein may include additional support guides. The elongate inversion support of FIG. 8B is shown with a tractor 711and puller 712 in FIG. 43C. As mentioned, this variation may be particularly well suited for use with an intermediate (e.g., "outer") catheter, sleeve, or the like 809, as shown in FIG. 43D.

POWER DRIVEN TRACTORS

[000219] Also described herein are mechanical thrombectomy apparatuses in which the tractor is power driven. Any of the tractors described herein may also be driven by a motor, instead of or in addition to the manual driven tractor described. For example, a power-driven tractor may is shown in FIGS. 38A-38B and 39A-39C. In FIG. 38A the tractor is a continuous tractor. FIG. 38B illustrates the catheter and tractor region, without the motor shown in FIG. 38A. The tractor comprises a plurality of belts, chains, lengths, etc. that run longitudinally and may act like a conveyor to pull clot into the apparatus. The loops of material may therefore be run as a power-driven tractor. FIGS. 39A-39C illustrate the operation of the apparatus of FIGS. 38A-38B, shown grabbing a clot.

[000220] Any of the methods (including user interfaces) described herein may be implemented as software, hardware or firmware, and may be described as a non-transitory computer-readable storage medium storing a set of instructions capable of being executed by a processor (e.g., computer, tablet, smartphone, etc.), that when executed by the processor causes the processor to control perform any of the steps, including but not limited to: displaying, communicating with the user, analyzing, modifying parameters (including timing, frequency, intensity, etc.), determining, alerting, or the like.

EXPANDABLE DISTAL ENDS

[000221] Any of the mechanical thrombectomy apparatuses described herein may include an elongate inversion support having a distal end that is expandable from a smaller diameter aperture (e.g., distal end opening) to a larger-diameter aperture. This expansion may be performed by pulling the clot within the catheter. For example, FIGS. 44A-44C illustrates the operation of an example of an elongate inversion support configured as a catheter having an expandable distal end. In this variation the catheter distal end 4401 may include slots or slits 4403 formed or cut, e.g., by laser-cutting, in the distal end of the catheter of the elongate inversion support. The apparatus may be operated as described above, positioning near (e.g., against or adjacent to) a clot, and pulling proximally on the puller to draw the tractor 4405 into the catheter, as shown in FIG. 44B. Although the apparatuses described herein may generally compress a clot greatly, compression may be made easier and/or more efficient by providing a more gradual decrease in radial diameter. As shown in FIG. 44B, when the tractor is rolled over the distal end opening and inverted, the clot maybe drawn in along with the tractor. As the large clot 4413 is brought into the distal end opening, the distal end

opening may expand and open along the slots or slits 4403, as shown in FIG. 44C, so that the distal end opening flares out. In some variations an elastic sleeve, gasket, ring or cover (not shown in FIG. 44A-44C) may be included at least partially covering the distal end to prevent the edge from catching the tractor. For example, and elastic or stretchable layer may cover the cut distal end so that the distal end may be opened to form an outward flare. In FIG. 44C the outward-flared distal end is shown forming a funnel-shape into which the clot may be pulled. This funnel-shaped opening may help compress the clot so that it may be drawn into the mechanical thrombectomy apparatus.

[000222] In some variations the elongate inversion support may be configured to have, or to assume, a funnel-shape at the distal-facing end. The distal-facing end may always have a funnel-shaped mouth at the distal end opening, or the distal end opening may be configured to assume a funnel shape, as shown in FIGS. 44A-44C. In some variations the distal end of the elongate inversion support is configured to be elastic in a radial directly, but maintain stiffness along the proximal-to-distal axis (in compressive load). For example, the distal end of the elongate inversion support may be configured with strands or rods extending in the proximal-to-distal axis that have a high compressive load strength, but which may separate from each other to enlarge the distal end opening; for example they may be connected by rings in which more distal rings are more elastic/stretchable than more proximal rings.

[000223] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[000224] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the

context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000225] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000226] Although the terms “first” and “second” may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[000227] Throughout this specification and the claims which follow, unless the context requires otherwise, the word “comprise”, and variations such as “comprises” and “comprising” means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term “comprising” will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000228] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may

alternatively be exclusive, and may be expressed as “consisting of” or alternatively “consisting essentially of” the various components, steps, sub-components or sub-steps.

[000229] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or “approximately,” even if the term does not expressly appear. The phrase “about” or “approximately” may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point “10” and a particular data point “15” are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000230] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary

purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[000231] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
    an elongate inversion support comprising a catheter having a distal end and a distal end opening;
    a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; and
    a plurality of projections that extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, wherein the plurality of projections do not extend from the tractor as it extends proximally in the inverted configuration along the distal end of the catheter.

2. The apparatus of claim 1, wherein the tractor is sufficiently soft such that without support from the catheter, it collapses radially under an axial compression of less than 200g of force when inverting.

3. The apparatus of claim 1, wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration.

4. The apparatus of claim 1, further comprising a guidewire lumen extending through the elongate inversion support and the tractor and configured to pass a guidewire.

5. The apparatus of claim 1, wherein the proximal end of the elongate inversion support comprises a skived proximal end of the catheter.

6. The apparatus of claim 1, wherein the catheter comprises a plurality of lateral openings along the distal end.

7. The apparatus of claim 1, wherein the tractor comprises a plurality of woven ribbons forming the tubular wall, further wherein the plurality of projections comprises edges of the ribbons.

8. The apparatus of claim 7, wherein the ribbons have a rectangular cross-section.

9. The apparatus of claim 7, wherein the ribbons are arranged in a woven helical pattern.

10. The apparatus of claim 7, wherein he ribbons are formed of a metallic or polymeric material.

11. The apparatus of claim 1, wherein the tractor comprises a knitted material.

12. The apparatus of claim 1, wherein the tubular wall of the tractor comprises steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.

13. The apparatus of claim 1, wherein the projections are cut from the tubular wall.

14. The apparatus of claim 1, wherein each of the plurality of projections have a width in a direction transverse to a long axis of the tractor and a length in a direction along the long axis of the tractor, further wherein the ratio of length to width is between 10 and 100.

15. The apparatus of claim 1, wherein each of the plurality of projections has one or more of: a paddle shape, a scoop shape, and spike shape.

16. The apparatus of claim 1, wherein the plurality of projections comprise sharp ends.

17. The apparatus of claim 1, wherein the material hardness of catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile.

18. The apparatus of claim 1, wherein there is a non-uniform density of projections along the length of the tractor.

19. The apparatus of claim 1, wherein the projections are oriented relative to the tractor so that the projections extend in the distal direction when the tractor is on the outer diameter of the catheter.

20. The apparatus of claim 1, wherein the projections further comprising a plurality of slots or openings through the tubular wall of the tractor.

21. The apparatus of claim 1, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.

22. The apparatus of claim 1, wherein the tubular wall of the tractor has a pore pattern having a longitudinal separation between pores of less than about 0.005 inches.

23. The apparatus of claim 1, further comprising a releasable attachment between the tractor and an outer surface of the catheter, wherein the releasable attachment is configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold.

24. The apparatus of claim 19, wherein the releasable force threshold is 0.01 N.

25. The apparatus of claim 1, further comprising a sleeve extending over the catheter and tractor.

26. The apparatus of claim 1, further comprising an elongate puller extending proximally from the first end of the tractor, wherein the puller is coupled to the first end of the tractor.

27. The apparatus of claim 26, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with a lumen though the tractor.

28. The apparatus of claim 1, wherein the tractor a lumen within the catheter having an inner diameter that is 80 % or greater than an inner diameter of the catheter, so that the tractor does not collapse closed within the catheter.

29. The apparatus of claim 1, wherein the tractor is 3 cm to 50 cm long.

30. The apparatus of claim 1, wherein the apparatus is configured so that the tractor is retractable into the catheter by applying 300 g of force or less to a distal end of the tractor.

31. The apparatus of claim 1, wherein the proximal end of the tractor is loose so that it may be pulled along an outer diameter of the catheter as the tractor is pulled proximally within the catheter.

32. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening;

a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, the flexible tube comprising a plurality of ribbons having a square or rectangular cross-section woven together, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, wherein a plurality of edges of the plurality of ribbons extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, further wherein the projecting edges are not extended from the tractor in a portion of the tractor that extends over the distal end of the catheter; and

a guidewire lumen extending through the catheter and the tractor and configured to pass a guidewire.

33. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening; and

a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, the tractor comprising a tubular wall, wherein the tractor

is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter, further wherein the tractor comprises a plurality of projections formed from the tube wall that extend from a portion of the tractor that is inverted over the distal end opening of the catheter as the tractor rolls over the distal end opening of the catheter, wherein the plurality of projections are not extended from the tractor in a portion of the tractor that extends proximally in the inverted configuration along the distal end of the catheter;

wherein the tractor is sufficiently soft such that without support from the catheter, the tractor collapses radially under an axial compression of less than 200g of force when inverting.

34. A method of removing a clot using a mechanical thrombectomy apparatus, the method comprising:

positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;

pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and extends a plurality of projections from the tractor;

grabbing the clot with the plurality of projections; and

drawing the clot into the catheter.

35. A method of removing a clot using a mechanical thrombectomy apparatus, the method comprising:

positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a soft tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter, wherein the tractor is sufficiently soft such that without support from the catheter, the tractor collapses

radially under an axial compression of less than 200g of force when inverting;

pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and extends a plurality of projections from the tractor;

grabbing the clot with the plurality of projections; and

drawing the clot into the catheter.

36. The method of claim 34 or 35, further comprising macerating the clot with the plurality of projections.

37. The method of claim 34 or 35, wherein the tractor comprises a plurality of ribbons having a square or rectangular cross-section, further wherein pulling the distal end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter comprises extending a plurality of edges of the ribbons from an inverting portion of the tractor as the tractor is rolled over the distal end of the catheter.

38. The method of claim 34 or 35, wherein the tractor comprises a plurality of cut-out regions formed in the tractor, wherein pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter extends the cut-out regions from an inverting portion of the tractor as the tractor is rolled over the distal end of the catheter.

39. The method of claim 34 or 35, further comprising sliding a loose second end of the tractor over the catheter as the first end of the tractor is pulled proximally.

40. The method of claim 34 or 35, wherein positioning the distal end of the mechanical thrombectomy apparatus comprises sliding the mechanical thrombectomy apparatus over a guidewire.

41. The method of claim 34 or 35, further comprising releasing a releasable attachment between the tractor and an outer surface of the catheter.

42. The method of claim 34 or 35, wherein pulling the first end of the tractor proximally comprises maintaining an inner diameter of the tractor within the catheter at greater

than 60 % of an inner diameter of the catheter to prevent the tractor from locking over the distal end of the catheter.

43. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening;

a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to invert and extend over the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness; and

a puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening.

44. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening;

a tractor comprising a flexible tube extending longitudinally within the catheter, doubling back over the distal end of the catheter, and extending over the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness, wherein the regions of higher stiffness have a stiffness that is greater than the regions of lower stiffness, further wherein a diameter of a distal-facing doubled-back region of the tractor oscillates as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter;

a puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening.

45. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening having a radius and a catheter wall thickness at the distal end opening;

a tractor comprising a flexible tube extending longitudinally within the catheter and doubling back over the distal end of the catheter to extend over the distal end of the catheter, wherein the flexible tube comprises longitudinally alternating regions of higher and lower stiffness helically arranged around the flexible tube, wherein the regions of higher stiffness have a first length and a stiffness that is greater than the regions of lower stiffness, wherein the first length is between 1.1 times the catheter wall thickness at the distal end opening and 1.1 times the radius of the catheter; and

a puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening.

46. The apparatus of claim 43 or 44, wherein the regions of higher stiffness have a longitudinal length along the flexible tube that is 1.1 times the radius of the catheter or less.

47. The apparatus of claim 43 or 44, wherein the regions of higher and lower stiffness are helically arranged around the flexible tube.

48. The apparatus of claim 43 or 45, wherein a diameter of the distal-facing end of the tractor oscillates as the tractor is pulled proximally within the catheter to invert the tractor over the distal end of the catheter.

49. The apparatus of claim 43, 44 or 45, wherein the tractor comprises a knitted material.

50. The apparatus of claim 43, 44 or 45, wherein the tractor comprises a knitted material comprising one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), and Nitinol.

51. The apparatus of claim 43, 44 or 45, wherein the tractor comprises a sheet of one or more of: steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.

52. The apparatus of claim 51, wherein the sheet comprises a plurality of cut-out regions modifying the stiffness.

53. The apparatus of claim 43, 44 or 45, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.

54. The apparatus of claim 43, 44 or 45, wherein the tractor has at least one porous section having a pore pattern having a longitudinal separation between pores of less than about 0.005 inches in width.

55. The apparatus of claim 43, 44 or 45, further comprising a releasable attachment between the tractor and an outer surface of the catheter, configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold.

56. The apparatus of claim 55, wherein the releasable force threshold is 0.01 N.

57. The apparatus of claim 43, 44 or 45, further comprising an outer catheter or sleeve extending over the catheter and flexible tube.

58. The apparatus of claim 44 or 45, further wherein the puller comprises a hypotube having an inner lumen that is continuous with a guidewire lumen though the flexible tube.

59. The apparatus of claim 43, 44 or 45, wherein an inner diameter of the portion of the tractor within the catheter is greater than 80 % of an inner diameter of the catheter so that the tractor does not collapse closed within the catheter.

60. The apparatus of claim 43, 44 or 45, wherein the tractor is 3 to 50 cm long.

61. The apparatus of claim 43, 44 or 45, wherein the apparatus is configured so that the tractor may be retracted into the catheter by applying less than 300 grams of force to a distal end of the flexible tube.

62. A mechanical thrombectomy apparatus for removing a clot from a vessel without jamming, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening;

a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the

catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter,

wherein the tractor is biased to expand to have an inner diameter that is greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to have an inner diameter that is greater than the inner diameter of the catheter in the un-inverted configuration; and

an elongate puller coupled to the first end of the tractor.

63. A mechanical thrombectomy apparatus for removing a clot from a vessel without jamming, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening;

a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor comprises a tubular wall, further wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter,

wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration;

an elongate puller coupled to a first end of the tractor and configured to pull the tractor proximally to invert the tractor over the distal end opening; and

a guidewire lumen extending through the elongate inversion support, puller, and tractor that is configured to pass a guidewire.

64. The apparatus of claim 62 or 63, wherein the tractor comprises a woven tube.

65. The apparatus of claim 62 or 63, wherein the tractor comprises a braided tube.

66. The apparatus of claim 62 or 63, wherein the tractor comprises a knitted material.

67. The apparatus of claim 62 or 63, further comprising an outer catheter within which the elongate inversion support extends distally.

68. The apparatus of claim 62 or 63, further comprising outer catheter within which the elongate inversion support extends distally and a vacuum source coupled to a proximal end of the outer catheter.

69. The apparatus of claim 62 or 63, further comprising outer catheter within which the elongate inversion support extends distally, and a vacuum source coupled to a proximal end of the outer catheter, wherein there is at least about 0.002 inches or greater between the outer diameter of the catheter and the inner diameter of the outer catheter.

70. The apparatus of claim 62 or 63, wherein the tractor is sufficiently soft such that without support from the catheter, it collapses radially under an axial compression of less than 200g of force when inverting.

71. The apparatus of claim 62 or 63, wherein the elongate inversion support is configured to withstand buckling of an axial compression of greater than 500 g of force.

72. The apparatus of claim 62 or 63, wherein the elongate inversion support is configured to withstand buckling of an axial compression of greater than 1500 g of force.

73. The apparatus of claim 62 or 63, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.

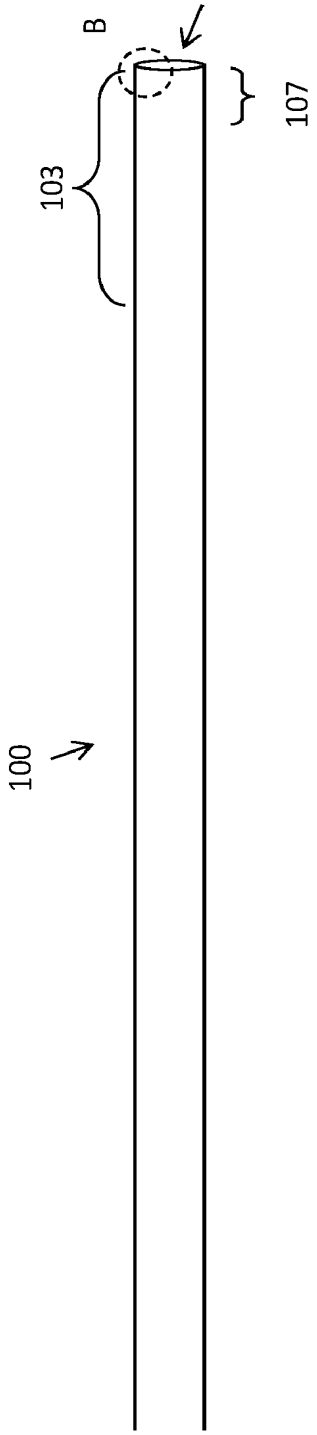


FIG. 1A

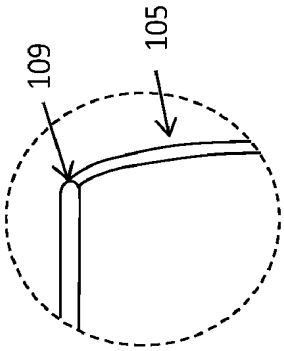


FIG. 1B

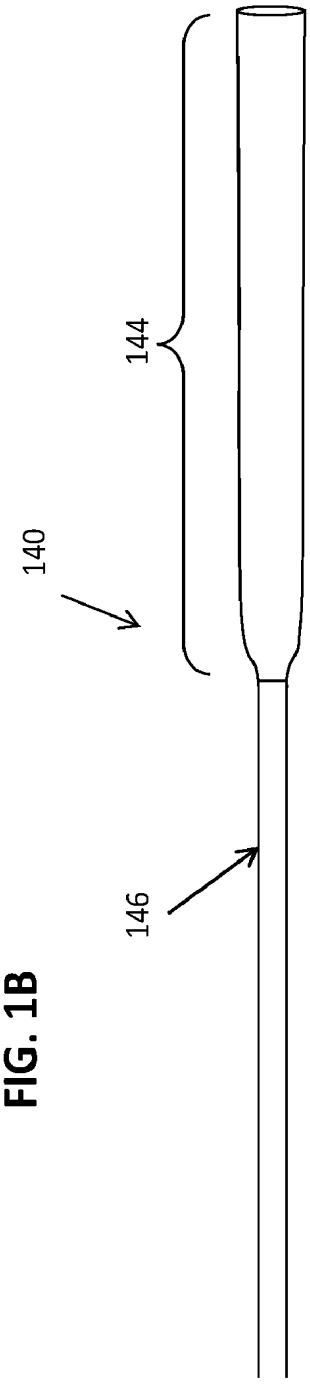


FIG. 1C

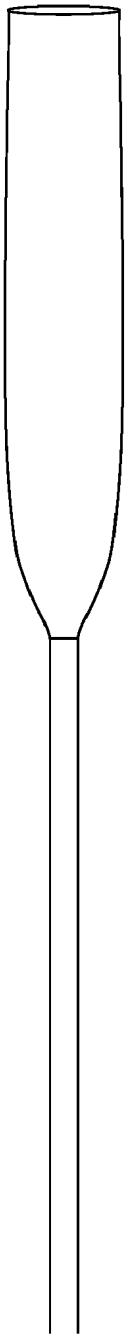


FIG. 1D

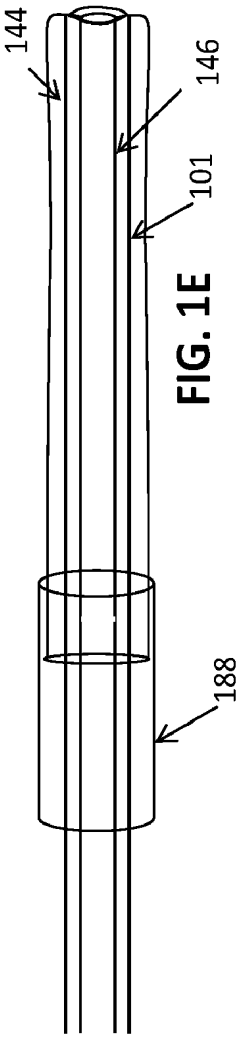


FIG. 1E

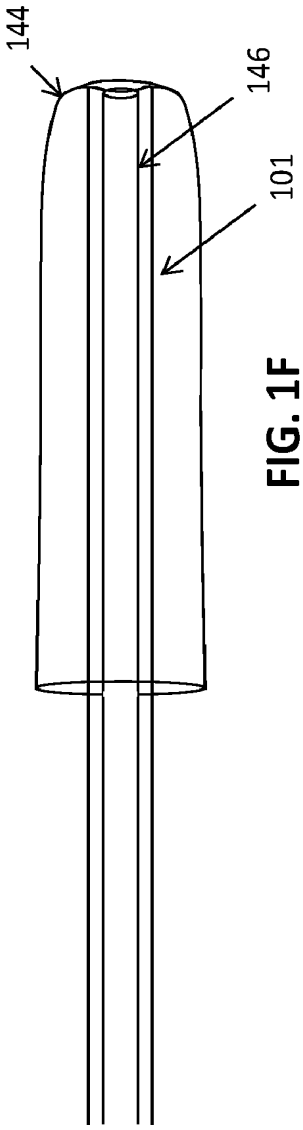


FIG. 1F

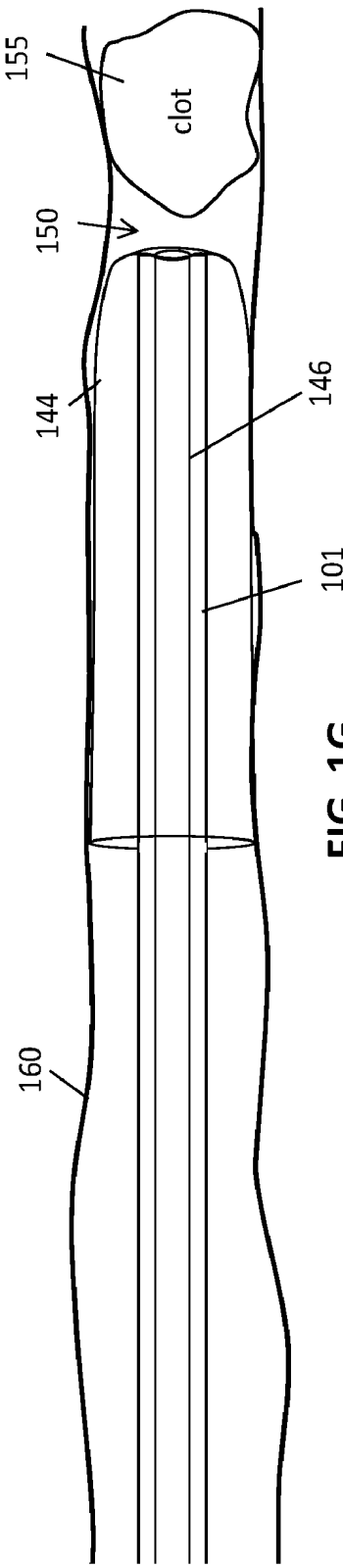


FIG. 1G

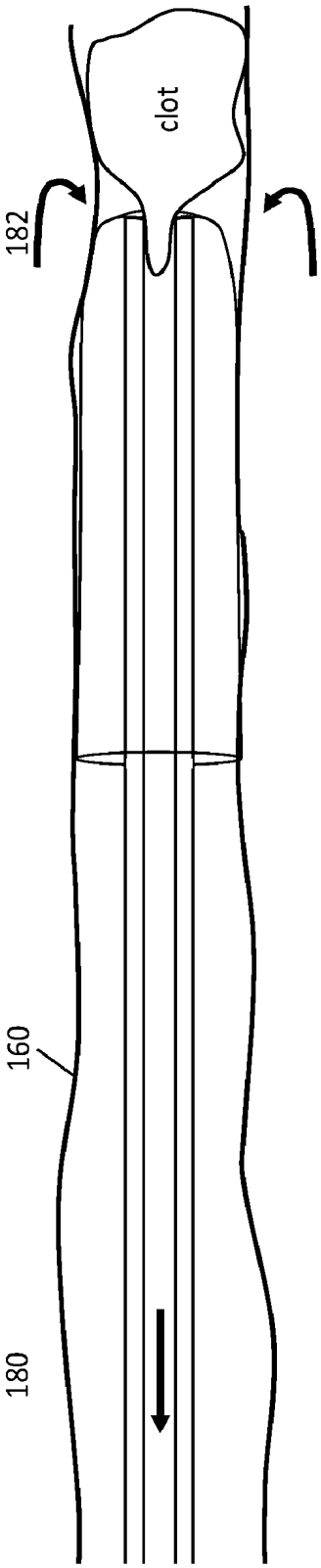


FIG. 1H

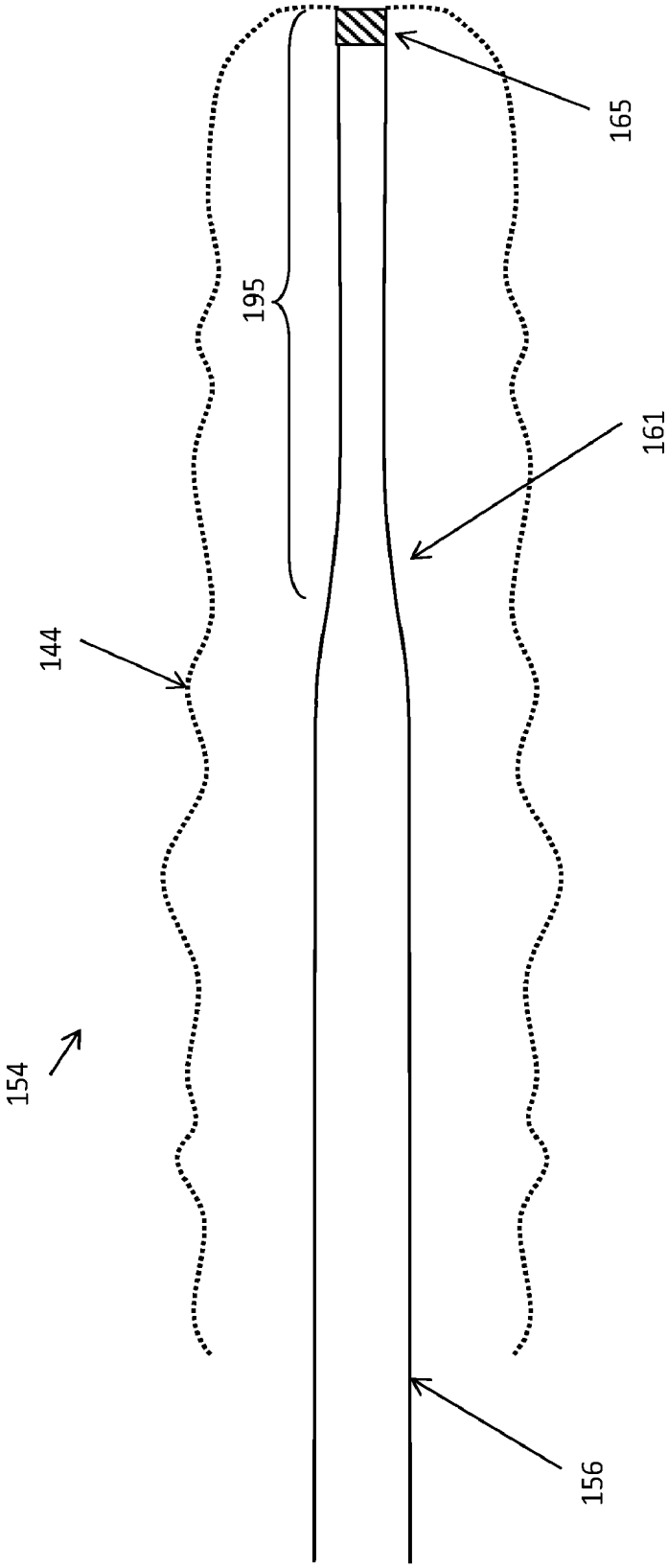


FIG. 1I

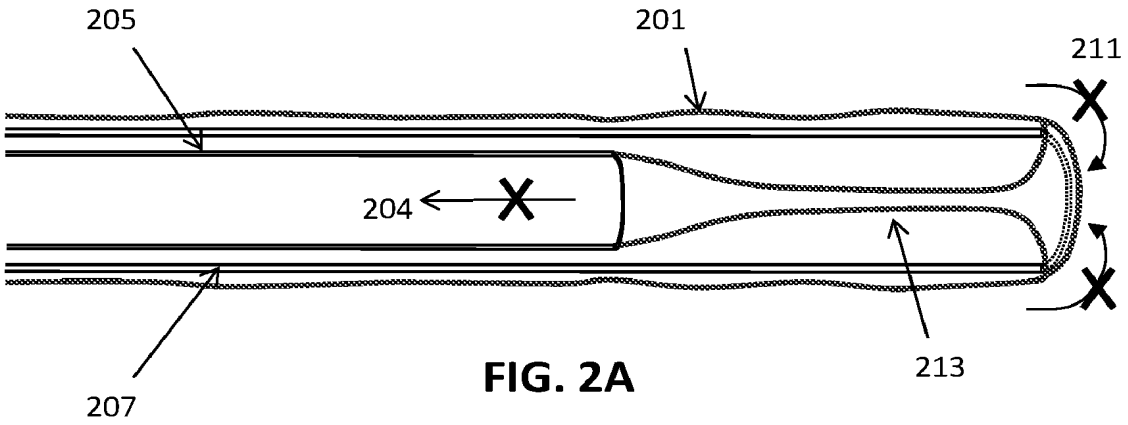


FIG. 2A

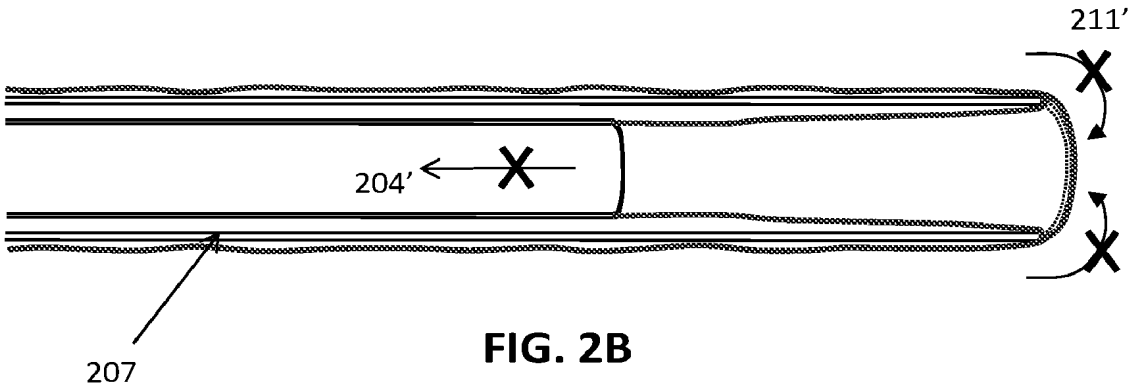


FIG. 2B

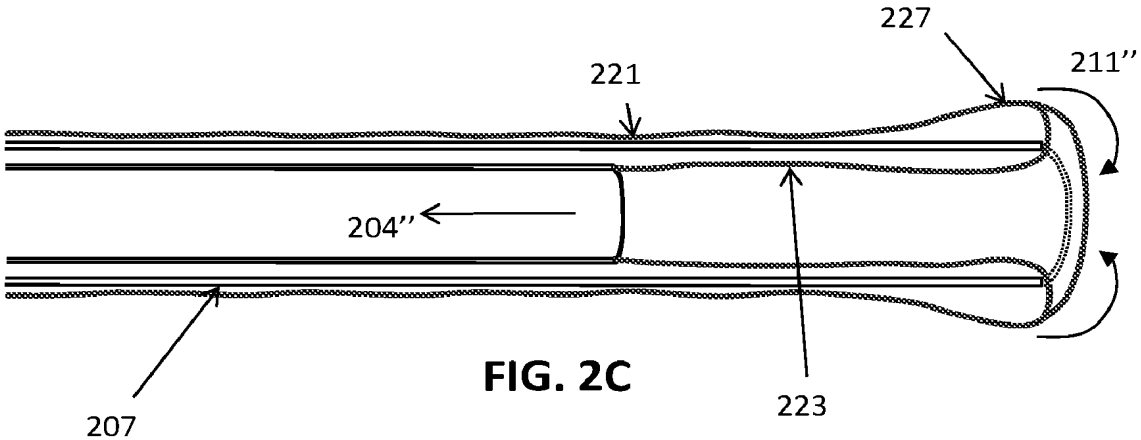


FIG. 2C

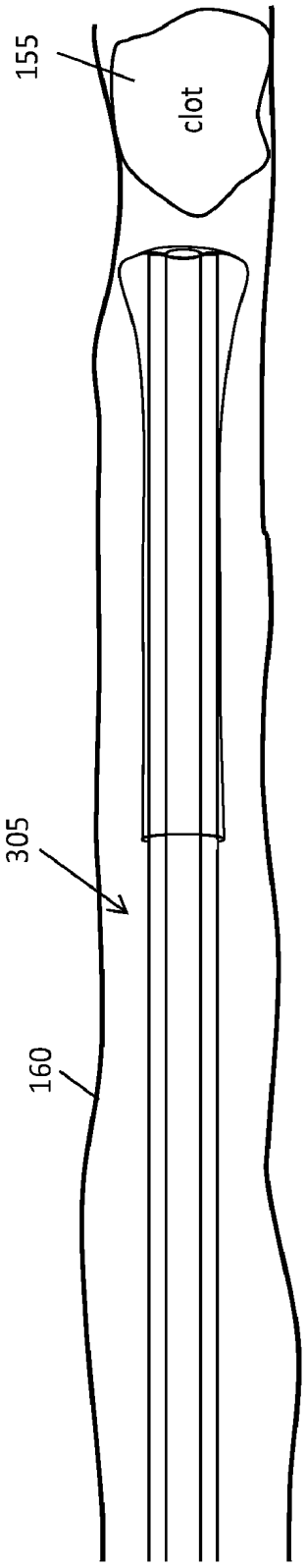


FIG. 3A

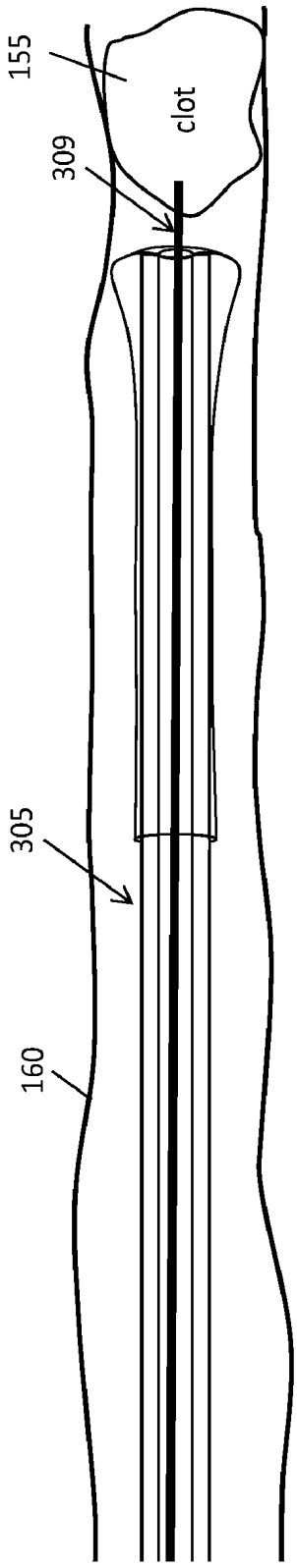


FIG. 3B

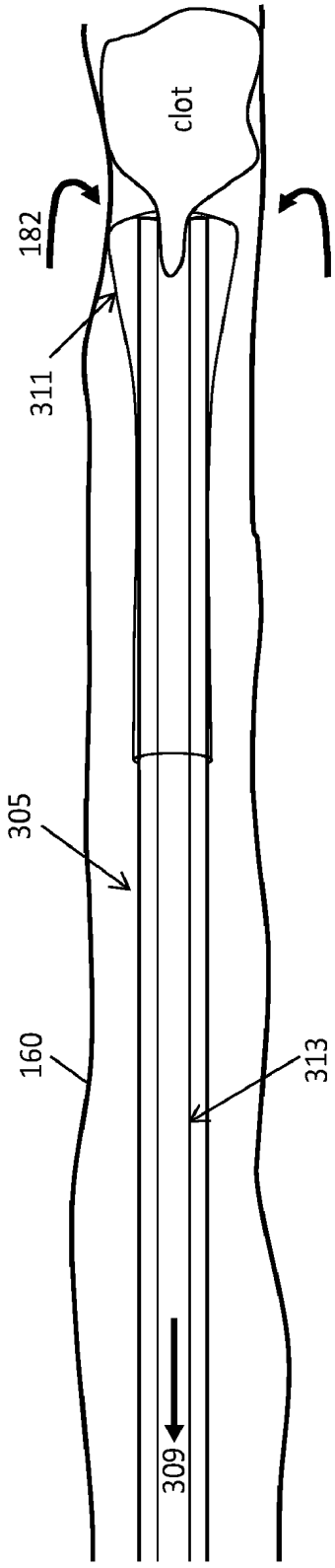


FIG. 3C

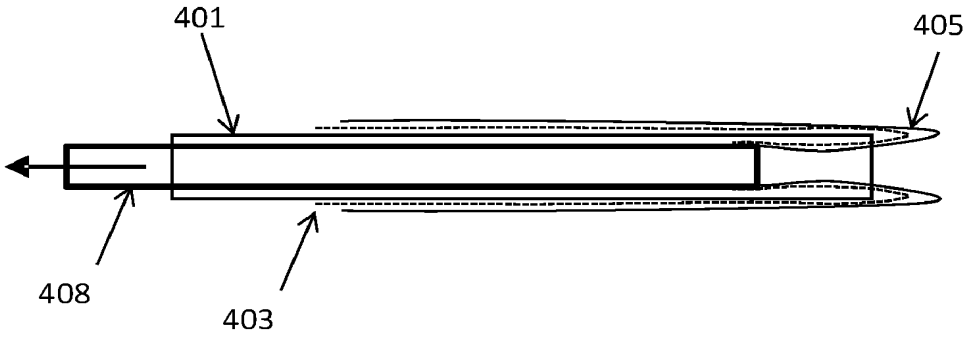


FIG. 4A

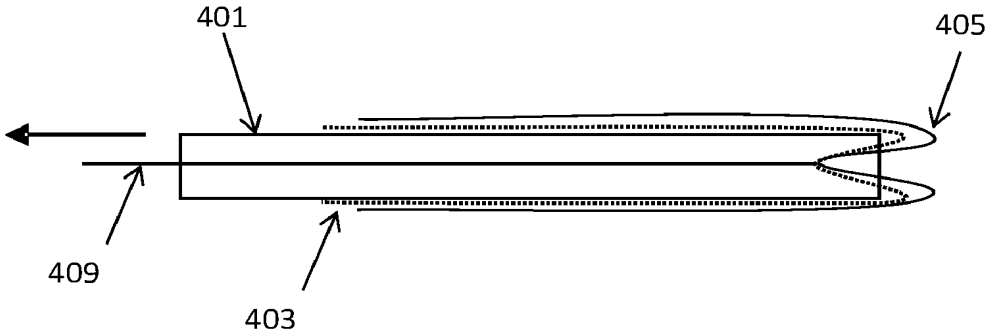


FIG. 4B

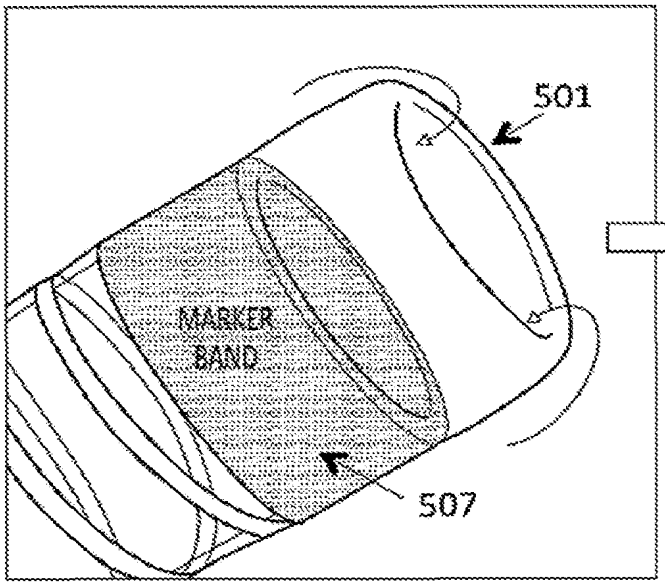


FIG. 5A

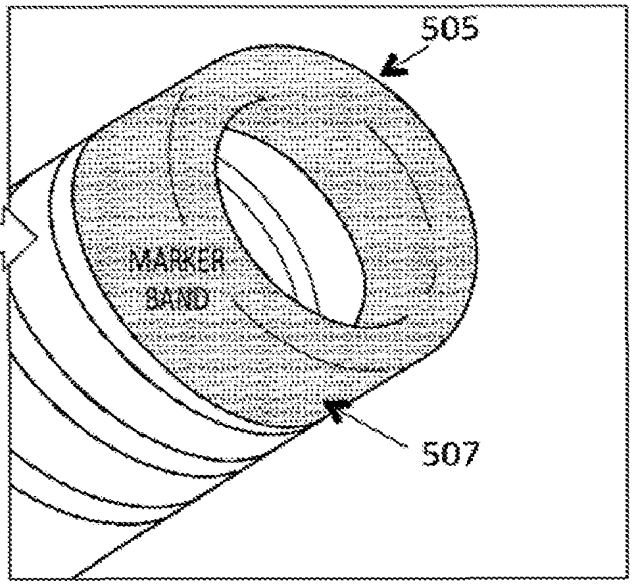


FIG. 5B

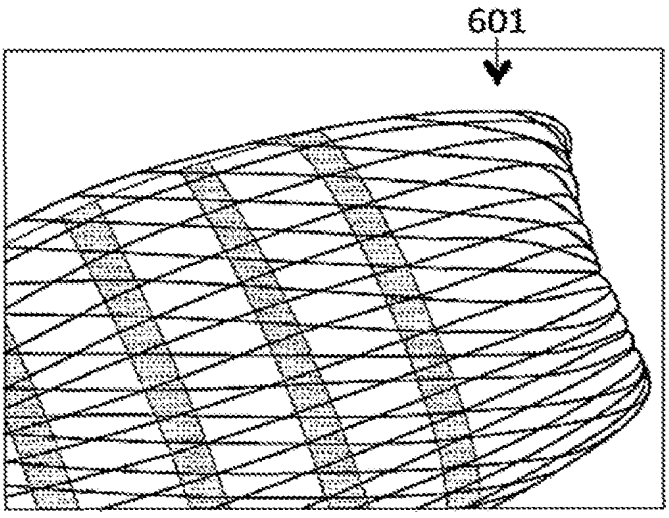


FIG. 6A

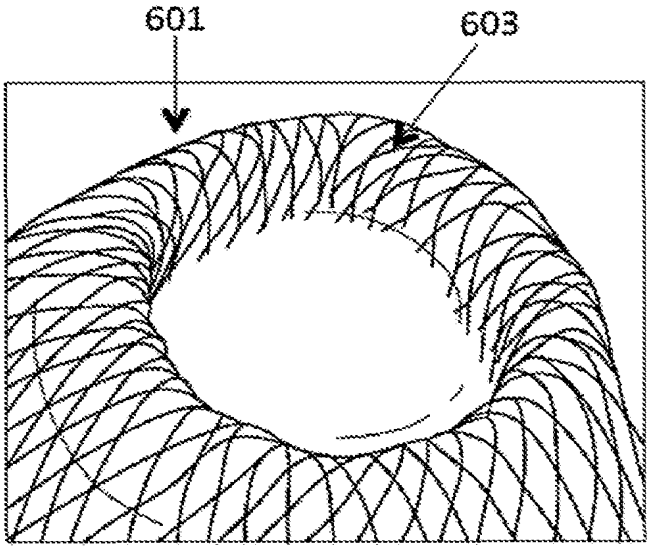
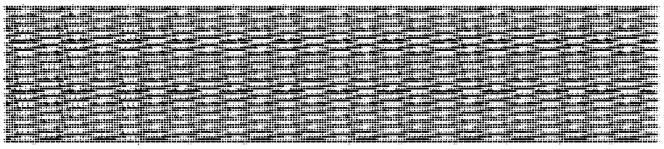
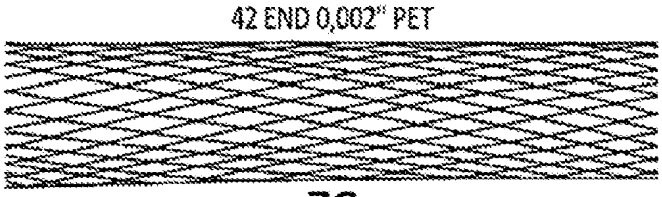


FIG. 6B

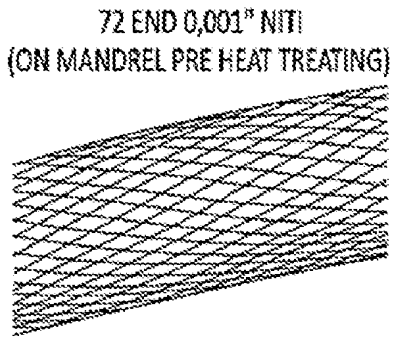
7A



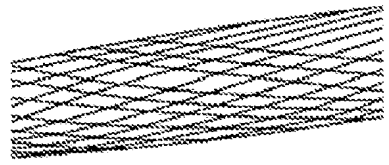
7B



7C

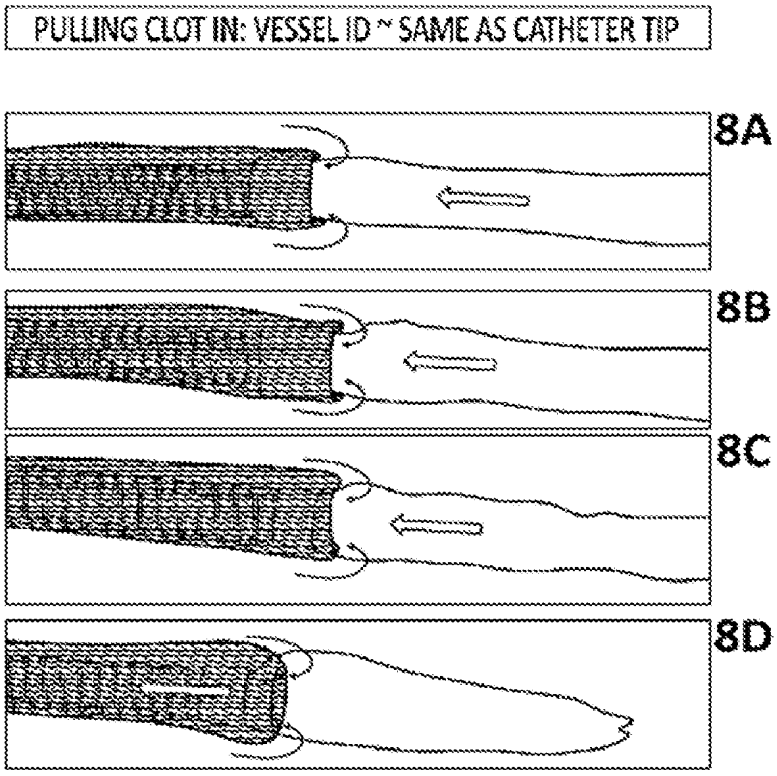


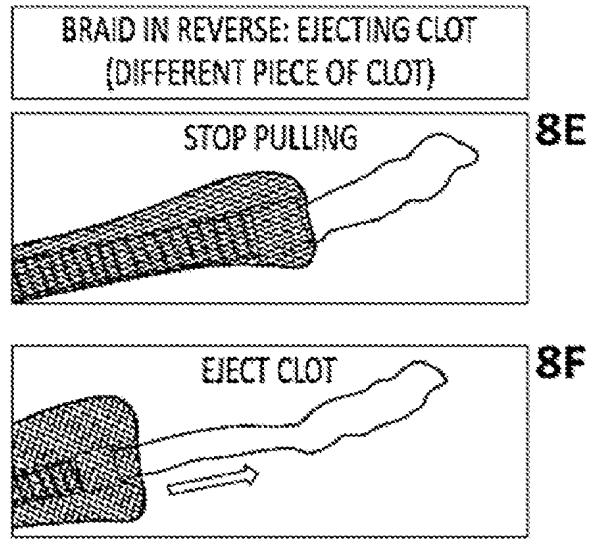
7D



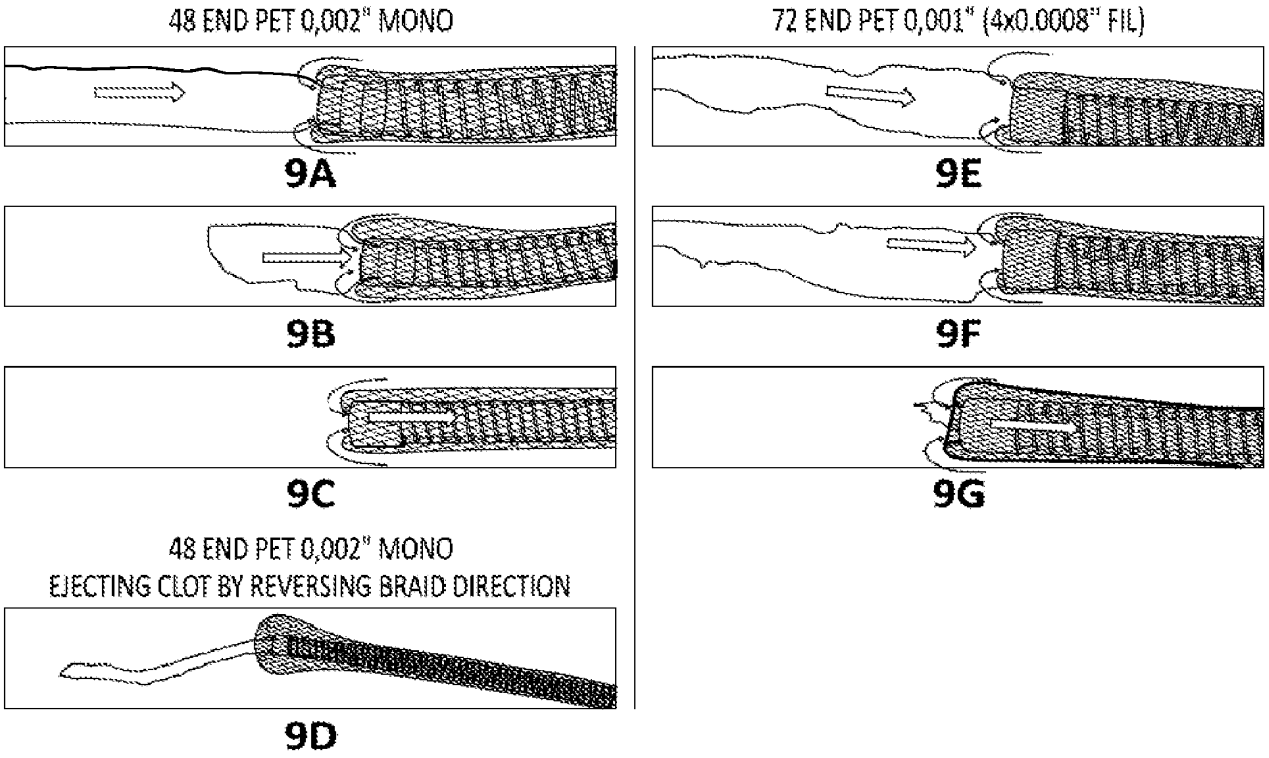
7E

FIGS. 7A-7E

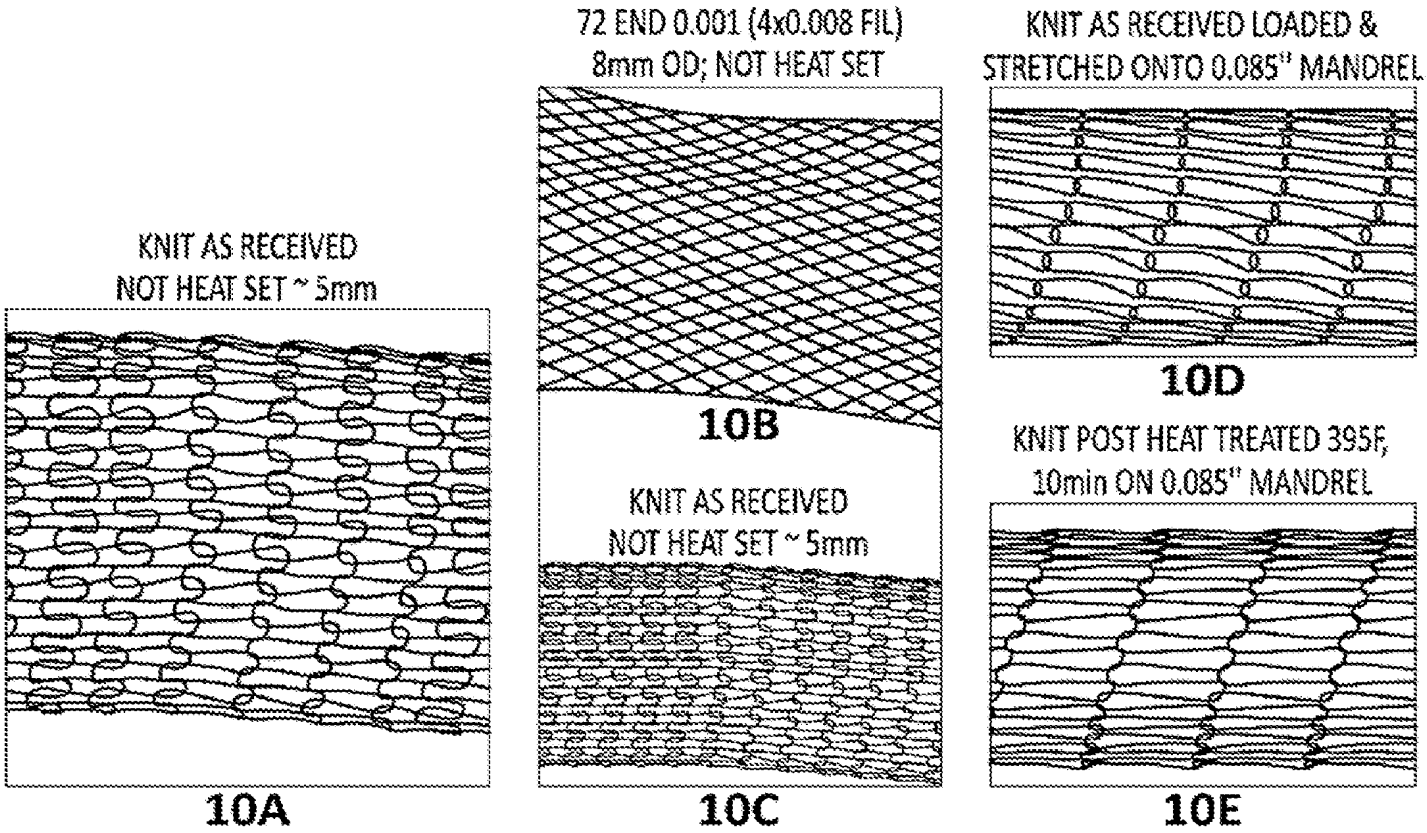




FIGS. 8A-8F



FIGS. 9A-9F



FIGS. 10A-10E

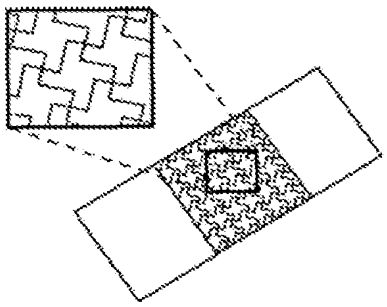


FIG. 11A

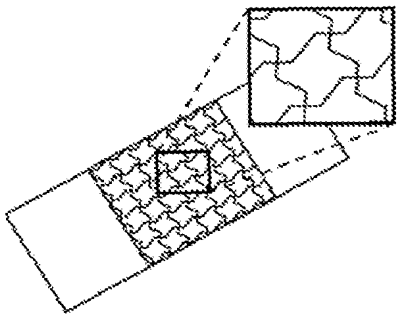


FIG. 11B

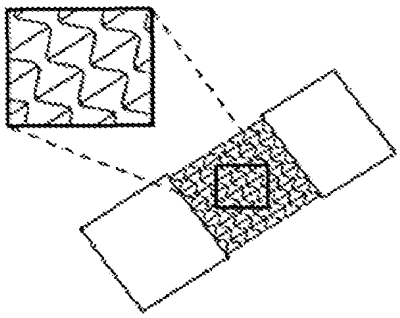


FIG. 11C

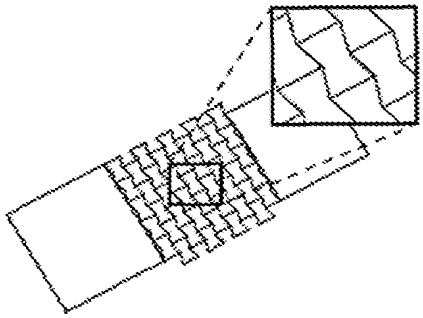


FIG. 11D

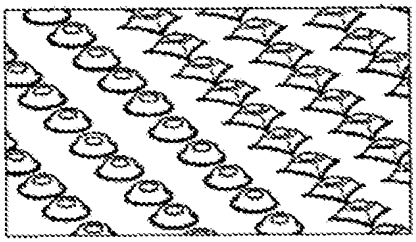


FIG. 12A

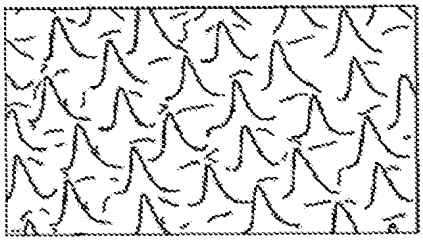


FIG. 12B

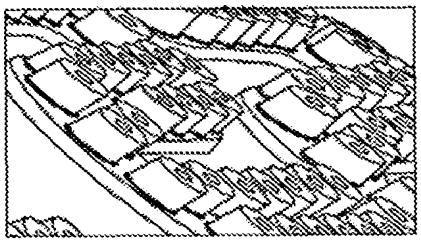


FIG. 12C

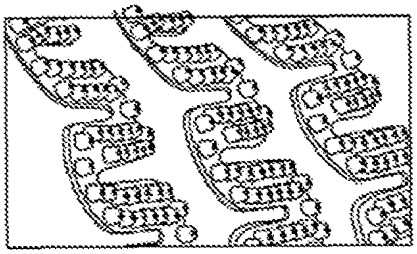


FIG. 12D

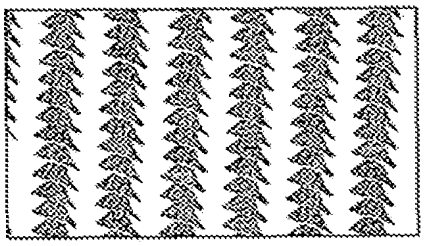


FIG. 12E

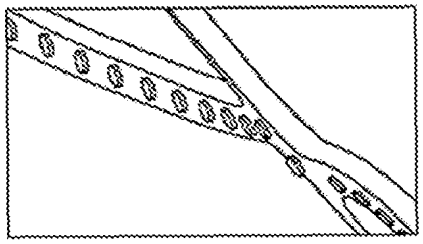


FIG. 12F

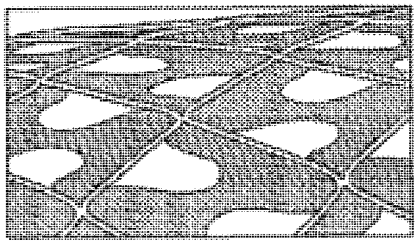


FIG. 12G

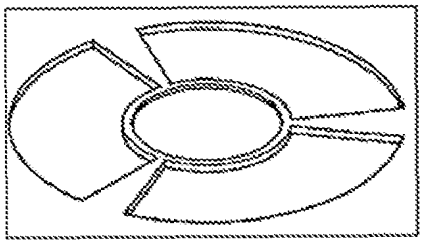


FIG. 12H

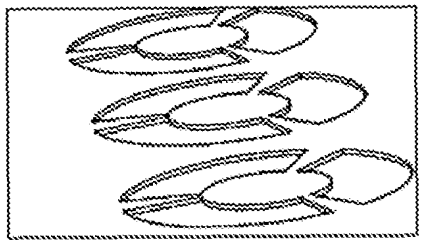


FIG. 12I

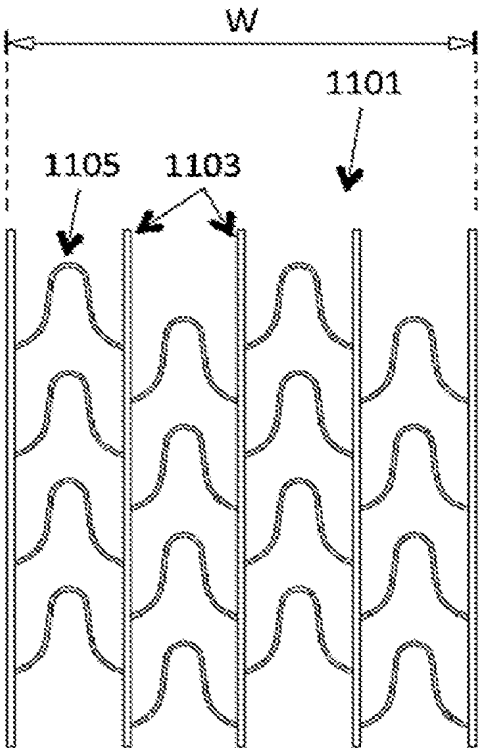


FIG. 13A

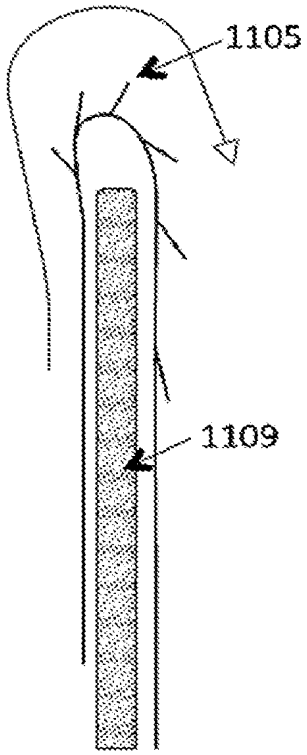


FIG. 13B

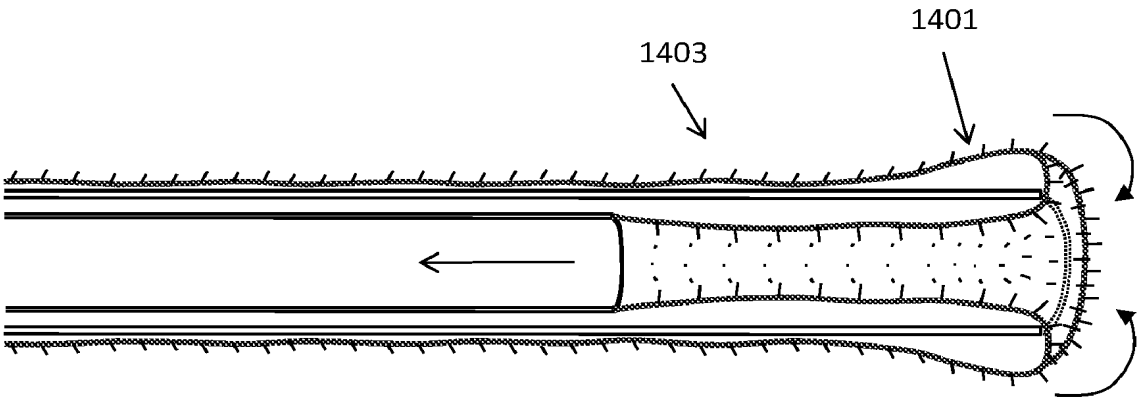


FIG. 14

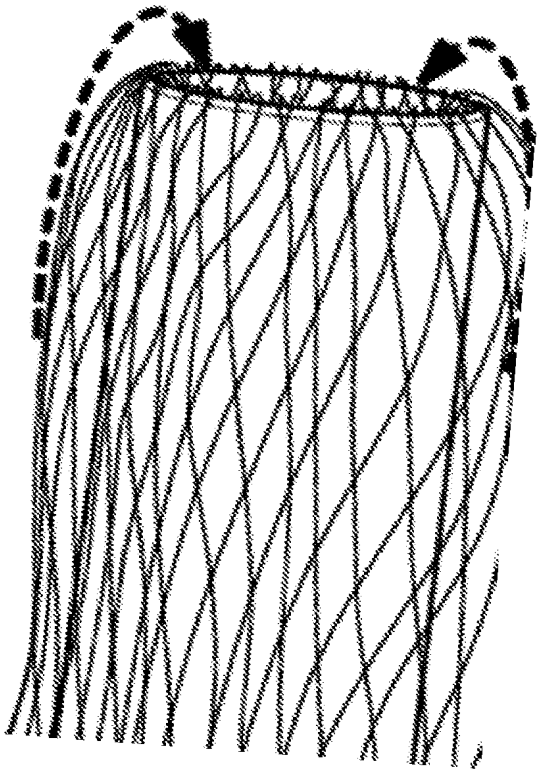


FIG. 15A

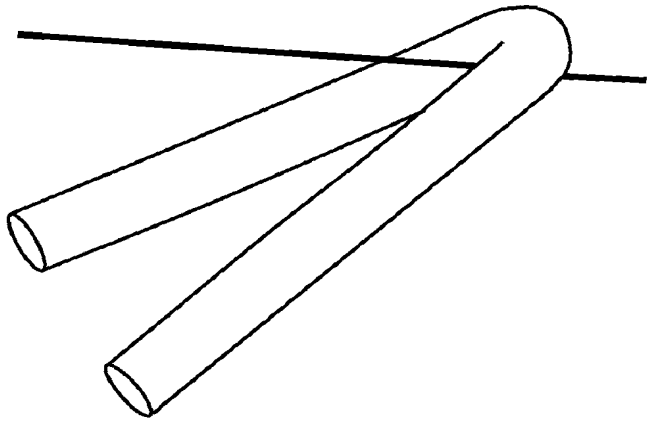


FIG. 15B

FIG. 15C

FIG. 15D

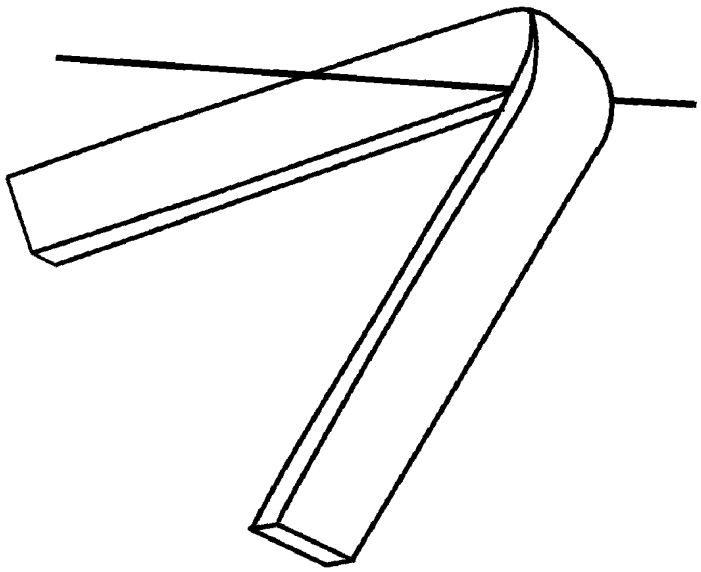


FIG. 15E

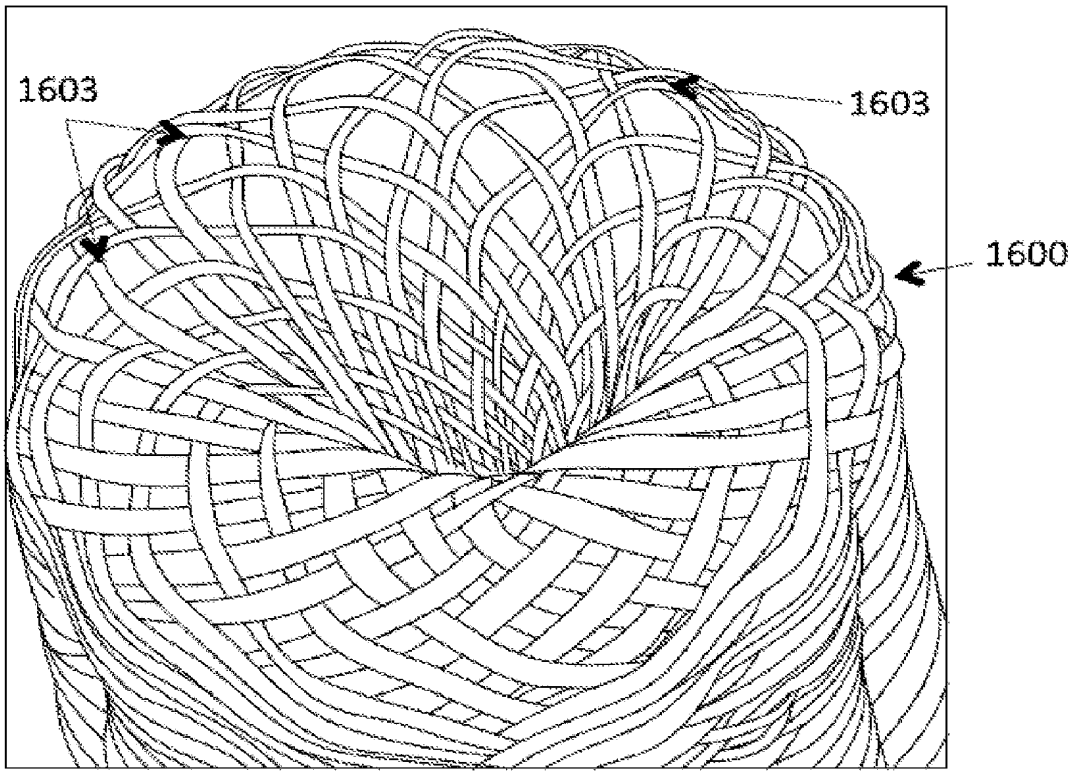


FIG. 16A

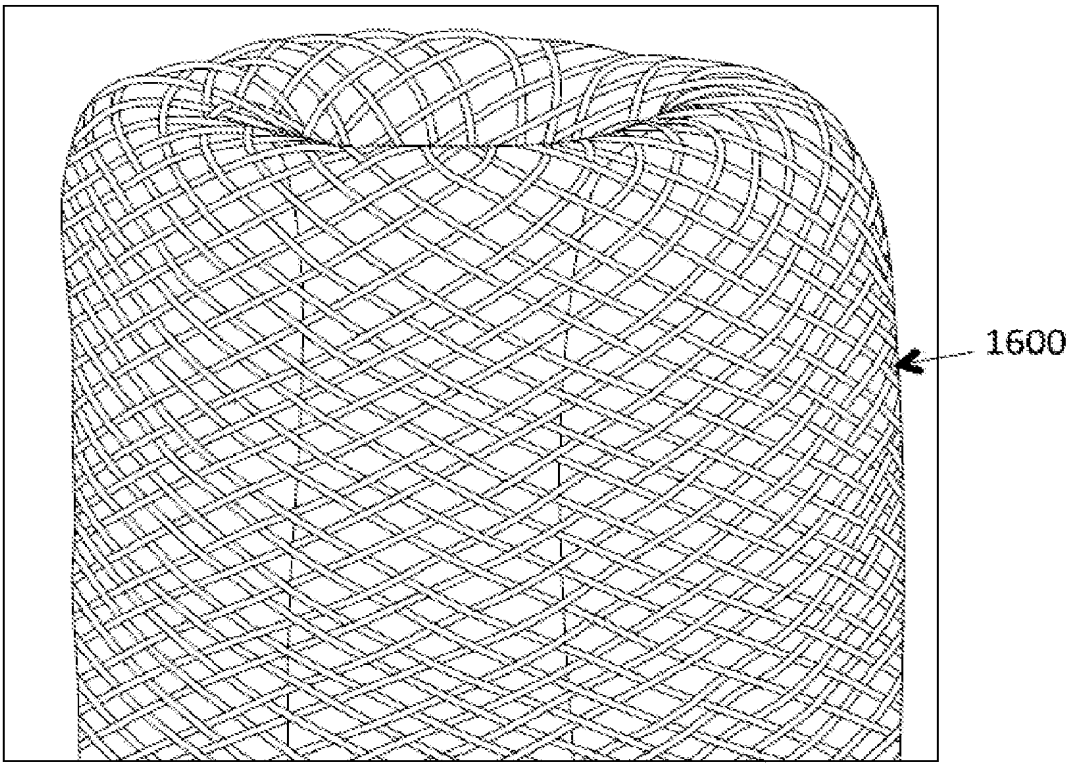


FIG. 16A

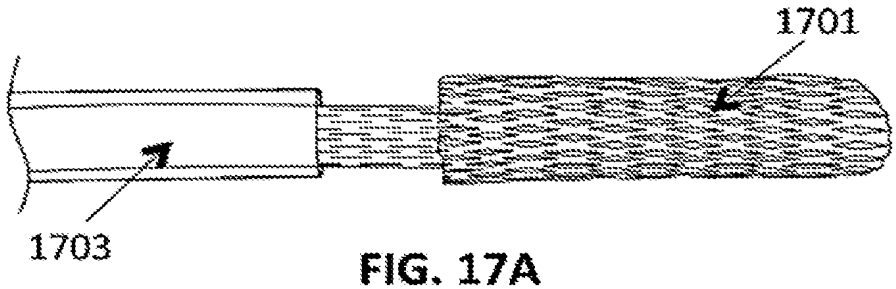


FIG. 17A

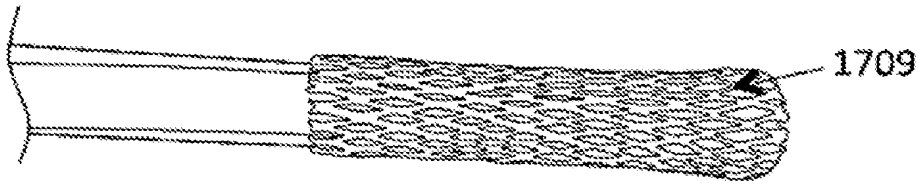


FIG. 17B

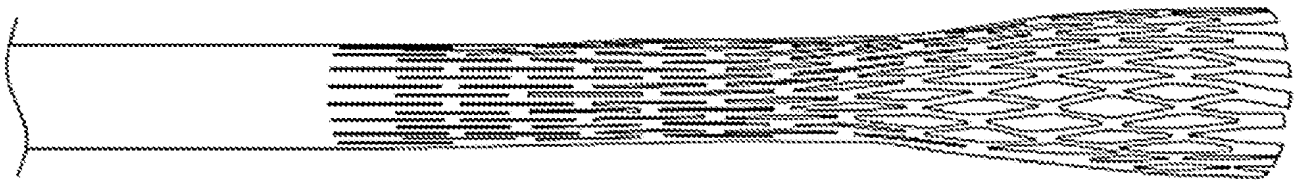


FIG. 17C

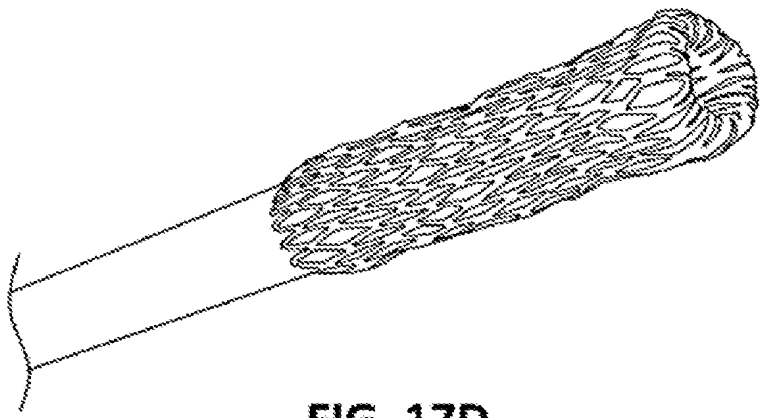


FIG. 17D

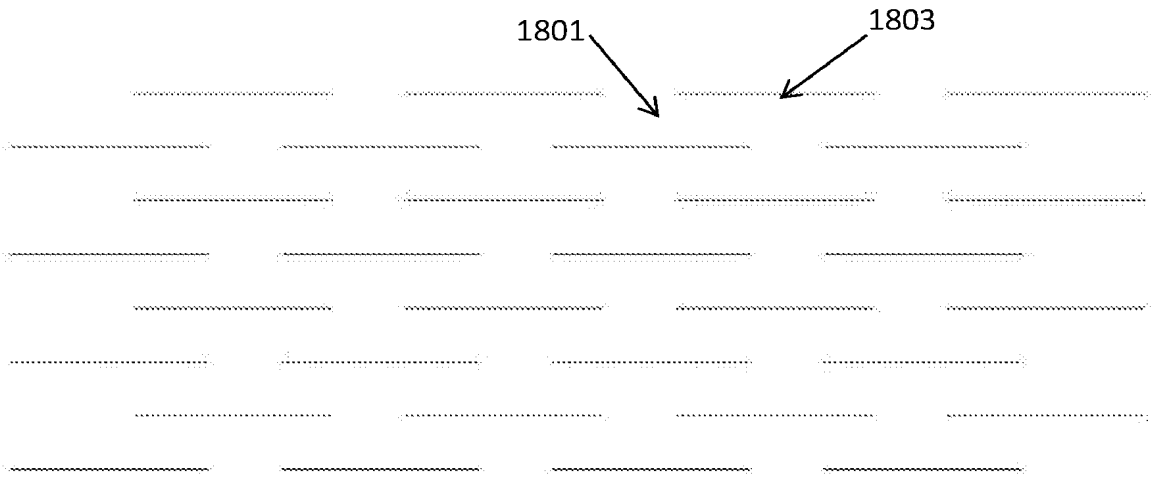


FIG. 18A

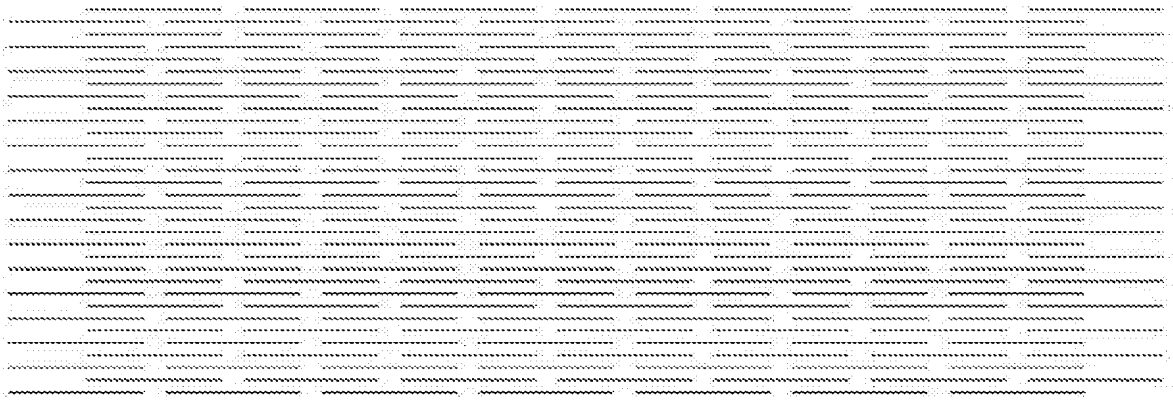


FIG. 18B

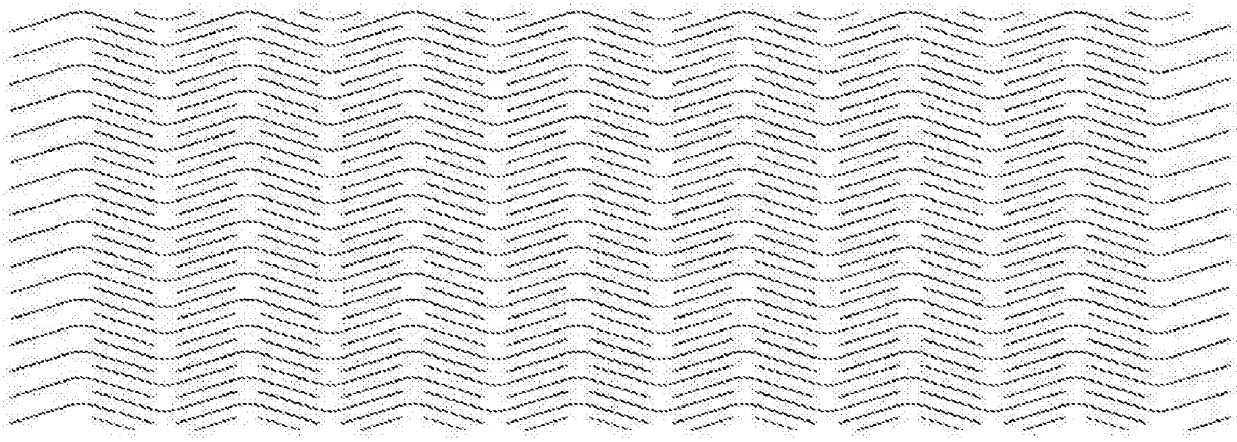


FIG. 18C

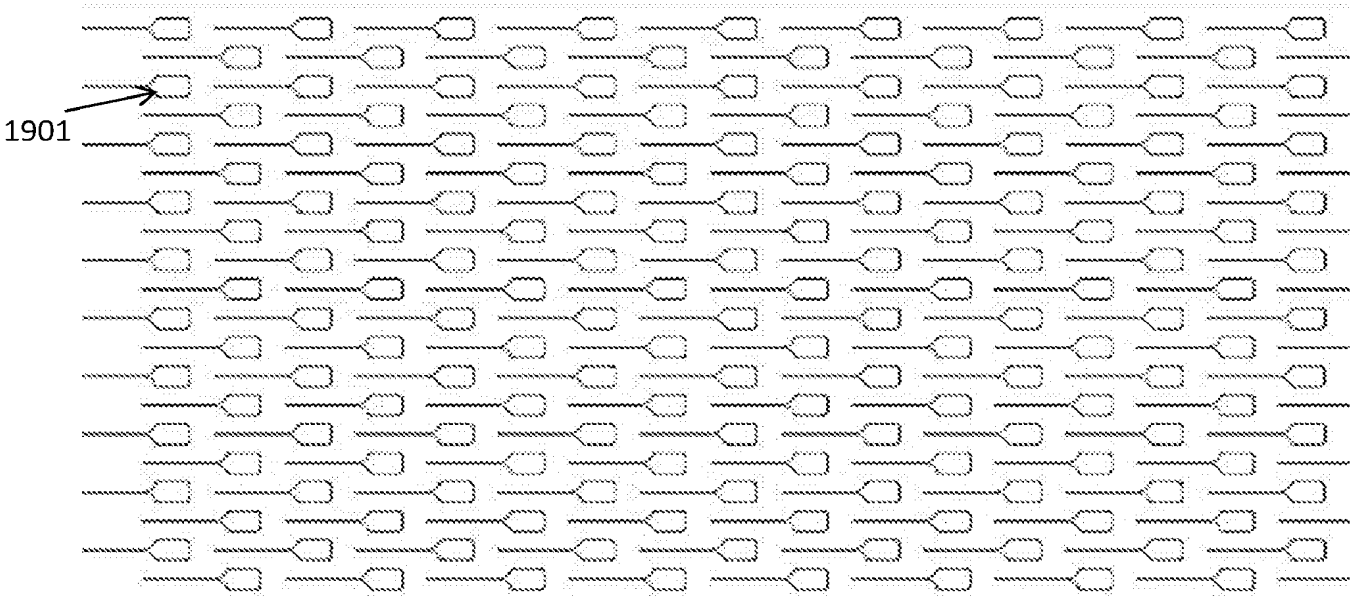


FIG. 19

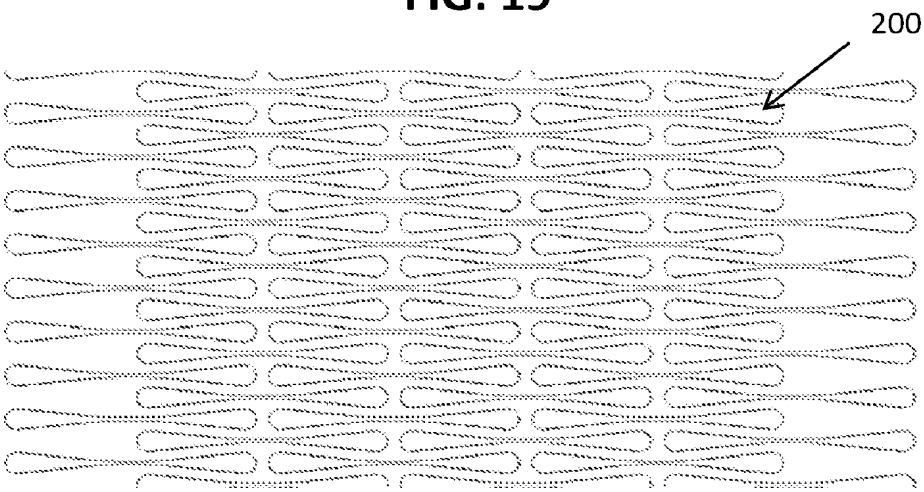


FIG. 20A

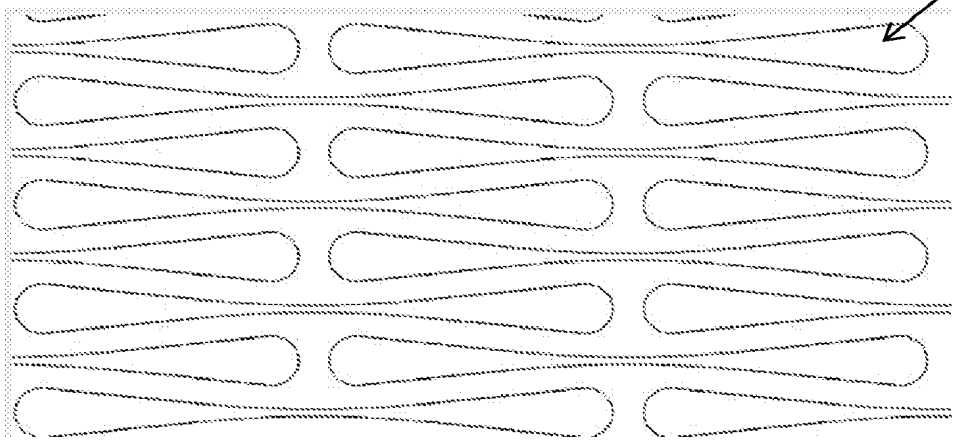


FIG. 20B

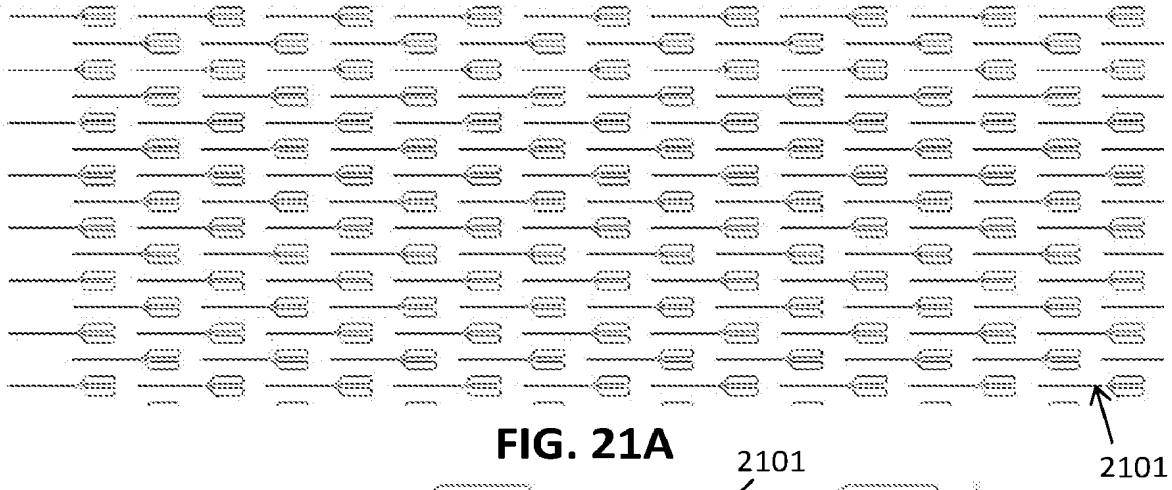


FIG. 21A

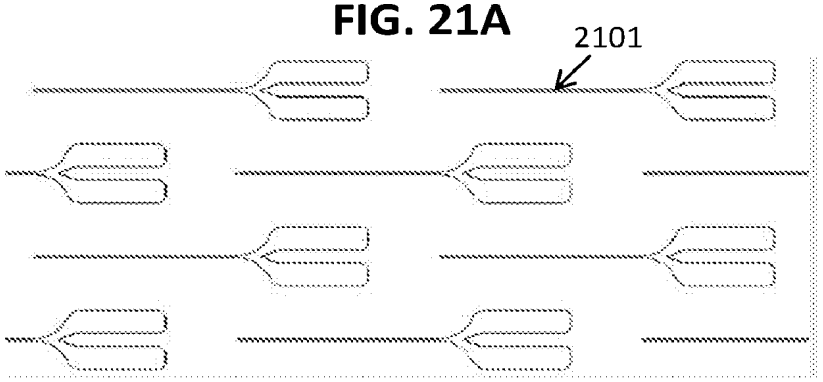


FIG. 21B

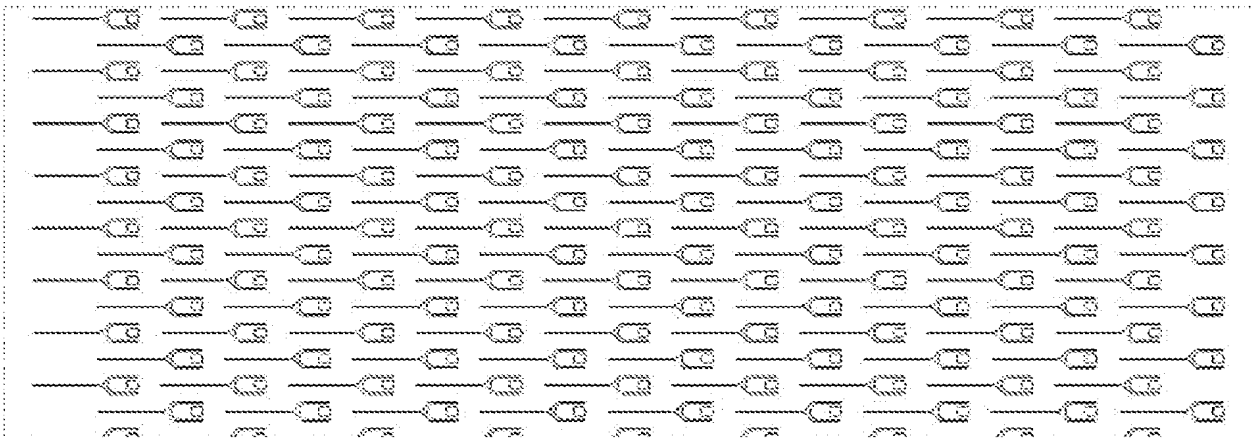


FIG. 22A

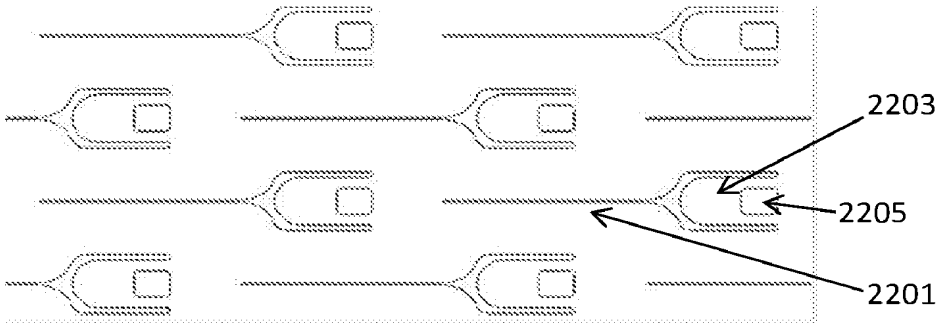


FIG. 22B

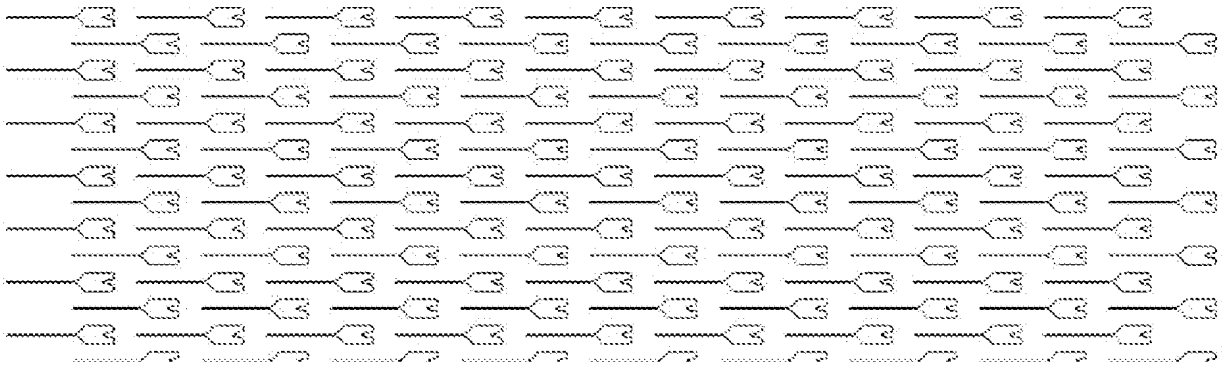


FIG. 23A

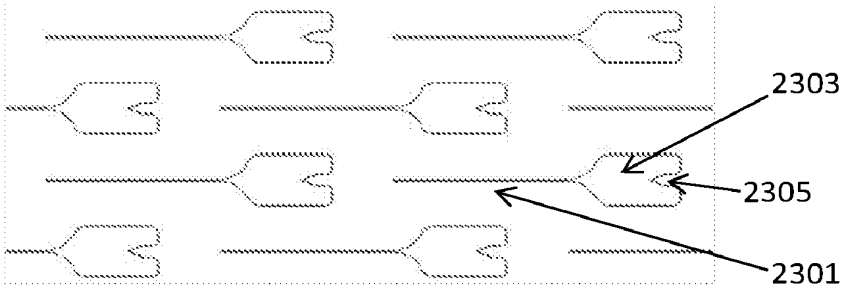


FIG. 23B

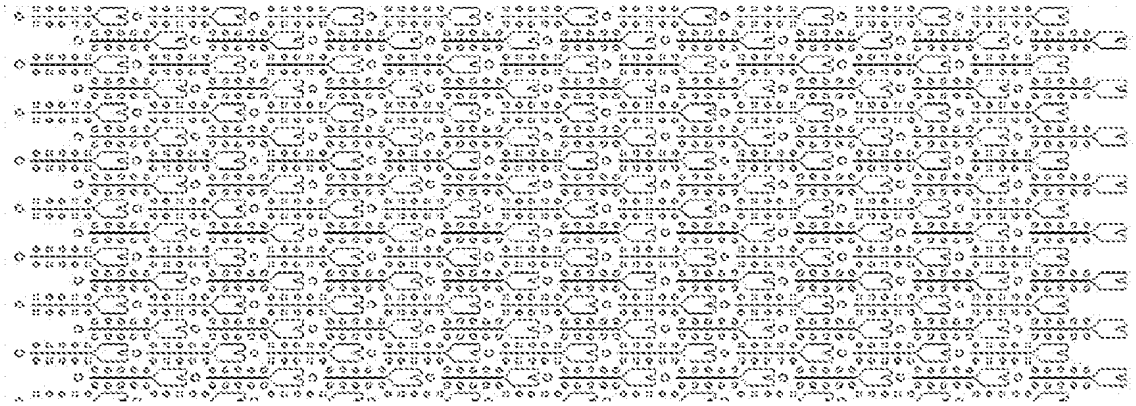


FIG. 24A

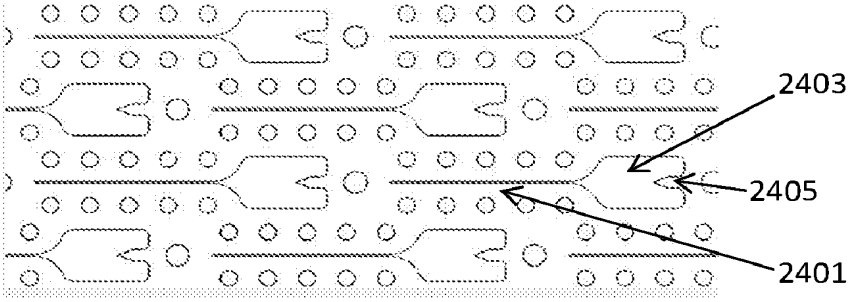


FIG. 24B

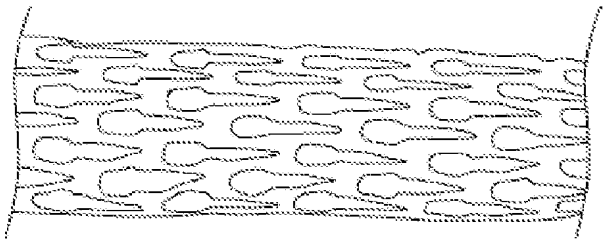


FIG. 25A

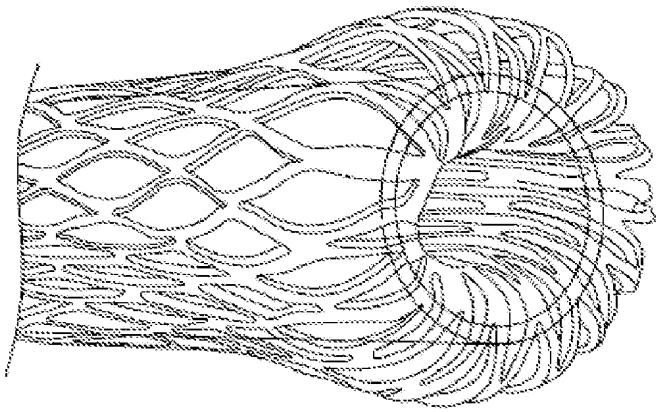


FIG. 25C

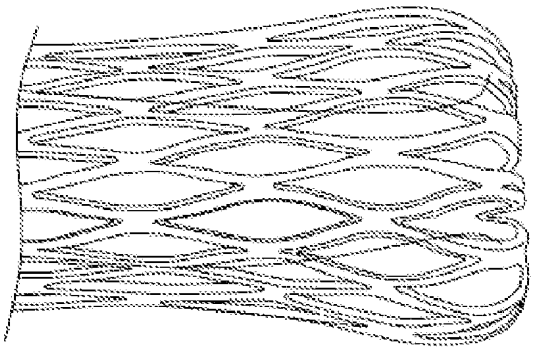


FIG. 25B

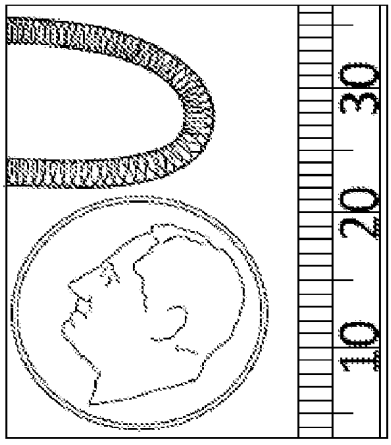


FIG. 26A

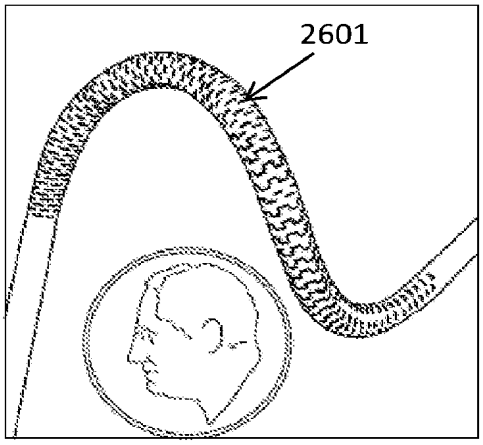


FIG. 26B

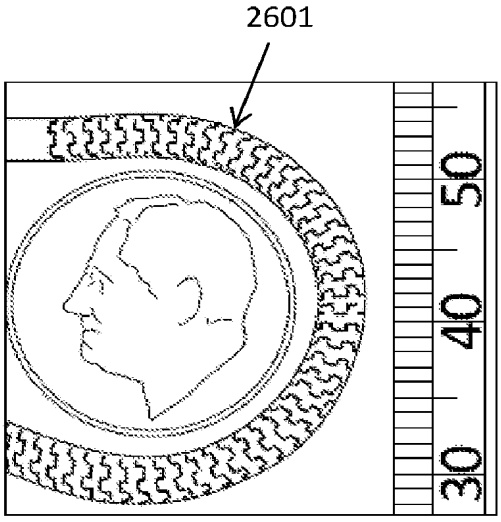


FIG. 26C

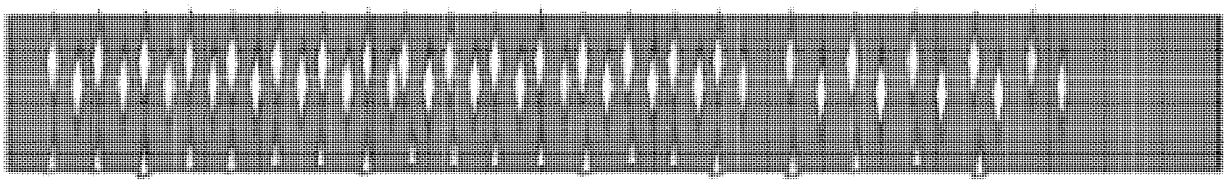


FIG. 27

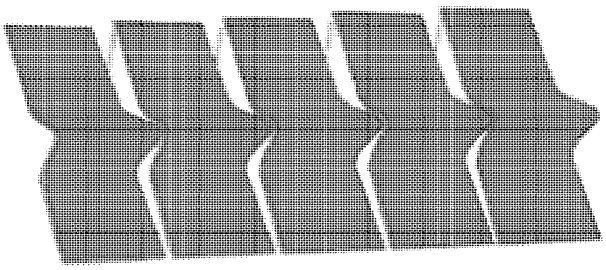


FIG. 28A

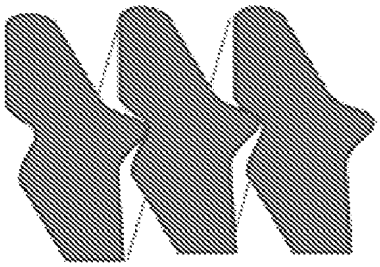


FIG. 28B

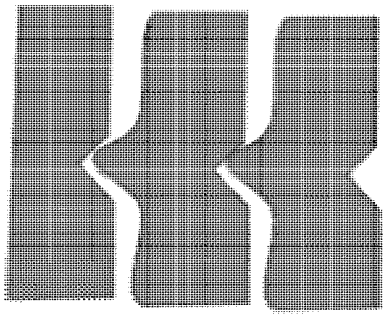


FIG. 29A

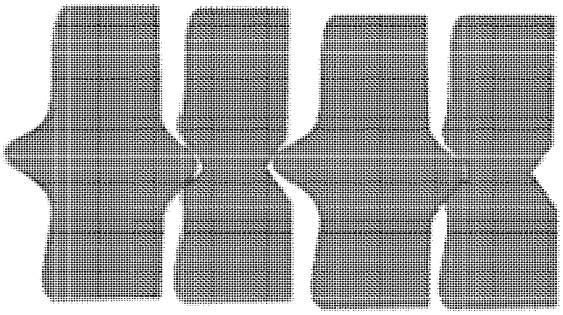
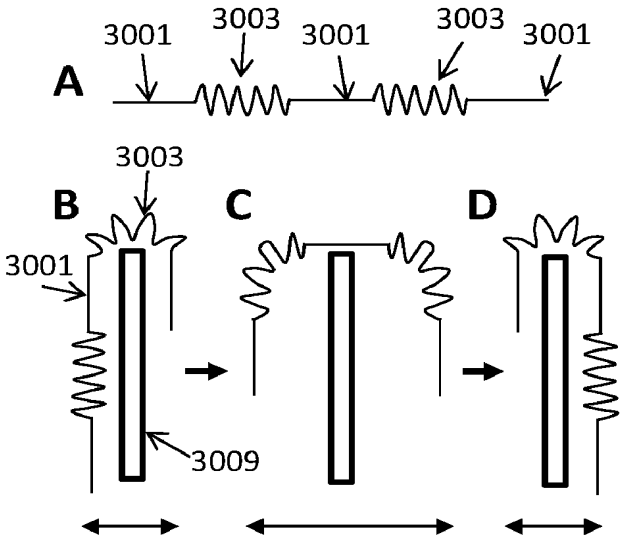


FIG. 29B



FIGS. 30A-30D

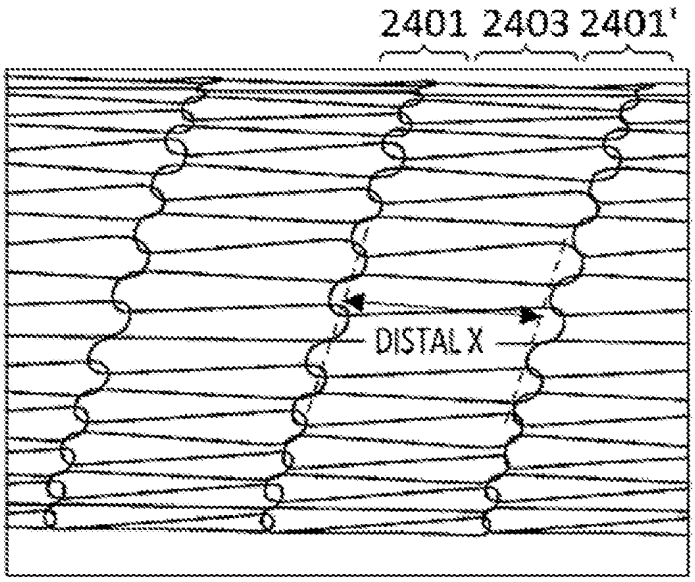
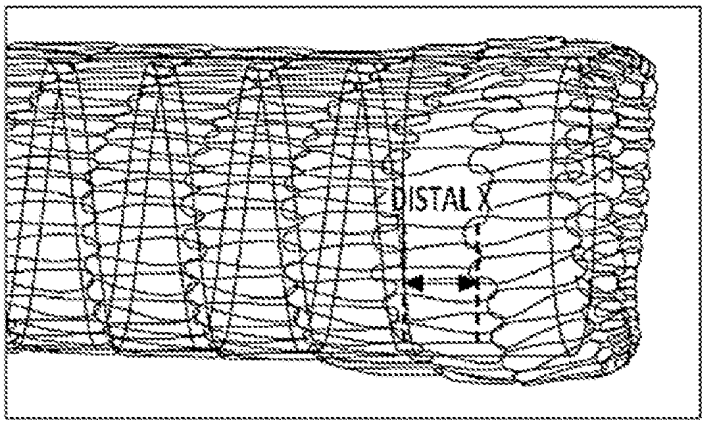
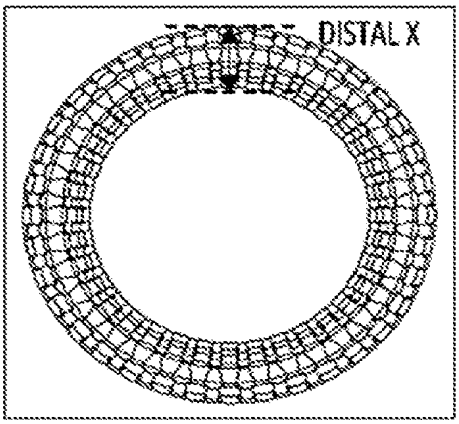


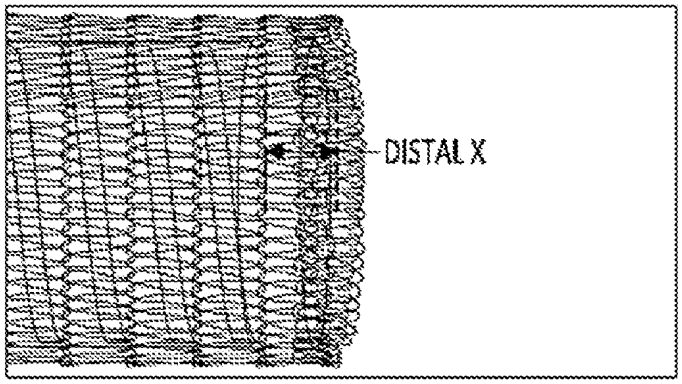
FIG. 31A



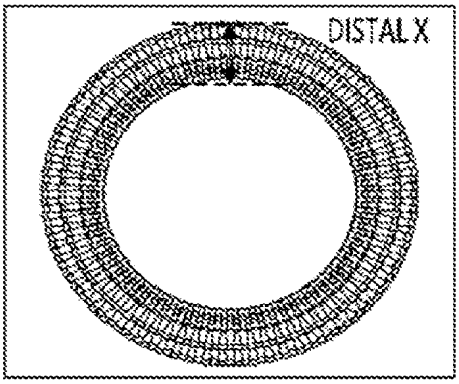
31B



31C



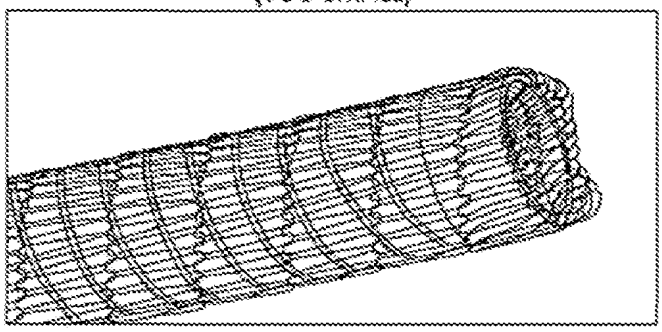
31D



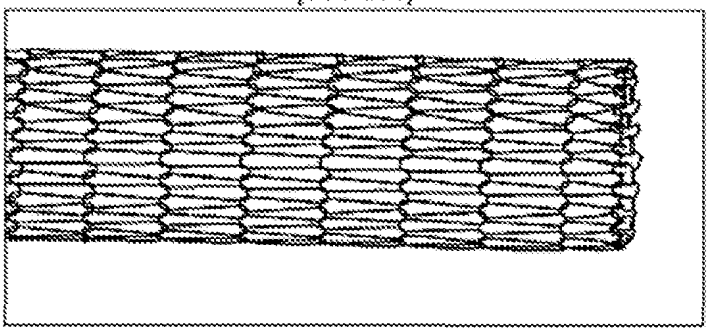
31E

FIGS. 31B-31E

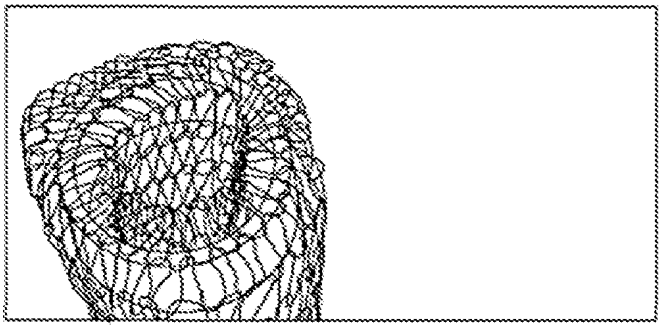
32A 0.045" ID CATHETER, 0.055 OD (TOO SMALL)



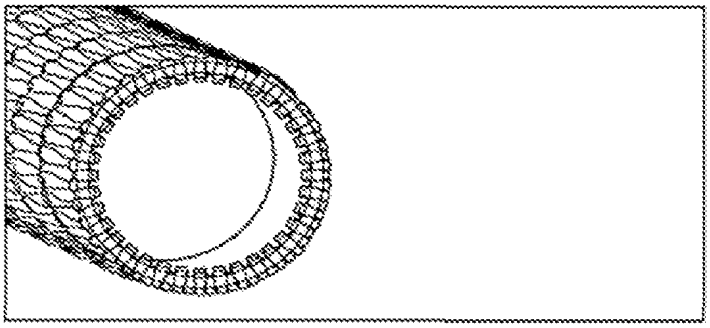
32C 0.085" ID 72D PEBAX, 0.95" OD (TOO BIG)



32B



32D



FIGS. 32A-32D

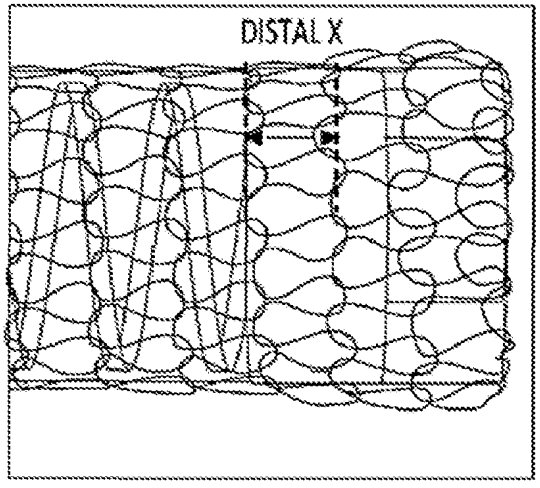


FIG. 33A

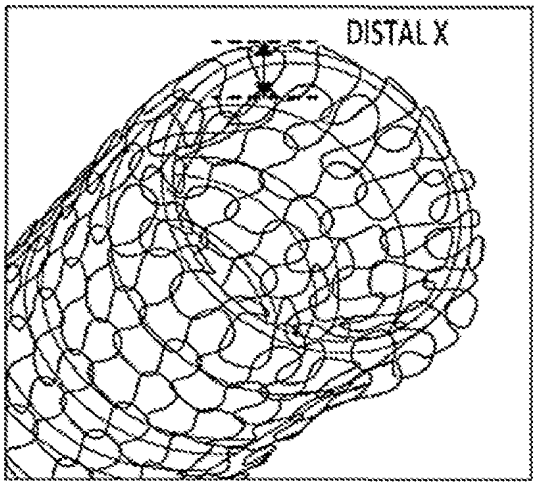


FIG. 33B

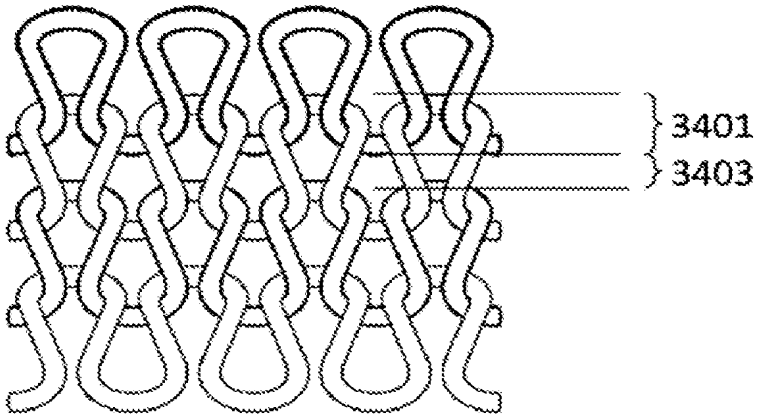


FIG. 34

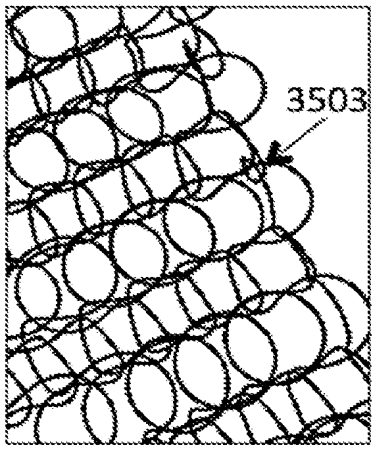


FIG. 35A

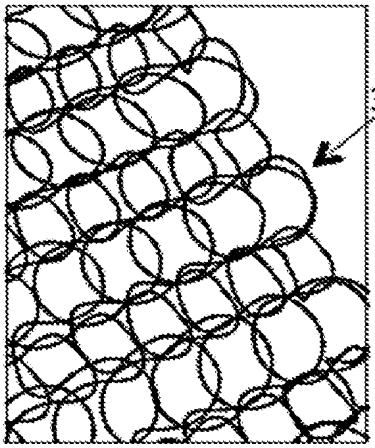


FIG. 35B

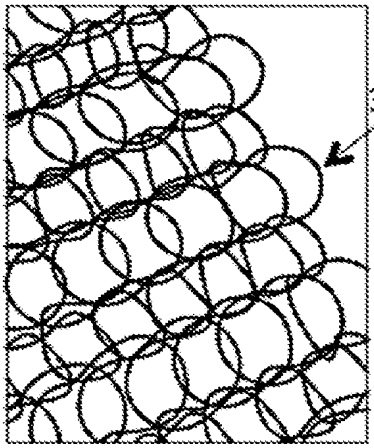


FIG. 35C

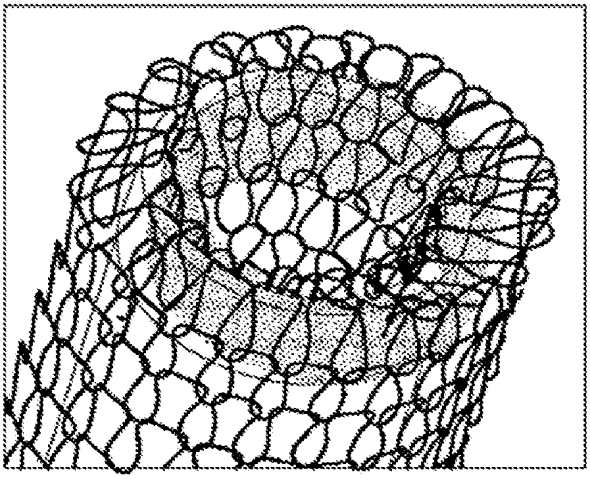


FIG. 36A

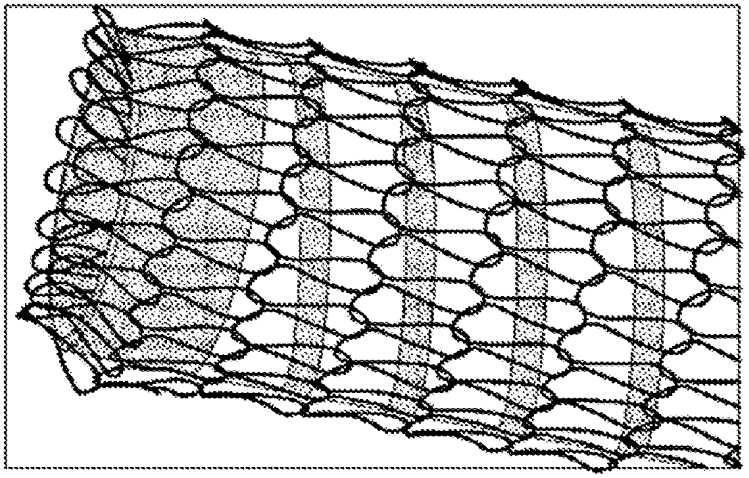


FIG. 36B

FIG. 37A

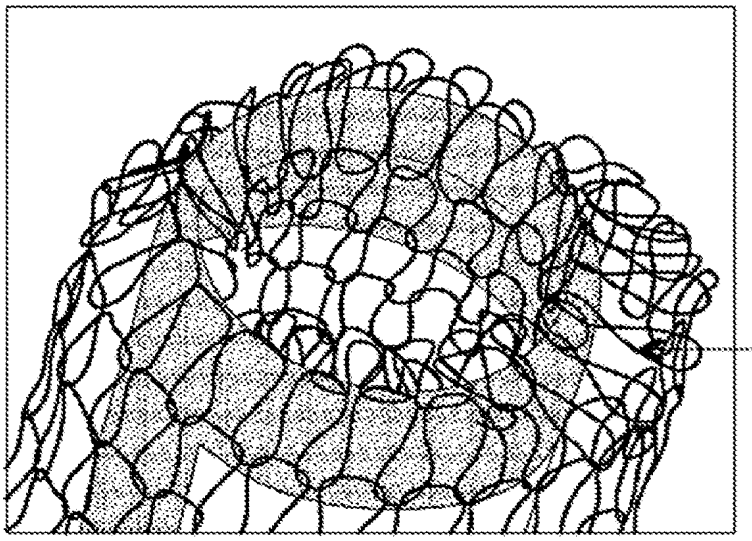


FIG. 37B

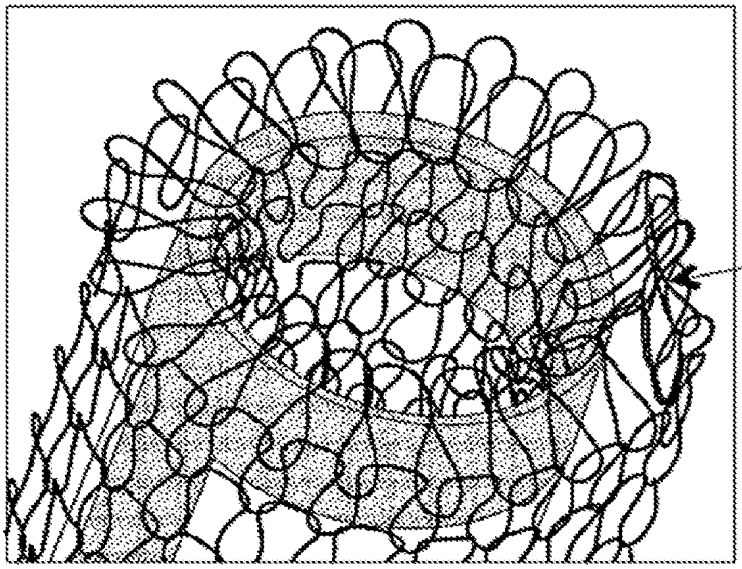
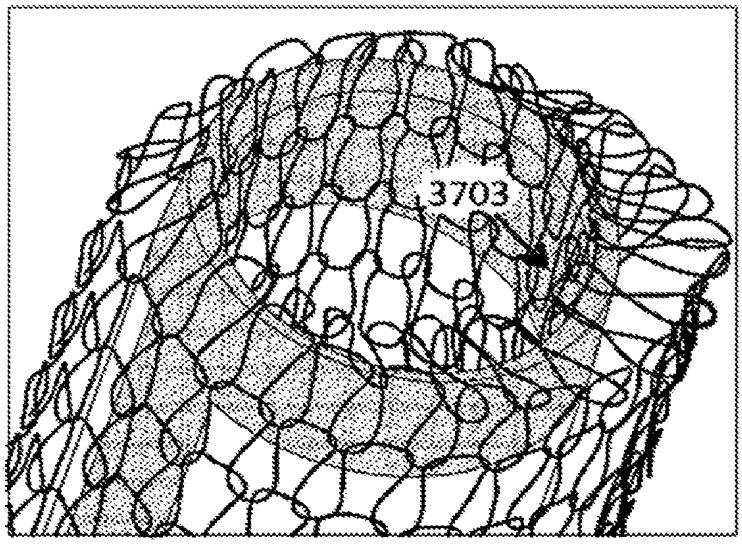


FIG. 37C



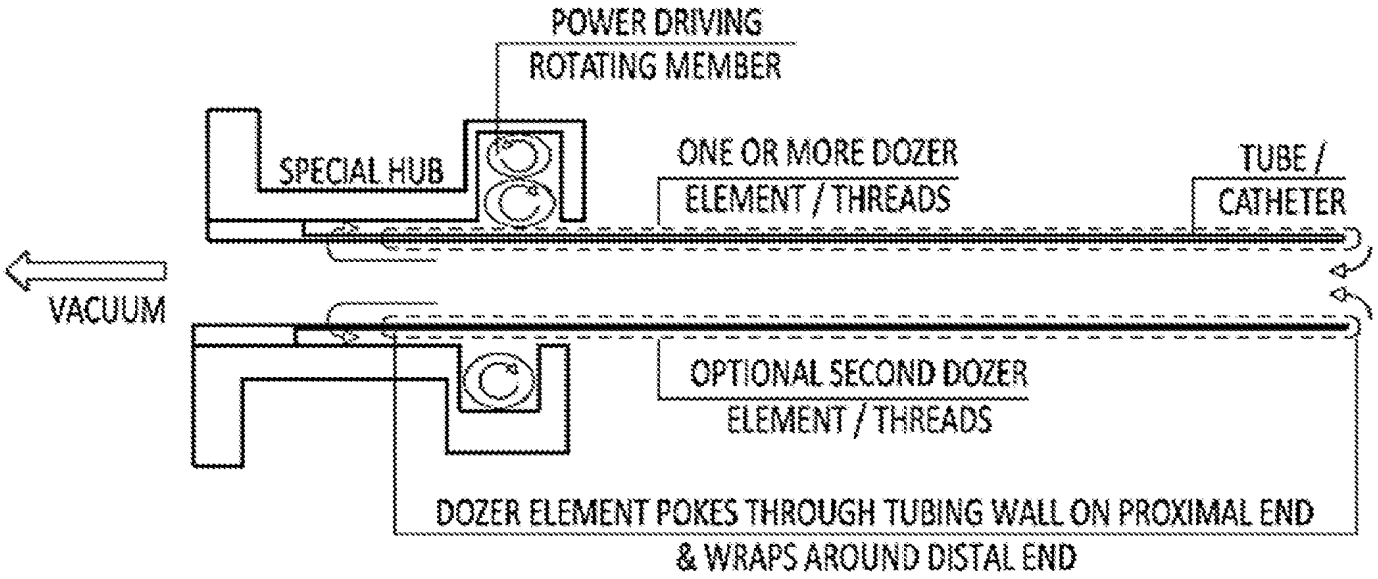


FIG. 38A

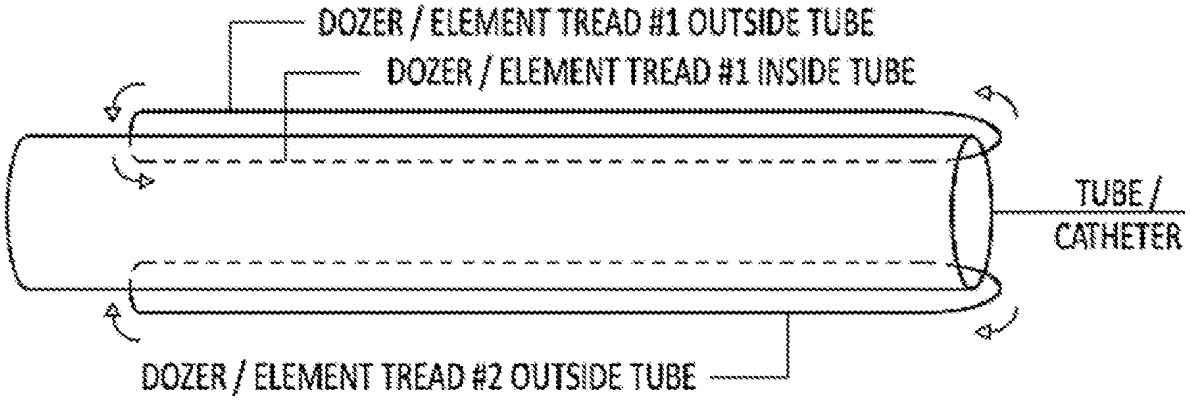


FIG. 38B

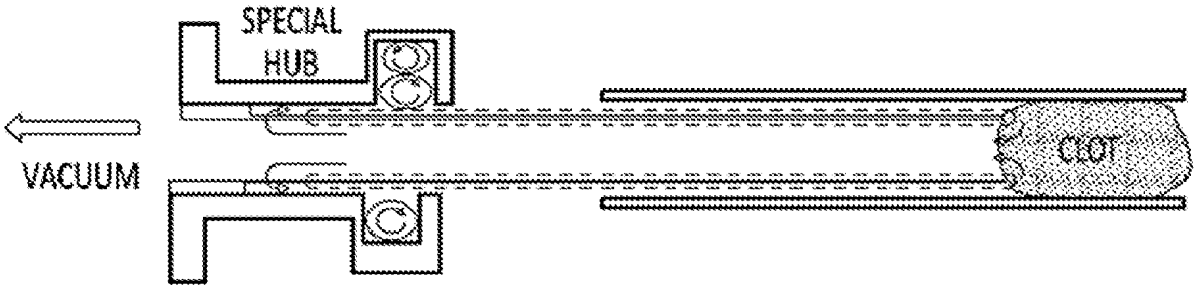


FIG. 39A

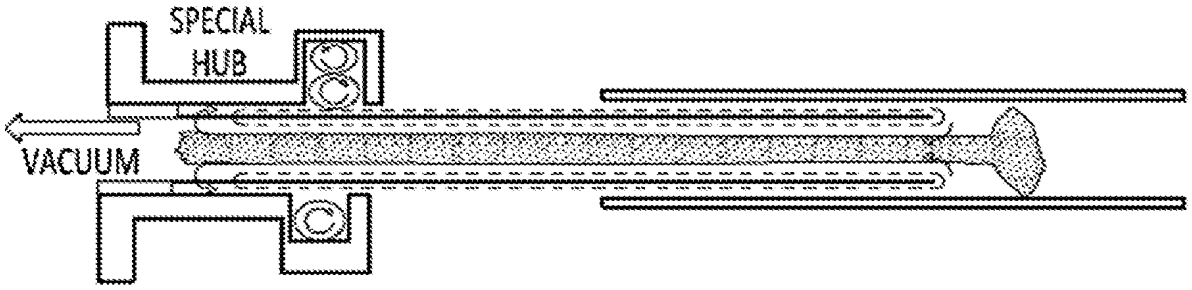


FIG. 39B

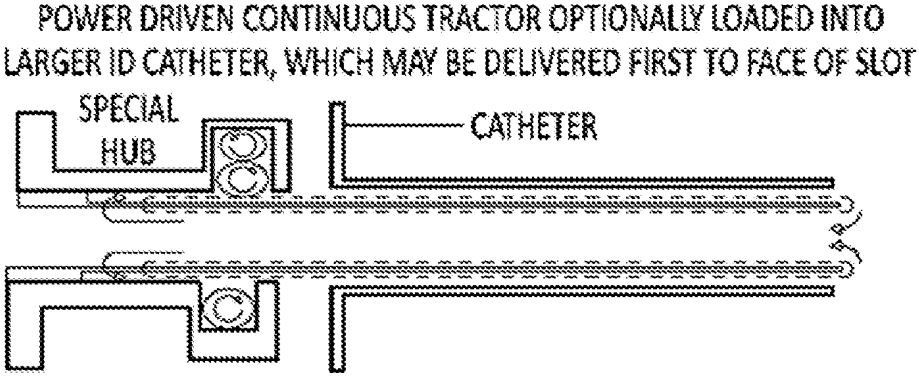


FIG. 39C

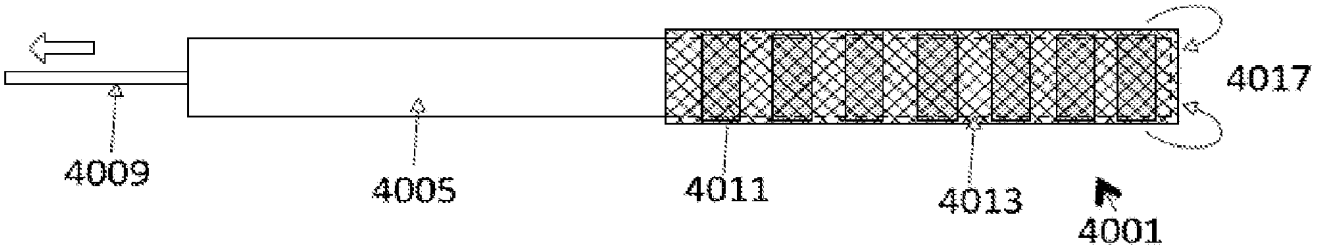


FIG. 40A

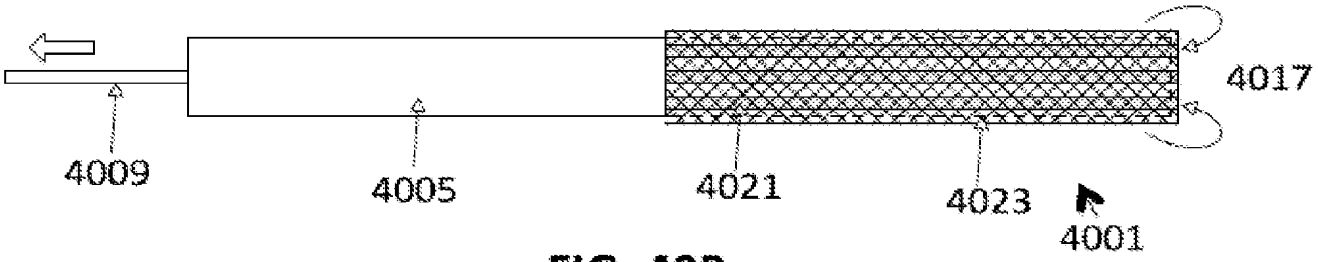


FIG. 40B

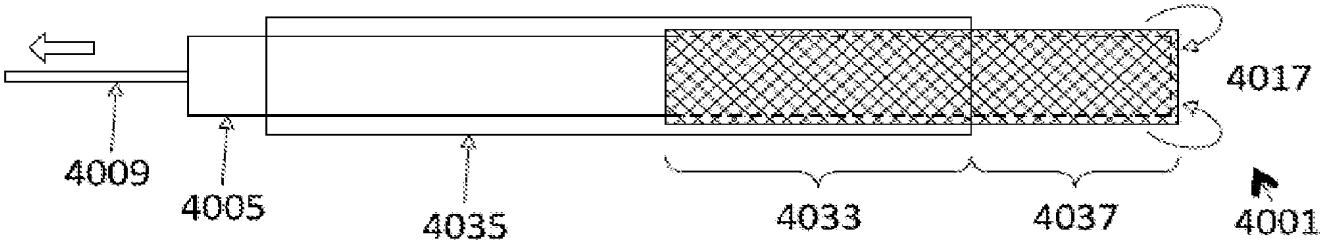


FIG. 40C

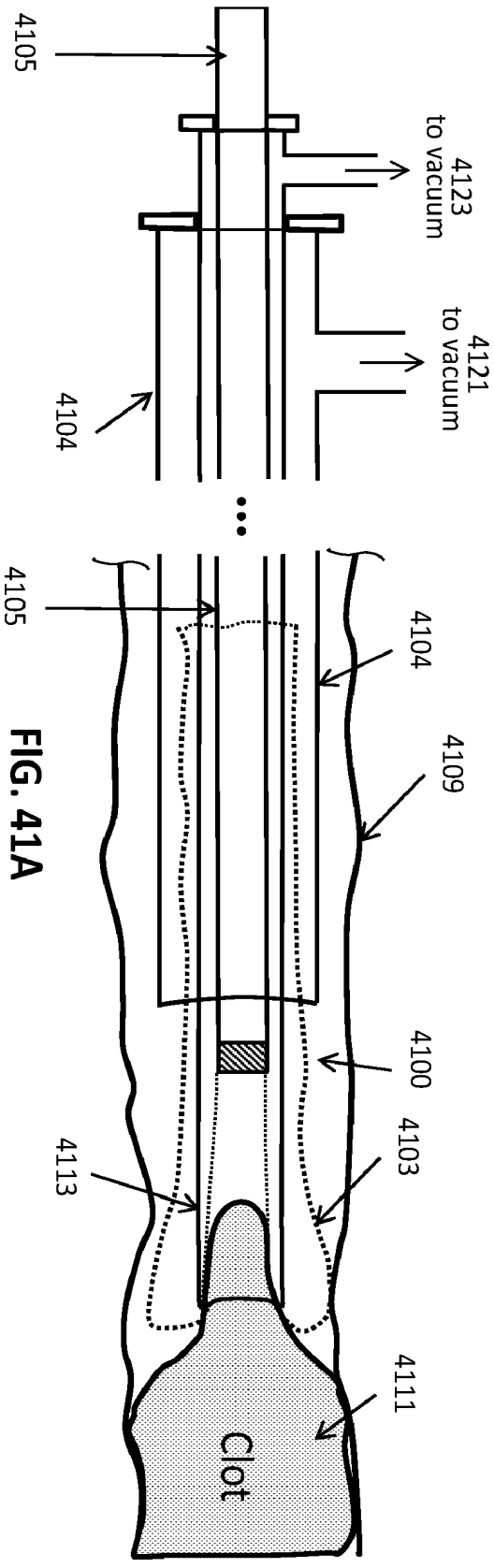


FIG. 41A

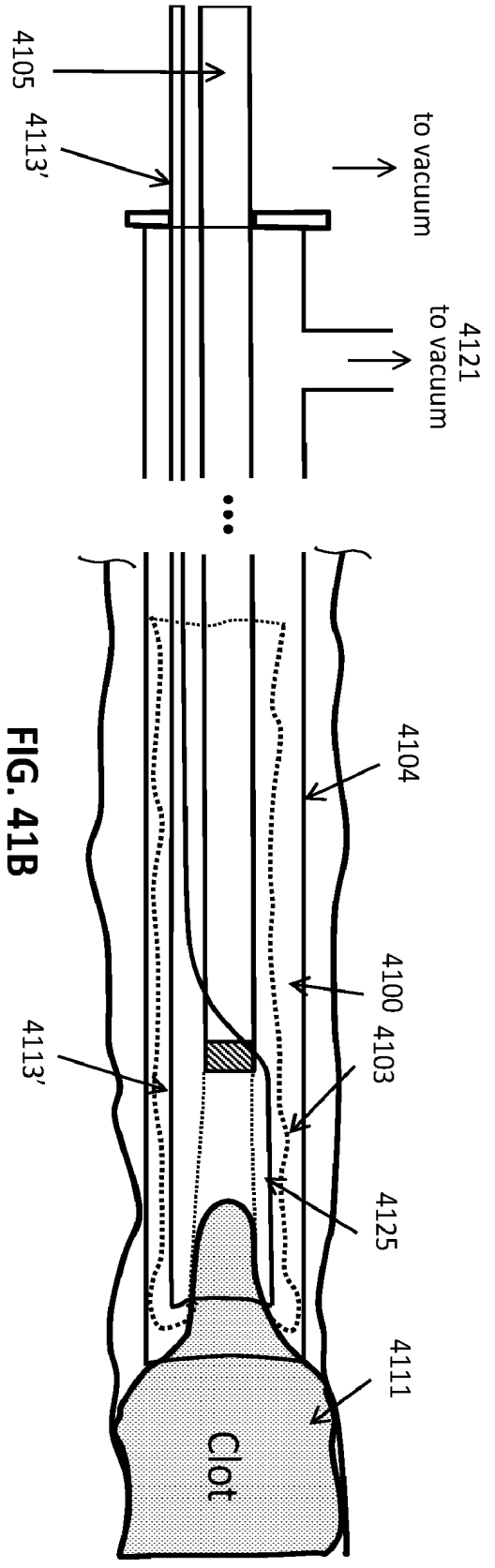


FIG. 41B

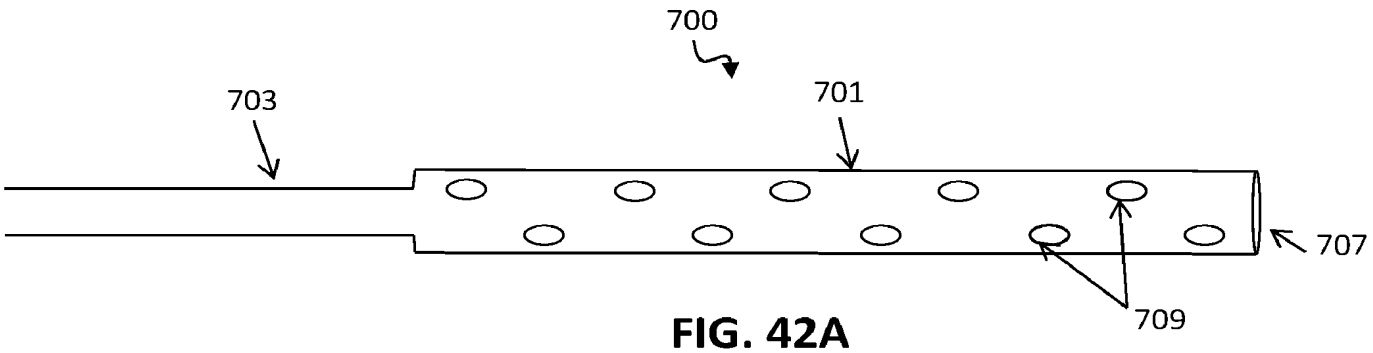


FIG. 42A

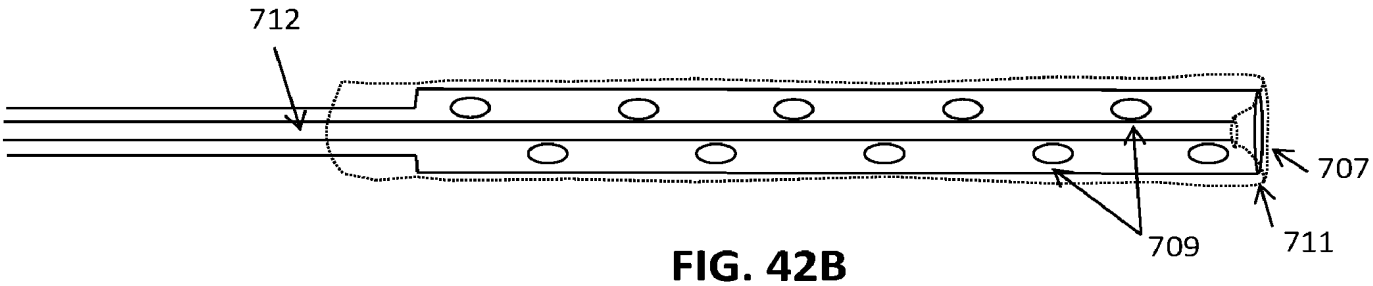


FIG. 42B

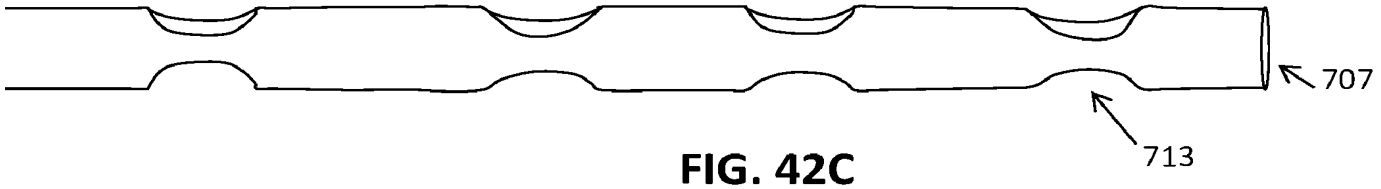


FIG. 42C

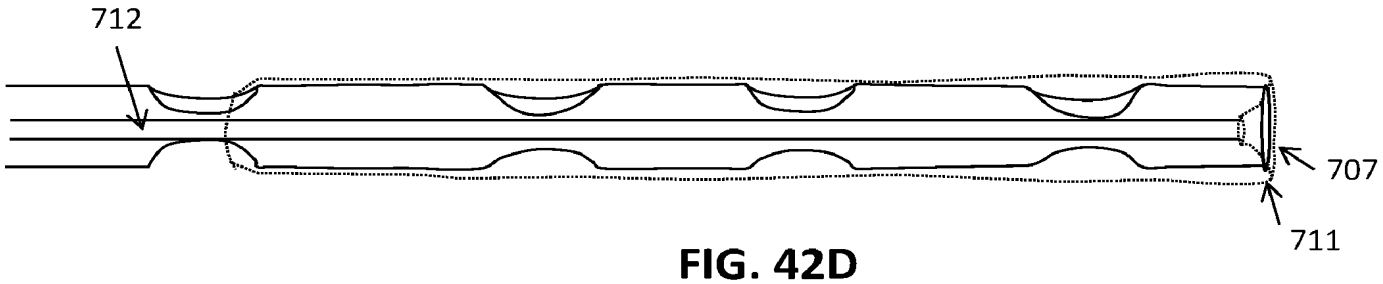


FIG. 42D

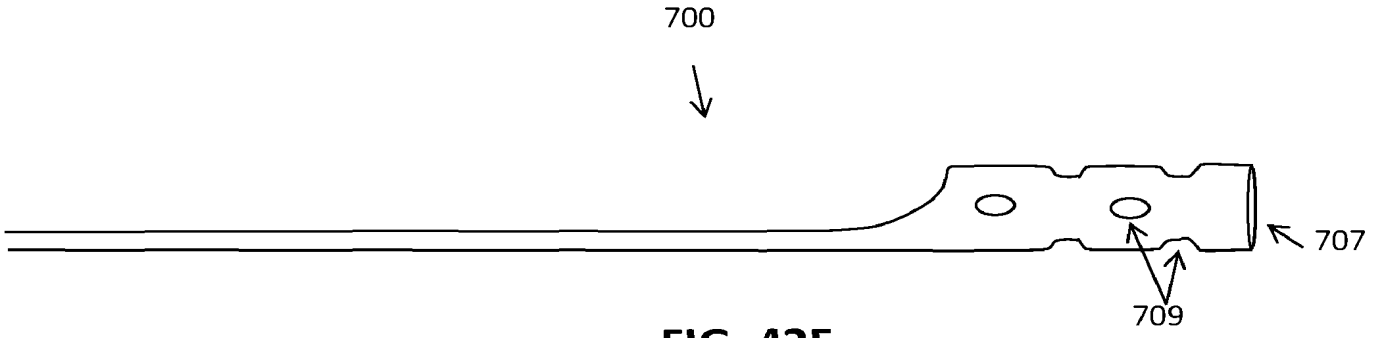


FIG. 42E

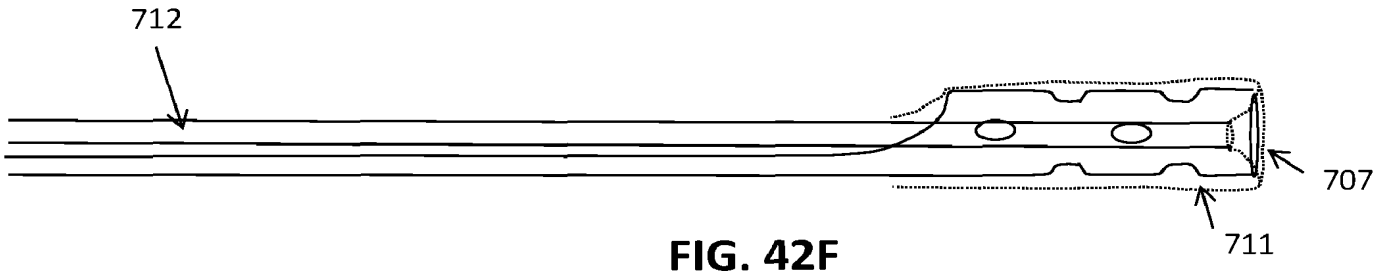


FIG. 42F

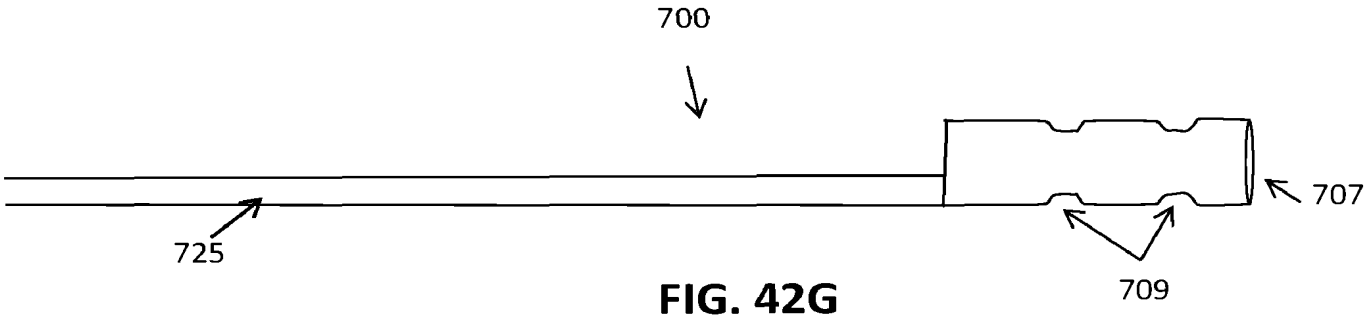


FIG. 42G

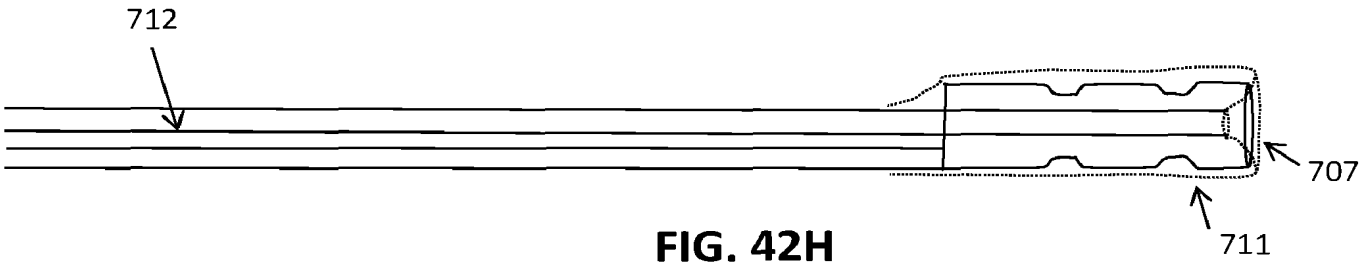


FIG. 42H

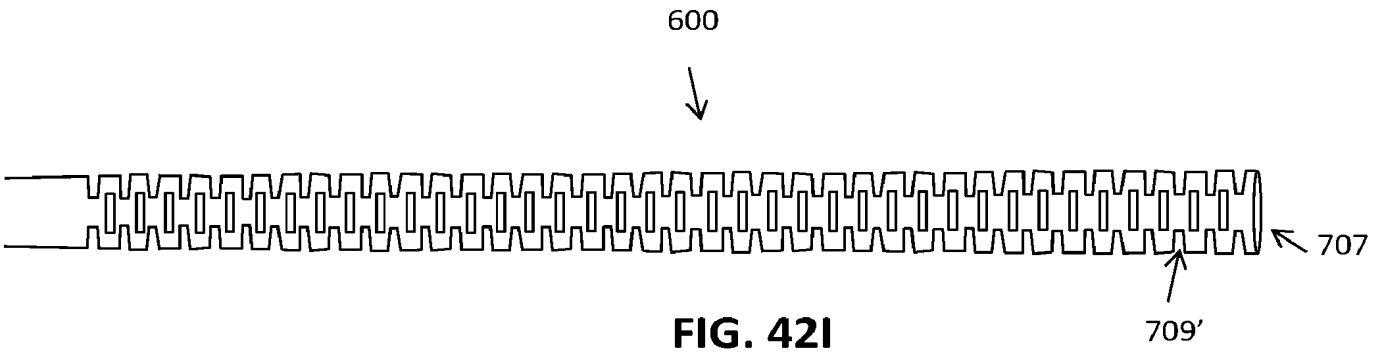


FIG. 42I

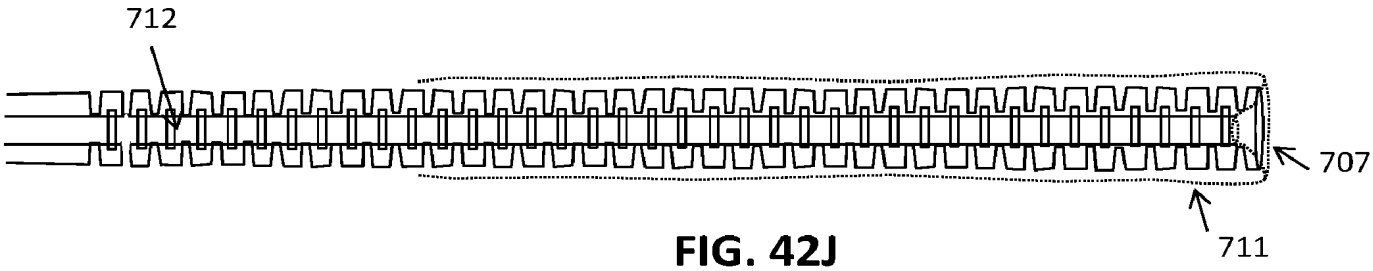


FIG. 42J

FIG. 42K

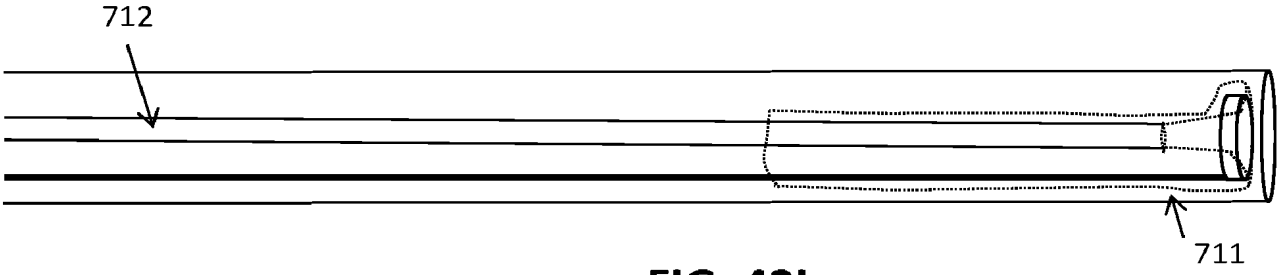


FIG. 42L

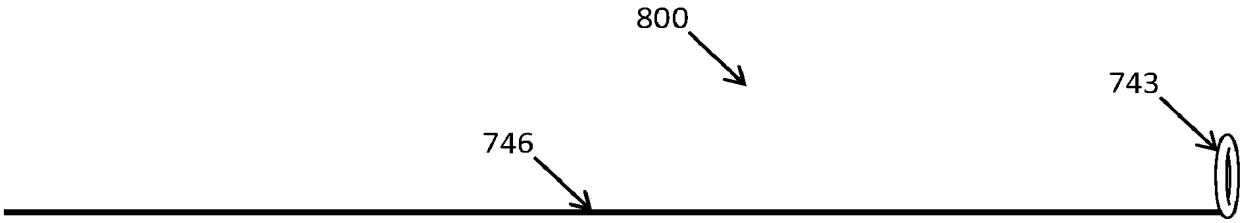


FIG. 43A

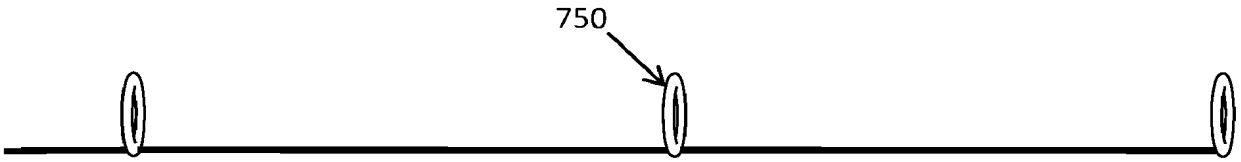


FIG. 43B

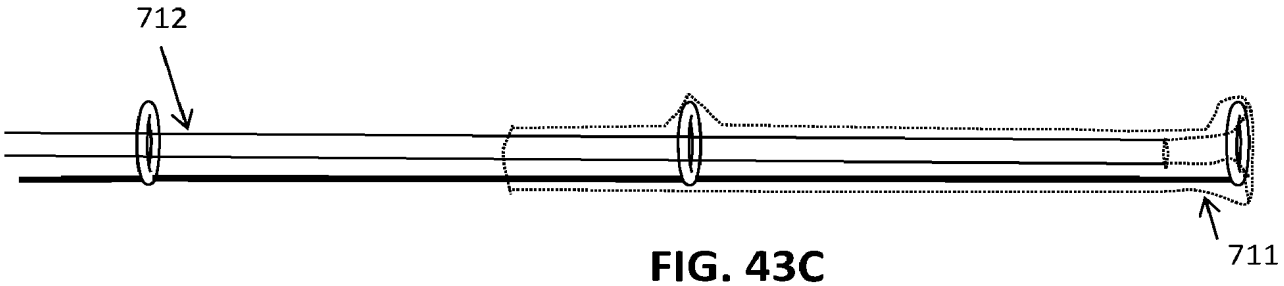


FIG. 43C

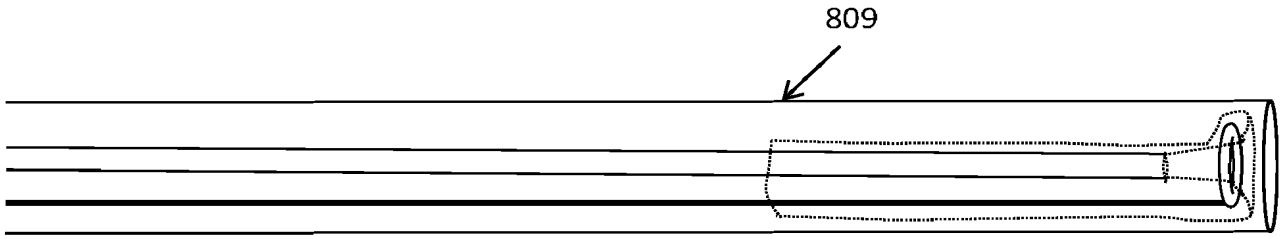


FIG. 43D

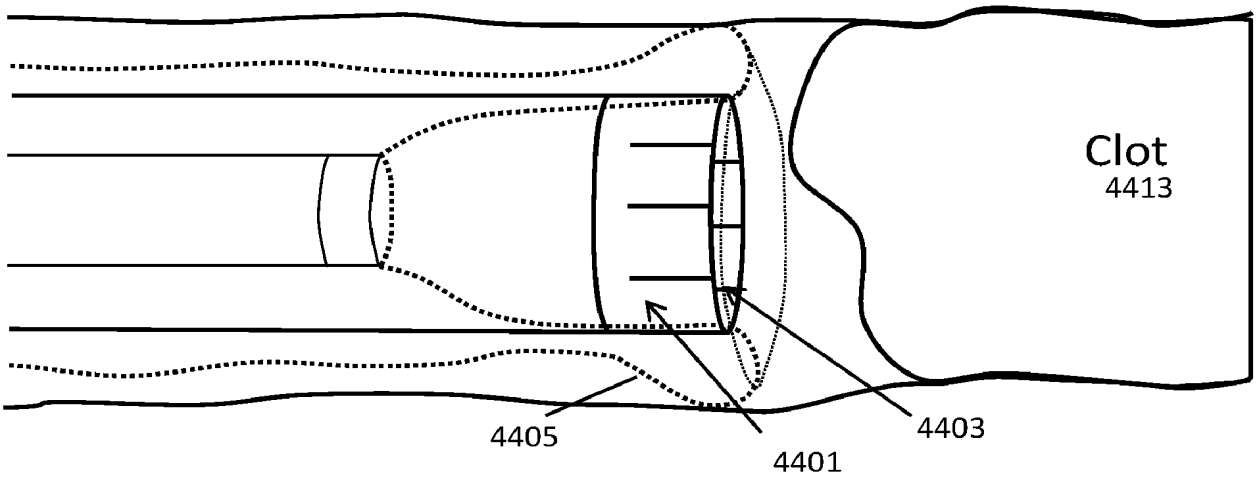


FIG. 44A

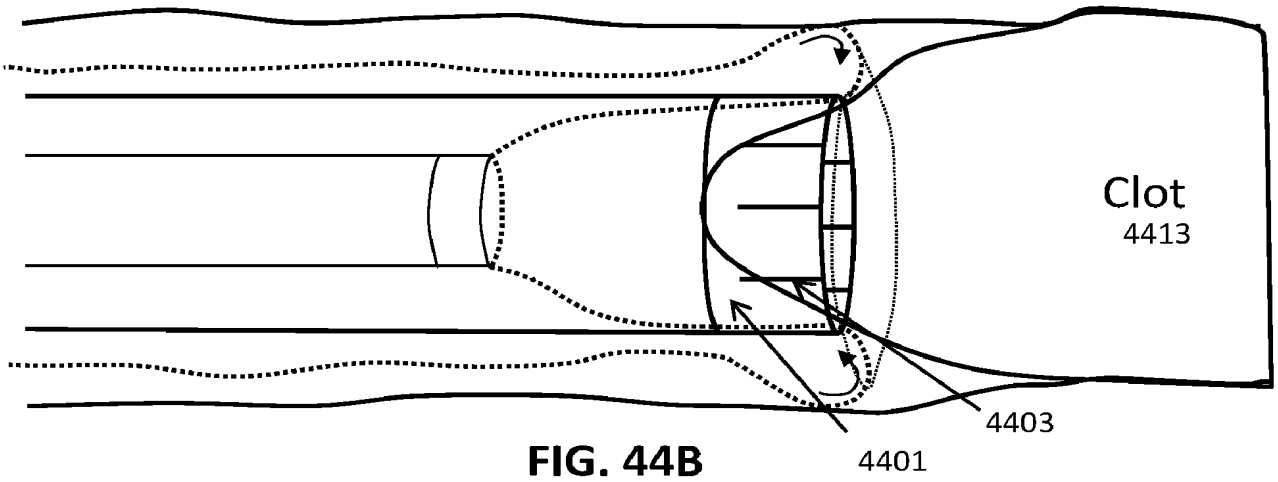


FIG. 44B

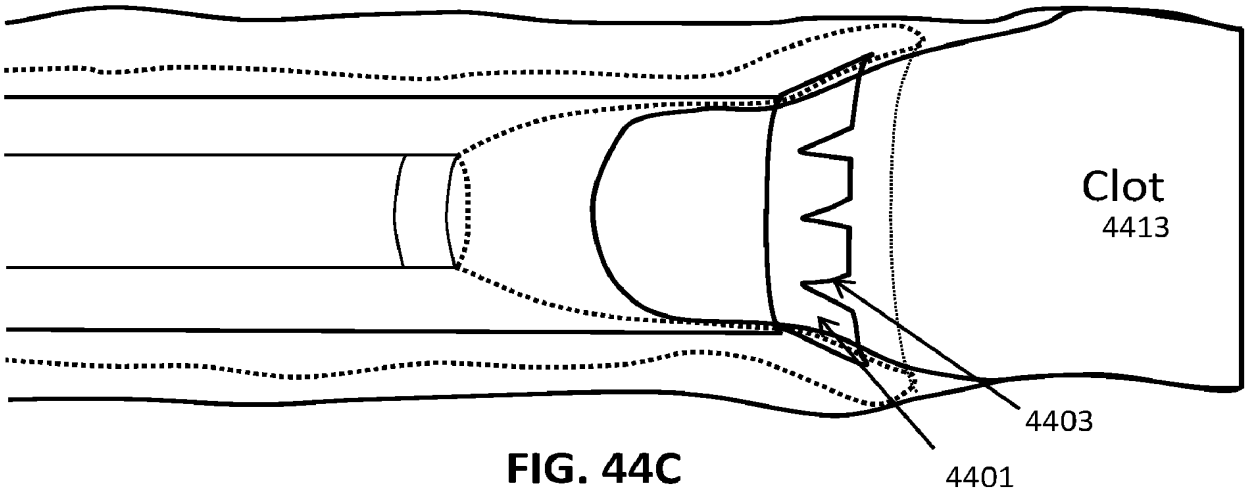


FIG. 44C

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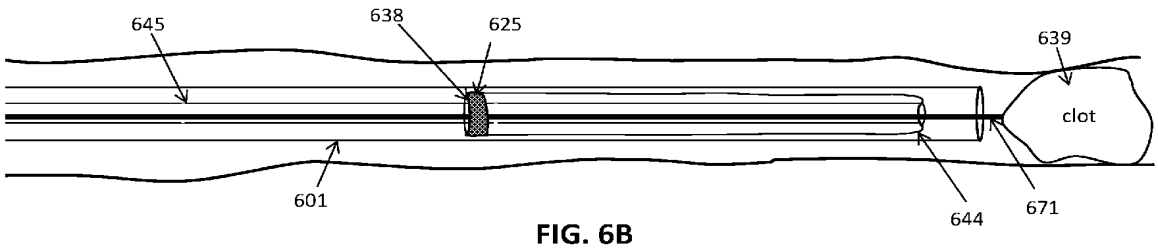

FIG. 6B

(57) Abstract: Rolling tractor tube mechanical thrombectomy apparatuses that may be deployed from out of a catheter *in situ* are described herein. These apparatuses may be delivered out of a catheter from a collapsed delivery configuration within the catheter to a deployed configuration out of the catheter, in which the same catheter is re-inserted between a tubular tractor and an elongate puller. In particular, any of these methods and apparatuses may be adapted to work with a tractor tube having an open end that is biased open, including using an annular bias.

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INVERTING THROMBECTOMY APPARATUSES

FIELD

[0001] The apparatuses described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses.

BACKGROUND

[0002] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient conditions and quality of life.

[0003] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0004] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, inventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[0005] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to mechanical retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and illustrative methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0006] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and illustrative methods of using and making them. These apparatuses may be configured for reliable operation in particular in narrow regions of the body, including peripheral vascular and neurovascular regions. Typically, the mechanical thrombectomy apparatuses described herein are inverting tractor thrombectomy apparatuses that includes a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

[0007] The apparatus may be deployed from a collapsed configuration using an in situ deployment, wherein the tractor is folded over an elongate puller/pusher member (which may be a hollow tube, wire or the like), and is collapsed down into a compact form for positioning within the vessel. Once the distal end of the tractor is in position within the vessel, the tractor may be expanded open and the distal end of the catheter over which the tractor is to be rolled or inverted is advanced distally between the tractor and the puller/pusher member, so the

distal end opening of the catheter is positioned distally and the tractor can roll over the distal end and invert when the puller/pusher is pulled proximally.

[0008] In practice, it is beneficial to provide a tractor that is able to be radially compacted to a large degree (e.g., to less than 0.7x the diameter, 0.6x the diameter, 0.5x the diameter, 0.4x the diameter, 0.3x the diameter 0.2x the diameter, 0.1x the diameter, etc.) while still maintaining high degree of flexibility for ease in rolling and inverting over the distal end. Further, the tractor may be advantageously biased so that it has an outer diameter when collapsed into the catheter (after being rolled and inverted into the catheter) that is greater than 0.7x the inner diameter of the catheter (e.g., greater than 0.7x, 0.75x, 0.8x, 0.85x, 0.9x, 0.95x, etc.). In some variations, it may be particularly beneficial if the outer diameter of the portion of the tractor that extends along the outer diameter of the catheter is biased to have an inner diameter that is between 1.1x and 2x the outer diameter of the catheter (e.g., between 1.1x and 1.9x, between 1.1x and 1.8x, between 1.1x and 1.7x, between 1.1x and 1.6x, between 1.1x and 1.5x, etc.).

[0009] Unfortunately, when performing an in situ deployment, it has proven particularly difficult to provide a tractor having an open end region into which the distal end of the catheter may be easily, reliably and robustly inserted between the expanded tractor and the inner puller/puller, particularly when the apparatus is deployed within a curved, bent, or tortious portion of the body. If the catheter distal end does not clearly and cleanly enter between the outer end of the tractor and the puller/pusher, it may get caught on the tractor and may prevent successful operation.

[00010] Described herein are apparatuses for improving and enhancing deployment, and particularly in situ deployment, of the apparatus so that the distal end (tip) of the catheter can be deployed distally between the free tractor end and a puller/pusher to which the other end of the tractor is attached and inverted.

[00011] For example, described herein are mechanical thrombectomy apparatuses to be used for removing a clot from a vessel. Any of these apparatuses may include an annular bias that holds the flexible tractor tube open so that an elongate inversion support catheter can be inserted through the annular bias and between the flexible tractor tube and the elongate puller/pusher ("elongate puller") to prepare the apparatus for rolling the flexible tractor tube over the distal end opening of the elongate inversion support catheter, even where the flexible tractor tube is expanding from a collapsed configuration within the elongate inversion support catheter.

[00012] For example, an apparatus as described herein may include: an elongate inversion support catheter having a distal end and a distal end opening; an elongate puller extending within the elongate inversion support catheter; a flexible tractor tube having a free first end and a second end that is attached to a distal end region of the elongate puller, wherein the flexible tractor tube is inverted over the elongate puller and is held within the elongate inversion support catheter in a collapsed first configuration; and an annular bias around the free first end of the flexible tractor tube, wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to expand into an expanded second configuration, wherein the annular bias has a diameter that is larger than an outer diameter of the elongate inversion support catheter in the expanded second configuration (e.g., between 1.1 and 10 times the OD of the elongate inversion support catheter in the expanded second configuration, between 1.1x and 10x, etc.).

[00013] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support catheter having a distal end and a distal end opening; an elongate puller extending within the elongate inversion support catheter, wherein the elongate puller comprises a central lumen; a flexible tractor tube having a free first end and a second end that is attached to a distal end region of the elongate puller, wherein the flexible tractor tube comprises a woven, braided, mesh or knitted material and is inverted over the elongate puller and is held within the elongate inversion support catheter in a collapsed first configuration; further wherein the flexible tractor tube is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in an un-inverted configuration and is further biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration; and an annular bias around the free first end of the flexible tractor tube, wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to expand into an expanded second configuration, wherein the annular bias has a diameter that is larger than (e.g., greater than 1.1 times, etc.) the outer diameter of the elongate inversion support catheter in the expanded second configuration so that the elongate inversion support catheter may be pushed through the annular bias and between the flexible tractor tube and an outer diameter of the elongate puller.

[00014] The annular bias may be any appropriate bias, including a ring, a stent (e.g., a stent having a zig-zag strut pattem), a lobed bias, etc. The annular bias may be attached the free, open end of the flexible tractor tube. The annual bias may be attached by stitching,

adhesive, etc. Alternatively or additionally, the annular bias may be formed by shape-setting the open end of the flexible tractor tube.

[00015] In particular, the flexible tractor tube may be biased to expand to between 1.1 and 4 times the outer diameter of the elongate inversion support catheter in an un-inverted configuration and may further be biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration.

[00016] The elongate inversion support catheter may be configured to be pushed through the annular bias and between the flexible tractor tube and an outer diameter of the elongate puller when the flexible tractor tube is in the expanded second configuration.

[00017] In general, the flexible tractor tube may comprise a woven, braided, mesh or knitted material. For example, the flexible tractor tube may be a knitted material. The flexible tractor tube is typically formed of a soft material that may readily roll over the distal open end of the elongate inversion support catheter. For example, the flexible tractor tube may be sufficiently soft such that without support, it collapses radially under an axial compression of less than 200g of force. The flexible tractor tube may comprise steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.

[00018] Any of these apparatuses may be configured for use with a guidewire. For example, any of these apparatuses may be configured to include a guidewire lumen extending through the elongate puller that is configured to pass a guidewire.

[00019] Although any appropriate elongate inversion support catheter may be used, in particular, the elongate inversion support catheter may have a harness profile such that this distal end is generally soft, until the very distal end, which may be harder than the more proximal region (e.g., the distal most 5 mm, distal most 4 mm, distal most 3 mm, distal-most 2 mm, distal most 1mm, etc. has a hardness that is greater than the region immediately proximal, which otherwise gradually becomes softer along the distal length). For example, the material hardness of the elongate inversion support catheter may generally decrease over the distal end of the catheter until the distal end opening, wherein the distal end opening may have a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile.

[00020] The elongate puller may comprise a hypotube. The flexible tractor tube may be any appropriate length. For example, the flexible tractor tube may be between 3 cm to 50 cm long.

[00021] The elongate inversion support catheter of the any of the apparatuses described herein may be or may include (particularly at its distal end) any appropriate catheter, e.g., a

flexible tube that can be inserted into a body vessel (e.g., blood vessel) into which the more flexible tractor portion can be withdrawn by pulling against the elongate inversion support. The elongate inversion support catheter may, in some variations, also be referred to as an outer catheter (e.g., when the puller for the tractor is referred to as an inner catheter) and/or inversion catheters and/or support catheter, as it may support the inversion of the tractor around the distal end opening of the catheter. The elongate inversion support catheter may include a braided or woven portion, a spiral or coiled portion, etc. (e.g., having a braided shaft), may have a single layer or multiple layers, and may be formed of biocompatible materials, including polymers, metals, etc. (e.g., PTFE). Examples of vascular catheters that may form the elongate inversion support include micro catheters.

[00022] The flexible tractor tube may be referred to as simply a tractor or as a tractor region , and may be configured to prevent jamming, while still able to efficiently "grab" a clot from within a vessel. For example, described herein are mechanical thrombectomy apparatuses that may be configured to grab or grasp a clot as it is mechanically drawn into the apparatus for removal. Although suction may be used in addition to the mechanical grabbing of the clot, in some variations suction is not used.

[00023] The flexible tractor tube may include projections that extend from the tractor region, particularly or exclusively as it bends around during inverting (e.g., at the distal end of the device). These projections may remain flat or non-extending when the tractor is held in parallel with the elongate inversion support. Alternatively, the projections may extend at all times. In general, the tractor may be formed of a woven materials, knitted material, or laser-cut sheet of material. The knitted and/or woven materials may be fibrous materials (including natural fibers, synthetics fibers, etc.), polymeric materials, or the like. For example, the material (e.g., strands) forming the woven or knitted material may be one or more of: monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Cobalt chromium alloy filament, Cobalt chromium alloy tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene. The sheets of material (e.g. a solid sheet of material) formed into the tractor region may be one or more of: polymeric material (e.g., PTFE), silicone materials, polyurethanes, shape memory alloys, stainless steels, etc. The sheets may be extruded, glued, or the like. The sheets may be cut to form pores and/or projections. For example, the sheets may include one or more laser-cut projections. Any of these apparatuses may be coated with a hydrophilic and/or hydrophobic coating, and/or may include pores. The tractor may have a

porosity of greater than >60% (greater than 70%, greater than 75%, greater than 80%, greater than 85%, etc., between 60-95, 65-95, 70-95%, etc.).

[00024] In any of the apparatuses described herein, the elongate inversion support catheter may be adapted to enhance rolling of the tractor region (inverting) over the distal end. For example, in any of the apparatuses described herein, the catheter may be configured so that the material hardness of the catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile. The catheter distal end may be stiffer because it is thicker (e.g., it may be formed by inverting the distal end of the catheter back over itself, and/or it may be formed of a stiffer material than the adjacent more proximal region (including by including a reinforcing material).

[00025] In any of the apparatuses described herein, the flexible tractor tube may include one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating. In particular the tractor may include a uniform or non-uniform lubricious (e.g., hydrophilic) coating.

[00026] As mentioned, any of these apparatuses may include a puller, e.g., an elongate puller coupled to a distal end of the tractor. Any of these apparatuses may include an elongate puller within the catheter coupled to a distal end of the tractor. The elongate puller may comprise a hypotube having an inner lumen that is continuous with the guidewire lumen though the flexible tube.

[00027] In general, the tractor may be any appropriate length. For example, the tractor may be between 3 to 100 cm long (e.g., between 3 and 50 cm, between 3 and 40 cm, between 3 and 30 cm, between 3 and 20 cm, between 10 and 100 cm, between 10 and 50 cm, between 20 and 100 cm, between 20 and 50 cm, etc.).

[00028] In any of these apparatuses, the apparatus may be configured so that the tractor may be inverted and rolled into the catheter by applying less than 300 grams of force (e.g., less than 400 g of force, less than 300 g of force, less than 200 g of force, less than 100 g of force, less than 90 g of force, less 80 g of force, less than 70 g of force, less than 60 g of force, less than 50 g of force, less than 10 g of force, etc.) to a distal end of the flexible tube, e.g., by pulling the elongate puller. For example, as mentioned above, the apparatus may include a hydrophilic coating, a lubricant on the catheter and/or tractor, a sleeve between the tractor and catheter, etc. This force required to retract the tractor into the catheter typically refers to the force required to roll the tractor over the distal end of the tractor.

[00029] Any of the apparatuses described herein may be configured so that the tractor is highly soft, and therefore rolls around the distal end of the catheter forming the elongate inversion support easily without jamming and/or requiring a large force to roll the tractor over the distal end opening of the catheter. In particular, tractors having a low axial compression strength, that would, but for the elongate inversion support, typically buckle, have been found to prevent jamming of the elongate inversion support as the tractor inverts. In particular, unsupported tractors (e.g., tractor that are not rolling over a catheter supported annular opening) that are configured to collapse radially under an axial compression of less than about 500g of force (e.g., less than: about 500g force, about 400g force, about 300g force, about 200g force, about 150 g force, about 100 g force, about 50 g force, etc.) may be particularly helpful in preventing jamming. For most knitted, woven, and braided tractors, including those described herein, when the tractor is configured to withstand greater that this amount of axial compression force, the tractor may jam, and/or may require excessive force to invert. Thus, in any of the apparatuses and methods described herein, the tractor maybe sufficiently soft such that without support from the catheter, the tractor collapses radially under an axial compression of less than 200g of force when inverting (and may instead buckle).

[00030] Further, in any of the apparatuses described herein, the tractor may be biased to expand to greater than the outer diameter of the catheter in a second configuration (that is inverted relative to the first configuration) where the tractor is extending over the outer diameter of the catheter. The same tractor may be biased to expand to greater than the inner diameter of the catheter of the elongate inversion support in the first (e.g., un-inverted), configuration where the tractor is within the catheter of the elongate inversion support. Thus, in relaxed configuration, prior to assembling with the elongate inversion support, the tractor may be oversized compared to the catheter of the elongate inversion support; the portion of the tractor that extends within the catheter of the elongate inversion support, referred to as "un-inverted," may have an inner diameter that is greater than the inner diameter of the catheter, which may tend to drive the tractor toward the walls of the inner diameter of the catheter without collapsing down into the catheter. Further, the inner diameter of the tractor in the "inverted" configuration, e.g., the configuration of the portion that is doubled back over and along the catheter of the elongate inversion support, may be greater than the outer diameter of the catheter of the elongate inversion support. This arrangement may prevent jamming and an increased resistance between the tractor and the outside of the catheter of the elongate inversion support. The catheter may be biased to expand in both the inverted and

un-inverted configurations by, e.g., heat setting. The tractor may be inverted to transition between the first and second configurations by rolling over the distal end of the catheter; the terms "inverted" and "un-inverted" are therefore relative terms.

[00031] The annular bias may be biased to have an expanded, open configuration that has a slightly larger (e.g., greater than 5%, greater than 10%, greater than 15%, greater than 20%, greater than 25%, etc., larger than the expanded diameter of the flexible tractor tube. In addition, the annular bias may be relatively "stiffer" than the open (free) end of the flexible tractor tube, to prevent buckling, collapse, etc. In some variations, the annular bias has a smooth and/or curved edge to prevent getting caught on the elongate inversion support catheter when it is inserted into the annular bias.

BRIEF DESCRIPTION OF THE DRAWINGS

[00032] The novel features of embodiments of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00033] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows an example of an elongate inversion support catheter portion of an apparatus. At least the distal end of the elongate inversion support is configured as a catheter. FIG. 1B shows an enlarged view of a partial section of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a flexible tractor tube attached over a puller (the puller in this example is configured as a catheter). The tractor is shown in a first configuration. In some variations, the flexible tractor tube may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus includes an elongate inversion support catheter having a distal end and a distal end opening; the elongate puller extends within the elongate inversion support catheter and a flexible tractor tube is connected at one end to the elongate puller. The flexible tractor tube and puller may be extended through the

elongate inversion support catheter, including extended out of the distal end (e.g., by pulling the elongate inversion support catheter proximally and/or by pushing the elongate puller distally). The flexible tractor tube may initially be held in a collapsed first configuration (as shown in FIG. 1E) for positioning within a vessel; it may be deployed and expanded, as shown in FIG. 1F, with the elongate inversion support catheter positioned between the flexible tractor tube and the elongate puller. The flexible tractor tube may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support.

[00034] FIGS. 1G and 1H illustrate the use of the an apparatus such as the one shown in FIGS. 1E and 1F to remove a clot by drawing the flexible tractor tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00035] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00036] FIGS. 2A -2F illustrate an exemplary (in situ) method of deploying a mechanical thrombectomy apparatus designed in accordance with the disclosed embodiments. In FIG. 2A the elongate inversion support catheter (either alone or with a guidewire) is positioned within the vessel, near a clot. In some variations the flexible tractor tube and elongate puller may already be positioned within the elongate inversion support catheter, e.g., near the distal end, or it may be moved into position thereafter, as shown in FIG. 2B. In FIG. 2C, the flexible tractor tube is deployed out of the elongate inversion support catheter and allowed to expand. Thereafter, the elongate inversion support catheter is moved distally between the flexible tractor tube and the elongate puller, as shown in FIG. 2D. Once the elongate inversion support catheter is positioned distally between the flexible tractor tube and elongate puller, as shown in FIG. 2E, the flexible tractor tube may be rolled and inverted into the elongate inversion support catheter, as shown in FIG. 2F. In this example, the inverting flexible tractor tube is shown grabbing a clot may as it is inverted into the elongate inversion support catheter. The flexible tractor tube extends from the distal end opening of the elongate inversion support catheter and expands into an expanded second configuration; the flexible

tractor tube is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in an un-inverted configuration (e.g., FIG. 2D) and is further biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration (when drawn into the catheter as shown in FIG. 2F).

[00037] FIGS. 3A-3B illustrate a first variation of an apparatus having an elongate puller with a stepped outer diameter into which the flexible tractor tube may be compressed. This configuration may provide improved mobility within the elongate inversion support catheter. This variation may also be readily adapted for application to a vacuum through the hollow elongate puller. In FIG. 3A the flexible tractor tube is collapsed. In FIG. 3B the flexible tractor tube is expanded, as shown.

[00038] FIGS. 4A-4C illustrate deployment of the elongate puller with a stepped outer diameter shown in FIGS. 3A-3B. In FIG. 4A the elongate puller is positioned at the distal end of the elongate inversion support catheter, and extended from the distal end opening of the catheter until the collapsed flexible tractor tube is expanded at least slightly, as shown in FIG. 4B. An annular bias, described in greater detail below, may be used in this variation as well. As shown in FIG. 4C, the elongate inversion support catheter may then be positioned between the flexible tractor tube and the elongate puller, so that the elongate inversion support catheter can support the flexible tractor tube until it can be pulled proximally by pulling the elongate puller to invert into the elongate inversion support catheter.

[00039] FIG. 5A-5F illustrate the use of the apparatus of FIG. 3A-3B, including an annular bias, to remove a thrombus (clot) from within a vessel. In FIG. 5A the elongate inversion support catheter is positioned near the clot in the vessel. The elongate pusher to which a flexible tractor tube is attached at a first end, with an annular bias on an open, free second end, is extended distally through the catheter and out of the distal end of the elongate inversion support catheter, as shown in FIG. 5B. In FIG. 5C, the annular bias holds the free end of the flexible tractor tube open. In some variations the flexible tractor tube is biased to expand to diameter that is slightly greater than the outer diameter of the catheter (e.g., greater than 1.1x the outer diameter of the elongate inversion support catheter), however the annular bias may be open even slightly more, and may be more rigid when expanded open, as shown. The elongate inversion support catheter may then be inserted distally through the annular bias and between the flexible tractor tube and the elongate puller, as shown in FIGS. 5D-5E. A vacuum may be applied through the elongate puller and/or elongate inversion support catheter, as shown in FIG. 5E. In FIG. 5F, withdrawing the elongate puller proximally (with or without a vacuum) to roll the flexible tractor over the distal end of the

elongate inversion support catheter so that it inverts into the elongate inversion support catheter may draw the clot into the elongate inversion support catheter, as shown.

[00040] FIGS. 6A-6F illustrate another variation of an apparatus including an annular bias on an open, free, end of the flexible tractor tube. In FIG. 6A, the elongate inversion support catheter is positioned, shown here with the optional use of a guidewire, within the lumen of the vessel. In FIG. 6B, the elongate puller and flexible tractor tube are positioned distally within the elongate inversion support catheter, also over the guidewire; the flexible tractor tube is attached at one end of the flexible tractor tube, with the other end of the flexible tractor tube attached to an annular bias at a free (loose) end. The guidewire may be removed or left in position when deploying the flexible tractor tube from the distal end of the elongate inversion support catheter. In FIG. 6C, the distal end of the puller including the entire flexible tractor tube is extended distally from the elongate inversion support catheter and the annular bias expands to a diameter that is greater than the outer diameter of the elongate inversion support catheter. In FIG. 6D and 6E, the elongate inversion support catheter is advanced distally within the annular bias and between the flexible tractor tube and the elongate puller, so that the elongate inversion support catheter may support the flexible tractor tube as it is pulled proximally by the elongate puller to invert over the distal end opening of the elongate inversion support catheter. The apparatus may be advanced (e.g., while pulling the elongate puller proximally) to grab and remove a clot from the vessel, as shown in FIG. 6E.

[00041] FIGS. 7A-7D illustrate four variations of annular biases that may be used to support the expanded open (free) end of the flexible tractor tube in any of the variations described herein. The vertical columns illustrate an expanded end view, an expanded side view, a collapsed end view (e.g., within the elongate inversion support catheter) and a side view shown attached to a flexible tractor tube, respectively, from left to right. In FIG. 7A, a ring-shaped annular bias is shown. In FIG. 7B the annular bias is a member having lobes or petals, which may predictably collapse when compressed (e.g., see the collapsed end view). In FIG. 7C the annular bias is a stent-like structure having a plurality of zig-zagging struts (members).

[00042] FIGS. 8A-8C illustrate an example of an apparatus including a flexible tractor tube having a stent-like annular bias (formed of a loop of a sinusoidally arranged strut(s) having a 0.002" thickness attached to the open end of a 144 end 0.00075" NiTi braid flexible tractor tube). FIGS. 8A sows the expanded annular bias, shown attached to the flexible

tractor tube in FIG. 8B. The flexible tractor tube with the annular bias of FIG. 8A is shown attached to an elongate puller in FIG. 8C.

[00043] FIG. 9A shows another example of a flexible tractor tube (144 end 0.00075" NiTi) having an annular bias. FIG. 9B shows the open end of the flexile tractor tube rolling over the open distal end of the elongate inversion support catheter. FIG. 9C shows a schematic of the stent-like annular bias including lead-in arms that may help it roll over the elongate inversion support catheter.

[00044] FIG. 10 illustrates an example of a flexible tractor tube that is heat-set at the open end to have an inverted shape to allow for ease of insertion of the elongate inversion support catheter. In FIG. 10, the open (loose) end of the flexible tractor tube folds back under itself which may help guide the elongate inversion support catheter into the space between the flexible tractor tube and the elongate puller. In this example, the flexible tractor tube may not require an additional annular bias.

DETAILED DESCRIPTION

[00045] In general, described herein are mechanical thrombectomy apparatuses having an inverting flexible tractor tube that is configured to be deployed in situ (e.g., within a catheter) without jamming. Any of these apparatuses may include an elongate elongate inversion support catheter over which the flexible tractor tube inverts at the distal end. In the deployment configuration, the flexible tractor tube may comprise a flexible tube that doubles back (e.g., inverts) over the distal end opening of the elongate inverting support catheter so that the tractor tube extends into the opening of the elongate inverting support catheter when the tractor tube is pulled proximally. The tractor tube may be attached at one end to an elongate puller. Pulling the elongate puller proximally will roll and invert the tractor over the distal end opening of the elongate inverting support catheter which may capture a clot and pull it into the elongate inversion support catheter.

[00046] Any of the apparatuses may include a coating (e.g., hydrophilic, lubricious coating, etc.) or the like to enhance the sliding and inverting of the tractor over the distal end. Further, any of these apparatuses may include one or more projections that are configured to enhance grabbing and/or maceration of a clot.

[00047] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support catheter having a distal end and a distal annulus (distal end opening), and a flexible tractor assembly

including a flexible tractor tube coupled to an elongate puller. The flexible tractor tube is configured to roll and invert over the distal end opening of the elongate inverting support catheter.

[00048] In many of the examples described herein, the tractor assembly is configured to extend within the elongate inversion support catheter when deployed. Any of these apparatuses may switch between a delivery configuration, e.g., in which the entire tractor assembly may be held within the elongate inversion support catheter prior to deployment, and a deployed configuration, e.g., in which the elongate inversion support catheter is positioned between the flexible tractor tube and the elongate pusher to support the flexible tractor tube as it is pulled into the elongate inversion support catheter distal end opening to roll and invert into the elongate inversion support catheter. In particular, the apparatuses may be configured so that the transition between the delivery configuration and the deployed configuration is robust. For example, as will be described in greater detail herein, any of the apparatuses described herein may include an annular bias that enhances the ability of the elongate inversion support catheter to be inserted between the flexible tractor tube and the elongate puller.

[00049] FIGS. 1A to 1I illustrate various components of a mechanical thrombectomy apparatus that may include any of the features described herein. For example, FIG. 1A shows a catheter (e.g., an elongate inversion support catheter) that may form part of the apparatuses described herein. In this example, the elongate inversion support catheter includes a catheter body 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00050] In FIG. 1A, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled

over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1A the catheter 100 of the elongate inversion support catheter may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00051] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00052] FIG. 1C shows an example of a flexible tractor tube 144 coupled to an elongate puller 146, forming a pullable tractor assembly 140. In this example, the tractor tube is shown integrated with the puller and extending back over the puller, forming the assembly. The opposite end of the flexible tractor tube 147 is open and free (e.g., not connected to the puller or catheter). As will be described in greater detail below, this open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIG. 1C, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). For example, the tractor 144 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first

configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1D, the tractor tube has a larger expanded diameter than the variation shown in FIG. 1C in a relaxed configuration. In any of these variations, the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00053] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor tube 144 and a less expandable (or non-expandable) proximal portion comprising the elongate puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00054] In FIG. 1E, the tractor assembly (flexible tractor tube 144 and puller 146 of FIG. 1D) are shown within an elongate inversion support catheter 100. The tractor is collapsed down 101, e.g., onto the puller, and may be held collapsed within the elongate inversion support catheter. Thus, FIG. 1E shows the pre-deployment (e.g., delivery) configuration. The tractor assembly may be axially movable (slidable) within the catheter so that it can be positioned within the catheter and within the vessel.

[00055] FIG. 1F shows a fully deployed apparatus. In FIG. 1F, the tractor tube is in an unconstrained or deployed configuration, and the elongate inversion support catheter is positioned between the tractor tube and the puller so that the tractor tube can be pulled proximally by pulling on the puller and rolling the tractor tube into the elongate inversion support catheter so that it inverts. In FIG. 1F, the tractor in this deployed configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, as will be described in relation to FIGS. 1G and 1H, below, the tractor tube may also be configured (e.g., by heat setting, etc.) so that when the tractor tube is inverted and pulled into the elongate inversion support catheter, the outer diameter of the inverted tractor tube has an outer diameter that is greater than 0.5x (e.g., greater than 0.6x, greater than 0.7x, greater than 0.75x, greater than 0.8x, greater than 0.9x, greater than 1x, etc.) the inner diameter (ID) of the

elongate inversion support catheter. This combination of an un-inverted diameter of the tractor tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the tractor tube of greater than 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the tractor over the distal end opening of the elongate inversion support catheter to grab a clot. The tractor may be expandable and may be coupled to the puller as shown. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00056] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus components of FIGS. 1A and 1E. The apparatus 10 is shown in a deployed state. In this example the thrombectomy apparatus 10 is configured as a thrombectomy apparatus including an elongate inversion support catheter 100 and a flexible tractor tube 144 that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner, less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be "loose" relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor tube 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[00057] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00058] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions.

[00059] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around

the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00060] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00061] In any of the variations described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily side over the catheters distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00062] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[00063] The stiffness of the distal of the catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inward ward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[00064] It may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters

will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[00065] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[00066] Reducing the sliding friction of tractor to outer catheter wall, improving tractor to tip rolling, and/or enhancing tractor to inner catheter sliding may also be achieved by including a sliding skin or sleeve. For example, a thin (e.g., ultrathin) sleeve may be used. The sleeve would be made from low friction polymer (PET, PE, PP, PTFE, ePTFE, pebax, urethanes) by braiding, knitting, weaving, extrusion, melt blown, melt spinning, etc. The sleeve could be made from laser slotted tubing, chemical etching, micro machining. The sleeve could be also coated with a lubricious coating such as a hydrophilic coating. Lubricious coatings can be located on the outside and/or inside surfaces. The sleeve may be placed between the dozer element and the catheter wall and attached to the puller element. The sleeve may be less than 0.002" thick, ideally, less than 0.001" wall thickness. The sleeve may decouple the tractor clot grabbing system from the catheter wall, tip rolling and inner catheter dragging friction. The sleeve could be totally free from the tractor, connected to the tractor in discrete locations or connected fully to the tractor. This may allow the tractor to be designed to grab clot (larger wires: 0.001" to 0.002" for neuro, and 0.002" to 0.007" for other applications) and the skin to minimized in thickness and structure to reduce friction and skin bending stiffness.

[00067] In some variations, the tractor region may be formed of with a mixed or hybrid structure, combining one or more of interwoven or knitted braid polymer filaments with metallic filaments. The mixed structure (hybrid structure) may leverage both metallic elements interwoven with low friction polymer elements. The metallic filaments may create stiffness elements that may grip/grab a clot. The polymer filaments may aid in grabbing clot but may provide surface friction reduction to the outer catheter wall, the catheter tip and the inner catheter wall once around the tip.

[00068] Any of the apparatuses described herein may include a tractor having a hydrophilic/lubricous coating on the inside surface, e.g., for braided/knitted tractors, on the

inside surface (contacting the outer and inner diameter of the catheter) of the braid/knit, which is in contact with the outside of the catheter. Examples of lubricous coatings include hydrophilic coatings (e.g.,. hydrogels) and hydrophobic coatings (e.g., fluorine coating such as PTFE & FEP, parylene, silicone, siloxane (silicone additive) added to various polymers including pebax to make any material more lubricious, Polyethylene, polypropylene, FEP)

[00069] As mentioned above, any of these apparatuses may include a distal tip that is less rigid (e.g., 'softer') than the more proximal regions of the distal tip. This may be achieved by having a structural supporting member reinforcing the distal tip, or by modifying the material forming the distal tip.

[00070] Any of the tractors described herein may include a marker or makers (e.g., radiopaque markers, such as gold, Pt, etc.).

[00071] For purposes of illustration and to better understand the disclosed apparatuses, FIGS. 2A-2F illustrate an in situ method of deploying a mechanical thrombectomy apparatus constructed according to embodiments of the present invention. In FIG. 2A the elongate inversion support catheter 201 is positioned within the vessel, near a clot 239, e.g., by moving the elongate inversion support catheter distally 210 towards the clot. The elongate inversion support catheter may be positioned with a guidewire (not shown), or without a guidewire. The tractor assembly portion of the apparatus, e.g., a flexible tractor tube 244 and elongate puller 245 may be positioned with the catheter, or it may be moved through the catheter once it is in position within the vessel. In FIG. 2B, the tractor assembly 240 is positioned within the elongate inversion support catheter near the distal end. Once it is in an approximate location (e.g., near the clot 239), the flexible tractor tube 244 may be extended 212 from the distal end of the elongate inversion support catheter, as shown in FIG. 2C. The flexible tractor tube may be deployed out of the elongate inversion support catheter by pulling 214 the elongate inversion support catheter proximally and/or pushing the flexible tractor tube distally; once out of the elongate inversion support catheter, the flexible tractor tube is allowed to expand into a second (expanded configuration) outside of the elongate inversion support catheter. As mentioned, the flexible tractor tube may be biased so that in this un-inverted configuration the diameter of the flexible tractor tube is between 1.1x and 5x the OD of the elongate inversion support catheter (e.g., typically between 1.1x and 3x the OD of the elongate inversion support catheter, etc.). The elongate inversion support catheter may then be moved back distally, between the flexible tractor tube 244 and the elongate puller 245, as shown in FIG. 2D.

[00072] In practice, the catheter must fit into the open (free) end of the flexible tractor portion. The apparatus may be modified, e.g., by including an annular bias at or near the open end of the flexible tractor portion. Alternatively or additionally, the open end may be biased (e.g., heat set, shape set, etc.) to invert over or under itself.

[00073] In FIG. 2E, once the elongate inversion support catheter is positioned distally between the flexible tractor tube and elongate puller, the flexible tractor tube may be rolled and inverted 266 into the elongate inversion support catheter, as shown in FIG. 2F. In this example, the elongate puller 245 may be pulled through the elongate inversion support catheter proximally 218 to pull the flexible tractor tube proximally into the elongate inversion support catheter. In FIG. 2F, the rolling tractor is shown grabbing the clot 239, and inverting into the elongate inversion support catheter while pulling the clot into the elongate inversion support catheter. The flexible tractor tube in this example is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in an un-inverted configuration (e.g., FIG. 2D) and is further biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration (when drawn into the catheter as shown in FIG. 2F).

[00074] FIGS. 3A-3B illustrate another example of a tractor assembly including a flexible tractor tube 344 attached at one end to an elongate puller 345. In this example, similar to FIG. 1I, the elongate puller has a stepped profile. The narrower-diameter region formed in the elongate puller by the stepped profile may allow the flexible tractor tube of the tractor assembly 334 to be compressed with a smaller profile within the elongate inversion support catheter. In FIG. 3A the flexible tractor tube 344 is shown collapsed (compressed) against the elongate puller. This configuration may provide improved mobility within the elongate inversion support catheter. This variation may also be readily adapted for application to a vacuum through the hollow elongate puller. In FIG. 3A the flexible tractor tube is shown as compressed or collapsed. FIG. 3B shows the flexible tractor tube in an expanded configuration. In this example, the flexible tractor tube 244 is expanded outward from the puller. The tractor tube may be biased (e.g., heat set, shape set, etc.) in this configuration. Alternatively or additionally, the apparatus may be compressed and held within an elongate inversion support catheter.

[00075] FIGS. 4A-4C illustrate deployment of the elongate puller with a stepped outer diameter, such as the variation shown in FIGS. 3A-3B, from a delivery configuration to a deployed configuration. In FIG. 4A the elongate puller 445 is positioned at the distal end of the elongate inversion support catheter 401; the flexible tractor tube 444 is attached at one

end to the puller. In FIG. 4B, the flexible tractor tube 444 is extended from the distal end opening of the elongate inversion support catheter and expanded 449 at least slightly. In this example, the elongate inversion support catheter 401 may be withdrawn proximally 410. An annular bias, described in greater detail below, may be used in this variation as well, to hold the free, open end 433 of the tractor tube 444 open. As shown in FIG. 4C, the elongate inversion support catheter 401 may then be positioned 412 between the flexible tractor tube 444 and the elongate puller 445, so that the elongate inversion support catheter 401 can support the flexible tractor tube a the distal end so that it can roll and invert into the elongate inversion support catheter, e.g., by pulling the elongate puller to invert into the elongate inversion support catheter.

[00076] FIG. 5A-5F illustrate the use of the apparatus of FIGS. 3A-3B, including an annular bias, to remove a thrombus (clot) from within a vessel. In FIG. 5A the elongate inversion support catheter 501 is positioned near a clot 539 in the vessel 550. The elongate pusher 545, to which a flexible tractor tube 544 is attached, forming a tractor assembly, may be positioned in the elongate inversion support catheter at the distal end. In FIG. 5B the elongate pusher is attached to the first end of the tractor tube 544 at a first end, with an annular bias open and unsecured (e.g., free) at the second end. The second, open or free end 533 may include one or more annular biases 525 that may is extended distally through the catheter and out of the distal end of the elongate inversion support catheter 501, as shown in FIG. 5B. In FIG. 5C, the annular bias 525 holds the free end 533 of the flexible tractor tube open. Alternatively or additionally, the flexible tractor tube may be biased to expand to diameter that is slightly greater than the outer diameter of the catheter 501 (e.g., greater than 1.1x the outer diameter of the elongate inversion support catheter), however the annular bias 525 may be open even slightly more, and may be stiffer (e.g., more rigid) when expanded open, as shown in FIG., 5C. The elongate inversion support catheter 501 may then be inserted distally through the annular bias 525 and between the flexible tractor tube 544 and the elongate puller 545, as shown in FIGS. 5D-5E. The entire apparatus may be advanced distally 552, either before or while rolling the tractor into the elongate inversion support catheter 501. A vacuum 560 (optional) may be applied through the elongate puller 544 and/or elongate inversion support catheter and/or the puller may be drawn proximally 554, as shown in FIG. 5E. In FIG. 5F, withdrawing 556 the elongate puller proximally (with or without a vacuum) to roll the flexible tractor over the distal end of the elongate inversion support catheter so that it inverts into the elongate inversion support catheter may draw the clot into the elongate inversion support catheter, as shown.

[00077] The variations shown in FIGS. 3A-3B, 4A-4C and 5A-5F having a stepped outer diameter in the puller may maximize the inner diameter of the tractor assembly, which may aid in aspiration (mechanical or by vacuum). In any of these variations, a vacuum can be applied to the apparatus (e.g., the tractor assembly) and/or the elongate inversion support catheter. In some variations the OD of the puller along at least part of its length (e.g., proximal to the free end of the tractor tube) may be approximately the same as the ID of the elongate inversion support catheter. This may aid in forming a seal such that vacuum applied through the elongate puller may be maintained the distal end of the elongate inversion support catheter and/or puller, which may help in grabbing the clot.

[00078] FIGS. 6A-6F illustrate another variation of an apparatus including an annular bias 625 on an open, free, end 638 of the flexible tractor tube 644. In FIG. 6A, the elongate inversion support catheter 601 is positioned in the vessel. In FIG. 6A, a guidewire 671 is shown. The catheter may be advanced over the guidewire, to approach the clot 639. In FIG. 6B, the elongate puller 645 and flexible tractor tube 644 are positioned distally within the elongate inversion support catheter 601, also over the guidewire 671. The tractor assembly includes the flexible tractor tube 644 attached at one end to the elongate puller 645, with the other end of the flexible tractor tube open and free (e.g., not attached to the puller or catheter), but coupled to an annular bias 625. The guidewire 671 may be removed or left in position when deploying the flexible tractor tube from the distal end of the elongate inversion support catheter. In FIG. 6C, the tractor assembly, including the distal end of the elongate puller 645 and the entire flexible tractor tube 644 is extended distally from the elongate inversion support catheter 601. The annular bias 625 expands 674 to a diameter that is greater than the outer diameter of the elongate inversion support catheter 601 (e.g., greater than 1.1x the diameter of the elongate inversion support catheter). The annular bias may also act to stiffen or otherwise stabilize this end region of the tractor tube (which may be on or near the open end of the tractor tube) so that the elongate inversion support catheter 601 can be inserted through the annular bias, as shown in FIG. 6D.

[00079] In FIG. 6D and 6E, the elongate inversion support catheter 601 is advanced distally 671 within the annular bias and between the flexible tractor tube 644 and the elongate puller 645, so that the elongate inversion support catheter can support the flexible tractor tube 644 as it is pulled 678 proximally by the elongate puller 645 to roll 663 and invert over the distal end opening of the elongate inversion support catheter (as shown in FIG. 6F). The apparatus may be advanced (e.g., while pulling the elongate puller proximally) to grab and remove a clot 639 from the vessel, as shown in FIG. 6E.

[00080] In any of these variations, the annular bias may be configured to keep the free end of the tractor tube open when deployed. The annular bias may be welded braided, bonded, glued and/or integral to the tractor tube. The annular bias may be attached to an outside, an inside or both (e.g., may be folded over the open end of the tractor tube, or may be attached on either side of the tractor tube.

[00081] FIGS. 7A-7D illustrate four variations of annular biases that may be used to support the expanded open (free) end of the flexible tractor tube in any of the variations described herein. For example, FIG. 7A shows an annular bias forming a circular loop in the expanded end view. The loop may be formed of a shape memory material, such as Nitinol, or a polymeric material. The loop may be orthogonal to the braid or weave of the tractor tube, which may aid in compressing when rolling over the distal end opening of the elongate inversion support catheter. In some variations the annular bias may be heat set to an irregular circular shape to aid in folding or may include buckling points around the perimeter of the annular bias. In the side view shown of the annular bias of FIG. 7A the annular bias is angled relative to the long axis of the tractor tube; alternatively, the annular bias may be attached perpendicular to the long axis (similar to FIG. 7B.

[00082] In any of the variations described herein, the annular bias may be configured to include one or more predetermined collapse/expansion locations about which the annular bias is configured to collapse or expand as it transitions between an expanded and a collapsed configuration. For example, the predetermined locations may be defined by the one or more lobes or vertices forming the annular bias. FIG. 7B shows an example in which the annular bias includes folds or bends that may control the collapsed configuration. In this example, the annular bias has lobes or petals, which may predictably collapse when compressed (e.g., see the collapsed end view). The annular bias may be shaped to compress into a small diameter as the tractor tube rolls around the tip of the elongate inversion support catheter. The u-shaped features (lobes, petals, etc.) at noon, 3 o'clock, 6 o'clock, and 9 o'clock are one example. Other examples include the use of fewer (e.g., 2 lobes, 3 lobes) or more (e.g., 5 lobes, 6 lobes, etc.).

[00083] In general, the annular bias has a stiffness that is greater than the stiffness of the flexible tractor tube (e.g., greater than 1.5x the stiffness, greater than 2x the stiffness, etc.).

[00084] In FIG. 7C the annular bias is a stent-like structure having a plurality of zig-zagging struts (members). The stent-like annular bias may easily invert when rolling around the catheter tip. The length of the zig-zags may be limited to < about 5-10 mm. In some variation multiple rows of zig-zags may be used.

[00085] FIG. 7D shows an example of an annular bias that is funnel-shaped. In operation, this structure may both help the insertion of the elongate inversion support catheter between the tractor tube and the elongate puller, and may also help with inverting the end of the tractor tube and pulling it into the elongate inversion support catheter.

[00086] An example of a stent-like annular bias is shown in FIGS. 8A-8C. In this example the annular bias is formed of a sinusoidally arranged loop of wire (though multiple wires/struts may be used) having a 0.002" thickness, which is attached to the open end region of a 144 end 0.00075" NiTi braid flexible tractor tube. FIGS. 8A shows the expanded annular bias 803, shown attached to a flexible tractor tube 801 in FIG. 8B. The flexible tractor tube 801 with the annular bias 803 of FIG. 8A is shown attached to an elongate puller 805 in FIG. 8C. In the example shown in FIG. 8, the annular bias is attached near the open (free) end of the tractor tube at the distal end region, but is slightly distal to the end. In some variations the annular bias is attached at the very end (or edge) of the open end of the flexible tractor tube.

[00087] Any of the annular biases described herein may also be configured to enhance rolling of the distal end of the apparatus over the tip of the elongate inversion support catheter. For example, FIG. 9A shows another example of a flexible tractor tube (144 end 0.00075" NiTi) having an annular bias, being rolled 961 into the elongate inversion support catheter by pulling proximally on the tractor tube. In FIG. 9B the open end of the flexile tractor tube (with an attached sent-like annular bias 903) is shown rolling over the open distal end of the elongate inversion support catheter. In order to enhance this rolling, in some variations, the annular bias may also include one or more extension (e.g., lead in arms) that may extend along the long axis (length) of the flexible tractor tube. A schematic of this configuration is shown in FIG. 9C. In FIG. 9C the stent-like annular bias includes lead-in arms that may help it roll over the elongate inversion support catheter. The lead-in arms may help the annular bias to roll around the catheter tip and into the ID of the elongate inversion support catheter. One or more (e.g., 1, 2, 3, 4, 5, 6, 7, 8, etc.) lead-in arms may be used; these lead in arms may be all the same length of different lengths.

[00088] FIG. 10 illustrates an example of a flexible tractor tube 1001 that is heat-set at the open end to have an inverted shape 1003 to allow for ease of insertion of the elongate inversion support catheter. In FIG. 10, the open (loose) end of the flexible tractor tube folds back under itself which may help guide the elongate inversion support catheter into the space between the flexible tractor tube 1001 and the elongate puller 1005. In this example, the flexible tractor tube may not require an additional annular bias.

[00089] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[00090] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[00091] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[00092] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[00093] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the claimed articles (e.g., compositions and apparatuses including devices and systems). For example, the term "comprising" will be understood to imply the inclusion of any stated elements but not the exclusion of any other elements.

[00094] In general, any of the apparatuses described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[00095] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a

number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[00096] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[00097] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate inversion support catheter having a distal end and a distal end opening;

an elongate puller extending within the elongate inversion support catheter;

a flexible tractor tube having a free first end and a second end that is coupled to a distal end region of the elongate puller, wherein the flexible tractor tube is inverted over the elongate puller and is held within the elongate inversion support catheter in a collapsed first configuration; and

an annular bias disposed at least partially around the free first end of the flexible tractor tube,

wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to expand into an expanded second configuration, and

wherein the annular bias has a diameter that is larger than an outer diameter of the elongate inversion support catheter when the flexible tractor tube is in the expanded second configuration.

2. The apparatus of claim 1, wherein the annular bias comprises a ring.

3. The apparatus of claim 1, wherein the annular bias comprises a stent having a zig-zag strut pattern.

4. The apparatus of any of claims 1-3, wherein the annular bias has a diameter that is between 1.1x and 5x of the outer diameter of the elongate inversion support catheter when the flexible tractor tube is in the expanded second configuration.

5. The apparatus of any of claims 1-4, wherein the annular bias comprises a plurality of pre-determined collapse locations about which the annular bias is configured to collapse or expand.

6. The apparatus of any of claims 1-4, wherein the annular bias comprises a plurality of lobes, wherein the plurality of lobes comprise a respective plurality of collapse locations on the annular bias.

7. The apparatus of any of claims 1-6, wherein the annular bias is coupled to one or more of an inner side and an outer side of the flexible tractor tube.

8. The apparatus of any of claims 1-7, wherein the annular bias comprises a plurality of lead-in arms oriented along a long axis of the flexible tractor tube.

9. The apparatus of any of claims 1-8, further wherein the flexible tractor tube in an un-inverted configuration is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter and wherein the flexible tractor tube is further biased in an inverted configuration to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter.

10. The apparatus of any of claims 1-9, wherein the elongate inversion support catheter is configured to be pushed through the annular bias and between the flexible tractor tube and an outer wall of the elongate puller when the flexible tractor tube is in the expanded second configuration.

11. The apparatus of any of claims 1-10, wherein the flexible tractor tube comprises a woven, braided, mesh or knitted material.

12. The apparatus of any of claims 1-11, wherein the flexible tractor tube is sufficiently soft so as to collapse radially under an axial compression of less than 200g of force.

13. The apparatus of any of claims 1-12, further comprising a guidewire lumen extending through the elongate puller, the guidewire lumen being configured to allow passage of a guidewire therethrough.

14. The apparatus of claim 11, wherein the flexible tractor tube is knitted.

15. The apparatus of any of claims 1-14, wherein the flexible tractor tube comprises one or more of steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, and a fabric.

16. The apparatus of any of claims 1-15, wherein a material hardness of the elongate inversion support catheter decreases along a length of the distal end thereof, wherein the distal end opening has a material hardness that is greater than a material hardness

of a region immediately proximal to the distal end, and wherein the distal end opening has a rounded lip profile.

17. The apparatus of any of claims 1-15, wherein the elongate puller comprises a hypotube.

18. The apparatus of any of claims 1-17, wherein the flexible tractor tube has a length between 3 cm to 50 cm.

19. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate inversion support catheter having a distal end and a distal end opening;

an elongate puller extending within the elongate inversion support catheter, wherein the elongate puller comprises a central lumen;

a flexible tractor tube having a free first end and a second end that is coupled to a distal end region of the elongate puller, wherein the flexible tractor tube comprises a woven, braided, mesh and/or knitted material, is inverted over the elongate puller, and is held within the elongate inversion support catheter in a collapsed first configuration, and wherein the flexible tractor tube is biased in an un-inverted configuration to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in and is further biased in an inverted configuration to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter; and

an annular bias disposed at least partially around the free first end of the flexible tractor tube, wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to expand into an expanded second configuration, wherein the annular bias has a diameter that is larger than an outer diameter of the elongate inversion support catheter in the expanded second configuration so that the elongate inversion support catheter may be pushed through the annular bias and between the flexible tractor tube and an outer wall of the elongate puller.

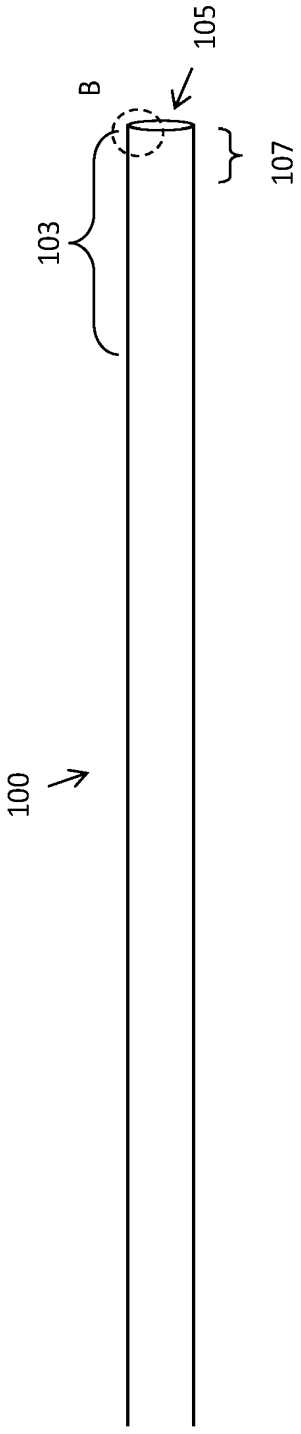

FIG. 1A

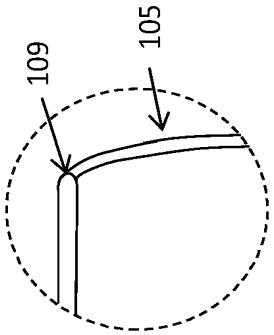

FIG. 1B

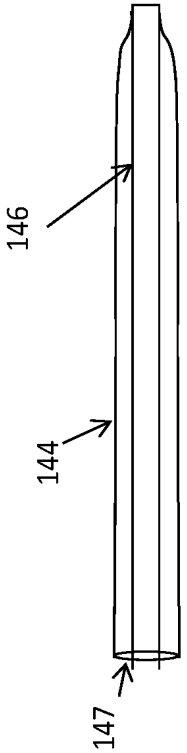

FIG. 1C

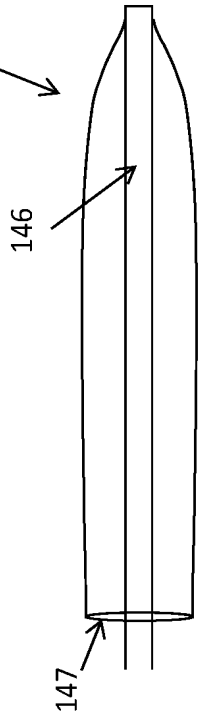

FIG. 1D

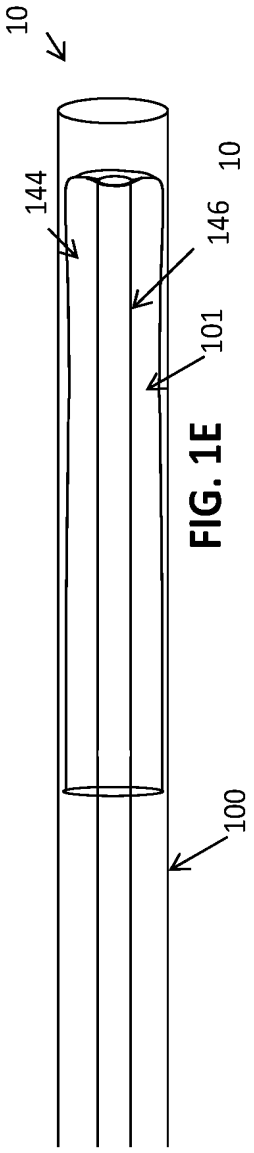

FIG. 1E

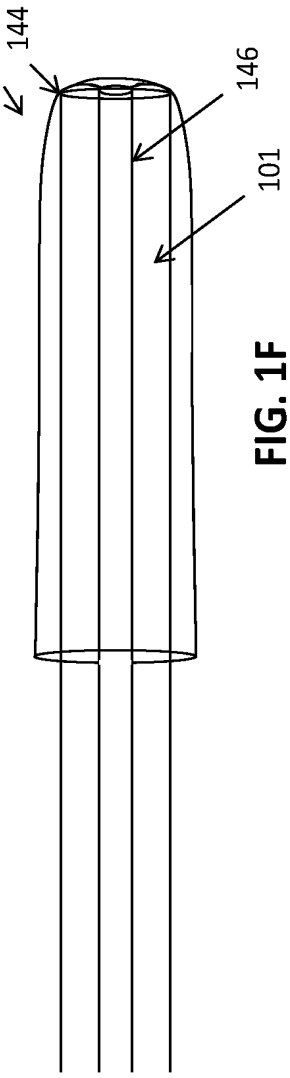

FIG. 1F

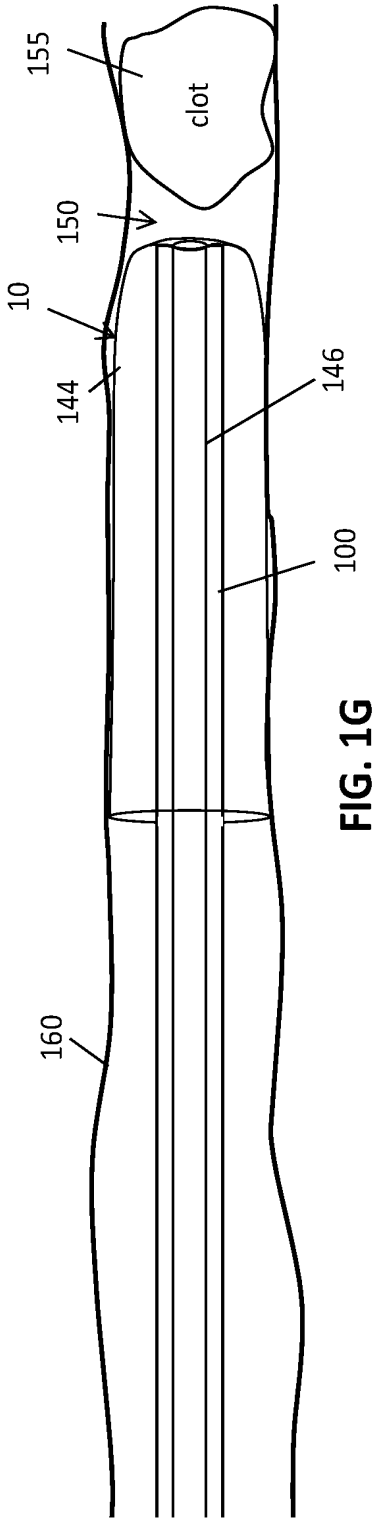

FIG. 1G

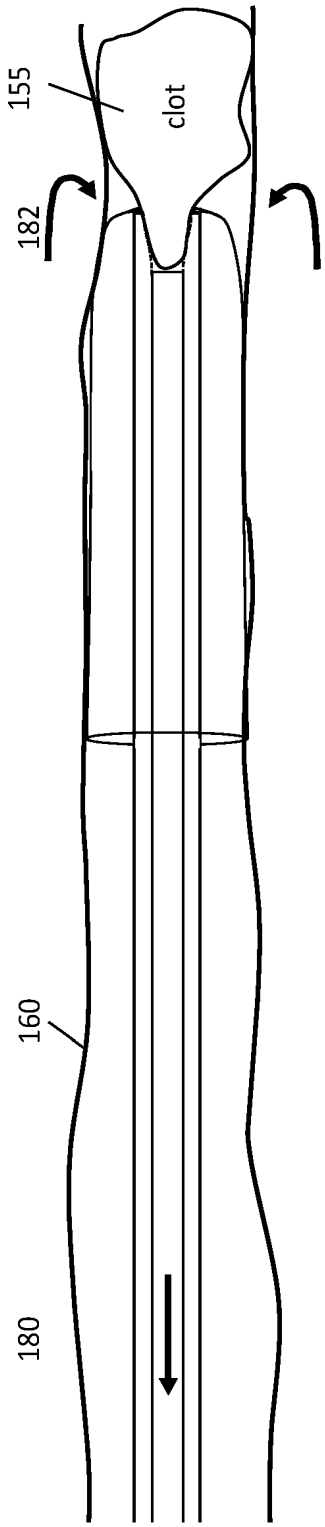

FIG. 1H

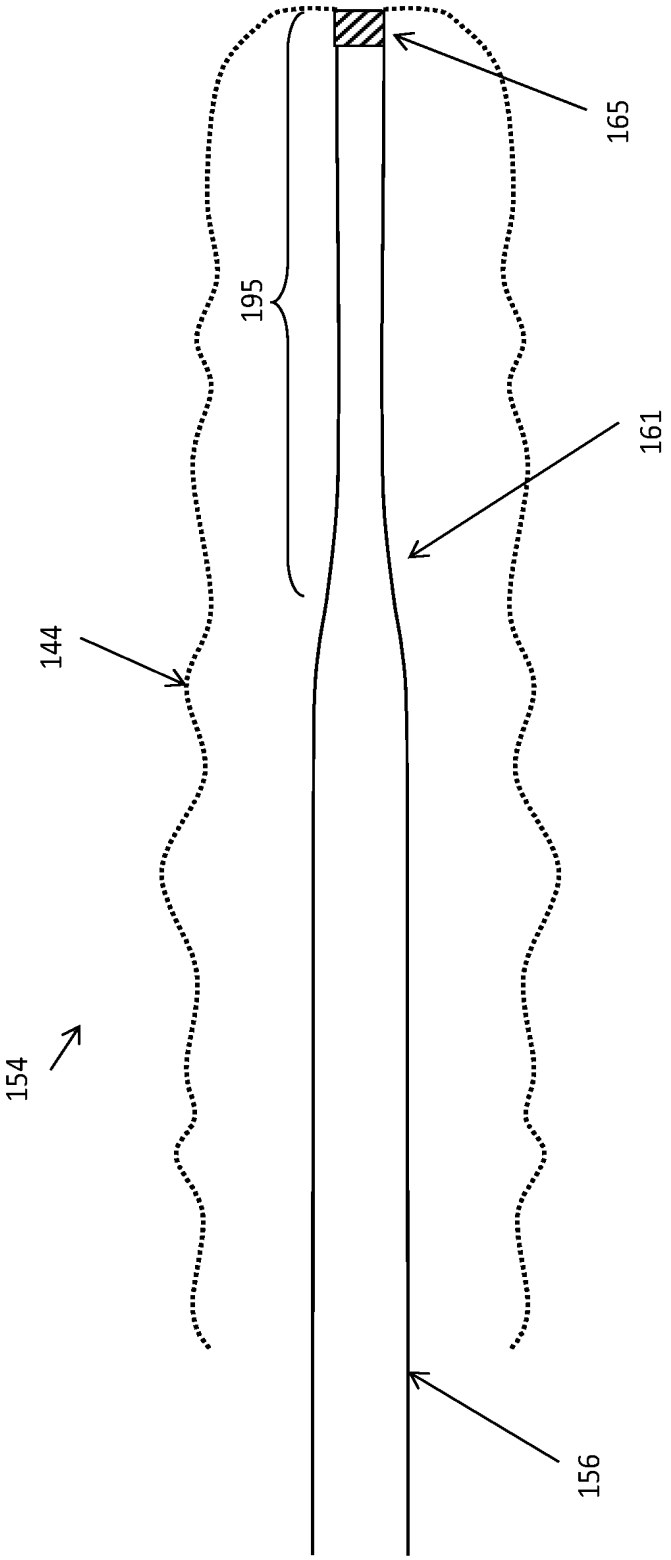

FIG. 1I

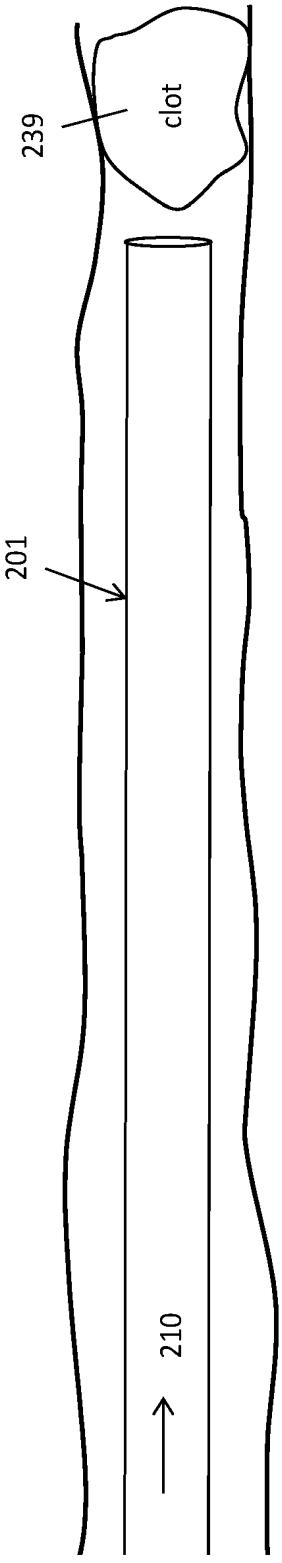

FIG. 2A

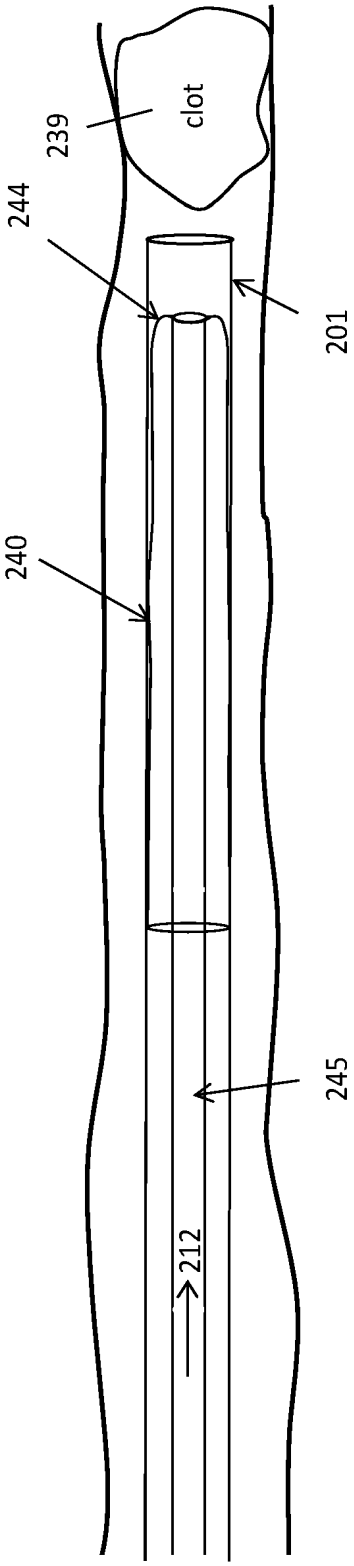

FIG. 2B

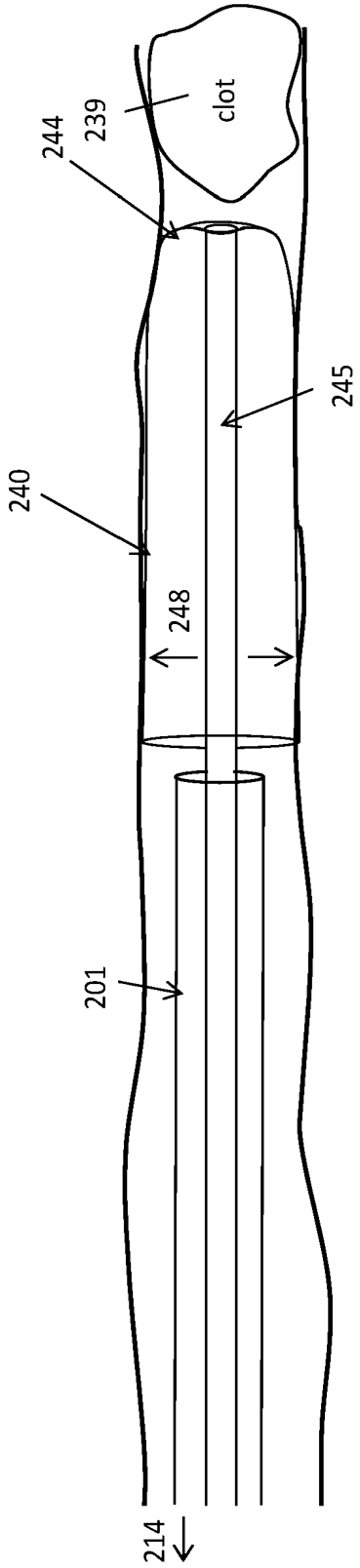

FIG. 2C

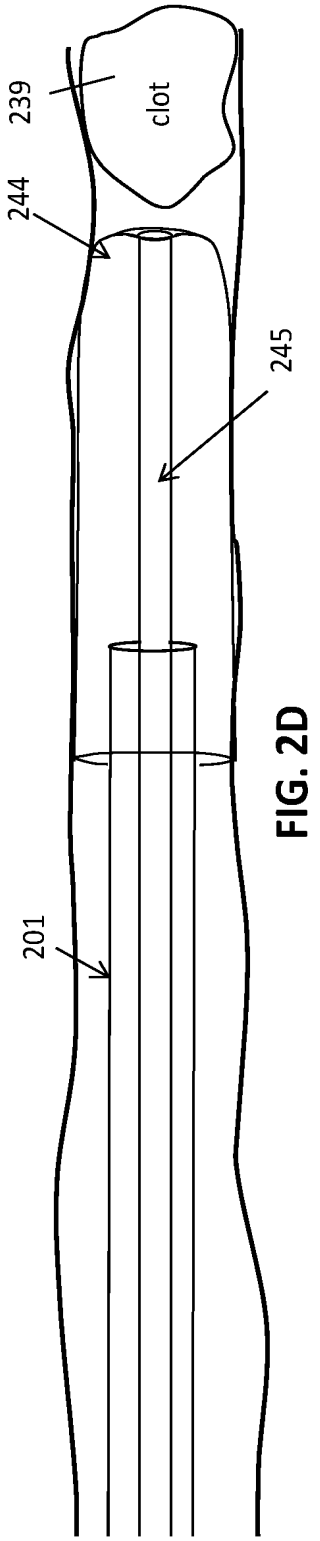

FIG. 2D

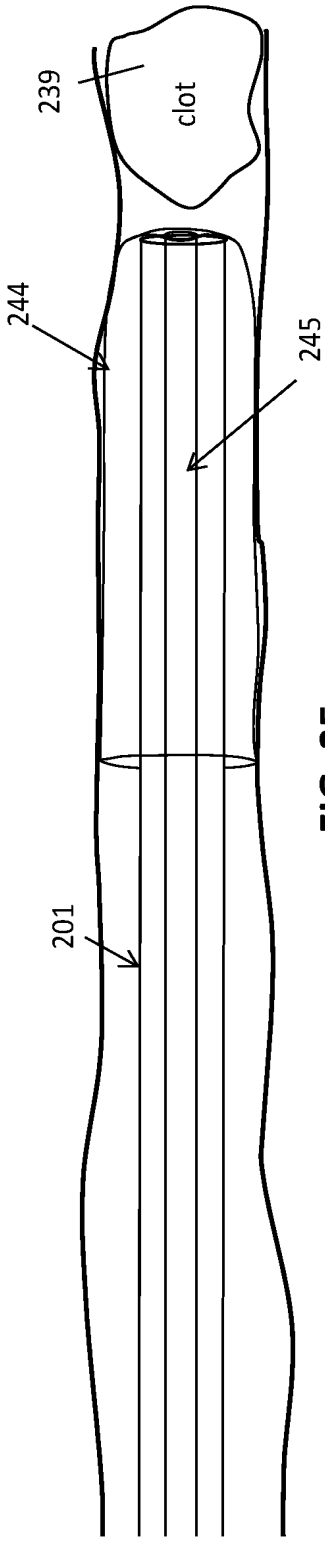

FIG. 2E

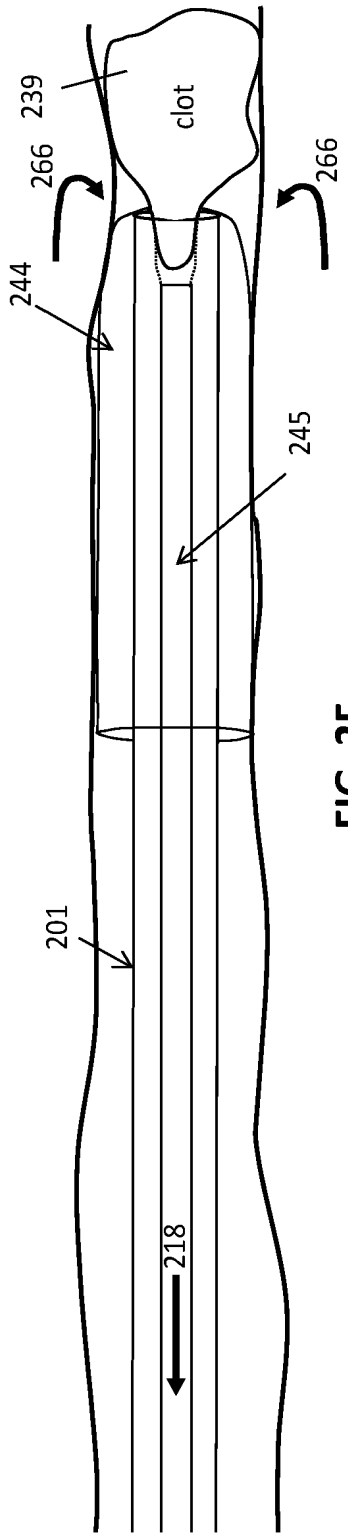

FIG. 2F

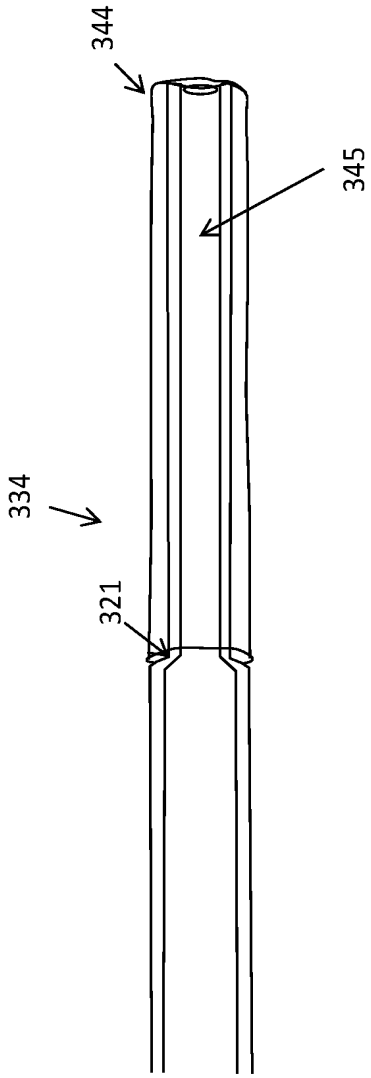

FIG. 3A

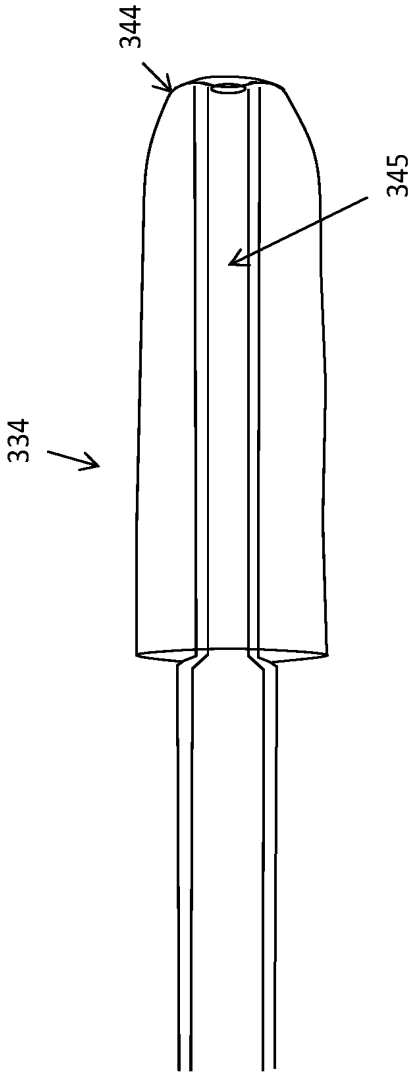

FIG. 3B

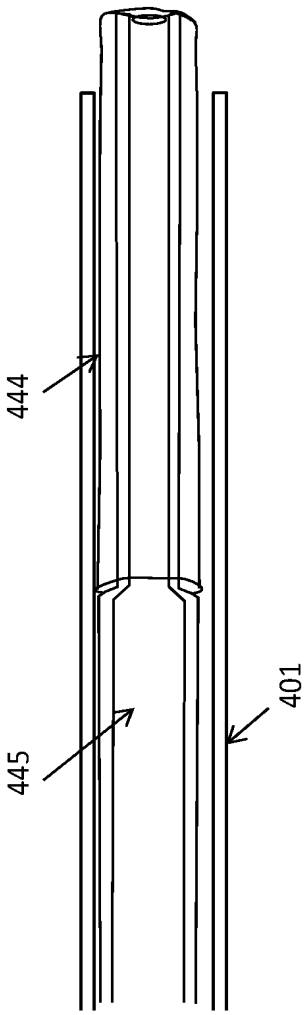

FIG. 4A

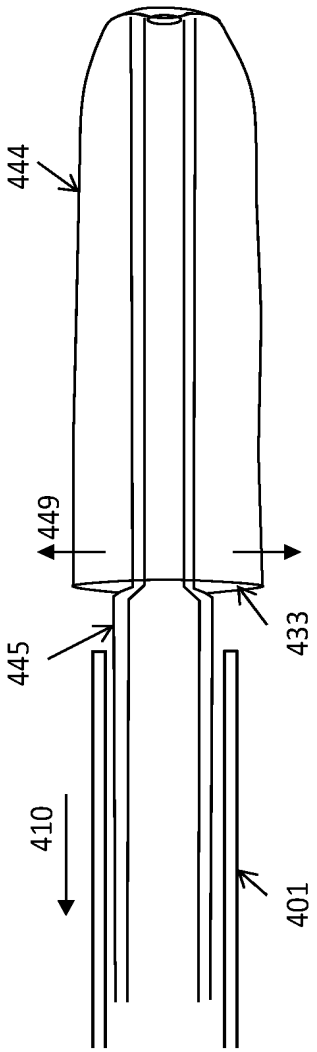

FIG. 4B

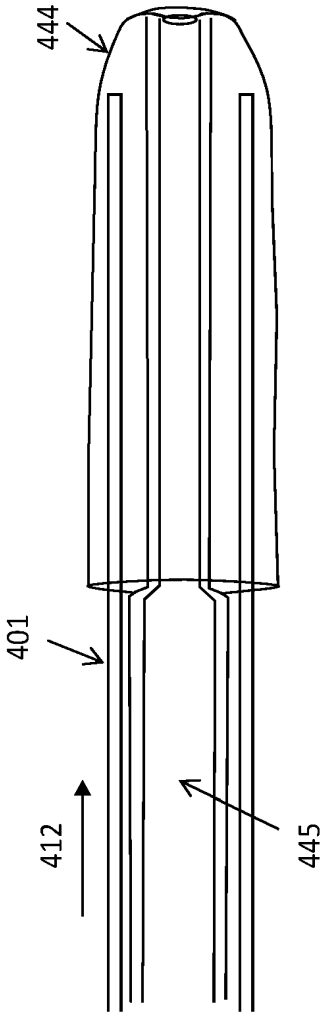

FIG. 4C

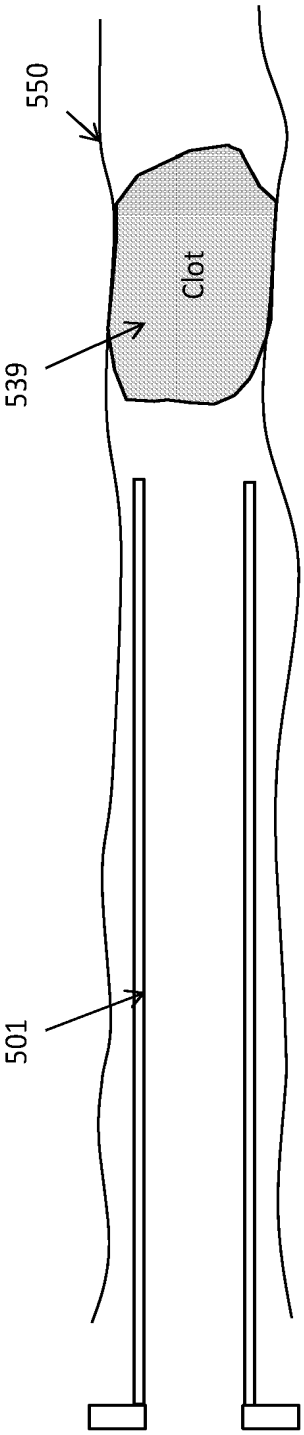

FIG. 5A

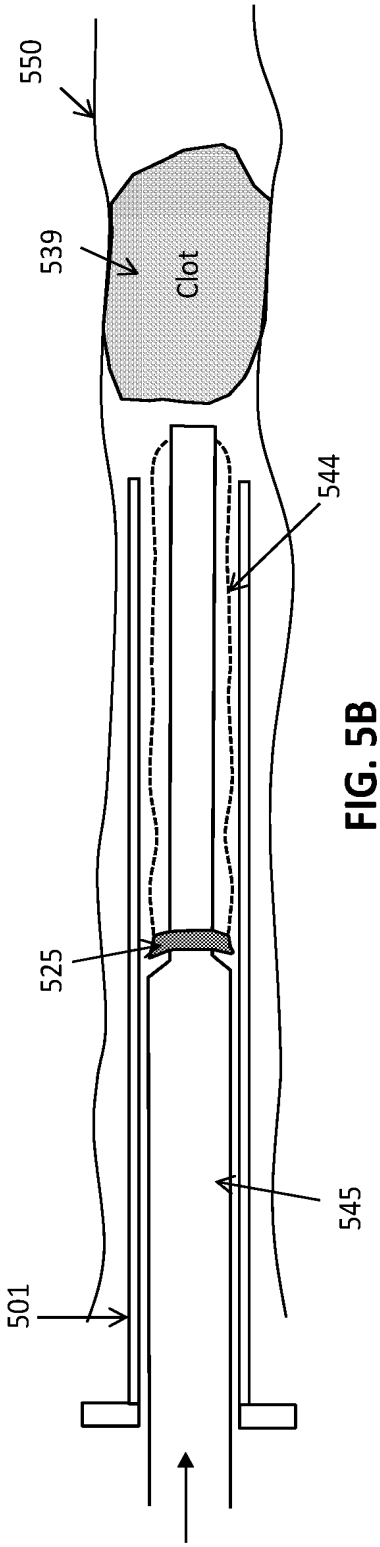

FIG. 5B

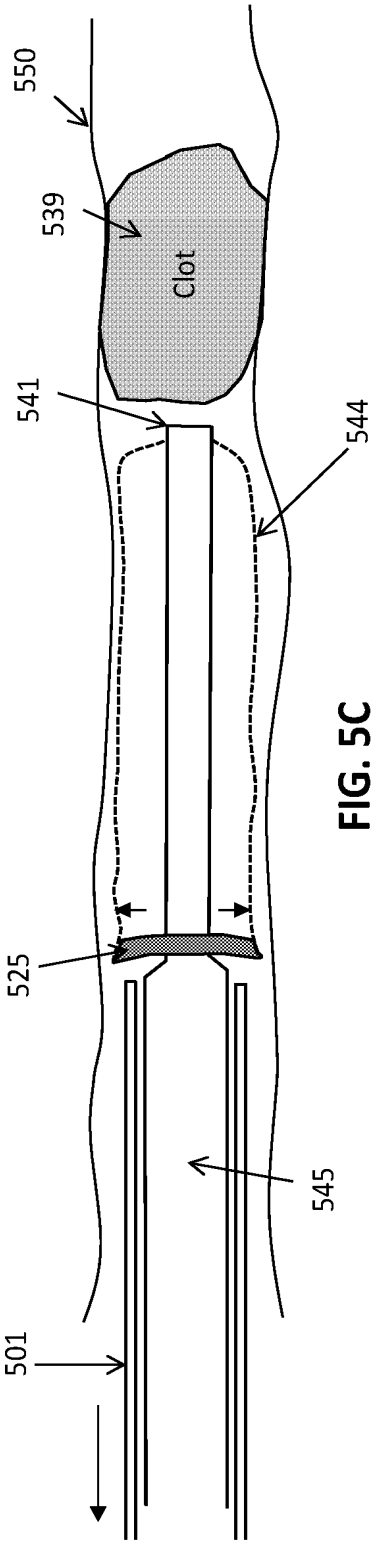

FIG. 5C

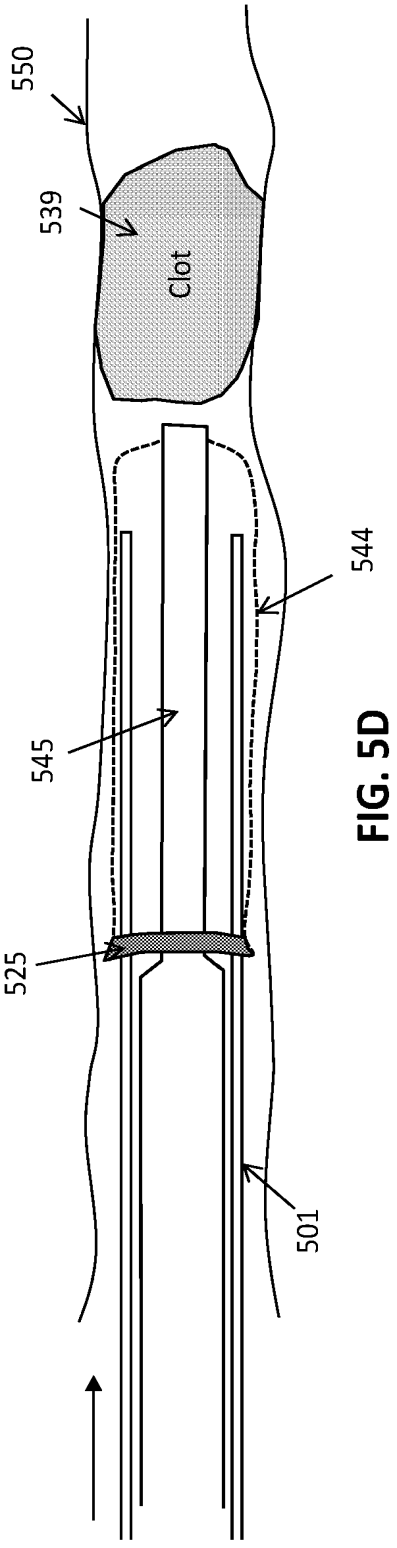

FIG. 5D

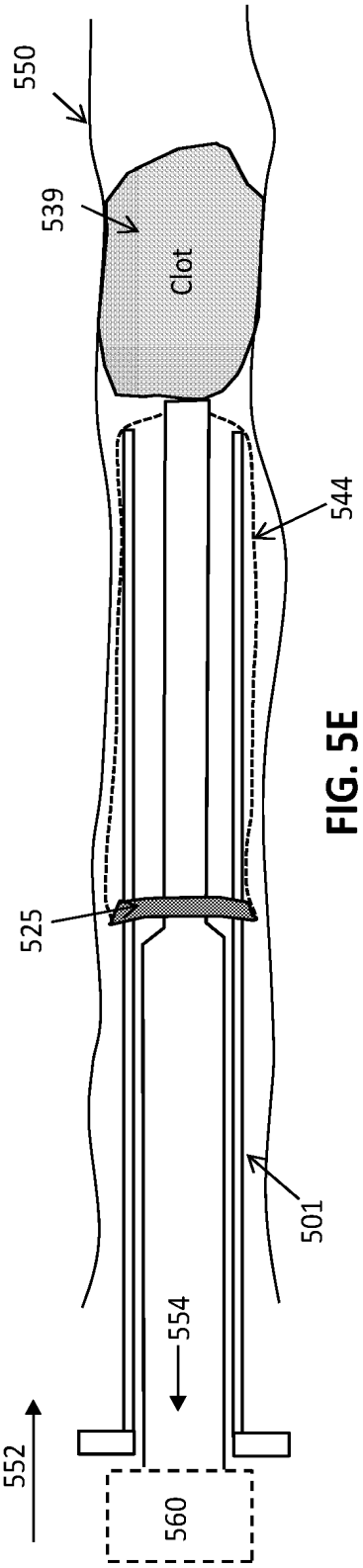

FIG. 5E

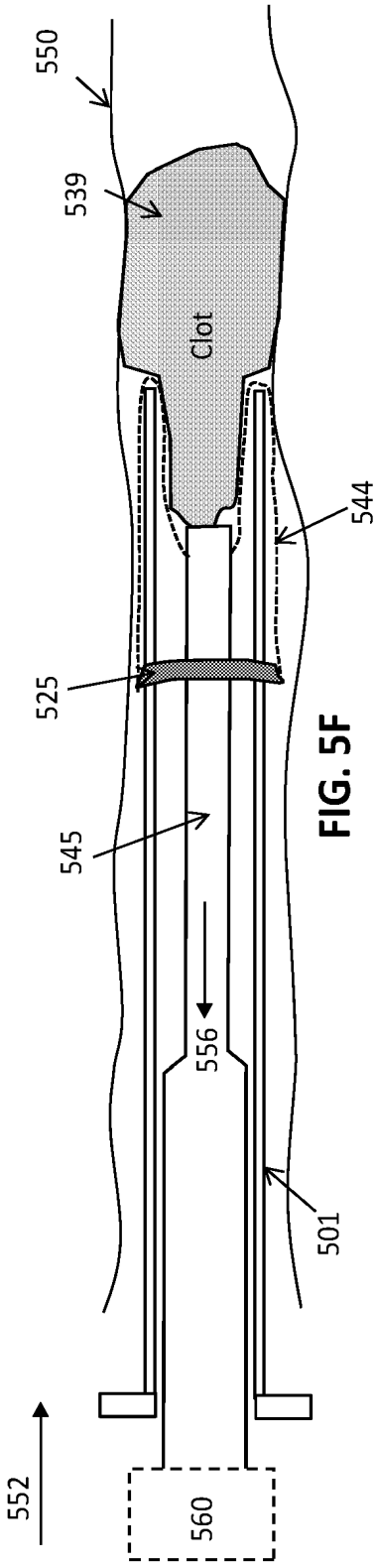

FIG. 5F

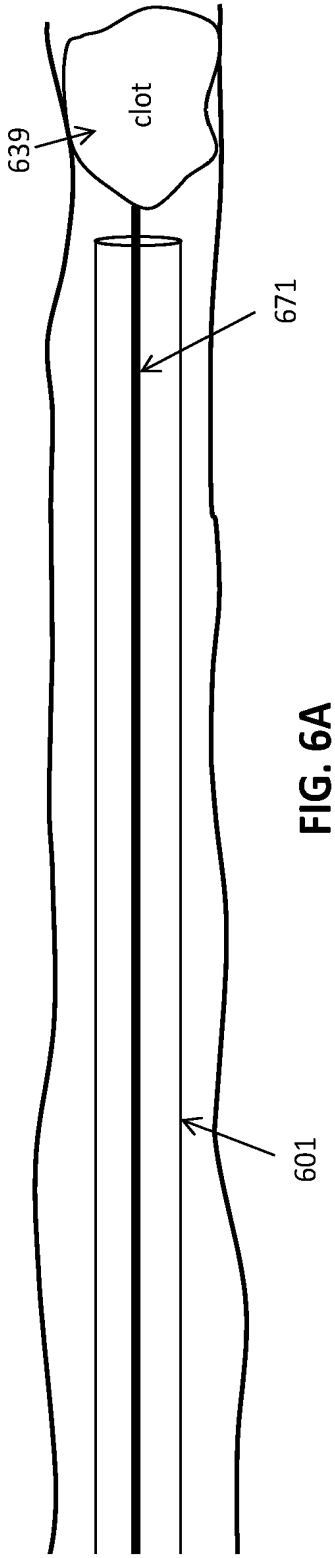

FIG. 6A

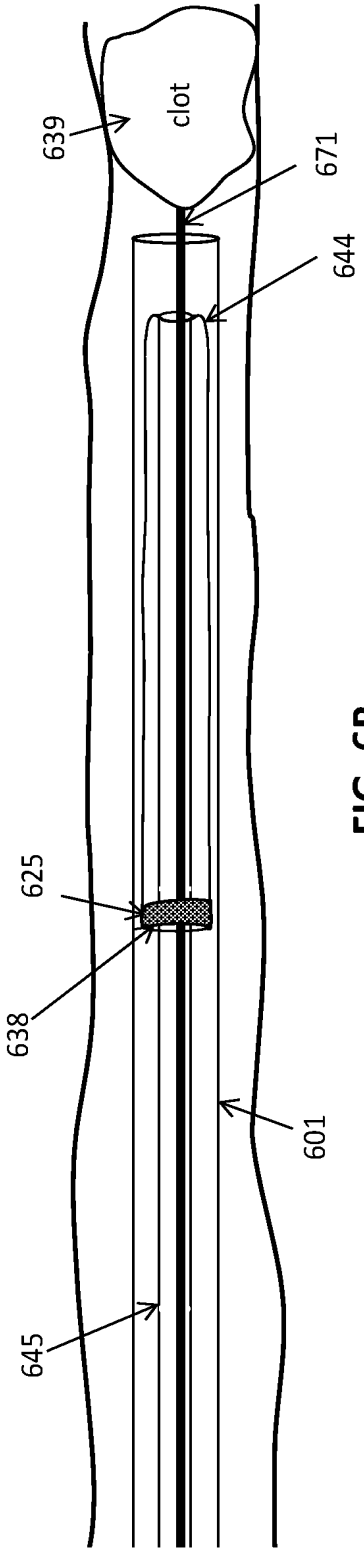

FIG. 6B

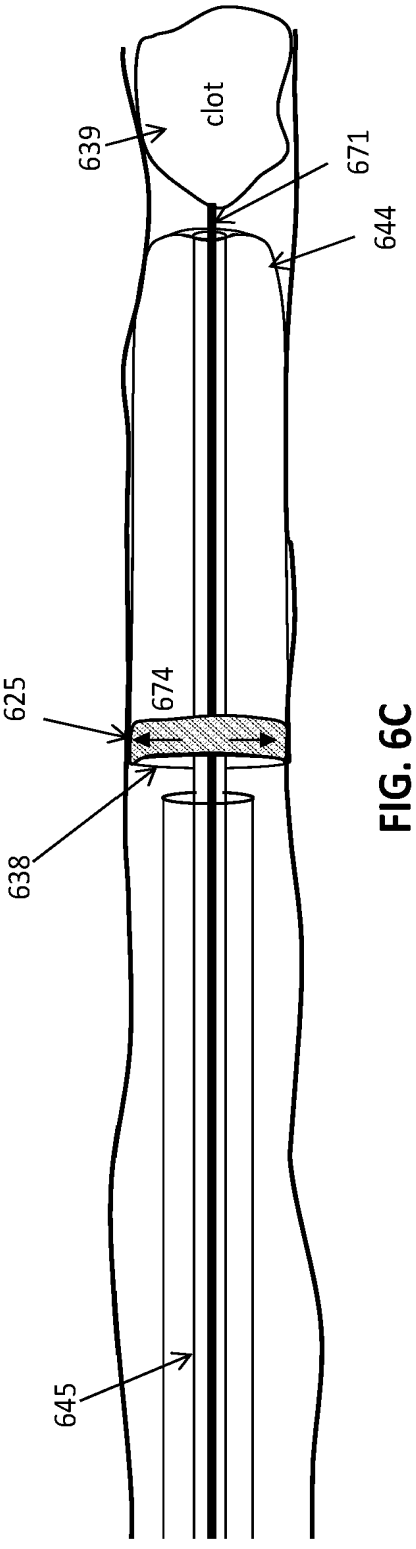

FIG. 6C

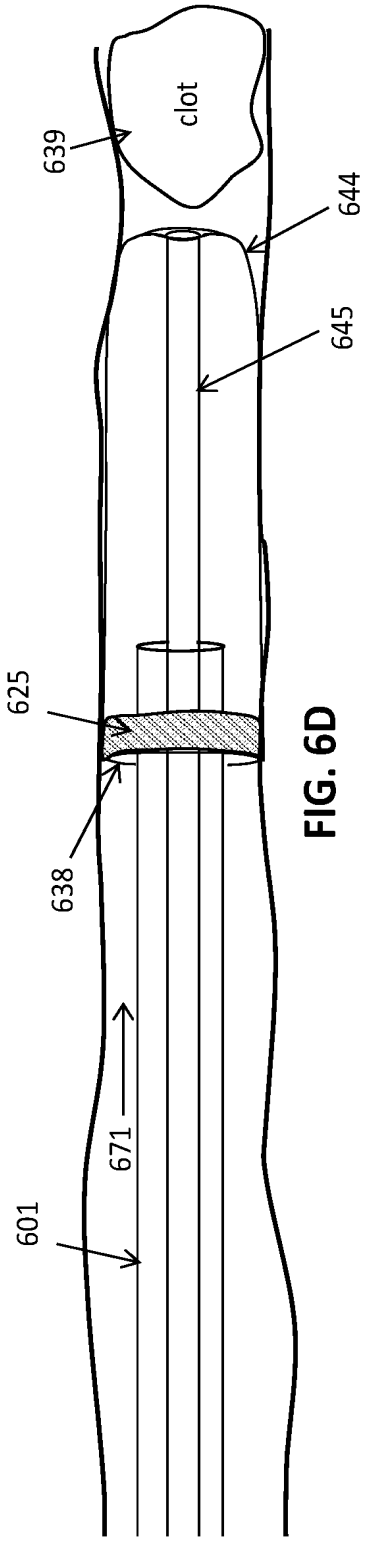

FIG. 6D

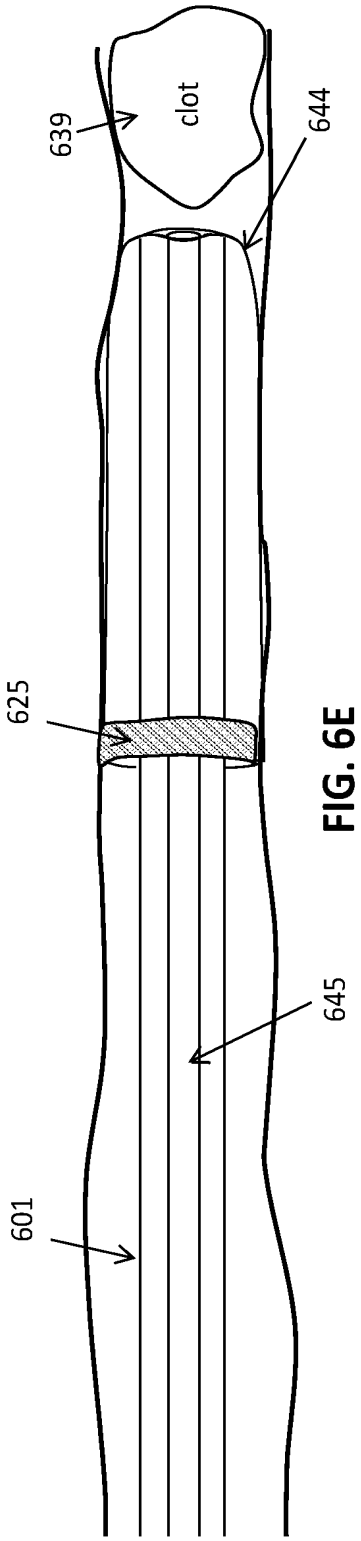

FIG. 6E

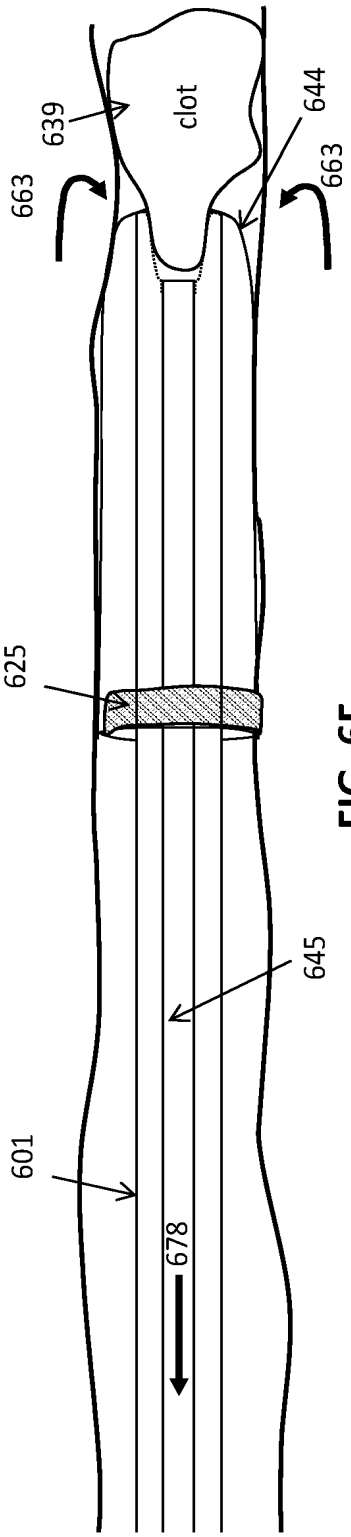

FIG. 6F

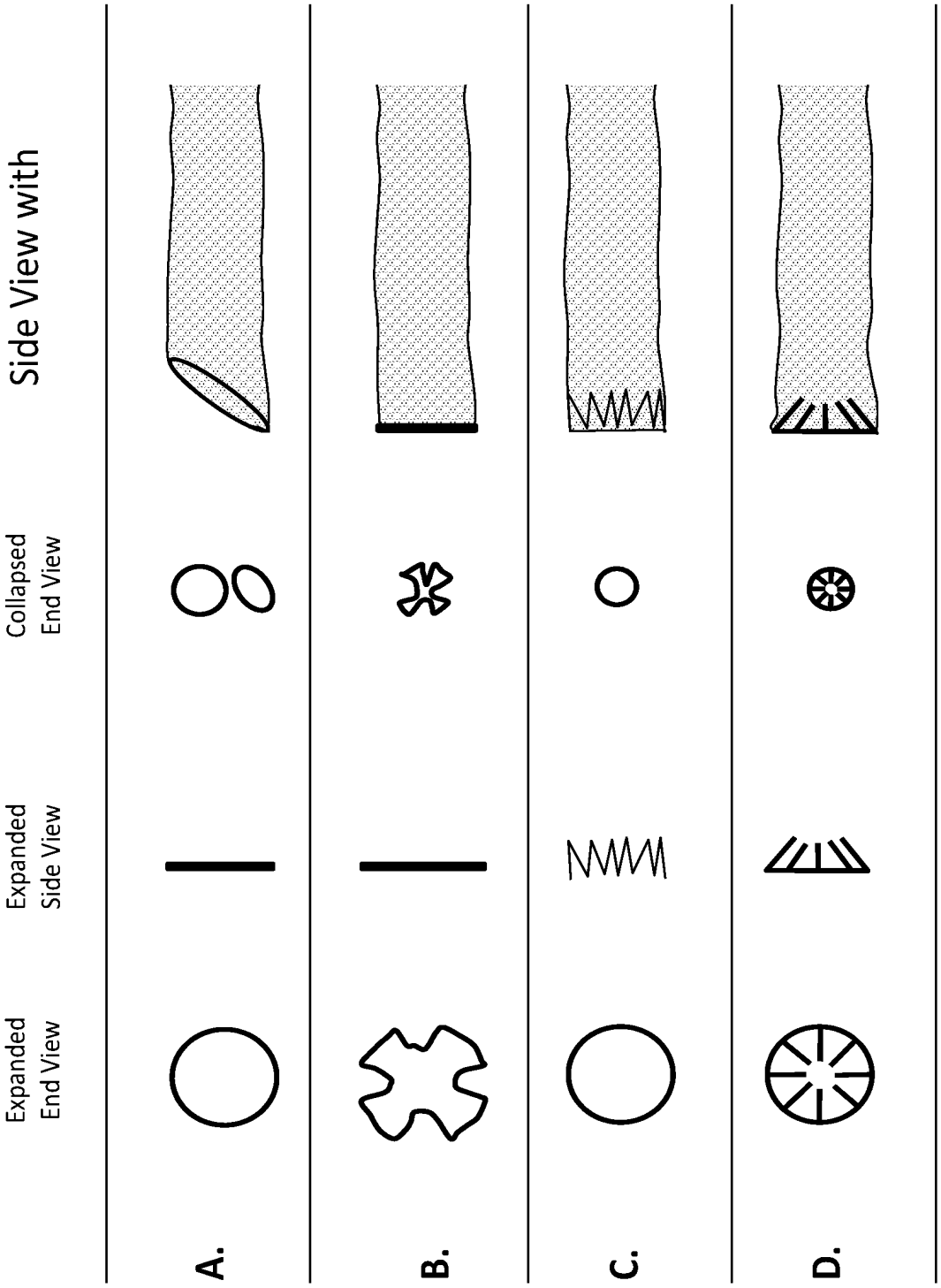
Expanded End View
Expanded Side View
Collapsed End View
Side View with
A.
B.
C.
D.

FIG. 7

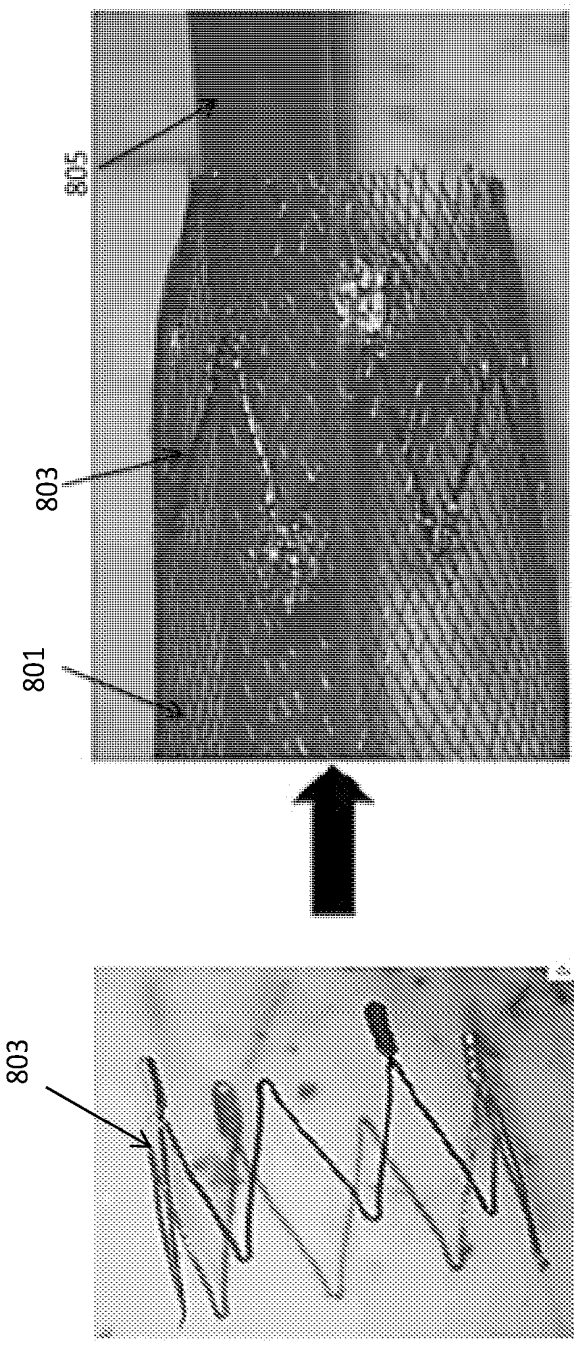

FIG. 8A

FIG. 8B

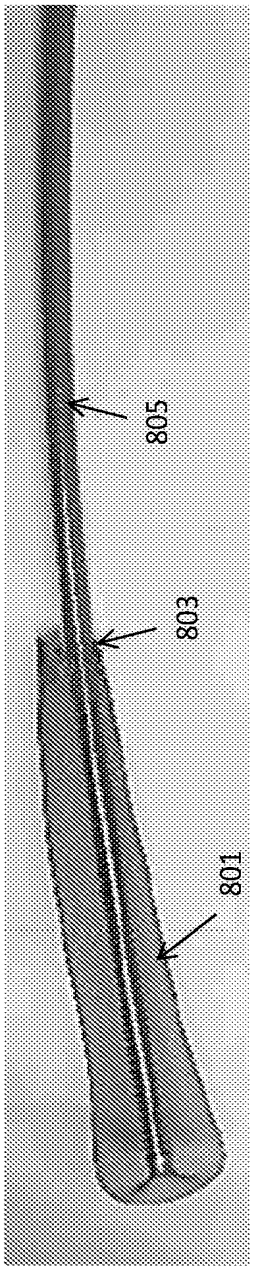

FIG. 8C

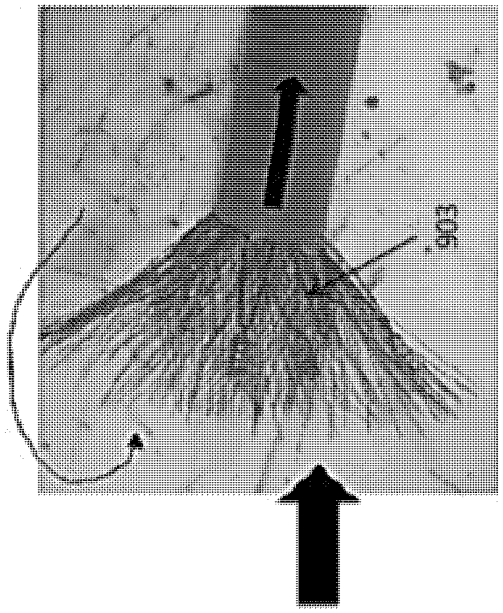

FIG. 9B

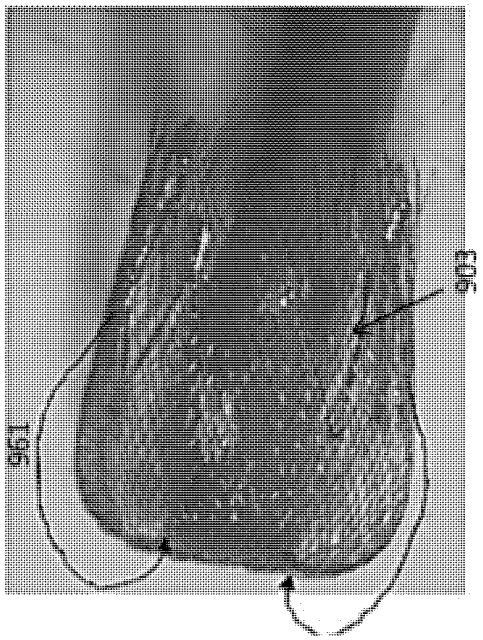

FIG. 9A

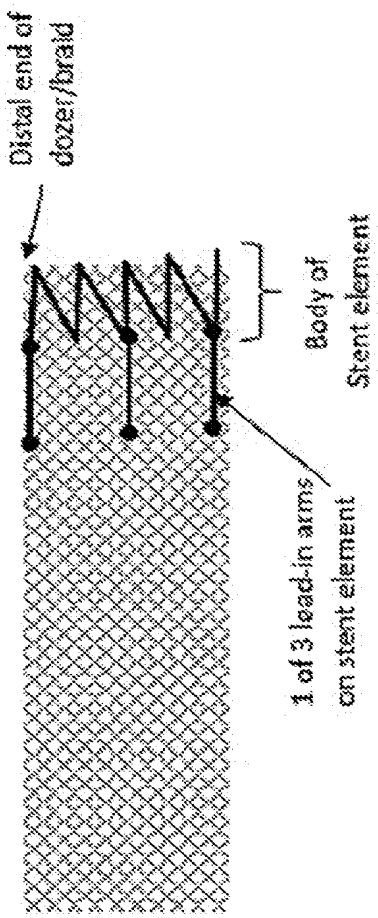

FIG. 9C

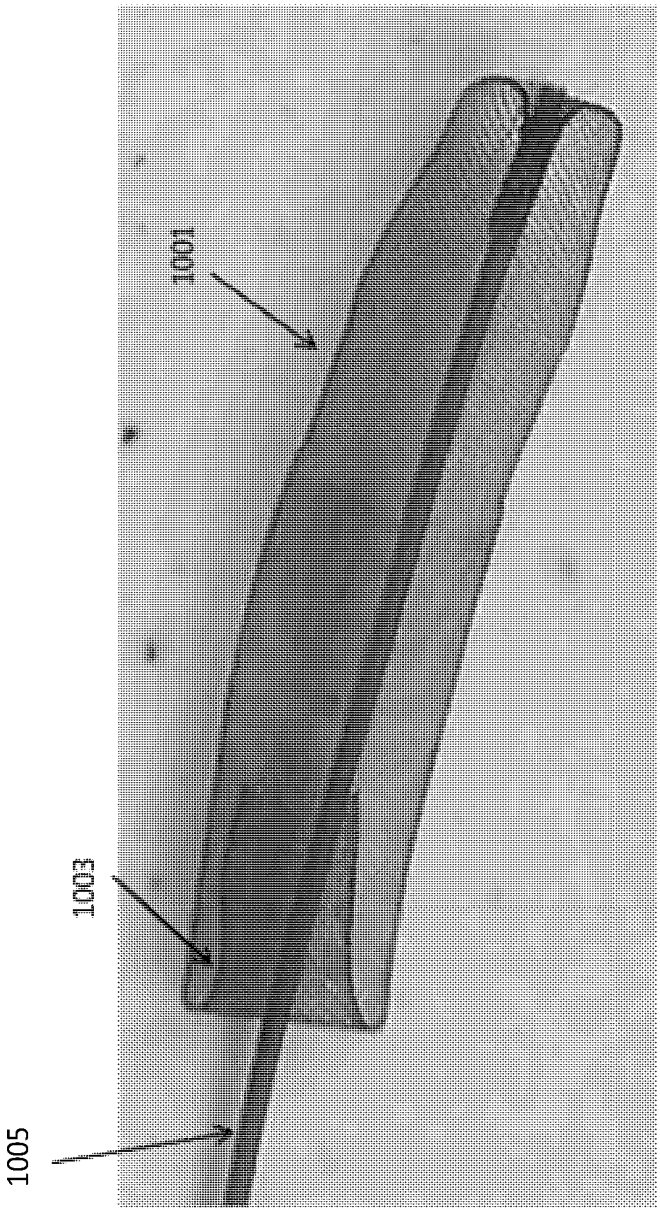

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/035543

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 5	1-19
Y	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1-19
X,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document	1-7,9-19

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 August 2017	14/08/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Giménez Burgos, R

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/035543

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2498349 A	17-07-2013	EP 2802275 A1	19-11-2014
		GB 2498349 A	17-07-2013
		US 2015005781 A1	01-01-2015
		WO 2013106146 A1	18-07-2013
WO 2012009675 A2	19-01-2012	US 2014005712 A1	02-01-2014
		WO 2012009675 A2	19-01-2012
WO 2017058280 A1	06-04-2017	US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		WO 2017058280 A1	06-04-2017

Form PCT/ISA/210 (patent family annex) (April 2005)

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(72) Inventors; and

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(74) Agent: **MCLEAN, Craig**; Novartis Pharma AG, Patent Department, CH-4002 Basel (CH).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

[Continued on next page]

(54) Title: SYRINGE

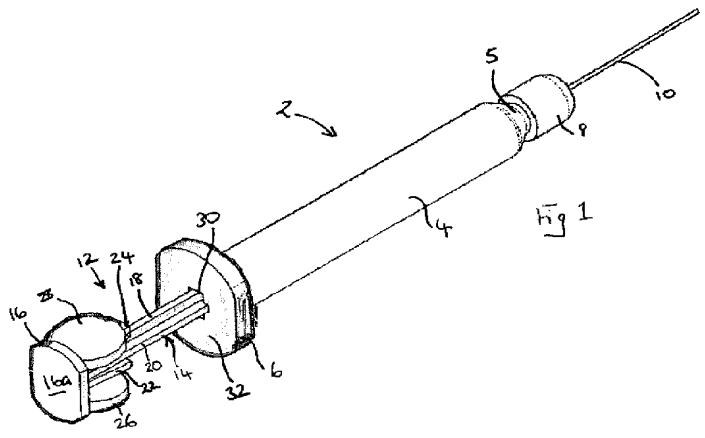


Fig 1

(57) Abstract: A syringe (2) including a barrel (4) with discharge end (5) defining a discharge passage, plunger (12) being adapted to move axially within the barrel and capable of displacing fluid from the chamber through the discharge end; the plunger includes a control arm (22, 24) including a first releasable stop element and a second non-releasable stop element, the first and second stops are both axially spaced from the rear end of the plunger, the control arm has a first configuration in which the first stop element is axially aligned with a stop surface (32) defined by a part of the barrel (4), the first stop element is adapted to limit the axial movement of the plunger; and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

WO 2011/073176 A1

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

Syringe

The present invention relates to a syringe and, in particular, to a syringe adapted to permit priming, followed by dosing of a pre-determined dose.

It is often desirable to deliver a relatively small volume of fluid from a syringe in a method that is both accurate and reproducible. Typically, syringes containing fluids are first primed, to ensure that no air or other gas is present in the syringe and then a second, delivery (dosage) step is performed to deliver the required volume of fluid. However, it is difficult to deliver accurately a relatively small volume of fluid during the delivery step using a conventional syringe.

WO01/62319, US3,934,586 and WO03/004080 all describe dual stage syringes, but none of them addresses the issue of delivering accurately and reproducibly a relatively small volume of a fluid.

According to a first aspect of the present invention, there is provided a syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm which includes a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

By having a first, releasable stop, a priming stroke can be defined in which the plunger is moved from a start position to the first stop. The first stop can then be removed or by-passed by moving the control arm from the first configuration to the second configuration. When the first stop is removed, by disposing it out of alignment with the stop surface, the syringe may

be used to deliver a dose of fluid contained therein by further movement of the plunger from the first to the second stop. The spacing between the first and second stops corresponds to a fixed dose for a given internal diameter of the barrel. Thus, the second stop element is disposed rearwardly from the first stop element and the spacing between the first and second stop elements defines the dosing stroke of the plunger.

Locating the first and second stops on a control arm and spacing both of the stops from the end of the plunger means that it is possible to achieve accurate and reproducible dosing of relatively small doses of the fluid by controlling the spacing between the stops. This is because the second stop is well defined. In the art, the second stop is often defined by a plunger button engaging or contacting the barrel body. However, this opens up the possibility that the user does not fully displace the plunger, resulting in an underdose being delivered. Additionally or alternatively, there is the possibility of foreign material becoming lodged at the rear of the barrel, which would prevent complete displacement of the plunger to the second stop. This would also result in an underdose being delivered. For doses having relatively small volumes, it is important that the dosing stroke is well defined.

In an embodiment of the invention as defined anywhere herein, the control arm is resiliently deformable, wherein the first configuration represents a rest or non-deflected position, and the second configuration represents a deflected position. In such an arrangement, the control arm must be urged from the first configuration to the second configuration in order to remove or release the first stop.

The plunger may include a retaining element to retain the control arm in the second configuration. For example, this might include an axially slidable collar or sleeve carried by the plunger or a two-part clip, wherein one part of the clip is carried by the control arm and the other part of the clip is carried by the plunger. In this arrangement, the syringe may be used one-handed, as the control arm does not need to be manually retained in the second configuration and the retaining element prevents the accidental return of the control arm to the first configuration from the second configuration and the consequent re-engagement of the first stop.

In a further embodiment of the invention as defined anywhere herein, the plunger includes a shaft connected at one end to a piston disposed in use within the barrel and connected at the other end to a push button, and the control arm is hingedly coupled to the shaft. This

arrangement provides a control arm which is relatively straightforward to engineer and is intuitive for a user to operate.

The barrel may include a collar comprising a collar body which defines therethrough a shaft guide channel, wherein the shaft of the plunger is slidably retained within the guide channel. The collar body may further define the stop surface.

The guide channel may be adapted to receive therein the first stop element when the control arm is in the second configuration.

In order to maintain the first stop element aligned with the stop surface, for example during the priming step, the shaft of the plunger may include an orientation controlling element which is adapted to maintain the axial orientation of the plunger shaft relative to the guide channel. This ensures that the plunger remains in the desired axial orientation until the priming step is complete and the first stop element of the plunger has engaged the stop surface.

In an embodiment of the invention as defined anywhere herein, the orientation controlling element includes a spline (a longitudinally extending rib) carried by the plunger shaft which is located in use within a spline channel defined through the collar.

The interaction of the spline carried by the plunger shaft with the spline channel prevents unwanted movement, e.g. rotation, of the plunger relative to the barrel.

The skilled person will appreciate that the plunger may include more than one spline, wherein the splines are circumferentially offset from each other.

In such an embodiment, the barrel and/or collar typically includes corresponding spline channels for each spline.

A common arrangement for plungers is to include a cruciform-shaped shaft. Thus, in an embodiment of the invention as defined anywhere herein, the plunger shaft has a cruciform cross sectional configuration. In such an embodiment, the collar body may define a guide channel having complimentary cruciform shape.

In embodiments where the spline channel is adapted to receive therein the first stop element when the control arm is in the second configuration, one or more of the splines may include a longitudinal notch which is capable of receiving therein at least a part of the control arm. Thus, the first stop element of the control arm may have a cross-section which is smaller than or congruent with the cross section of the notch formed within the respective spline, wherein the first stop element extends laterally outwards from the spline in the first configuration of the control arm and is axially aligned with the spline in the second configuration of the control arm. In other words, the first stop element may be contained within the notch in the second configuration of the control arm.

Of course, the first stop element may extend beyond the notch defined by the spline in embodiments where the spline channel is adapted to receive therein the first stop element, i.e. in addition to the spline itself.

The first stop element may be a forward facing end wall of the control arm.

The second stop element may extend outwardly from the first stop element. In such embodiments, the second stop element may be carried by the control arm and is spaced rearwardly from the first stop element to define a dosing stroke which is the spacing between the first and second stop elements.

The second stop element may be defined by an edge portion of a control button which defines a substantially planar button surface. In such an embodiment, it is clear to a user how to operate the syringe: the syringe is primed by urging the plunger forwards until the first stop engages or contacts the stop surface. The control button is then pressed, which moves the control arm from the first to the second configuration, whereupon the first stop element is disengaged from (moved out of alignment with) the stop surface. The plunger is then again urged forwards until the second, non-releasable, stop element engages or contacts the stop surface, at which point the dose stroke is complete.

In an embodiment of the invention as defined anywhere herein, the plunger includes a pair of opposed control arms. By having two or more control arms, the possibility of the first stop element accidentally and/or unintentionally being disposed out of axial alignment with the stop surface is significantly reduced.

According to a second aspect of the invention, there is provided a plunger assembly for use with a syringe barrel, the assembly including a collar adapted to engage one end of the barrel; and a plunger including a piston adapted to be located within the barrel, an elongate shaft extending from the piston and a push button at the end of the shaft opposite to the piston, wherein the elongate shaft is slidably retained within the collar, and wherein the plunger shaft includes a control arm which includes a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the push button and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by the collar, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

The additional features described and defined herein in connection with the first aspect of the invention may apply equally to the second aspect of the invention. Thus, the second aspect of the invention may include any, some or all of the additional features described hereinabove.

According to a third aspect of the invention, there is provided a syringe kit including a syringe barrel and a plunger assembly according to the second aspect of the invention.

According to a fourth aspect of the invention, there is provided a pre-filled syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, the barrel containing therein a medicament in fluid form; and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm which includes a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with

the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

The additional features described and defined herein in connection with the first aspect of the invention may apply equally to the fourth aspect of the invention. Thus, the fourth aspect of the invention may include any, some or all of the additional features described hereinabove.

As used herein, the term “forward” means towards the discharge end of the syringe and the term “rearward” means away from the discharge end of the syringe.

The skilled person will appreciate that the features specified above in connection with embodiments of the invention may be combined with each other and any of the aspects of the invention as defined. Thus, the present invention includes within its scope an aspect of the invention combined with two or more of the features described anywhere herein as optional features. All such combinations of features described herein are considered to be made available to the skilled person.

Embodiments of the invention will now be described in detail, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a perspective view of a syringe according to a first embodiment of the invention;
Figure 2 is side elevational view of the syringe shown in Figure 1;
Figure 3 is a plan view from above of the plunger assembly of the syringe shown in Figure 1;
Figure 4 is a perspective view of a syringe according to a second embodiment of the invention; and
Figure 5 is a side elevational view of the syringe shown in Figure 4.

For the avoidance of doubt, the skilled person will appreciate that in this specification, the terms “up”, “down”, “front”, “rear”, “upper”, “lower”, “width”, etc. refer to the orientation of the components as found in the syringe when installed for normal use as shown in the Figures.

A syringe 2 according to a first embodiment of the invention is shown in Figures 1, 2 and 3. The syringe 2 includes a barrel 4 defining a cylinder therein. Located at the rear of the barrel 4 is a collar 6 and at the opposite end, i.e. the front, of the barrel 4 is a discharge end 5

which defines therein a discharge passage. Secured to the discharge end 5 is a connecting collar 8 of a hypodermic needle 10.

The skilled person will appreciate that the hypodermic needle connecting collar 8 may be a simple friction fit with the discharge end 5 of the barrel 4 or it may be a locking collar, such as a Luer-Lok collar. The connection of hypodermic needles to syringe barrels is well known in the art and will not be described in detail herein.

The syringe 2 further includes a plunger assembly 12. The plunger assembly 12 consists of a plunger shaft 14 which terminates at its rearward end in a push button 16 and terminates at its forward end in a piston (not shown) located within the cylinder defined by the barrel 4. The plunger shaft 14 is slidably retained within the collar 6.

The push button 16 defines a rearward facing push button surface 16a which is substantially planar.

The plunger shaft 14 is cruciform in cross-section and defines a pair of opposed vertical splines 18 and a pair of opposed horizontal splines 20.

Included in the plunger assembly 12 is a pair of opposed control arms 22, 24 hingedly connected to the plunger shaft 14 adjacent to the push button 16. Figure 2 shows the control arms 22, 24 in a first configuration in which the distal ends of the control arms 22, 24 are laterally spaced from the plunger shaft 14. The forward facing end surfaces of the control arms 22, 24 define the first stop elements.

The width of each of the control arms 22, 24 is slightly greater than the width of the corresponding vertical spline 18, and the height of each of the control arms 22, 24 is slightly less than the corresponding vertical spline 18.

The collar 6 includes a body which defines therein a plunger shaft guide channel in the form of a cruciform aperture 30 substantially about the longitudinal axis of the barrel 4. Each of the four arms of the cruciform-shaped aperture 30 has a height which is slightly greater than the height of the corresponding spline 18, 20. The width of the horizontal arms is similarly slightly greater than the width of the corresponding horizontal splines 20. However, the width of the

vertical arms of the cruciform aperture 30 is such that they are slightly wider than the width of the corresponding control arms 22, 24.

The body of the collar 6 about the cruciform aperture 30 defines a stop surface.

The vertical splines 18 each define a notch 40 which is sized to accommodate the corresponding control arm 22, 24 in their second configuration in which the control arms 22, 24 are arranged axially within the corresponding vertical spline 18. Thus, each notch 40 is substantially equal in length to the corresponding control arm 22, 24 and the depth of each notch 40 is substantially identical to the height of the corresponding control arm 22, 24.

The front facing wall of each of the control arms 22, 24 includes a recess (not shown) which is configured to receive therein a corresponding protrusion (not shown) which extends outwards from the rear facing wall of each of the vertical splines 18.

Extending outwardly from the control arms 22, 24 are respective control buttons 26, 28 in the form of short cylindrical bodies. The forward facing side wall portion of each control button 26, 28 defines a respective second stop element.

In use, the barrel 4 includes a medicament in fluid form and the plunger is disposed in a start position in which the first stop elements defined by the forward facing walls of the control arms 22, 24 are spaced from the stop surface defined by the body of the collar 6. The control arms 22, 24 are in their rest position, as shown in Figure 2.

A user initiates a priming step to remove any gas or dead volume from within the barrel by urging the plunger forward via the rearward facing push button surface 16a. This causes the piston within the barrel 4 to move forward, expelling the unwanted gas and priming the syringe. The priming stroke is continued until the forward facing end walls of the control arms 22, 24 engage the stop surface defined by the body of the collar 6.

Once the priming step is complete, the user exerts a force on each of the two control buttons 26, 28 which urges them towards each other. This causes the control arms 22, 24 to be located within the corresponding notch 40 of the respective vertical spline 18 and for the forward facing end walls of the control arms 22, 24 to become axially aligned with the vertical arms of the cruciform aperture 30. Thus, in this second configuration of the control arms 22,

24, the forward facing end walls of the control arms 22, 24 are no longer axially aligned with the stop surface defined by the body of the collar 6 and are capable of being received into the vertical arms of the cruciform aperture 30.

When the control arms 22, 24 are fully located within the corresponding notch 40, the protrusions extending from the rearward facing end wall portions of the vertical splines 18 engage with the respective recesses formed in the forward facing end walls of the control arms 22, 24 such that the control arms 22, 24 are releasably retained in the second configuration.

Once the control arms 22, 24 are in their second configuration, the hypodermic needle 10 is inserted into or through the skin of a patient and the dose stroke is commenced. The dose stroke is defined by the short distance between the forward facing end walls of the control arms 22, 24 and the forward facing side walls of the cylindrical-shaped control buttons 26, 28. At the end of the dose stroke, the forward facing side walls of the cylindrical-shaped control buttons 26, 28 engage the stop surface defined by the body of the collar 6.

The skilled person will appreciate that the actual dose delivered by the syringe during the dose stroke is a function of the internal diameter of the barrel 4 and the spacing between the first stop elements (the forward facing end walls of the control arms 22, 24) and the second stops (the forward facing side walls of the cylindrical-shaped control buttons 26, 28). The delivery dose can be varied by varying one or both of these physical properties.

A second embodiment of the invention is shown in Figures 4 and 5.

A syringe 102 according to the second embodiment of the invention includes a barrel 104 defining a cylinder therein. Located at the rear of the barrel 104 is a collar 106 and at the opposite end, i.e. the front, of the barrel 104 is a discharge end 105 which defines therein a discharge passage. Secured to the discharge end 105 is a connecting collar 108 of a hypodermic needle 110.

The syringe 102 further includes a plunger assembly 112. The plunger assembly 112 consists of a plunger shaft 114 which terminates at its forward end in a piston (not shown) located within the cylinder defined by the barrel 4. The plunger shaft 114 is slidably retained within the collar 106.

A push button 116 is slidably coupled to a rear end portion of the plunger shaft 114 and defines a rearward facing push button surface 116a which is substantially planar. A cylindrical sleeve 150 extends forward from the push button 116 and overlies a portion of the plunger shaft 114. The push button 116 and associated sleeve 150 can move axially relative to the plunger shaft 114 within fixed limits.

The plunger shaft 114 is cruciform in cross-section and defines a pair of opposed vertical splines 118 and a pair of opposed horizontal splines 120.

Included in the plunger assembly 112 is a pair of opposed control arms 122, 124 hingedly connected to the plunger shaft 114 adjacent to the push button 116. A proximal portion of the control arms 122, 124 adjacent to the push button 116 is disposed within the sleeve 150.

Figure 5 shows the control arms 122, 124 in a first configuration in which the distal ends of the control arms 122, 124 are spaced from the plunger shaft 114. The hinged arrangement of the control arms 122, 124 is such that they are biased towards this first configuration and they provide a resistive force against movement towards each other.

The forward facing end surfaces of the control arms 122, 124 define the first stop elements.

The width of each of the control arms 122, 124 is substantially the same as the width of the corresponding vertical spline 118, and the height of each of the control arms 122, 124 is slightly less than the corresponding vertical spline 118.

The collar 106 includes a body which defines therein a plunger shaft guide channel in the form of a cruciform aperture 130 substantially about the longitudinal axis of the barrel 104. Each of the four arms of the cruciform-shaped aperture 130 has a height which is slightly greater than the height of the corresponding spline 118, 120 and a width which is similarly slightly greater than the width of the corresponding splines 118, 120.

The body of the collar 106 about the cruciform aperture 130 defines a stop surface.

The vertical splines 118 each define a notch 140 which is sized to accommodate the corresponding control arm 122, 124 in their second configuration in which the control arms

122, 124 are arranged axially within the corresponding vertical spline 118. Thus, each notch 140 is substantially equal in length to the corresponding control arm 122, 124 and the depth of each notch 140 is substantially identical to the height of the corresponding control arm 122, 124.

Extending outwardly from the control arms 122, 124 are respective lugs 126, 128 in the form of triangular-shaped wedges. The forward facing wall of each of the lugs 126, 128 defines a respective second stop element.

In use, the barrel 4 includes a medicament in fluid form and the plunger is disposed in a start position in which the first stop elements defined by the forward facing walls of the control arms 22, 24 are spaced from the stop surface defined by the body of the collar 6. The control arms 22, 24 are in their rest position, as shown in Figure 2.

A user initiates a priming step to remove any gas or dead volume from within the barrel by urging the plunger forward via the rearward facing push button surface 116a. As the frictional forces between the piston and the cylinder defined within the barrel 104 and between the plunger shaft 114 and the cruciform aperture 130 are less than the resistive forces exerted by the control arms 122, 124, the force exerted by the user on the push button 116 causes the piston within the barrel 104 to move forward, expelling the unwanted gas and priming the syringe 102. The priming stroke is continued until the forward facing end walls of the control arms 122, 124 engage the stop surface defined by the body of the collar 106.

When the forward facing end walls of the control arms 122, 124 engage the stop surface defined by the body of the collar 106, further movement of the plunger shaft forward is prevented.

At this point, the hypodermic needle 110 is inserted into or through the skin of a patient and the dose stroke initiated.

To initiate the dose stroke, the user continues to apply force to rearward facing surface 116a of the push button 116. As the plunger shaft 114 is prevented from moving forward by the forward facing end walls of the control arms 122, 124 contacting the stop surface, the force is directed through the sleeve 150 to the control arms 122, 124. This force overcomes the resistive force of the control arms 122, 124 and urges them towards each other until they

become axially aligned with the vertical splines 118 and contained within the respective notches 140. At this point the forward facing end walls of the control arms 122, 124 no longer contact the stop surface defined by the body of the collar 106 and the control arms 122, 124 are capable of entering the respective arms of the cruciform aperture 130.

When the forward facing end walls of the control arms 122, 124 disengage from the stop surface, the plunger shaft and the attached piston can continue to move forward for the dose stroke until the outwardly extending lugs 126, 128 contact the stop surface, at which point the dose step is complete.

Example 1

Tests of the first embodiment syringe described above were carried out as follows:

Test Apparatus

The syringe plunger and collar were assembled to a sample 1ml syringe barrel. A needle was fitted to the discharge end of the syringe barrel.

Preparation and Measurement

The syringe was filled with a nominal volume of RO/DI water, held vertically and tapped to release air bubbles, and primed to the first stop. A clean Eppendorf Tube was tared on an analytical balance. The control buttons were urged towards each other to release the first stops and to permit dosing, and the plunger depressed to the second stop, discharging the dose into the vial.

The vial was then closed and weighed.

The test was repeated, re-using the syringe, but taking a clean vial each time.

Calculation

Dose mass was calculated from the difference in weight of the vial.
Dose volume was calculated from the mass by dividing by density.
Density = 998.022kg/m^3 at lab conditions of 21°C and 42%RH

Apparatus

Sartorius ME235S-OCE analytical balance (5 decimal places / 1g)

300 µl Eppendorf Tubes

Syringe Device as described above

Results

Table 1

	mean	Standard deviation	lowest	highest
Mass (g)	0.0520	0.0032	0.0474	0.0584
Volume (µl)	52.11	3.21	47.52	58.52

The results from N = 10 measurements

The dose delivered by the prototype in the tests is in the range 53.02 ± 5.5µl i.e. 47.52 to 58.52µl.

The syringe delivered a well controlled dose, within a tolerance of ± 5.5µl, which is within the tolerance of ± 7.5µl associated with the acceptance limits.

Claims

1. A syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm including a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger; and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element, the control arm is resiliently deformable and the first configuration represents a rest or non-deflected position, and the second configuration represents a deflected position.

2. A syringe according to Claim 1, wherein the plunger includes a retaining element to retain the control arm in the second configuration.

3. A syringe according to Claim 2, wherein the retaining element is selected from an axially slidable sleeve and a two-part clip, wherein one part of the clip is carried by the control arm and the other part of the clip is carried by the plunger.

4. A syringe according to any preceding claim, wherein the plunger includes a shaft connected at one end to a piston disposed in use within the barrel and connected at the other end to a push button, and the control arm is hingedly coupled to the shaft.

5. A syringe according to Claim 4, wherein the barrel includes a collar comprising a collar body which defines therethrough a shaft guide channel, wherein the shaft of the plunger is slidably retained within the guide channel, and wherein the collar body defines the stop surface.

6. A syringe according to Claim 5, wherein the guide channel is adapted to receive therein the first stop element when the control arm is in the second configuration.

7. A syringe according to Claim 5 or 6, wherein the shaft of the plunger includes an orientation controlling element which is adapted to maintain substantially fixed the axial orientation of the plunger shaft relative to the guide channel.

8. A syringe according to Claim 7, wherein the plunger shaft has a cruciform cross-sectional configuration and the collar body defines a guide channel having a complimentary cruciform shape.

9. A syringe according to any preceding claim, wherein the first stop element includes a forward facing end wall of the control arm.

10. A syringe according to any preceding claim, where the second stop element is a projection from the control arm which extends outwardly from the first stop element and is spaced rearwardly from the first stop element.

11. A syringe according to Claim 10, wherein the second stop element is defined by a forward facing wall portion of a cylindrical control button carried by the control arm.

12. A syringe according to any preceding claim, which includes a pair of opposed control arms.

13. A plunger assembly for use with a syringe barrel, the assembly including a collar adapted to engage one end of the barrel; and a plunger including a piston adapted to be located within the barrel, an elongate shaft extending from the piston and a push button at the end of the shaft opposite to the piston, wherein the elongate shaft is slidably retained within the collar, and wherein the plunger shaft includes a control arm including a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the push button and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by the collar, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second

configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

14. A pre-filled syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, the barrel containing therein a medicament in fluid form; and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm including a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

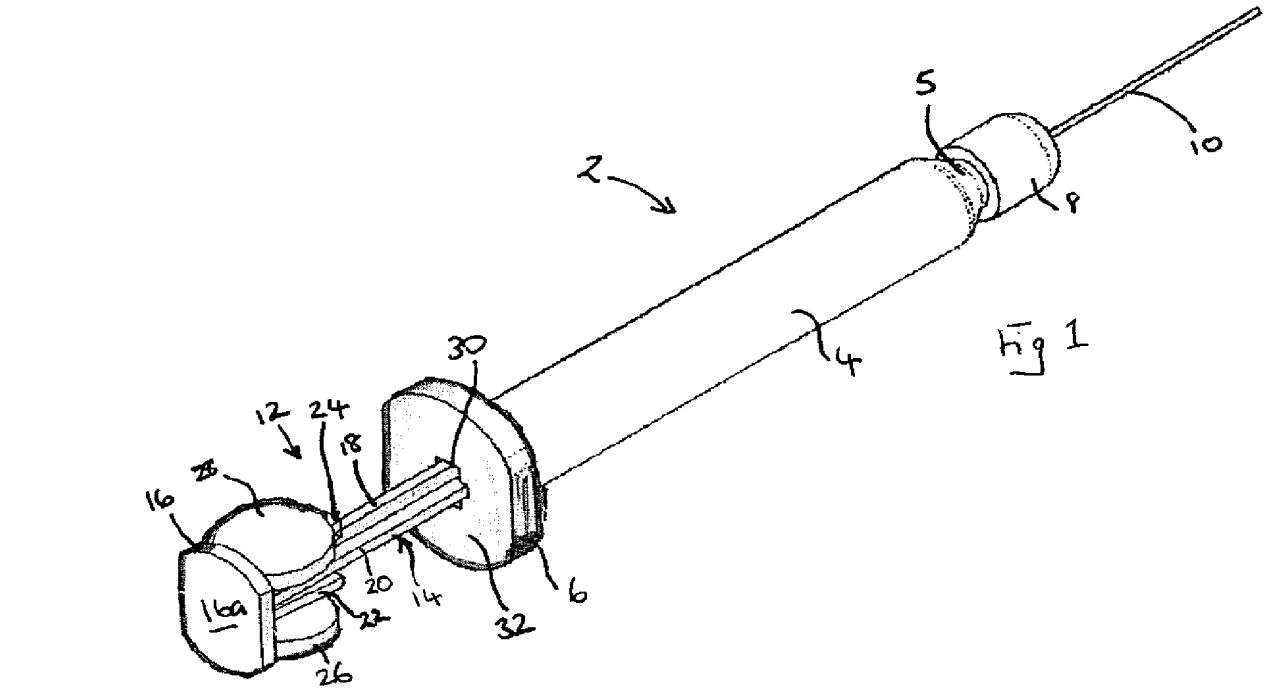


Fig 1

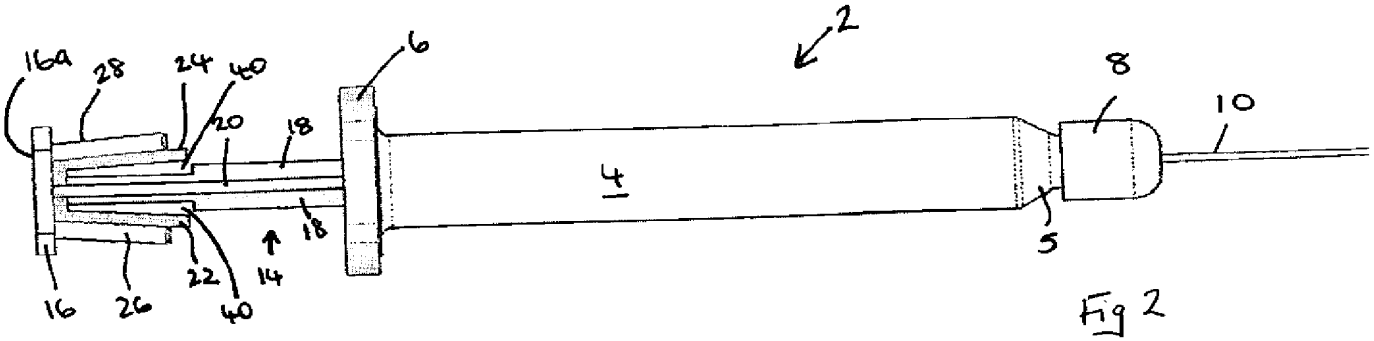


Fig 2

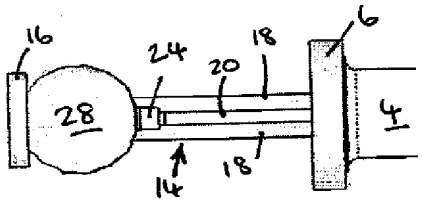
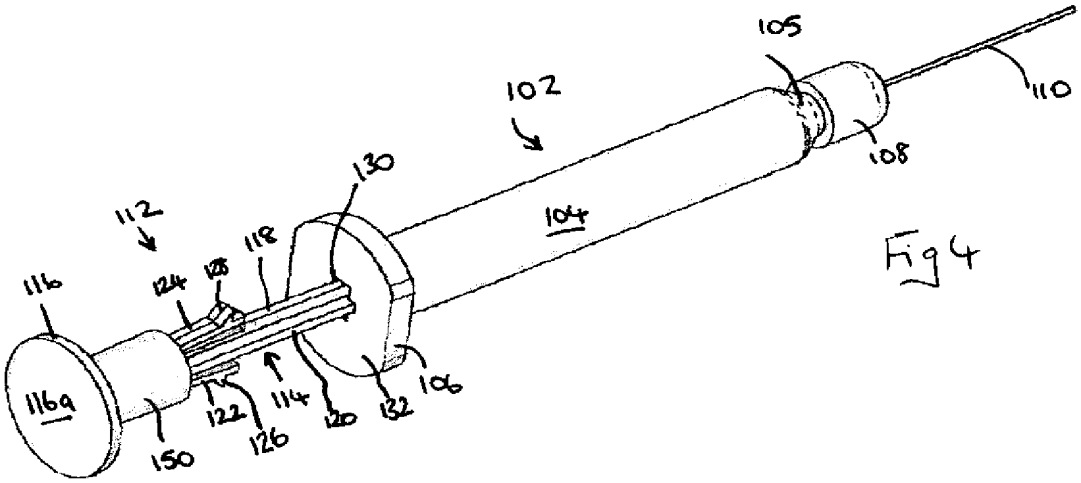


Fig 3


105
102
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130
112
104
118
116
124
128
116a
122
114
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132
106
126
150

Fig 4

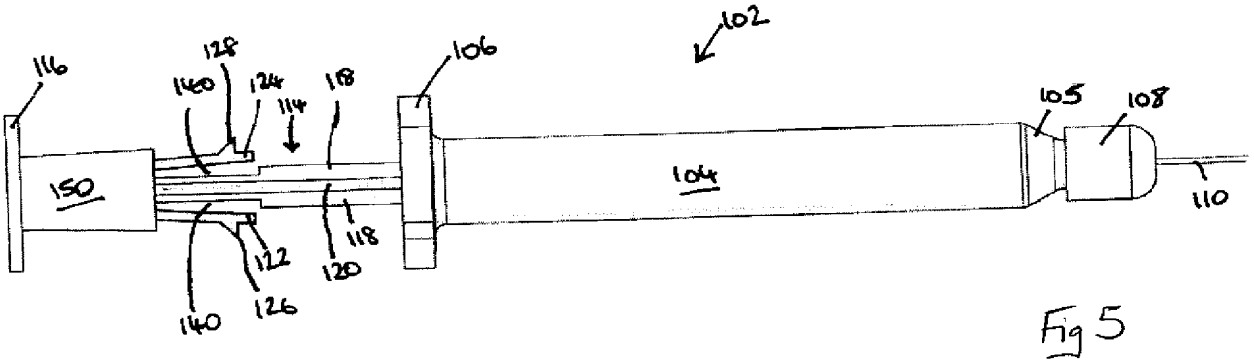
102
116
128
106
160
124
118
114
105
108
150
104
110
122
118
120
140
126

Fig 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/069597

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/315
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/004080 A1 (AKZO NOBEL NV [NL]; RIKKEN JOHANNES MATHIAS GERARD [NL]; NICKOLSON VIC) 16 January 2003 (2003-01-16) cited in the application	14
Y	page 4, line 5 - page 6, line 9	1,9,13
A	figures 1, 2A-2D	2-4

A	WO 01/62319 A2 (ABBOTT LAB [US]) 30 August 2001 (2001-08-30) page 12, line 12 - line 16 page 17, line 7 - line 27 figures 1B,1C,7A,7B	1,4-8

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 May 2011	31/05/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Sedy, Radim

2

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	page 2, line 21 - line 27 figures 1, 4	5,7,8

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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International Bureau

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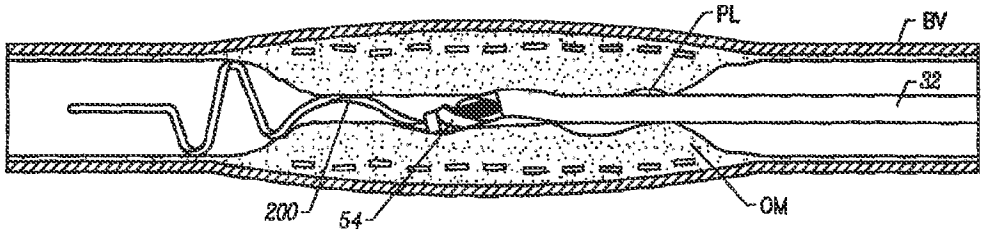

(57) Abstract

A system is provided having a catheter (32), a torque member (52) extending longitudinally through a lumen (50) of the catheter (32), a removal mechanism (54) secured to a distal end of the torque member (52), and a guide wire (46) having a guide section (200) that extends through a lumen of the removal mechanism (54). The guide section (200) defines a curved profile that is diametrically larger than the dimension of the removal mechanism (54). The guide section (200) of the guide wire (46) is adapted to be positioned inside a passageway of the occluding material providing a curved path along which the removal mechanism (54) can be advanced inside the passageway of the occluding material to separate, and remove occluding material. Methods of using the system, making the guide wire (46), and a perfusion wire system are also disclosed.

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METHODS AND SYSTEMS FOR TREATING OBSTRUCTIONS IN A BODY LUMEN

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to apparatus and methods for treating and removing occluding material from a body lumen, such as blood vessels. In particular, the present invention relates to apparatus and methods for guided atherectomy.

2. Description of the Prior Art

A number of methods and devices are currently available for removing stenotic or occluding material from a blood vessel, and for restoring adequate blood flow to the blood vessel. One common procedure is known as percutaneous transluminal angioplasty (PTA), in which a catheter that is provided with a dilatation balloon at its distal end is positioned in a blood vessel at the site of the stenosis. The balloon is then expanded to dilate the blood vessel in order to restore adequate blood flow to regions beyond the stenosis.

While often effective PTA suffers from certain limitations. For example, PTA can be effective only if the occluding material in the blood vessel has a sufficiently large opening to allow the balloon to be positioned inside the occluding material. Where the blood vessel is almost completely occluded, it is difficult if not impossible to position the balloon of a catheter inside the occluding material. In addition, PTA suffers from multiple intra-procedural and post-procedural problems: abrupt closure, elastic recoil, and restenosis. Abrupt closure is the rapid reocclusion of the blood vessel within hours of the initial treatment. Abrupt closure can result from rapid thrombus formation which occurs in response to injury of the vessel wall from the PTA procedure. Elastic recoil is the elastic recovery of the dilated vessel approaching its pre-procedural diameter. Restenosis is the re-narrowing of the blood vessel over the weeks or months following an

initial apparently successful PTA procedure. Restenosis occurs in up to 50% of all PTA patients and results from smooth muscle cell proliferation and migration and remodeling.

To overcome these limitations, a variety of catheters and techniques have been proposed which employ a removal mechanism to separate and remove occluding material from the luminal wall of the blood vessel. For example, rotational atherectomy devices (e.g., the Transluminal Extraction Catheter made by Interventional Technologies of San Diego, California, and the Rotablator, made by Boston Scientific of Bellevue, Washington) rely on a rotating removal mechanism that can be advanced axially through vessels that are almost entirely occluded. The mechanisms, however, are available only in predetermined sizes, such as predetermined outer diameters. As a result, these removal mechanisms are most effective when used in blood vessels having a lumen size that approximate the size of the removal mechanism. These removal mechanisms are difficult to use in smaller-diameter blood vessels, and are less effective in removing occluding material from blood vessels having lumen sizes larger than the size of the removal mechanisms. This is a significant limitation since the lumen size, the size and extent of the occluding material, and the location of the occluding material, will vary widely for different patients.

To address this problem, many currently-available devices (e.g., the Simpson Atherocath® atherectomy catheter made by Guidant Corporation of Santa Clara, California, and the Redha-Cut, made by Sherine Med of Utzenstorf, Switzerland) are provided with eccentrically displaceable or radially expandable removal mechanisms respectively. These removal mechanisms are introduced into the blood vessel in a collapsed or compressed state inside a sheath or delivery catheter, and are then radially expanded or eccentrically displaced (e.g., displaced eccentrically by a balloon) at the site of the occluding material to separate and remove the occluding material. Unfortunately, the buildup and formation of the occluding material is rarely consistent since more occluding material may have formed at one location than at another location in the stenosed or occluded region of the blood vessel. Since the radially expandable removal mechanisms are typically expanded by the same radial distance throughout, the removal mechanism will remove material at a generally equal rate in all radial directions and may not be effective in removing all of the occluding material at locations where there has been a greater build-up of occluding material. If the procedure is continued until all

material is removed, the removal mechanism may damage the vessel wall at locations where there was less build-up of occluding material.

In contrast, the eccentrically displaceable removal mechanisms can remove asymmetric build-ups of occluding material, but rely on the ability of the physician to orient the cutting window towards the occluding material, which may be at varying discrete locations along the length of the stenosis. Moreover, because they remove material in an asymmetric manner, if proper care is not exercised in their expansion, orientation and use, directional atherectomy devices can injure the luminal wall of the blood vessel (e.g. shaped wire multi-burr Rotational Ablation Device, U.S. Patent No. 5,584,843, and the Abrasive Drive Shaft Device for Directional Rotation Atherectomy, U.S. Patent No. 5,360,432). Thus, neither radially expandable nor eccentrically displaceable removal mechanisms are sufficiently capable of effectively adapting to the specific nature of the lumen and the occluding material.

The problems associated with proper sizing of the device, the nature and size of the occluding material, and the location of the occluding material are further magnified when treating stented regions of blood vessels that have restenosed. To address the problems of abrupt closure, elastic recoil, and restenosis described above, PTA procedures have been followed by implanting vascular stents inside the blood vessel at the treatment site. These stents are thin-walled scaffolds which are expanded at the treatment site to act as a mechanical support for the luminal wall of the blood vessel, thereby inhibiting elastic recoil. Although the stent diminishes the contribution of remodeling to vessel narrowing, restenosis still occurs frequently at the stented regions of blood vessels. This is because most stents comprise an open lattice, and cell proliferation (often referred to as hyperplasia) can occur in the interstices between the support elements of the lattice. As a result, instead of forming a barrier to hyperplasia and restenosis, the stent can become embedded within an accumulated mass of thrombus and tissue, and the treatment site becomes stenosed again. Treatment of an occluded stent faces all the difficulties discussed above with respect to treatment of initial occlusions and is further complicated by the need to avoid damaging the stent during the removal of the hyperplasia occluding material.

Thus, there remains a need for improved methods and apparatus for treating and removing occluding material from a blood vessel. In particular, it would be desirable to provide apparatus and methods which can remove material from vessels

which are almost fully occluded, which can treat vessels having a range of sizes, and which can conform to a particular vessel size and lumenal shape during the course of a procedure. In addition, the apparatus and methods of the present invention should be effective for use in removing occluding material that engulfs an implanted stent. Desirably, the apparatus and methods of the present invention will be easy to implement, present acceptable risks to the patient, and be readily performed by physicians who are familiar with balloon angioplasty and other conventional intravascular treatments. At least some of these objectives will be met by the embodiments of the present invention described below.

SUMMARY OF THE INVENTION

A system according to the present invention comprises a catheter, a torque member extending longitudinally through a lumen of the catheter, a removal mechanism secured to a distal end of the torque member, and a guidewire having a guide section which defines a curved profile that is diametrically larger than the dimension of the removal mechanism. The guide section of the guidewire is adapted to be positioned inside a passageway of the occluding material, and provides a curved path along which the removal mechanism can be advanced inside the passageway of the occluding material to separate and remove occluding material.

In the system of the present invention, the torque member is usually rotationally driven by a driver, typically a hand-held device. The driver houses a motor which rotates a proximal end of the torque member, thereby causing the removal mechanism to rotate. The removal mechanism can be any rotational atherectomy device, e.g. a rotatable helical cutter, a rotatable modified Forstner cutter, a rotary cutting burr, a sidecutter having a housing with a rotatable cutting window, or any other similar device that can be used to separate and remove occluding material from the wall of the body lumen. A bearing assembly is usually provided to allow rotation of the removal mechanism and the torque member, while preventing axial movement of the torque member and removal mechanism relative to the catheter.

The system of the present invention may further include a conveyor mechanism which is used to convey separated occluding material to a collection reservoir that is coupled to the proximal end of the catheter. The conveyor mechanism may be provided in the form of a "screw-pump" arrangement, e.g. an outer coil on the torque

member within the lumen of the catheter. Alternatively or additionally, the conveyor mechanism may comprise a vacuum source connected to the proximal end of the catheter to draw material back through the lumen thereof. Alternatively or additionally, the conveyor mechanism may comprise a plurality of propellers or impellers.

According to one non-limiting aspect of the present invention, the guide section of the guidewire is configured to exert a radial outward force against a luminal wall of a vessel into which it is positioned. In one embodiment, the guide section of the guidewire has a three-dimensional helical configuration which brings the removal mechanism in apposition with the occluding material of the stenosed portion of the luminal wall so that the removal mechanism can separate and remove the occluding material. The guide section of the guidewire will preferably assume a generally straightened configuration while in the lumen of the torque member. The guidewire can be provided with a generally straight proximal section extending proximally from the guide section, and a generally straight distal section extending distally from the guide section, with the distal and proximal sections of the guidewire extending along the same longitudinal axis.

Methods of the present invention create a series of diametrically larger passageways in the occluding material, until a passageway having the desired diameter has been obtained. A removal mechanism is advanced over a guide section of a guidewire to separate and remove occluding material and create curved channels or grooves in the occluding material. The removal mechanism may be repeatedly advanced and partially withdrawn over the guide section with optional periodic axial translation of the guide section of the guidewire within the passageway of the occluding material. By thus removing successive confluent channels of occluding material, a second passageway that is diametrically larger than the initial passageway is created.

Optionally, the width or diameter of the guide section of the guidewire can be increased to enhance the removal. For example, the existing guidewire can be exchanged for another guidewire having a diametrically larger guide section. Alternatively, shape memory alloy guidewires can be heated (or cooled) or otherwise have energy applied to effect a further shape change. The removal mechanism is then advanced over the larger guide section of the new guidewire to create a third passageway that is diametrically larger than the second passageway. This process can be repeated to

create progressively larger passageways, until a passageway having the desired diameter is obtained.

In a particular aspect of the apparatus of the present invention, the apparatus comprises a catheter and a guidewire. The catheter includes a catheter body having a proximal end, a distal end, and a lumen there through. A removal mechanism disposed at the distal end of the catheter body and arranged to excise material from a body lumen and direct the excised material into the lumen of the catheter. The removal mechanism will follow a curved path, usually comprising at least one cutting guide which excises material by forwardly advancing the blade into the material and forming a clear separation between two portions of the material. Such cutting mechanisms will not comprise abrasive surfaces of the type which may be employed in other aspects of the present invention. The guidewire will define a curved path, preferably a helical path, where the catheter body can be advanced over the guidewire to deflect the cutting mechanism over such curved path. Preferably, the cutting mechanism will have a width which is no more than 1.2 times the width of the catheter body at its distal end, preferably being equal to or of a lesser diameter than said distal end. More preferably, the cutting blade will comprise a helical blade or blade assembly which is attached to the distal end of the torque member disposed within the lumen of the catheter. The helical blade will preferably have a diameter no greater than that of the diameter of the catheter body at its distal end. An exemplary and preferred helical blade assembly comprises a pair of blades arranged as a double helix and tapered to a reduced diameter toward a distal end thereof.

In yet another aspect of apparatus of the present invention, a system comprises a catheter and a guidewire, where the guidewire may be the same as that described immediately above. The catheter will comprise a catheter body having a proximal end, a distal end, and a lumen there through. A helical blade will be disposed at the distal end of the catheter body, and the catheter will preferably comprise a torque member disposed within the lumen of the catheter body. The helical blade will preferably have the structures described immediately above.

In still another aspect of the apparatus of the present invention, an atherectomy catheter comprises a catheter body, a torque member, and a helical blade. As used herein, "atherectomy" is intended to refer to the removal of hyperplasia material following angioplasty and/or stenting as well as the removal of atheroma (from which the name is derived). The catheter body has a proximal end, a distal end, and a lumen there

through. The torque member also has a proximal end, a distal end, and a lumen there through, and the torque member is rotatably disposed in the catheter body lumen. An annular lumen is defined between the exterior surface of the torque member and the interior surface of the catheter body lumen, and a helical blade assembly is attached to the distal end of the torque member. The helical blade assembly comprises at least one helical blade which is tapered in the distal direction and which has an interior which is open to the annular lumen of the catheter body. In this way, the helical blade can be advanced through occluding material to excise that material and direct it into the annular lumen for collection and optionally disposal. Preferably, the helical blade assembly comprises at least two helical blades disposed as a double helix, i.e. in parallel to each other. In a still further preferred aspect, a helical screw may be formed over at least a distal portion of the torque member. In this way, as the torque member is rotated, the helical screw can act as an "Archimedes" screw pump to facilitate removal of excised material. Usually, the atherectomy catheter will further comprise a port or other means in fluid communication with the annular lumen for applying a vacuum to remove excised material through the annular lumen, either by itself or in combination with rotation of the helical screw pump, pump impellers, or other mechanisms.

In a specific aspect of the method of the present invention, a region of occluded material in a body lumen is treated by positioning a guidewire having at least one curve within the region of occluding material. The curve on the guidewire resiliently engages a peripheral portion of the region within the occluding material, and a cutting blade is advanced over the guidewire to excise occluding material from the lumen in order to enlarge said lumen. Preferably, the guidewire will be initially advanced in a straight configuration into the region. Thereafter, the straight guidewire will be allowed or induced to assume a geometry having at least one curve. For example, the guidewire may be heated to induce a phase change causing the guidewire to assume a helical configuration. Preferably, the guidewire will be constrained within a catheter, sheath, or other constrained body, and released at a target site to assure an unconstrained or partially constrained diameter within the body lumen. Further preferably, advancing the cutting blade will comprise rotating a helical blade as it is axially advanced over the guidewire. The method may further comprise collecting excised material from an interior volume within the helical blade and removing the collected material from the body lumen.

In another specific aspect of the method of the present invention, the region of occluding material in a body lumen is treated by introducing a guidewire through the region. The guidewire is then heated to induce at least one curve in the guidewire. A removal mechanism, such as a cutting blade, is then advanced over the guidewire, and the curve engages or deflects the removal mechanism against a peripheral portion of the region as the removal mechanism is advanced. Usually the guidewire is a shape memory alloy. Alternatively, the guidewire is a heat memory alloy where the heating step induces a phase change from martensitic to austenitic, wherein the austenitic phase has a curved memory. More preferably, the curve is a helix. Advancing of the removal mechanism generally comprises rotating a cutting blade, more usually where the cutting blade is a tapered helical cutting blade or cutting assembly.

In a still further aspect of method of the present invention, hyperplastic material may be removed from the interior of a stent within an artery by positioning a helical guidewire within the stented region of the artery. A removal mechanism, which can be any of the mechanisms described above, is then advanced over the guidewire to create a helical channel in the hyperplastic material. The removal mechanism is repeatedly advanced over the guidewire for a number of times sufficient to expose at least a portion of the stent to substantially all the hyperplastic material from within the lumen of the stent. Positioning of the guidewire preferably comprises advancing a straight guidewire into the stented region and thereafter inducing the helical geometry therein e.g. by heating the guidewire to induce a phase change. Advancing of the removal mechanism usually comprises rotating a cutting blade, more usually rotating a helical cutting blade having a tapered distal end. The removal step is usually repeated at least 2 times, preferably at least 3 times, more preferably at least 4 times, often at least 8 times, sometimes at least 12 times, and as many as 20 times or more in order to achieve the substantially complete removal of the hyperplastic material from within the stent.

A method of manufacturing a wire with a guide section comprises the steps of wrapping a core wire around a mandrel, securing the core wire about the mandrel, heating the mandrel assembly to a temperature between 300 degrees C and 800 degrees C, stopping the heating, cooling the mandrel assembly to room temperature and unwrapping the core wire from the mandrel.

The method is preferably done at operating temperatures of 450-550 degrees Celsius. If the mandrel assembly is heated in a conventional oven, the incubation

time is roughly five minutes. The wire only requires to be fully at temperature to retain the shape setting. An increase in the mass of the mandrel or wire may require a longer incubation period. It is possible to expedite the method using a "flash" heating process wherein the mandrel assembly is submerged in a molten salt pot or fluidized bath for 1-2 minutes.

In shape setting it is critical that the wire be wrapped with tension about the mandrel, and the wire not be allowed to relax or slip during the shape set process. A means for securing the wire in place is necessary, the means may be a mechanical element such as a sleeve that fits over the mandrel with extremely tight tolerance, a clamp or screw to hold the wire in place, or a torque device to keep the wire in tension. Non-mechanical means may be used such as a temporary weld, a heat resistant glue or other means understood to those in the art.

A mandrel is used for shape setting a wire having a radial expansible guide section. The mandrel comprises a temperature stable core, at least one screw thread having spaced apart roots capable of mechanically receiving a wire, said mandrel having at least one retaining device for securing said wire within said spaced apart roots and preventing said wire form slipping or shifting.

The mandrel generally has a uniform minor diameter between 0.5 and 20 mm, but may also have a nonuniform minor diameter. The mandrel also has a linear geometry, being its geometry along its long axis. This linear geometry may be regular or irregular, with any combination of cross section shapes along the linear geometry.

The pitch of the mandrel can vary from between 0.001" and 0.5". However the preferred pitch is from 1 mm to 3 mm. The mandrel may be hollow or solid, but should be of a temperature stable material for the shape setting method above (stainless steel, brass, titanium and ceramic materials to name a few). In order for the wire to obtain the proper shape set, the wire must be secured in place by some kind of retaining device. This may be a screw for locking down the ends, a tube which fits tightly over the mandrel and wire, holding all pieces in place, a non mechanical means such as soldering, gluing or chemical bonding.

Whatever shape parameters the mandrel has, will be imparted to the wire. The minor diameter of the mandrel corresponds to the inner diameter of the guide section. The outer diameter of the guide section is equal to the minor diameter of the mandrel plus twice the diameter of the core wire used. If the guide section is fitted with a coil wire,

then the inner diameter of the guide section is the minor diameter of the mandrel less twice the diameter of the coil wire and less twice the distance, if any, between the coil wire and the core wire.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a system according to the present invention.

Fig. 1A is a detail view of the distal end of the catheter and guidewire of the system of Fig. 1.

Fig. 2 is an enlarged broken-out view of the distal end of a catheter and removal mechanism that can be used with the system of Fig. 1.

Fig. 3 is a sectional view of the distal end of the catheter and removal mechanism of Fig. 2.

Fig. 4 is a partial cut-away side view of a torque member that can be used with the system of Fig. 1.

Fig. 4A is a partial side view of the torque member of Fig. 4 illustrating the torque member encased in a polymer jacket.

Fig. 4B is a partial side view of a alternative torque member configuration that can be used with the system of Fig. 1.

Fig. 5 is a perspective view of a snap ring of a bearing assembly that can be used with the system of Fig. 1.

Fig. 6 is a perspective view of a shell of a bearing assembly that can be used with the snap ring of Fig. 5, and with the system of Fig. 1.

Fig. 7 is an enlarged sectional view of a proximal connector assembly, a hand-held unit, and a collection reservoir that can be used with the system of Fig. 1.

Fig. 8 is a side view of the distal end of a guidewire that can be used with the system of Fig. 1.

Fig. 8A is a cross-sectional view of the distal end of the guidewire of Fig. 8.

Fig. 8B is a side view of portions of the helical section of the guidewire of Fig. 8 when the guide section of the guidewire is expanded by proportional control.

Fig. 8C is an exploded side view of a portion of the guidewire of Fig. 8.

Fig. 8D is a cross-sectional view of the distal end of another guidewire based on the principles of the guidewire of Fig. 8.

Fig. 8E-8H shows a mandrel used for making a guidewire with a guide section.

Figs. 9A-9D illustrate different embodiments of removal mechanisms that can be used with the system of Fig. 1.

Figs. 10A-10M illustrate one method of using the system of Fig. 1 for treating and removing occluding material from a blood vessel.

Fig. 11 illustrates a kit according to the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The following detailed descriptions are the best presently contemplated modes of carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating general principles of embodiments of the invention. The scope of the invention is best defined by the appended claims. In certain instances, detailed descriptions of well-known devices, compositions, components, mechanisms and methods are omitted so as to not obscure the description of the present invention with unnecessary detail.

The present invention provides apparatus and methods for use in treating and removing occluding material from a blood vessel or other body lumen of an animal or human. The system provides a removal mechanism that is secured at a distal end of a torque member. The torque member extends through a catheter that is used to carry and deliver the removal mechanism to the site of the occluding material inside the vessel, where the removal mechanism is actuated to separate and remove occluding material. A guidewire is used to guide the removal mechanism in a controlled manner at and along the location of the occluding material to separate and remove portions of the occluding material. In particular, the guidewire is provided with a helical distal guide section that guides the removal mechanism along the luminal wall to separate and remove the occluding material. The helical section of the guidewire may have an unconstrained diameter that is larger than the outer diameter or size of the removal mechanism. Passage of the removal mechanism over the deployed guidewire will remove one layer of occluding material to produce a diametrically larger passageway in the occluding

material. The helical guide section of the guidewire may be increased in size and/or exchanged with a guidewire having a larger helical diameter to remove additional layers of occluding material to provide diametrically larger passageways of the occluding material.

As used herein, "occluding material" means any proliferative or anomalous tissues or substances that occupy a lumen and represent a blockage that impedes the lumen's normal function. "Occluding material" can include, but is not limited to, such materials as thrombus, emboli, atheroma, smooth muscle cell hyperplasia, and other proliferative or anomalous tissues.

As used herein, "superelastic" refers to the property of a material, usually a metal alloy, which permits the material to return to its original shape upon unloading after a substantial deformation. Superelastic alloys can be strained up to ten times more than ordinary spring materials without being plastically deformed. The elasticity exhibited is unusually large and is caused by a stress induced phase transformation (i.e. austenite to martensite or stress induced martensite).

As used herein, "elastic and "resilient" refer to the property of a material to return to its original shape after unloading. The elastic properties of most materials are limited by plastic deformation which occurs at a relatively low degree of strain. Some materials, such as spring stainless steels, will posses sufficient elasticity for at least some applications within the present invention.

As used herein, "shape memory material" refers to those materials, usually metal alloys, which return to an original shape (which may be "set" during fabrication of the material) after heating above and/or within a characteristic temperature range (i.e. As - Af). If a straight piece of wire in the austenitic condition is cooled below and/or within a characteristic temperature range (i.e. Ms - Mf) to form martensite it remains straight. If the twinned martensite is deformed by bending it is converted to deformed martensite. On heating the transformation back to austenite occurs and the wire becomes straight again.

Some materials, such as certain nickel titanium alloys, e.g. Nitinol®, display both superelastic and shape memory properties and thus may be used according to more than one aspect of the present invention as described below in more detail.

Figs. 1, 1A and 2 illustrate a system 30 according to the present invention. The system 30 includes a catheter 32 which has a flexible elongate catheter body 34

having a proximal end 36 and a distal end 38, and defining at least one lumen 50 extending longitudinally there through. The catheter 32 is operatively coupled, by way of a proximal connector assembly 40, to a hand-held device 42 and a collection reservoir 44. The hand-held device 42 includes a motor for rotating a removal mechanism 54 provided at the distal end 38 of the catheter 32 to separate, remove and extract occluding material, as described in greater detail hereinbelow. The collection reservoir 44 collects occluding material that has been removed and extracted from the blood vessel. A guidewire 46 extends through, and is used in conjunction with, the catheter 32, as will be more fully described below.

Referring to Figs. 2 and 3, the catheter body 34 of the catheter 32 is preferably composed of a flexible polymer material that is biocompatible, kink resistant, and lubricious. Desirable polymer materials can include polyethylenes, polyurethanes, polyamides, fluoropolymers or the like. The flexible catheter body 34 is preferably in the form of an elongate tube having one lumen 50 extending longitudinally there through. Optionally, the catheter body 34 may be reinforced with a plurality of braids, helices, axial filaments, and the like, although the exemplary embodiment is free of such reinforcement. The tube may also be composed of composites and mixtures of more than one polymeric material. Extending longitudinally through the lumen 50 of the catheter body 34 is an elongate torque member 52 having a proximal end 64 (see Fig. 7) which is connectable to the hand-held device 42 for translating rotational motion from the hand-held device 42 to the removal mechanism 54 that is secured to its distal end.

1. The Torque Member 52

The torque member 52 is illustrated in greater detail in Fig. 4. The torque member 52 includes three layers of counterwound wires that form concentric coils. These three coiled layers include an inner coil 56, a middle coil 58 and an outer coil 60, all of which are secured together. In the embodiment illustrated in Fig. 4, the inner coil 56 is wound counterclockwise in a helical direction that is opposite to the clockwise helical winding direction of the middle coil 58. The inner coil 56 defines a hollow guidewire lumen 62. The inner coil 56 and the middle coil 58 operate together to transmit torque. The proximal end 64 of the middle coil 58 is rotatably connected to the hand-held device 42, as shown in Fig. 7 and described in greater detail hereinbelow. When the middle coil 58 is rotated in a clockwise direction, it attempts to become diametrically smaller due to

its clockwise winding direction. At the same time, the counterwound inner coil 56 attempts to become diametrically larger, again due to its counterclockwise winding direction. This creates a rotational engagement between the inner and middle coils 56, 58 that causes the coils 56 and 58 to lock together to create a reliable torque transmission member. This engagement between the inner and middle coils 56, 58 provides a torque transmission member which exhibits excellent torsional rigidity while allowing the torque member 52 to remain sufficiently flexible to navigate the tortuous paths of a patient's vasculature.

The inner and middle coils 56 and 58 are provided in filar groupings. Fig. 4 illustrates a quadrafilar coil construction (i.e., four wires wound together) for the inner and middle coils 56 and 58, but filar groupings having any number of wires wound together can also be chosen, depending on the requirements of the application. In this regard, the determination of the number of wires in a filar grouping is based on balancing three basic considerations. The first consideration relates to the inherent flexibility associated with a given number of wires in a group. In general, a more flexible torque member 52 is achieved if fewer wires are provided in each filar grouping. The second consideration relates to the total number of desired winds along the length of the torque member 52. For example, it would take fewer total winds (which translates to less manufacturing time) to manufacture a quadrafilar as opposed to a unifilar torque member 52 of the same length. The third consideration relates to energy storage when in torsion. With fewer wires in a grouping, greater rotational energy is stored along the length of the torque member. In other words, there is a phenomenon called "wind-up" (an input perspective) or "whip" (an output perspective) which requires more rotations at the proximal end before the distal end begins to follow. In general, when designing a torque member, it is desirable for the output (i.e., distal rotational performance) to closely follow the input (i.e., proximal rotational extent). The more wires in a grouping, the less torsional preload is required before the distal end follows the proximal end.

The inner and middle coils 56 and 58 can have the same or different helical angles and spacings. The helical angle used for the inner and middle coils 56 and 58 can range from approximately 5 to 85 degrees with respect to the longitudinal axis, and can be chosen based on the torque requirements of the application and the tortuosity of the patient's vasculature. The spacing between coils 56 and 58 can range from zero to the width of a filar grouping, and are also chosen based on the requirements of the

application. The helical angles and spacings for the inner and middle coils 56 and 58 are also related to and contribute to the "wind-up" phenomenon. For example, it is easier to achieve a tighter filar group spacing if the helical angle is steeper. There are also additional considerations. For example, steeper helical angles require the use of more wire, require greater wind-up, and achieve a more flexible torque member 52. Conversely, shallower helical angles require the use of less wire and require less wind-up. Shallower helical angles also occupy more radial space in a given torque member 52 because the "filar group ribbon" has to "twist", rather than lay flat, to achieve the shallower angle.

The outer coil 60 is not relied on to contribute to the torque transmission, but is used as part of a conveyor mechanism to transport separated and removed occluding material from the removal mechanism 54 along the lumen 50 of the catheter 32, and ultimately outside the patient's body to the collection reservoir 44. The transportion of separated and removed occluding material outside the patient's body is referred to hereinafter as "extraction". The outer coil 60 and the inner surface 66 of the lumen 50 together form a conveyor. To function as an effective conveyor, the diameter of the lumen 50 is selected to bring the inner surface 66 in close proximity to the outermost surface of the outer coil 60. The outer coil 60 is wound over the middle coil 58 in a winding direction that is opposite from the winding direction of the middle coil 58. The outer coil 60 is wound at about the same direction, and can even be wound at the same range of angles, as the inner coil 56. The outer coil 60 is spaced to form helical flutes 68 having a spacing 69 between adjacent windings in the outer coil 60. The spacing 69 is uniform throughout its length, and is chosen so that it forms a helical annulus through which fluid (e.g., saline, blood, Ringer's Solution, etc.) and excised occluding material can pass in an unrestricted manner. In particular, the spacing 69 is chosen so that the size of the largest tissue fragments that are separated and removed can travel unimpeded through the helical flutes 68. The arrangement and positioning of the outer coil 60 and the inner surface 66 of the catheter lumen 50 create an Archimedes-type of "screw pump". The utilization of this "screw-pump" arrangement can obviate the need for external aspiration, although an externally connected aspiration device (as described below) can be used to supplement and enhance the tissue extraction function of the "screw pump".

The winding directions of the inner, middle and outer coils 56, 58, 60 have been illustrated as being intended for clockwise rotation. If counter-clockwise rotation of the torque member 52 is desired, the winding directions for the inner, middle and outer coils 56, 58, 60 should be reversed.

The inner, middle and outer coils 56, 58, 60 can be formed from suitable wire materials such as stainless steel and other metals that are biocompatible and that are resistant to kinking. In addition, these coils 56, 58 and 60 can have a circular or ribbon-like cross-section. Figure 4B shows a modified configuration where wire 60 is replaced with a series of spaced impellers 61 to provide liquid pumping inside the lumen 50. The impellers 61 are fixedly attached to the torque member 52 and are pitched so fluid is pumped out of the body when the torque member 52 is rotationally engaged. Note it is possible to use wire 60 and impellers 61 in conjunction by creating cells where wire 60 runs for a predetermined length and are separated by impellers 61 as cell separators. Said cells being defined by a distance 63 between impellers 61.

It can be beneficial to encase the three layers of coils 56, 58, 60 in a polymer jacket 70 (see Fig. 4A), which serves to secure the coils 56, 58, 60 together. The polymer jacket 70 can be applied through one of a number of approaches. For example, the polymer jacket 70 can take the form of a thermoplastic sleeve which is melted around the coils 56, 58, 60 to fill their interstices and to create a barrier between the guidewire lumen 62 and conveyor defined by the outer coil 60 and the inner surface 66. Alternatively, the polymer jacket 70 can be a thermoplastic or thermosetting sleeve with shape-memory characteristics (e.g., cross-linked polyolefins, polyesters, fluoropolymers, etc.) that are shrunk onto the triple coil 56, 58, 60 assembly. As yet another alternative, the polymer jacket 70 can be a thermoset, such as polyimide, which is applied through dipping, casting, spraying, brushing or other similar techniques. In applications where the torque member 52 must be provided with a small size and profile, other thin thermoplastic jackets, such as parylene, can be vacuum deposited onto the torque member 52 and used as the polymer jacket 70.

The outer coil 60 does not need to be provided as a separate wire. For example, it is also possible to encase the inner and middle coils 56, 58 using any of the methods and polymeric materials described above, and then the outer coil 60 can be formed by selectively removing polymeric material to form the helical configuration of

the outer coil 60. This selective removal of polymeric material can be accomplished by using any known method, such as by cutting external threads on a lathe.

2. The Removal Mechanism 54 and The Bearing Assembly 100

A removal mechanism 54 is secured to the distal end 72 of the torque member 52. The removal mechanism 54 is used to excise occluding material from the luminal wall of a blood vessel or other body lumen. Excision can be accomplished by cutting, shearing, coring, scraping, or other known methods. The function of the removal mechanism 54 is to separate the occluding material from the luminal wall of a blood vessel, so that the occluding material can then be removed and extracted from the patient's vasculature.

One embodiment of a removal mechanism 54 is illustrated in Figs. 2 and 3. The removal mechanism 54 in Figs. 2 and 3 is a rotatable helical cutter. The helical cutter 54 has a plurality of counterclockwise helical turns 74 defining a lumen extending longitudinally there through, and shearing aspects extending longitudinally therealong. The helical turns 74 have a proximal cutting edge 76 that is adapted to cut occluding material during clockwise rotation of the helical cutter 54. In other words, the proximal edge 76 is in effect the leading edge when the cutter 54 is rotated in the clockwise direction. The number of helical turns 74 depends on the smoothness of the desired cut and the "aggressiveness" with which tissue is to be removed. In this regard, "aggressiveness" is defined as the degree of engagement of the removal mechanism 54 with the occluding material. For example, increasing the number of helical turns 74 over the same axial length provides a smoother cut, while decreasing the number of helical turns 74 provides a more aggressive cut. If the helical cutter 54 is to be rotated counter-clockwise, then the helical turns 74 should be spiraled in an opposite direction (i.e., in this case, clockwise).

The helical cutter 54 is secured to the distal end 72 of the torque member 52 in the following manner. Referring to Figs. 3-4, a length of the distal portions of the middle and outer coils 58 and 60 are peeled or cut back to a circumferential point 82 to expose a distal length 84 of the inner coil 56. This is illustrated in Figs. 3 and 4, where the middle and outer coils 58 and 60 are shown as extending from their proximal ends to a distal-most extent defined by the circumference 82. The distal-most ends 86 and 88 of the middle and outer coils 58 and 60, respectively, are then dressed and subsequently

secured (e.g., by welding, soldering, brazing or gluing) to prevent the middle and outer coils 58 and 60 from unravelling. The helical cutter 54 is then slid over the exposed distal length 84 of the inner coil 56 so that the inner coil 56 is received inside the lumen of the helical cutter 54, and the proximal end 90 of the helical cutter 54 is secured to the distal ends 86 and 88 of the middle and outer coils 58 and 60, respectively, by brazing, soldering, welding, adhesive bonding, or any other conventional methods. The distal end 92 of the helical cutter 54 is also secured, using one of the methods described above, to the outer surface of the inner coil 56 at a location slightly proximal from the distal tip 94 of the inner coil 56. It is also possible to secure the inner surfaces of the helical turns 74 along the outer surface of the inner coil 56. The flutes 96 defined between the helical turns 74 communicate with the flutes 68 of the outer coil 60 to deliver dislodged or cut occluding material to the conveyor defined by the outer coil 60 and the inner surface 66.

The torque member 52 is positioned inside the lumen 50 of the catheter 32 such that it extends longitudinally there through with most of the exposed distal length 84 of the inner coil 56 extending distal from and outside of the distal end 38 of the catheter 32. Therefore, the helical cutter 54 also extends partially outside of the catheter body 34. A bearing assembly 100 is provided to secure the distal end 72 of the torque member 52, and the removal mechanism 54 secured thereat, at a fixed axial position at the distal end 38 of the catheter body 34 while simultaneously allowing rotation of the torque member 52 and the removal mechanism 54.

Referring now to Figs. 2 and 5-6, the bearing assembly 100 includes a resilient snap ring 102 and an overlying shell 104. The snap ring 102 is best illustrated in Figs. 3 and 5, and has a cylindrical body 106 with an inner rib 108 extending circumferentially about an inner surface 110 of the cylindrical body 106. One longitudinal slit 112 can be provided along the cylindrical body 106 to allow the ring 102 to be compressed or radially expanded. The rib 108 is adapted to be fitted inside a circumferential groove 114 provided near the proximal end 90 of the helical cutter 54. The snap ring 102 is preferably made of stainless steel or other resilient alloys, and is preferably biocompatible and offers good resistance to fatigue resulting from elastic or plastic deformation.

The shell 104 is best illustrated in Figs. 3 and 6, and has a generally cylindrical body 120 having an annular distal lip 122 that extends radially inwardly to narrow the distal opening 124 of the cylindrical body 120. A ramp 126 extends from the

proximal end of the cylindrical body 120 and ramps radially inwardly to form a cylindrical barbed section 128 which has a diameter that is smaller than the diameter of the cylindrical body 120. A plurality of barbs 130 are provided on the outer surface 132 of the cylindrical barbed section 128. The shell 104 is preferably made of stainless steel or other resilient alloys, and is preferably biocompatible.

To assemble the bearing assembly 100, the snap ring 102 is first secured to the proximal end 90 of the helical cutter 54, and the shell 104 secured to distal end 38 of the catheter 32, before the snap ring 102 is fitted inside the shell 104.

Specifically, the torque member 52 and the proximal end 90 of the helical cutter 54 are first slid into the lumen of the cylindrical body 106 of the snap ring 102 until the circumferential rib 108 is fitted or seated inside the circumferential groove 114. The resiliency of the cylindrical body 106 provided by the slit 112 allows the body 106 to be stretched to permit the proximal end 90 of the helical cutter 54 to pass there through and over its rib 108 until the groove 114 receives the rib 108.

At the same time, the barbed section 128 of the shell 104 is slid inside the lumen 50 at the distal end 38 of the catheter body 34. The barbs 130 engage the inner surface 66 of the catheter body 34 to form a secure barb-hose type connection. The distal extremity of the catheter body 34 can be slid over the outer surface 132 of the barbed section 128 until it reaches the ramp 126, which acts as a stop that defines the limit of distal advancement of the catheter body 34 along barbed section 128. In addition, the outer surface 134 of the cylindrical body 120 of the shell 104 is preferably aligned with the outer surface 136 of the catheter body 34 to provide a smooth transition between the shell 104 and the catheter 32.

At this time, the distal lip 122 of the shell 104 is slid over the snap ring 102. Since the distal opening 124 of the cylindrical body 120 has a diameter which is smaller than the diameter of the cylindrical body 106 of the snap ring 102 in its normal relaxed state, the cylindrical body 106 will need to be radially compressed to allow the distal lip 122 to pass over it. The longitudinal slit 112 provides the resiliency to allow the cylindrical body 106 to be radially compressed without buckling its structure. Once the distal lip 122 has passed over the entire cylindrical body 106 of the snap ring 102, the resilient nature of the snap ring 102 will cause the cylindrical body 106 to spring back to its normal relaxed state, in which it will be seated inside the shell 104 between the distal lip 122 and the ramp 126, creating a secure interference fit.

Alternatively, the bearing assembly 100 can be assembled by first sliding the snap ring 102 inside the shell 104 in the manner described above. The shell 104 can then be secured to distal end 38 of the catheter 32, and the helical cutter 54 secured to the snap ring 102 using the methods described above.

The bearing assembly 100 performs two functions. First, the distal lip 122 and the ramp 126 together provide thrust confinement for a thrust bearing that consists of the snap ring 102 inside the shell 104. Second, the interaction between the snap ring 102 (which is securely coupled to the helical cutter 54 and the inner coil 56) and the shell 104 (which is securely coupled to the catheter body 34) provides smooth rotational bearing surfaces. In this manner, the rotational engagement between the rib 108 and the groove 114 allows the helical cutter 54 to rotate together with the inner coil 56, while the interference fit of the snap ring 102 inside the shell 104 between the distal lip 122 and the ramp 126 prevents axial displacement of the helical cutter 54 and the inner coil 56 with respect to the catheter body 34. The interface and interaction between the shell 104 and the snap ring 102 further enable the catheter body 34 to not be rotated when the torque member 52 and the helical cutter 54 are rotated.

3. Proximal Connector Assembly 40, Hand-Held Device 42 and Collection Reservoir 44

Referring now to Figs. 1 and 7, the proximal connector assembly 40 of the system 30 has an elongate, rigid body 150 defining frontal and rear portions. The frontal portion 152 of the body is firmly connected to the proximal end 36 of the catheter body 34. The proximal end of the frontal portion 152 is connected to the distal end of the rear portion 154 of the body 150. A lumen or passageway 156 extends longitudinally through the frontal portion 152 and the rear portion 154, and communicates with a hollow lumen inside a rotator shaft 158 provided inside the hand-held device 42. The torque member 52 extends through the passageway 156 and is secured inside the lumen of the rotator shaft 158. The rigid body of the proximal connector assembly 40 has a side arm 160 which is connected, by way of a tube 162, to a collection reservoir 44. A dynamic seal 164 is provided in the rear portion 154 to act as a seal around the torque member 52 to prevent fluid flow through the passageway 156 into the hand-held device 42, and to ensure that all occluding material and fluids (such as blood) are diverted to the side arm 160 and the collection reservoir 44. The dynamic seal 164 can be implemented in the form of an O-

ring, or a perforated gasket of an elastomeric material, either synthetic (e.g., silicone) or naturally occurring (e.g., natural rubber). A conventional male-female luer fitting 163 is also provided in the rear portion 154 to connect the proximal connector assembly 40 to a front portion 165 of the hand-held device 42.

The hand-held device 42 has a housing 166 that houses a motor 168 and a battery 170. The battery 170 provides electrical energy to the motor 168 via wire leads 172. A control switch 174 is coupled to the motor 168 and the battery 170 by similar wire leads 175 and 176, respectively, to control the operation of the motor 168. The motor 168 has a shaft 178 which carries a first driving gear 180 that rotatably engages a second gear 182 to rotatably drive the second gear 182. The second gear 182 is carried on the rotator shaft 158 so that rotation of the first driving gear 180 will cause the second gear 182 to rotate the rotator shaft 158, thereby rotating the torque member 52 retained therein. A first plurality of rotator shaft bearings 184 are provided to facilitate rotation of the rotator shaft 158, and a second plurality of gear bearings 186 are provided to facilitate rotation of the gears 180 and 182. The proximal end of the guidewire 46 extends from the proximal end 64 of the torque member 52 inside the hand-held device 42 and through an opening 188 provided at the proximal end of the housing 166 out of the hand-held device 42 to allow the physician to perform guidewire exchange and to manipulate the guidewire 46, as described in greater detail hereinbelow.

The collection reservoir 44 may be a ceramic or polymeric container that is transparent so that the physician can visually determine the fill volume of the reservoir 44. A first conventional male-female luer fitting 167 connects the tube 162 to the collection reservoir 44. The conveyor mechanism defined by the outer coil 60 and the inner surface 66 of the lumen 50 will cause occluding material to be conveyed from the distal end 38 of the catheter 34 to the rear portion 154 of the proximal connector assembly 40, where the occluding material will be diverted by the dynamic seal 164 into the collection reservoir 44 by the action of the "screw pump".

It is also possible to provide aspiration to the region of the blood vessel where the occluding material is being treated, even though the "screw pump" defined by the outer coil 60 and the inner surface 66 of the catheter lumen 50 may be sufficient to completely remove all separated occluding material from the blood vessel. This can be accomplished by providing the collection reservoir 44 with a second conventional male-

female luer fitting 190 that is connected to a vacuum pump 192 via a pump tube 194. Such aspiration will enhance the extraction of the excised occluding material.

4. Guidewire 46

The catheter 32 is preferably configured to operate in an over-the-wire mode. The catheter 32 can be used with conventional guidewires to form an initial pilot lumen equivalent in size to the outer diameter of the catheter 32 and the removal mechanism 54. The conventional guidewire can then be exchanged for the guidewire 46 of the present invention.

Fig. 8 illustrates an embodiment of a guidewire 46 that can be used with the system 30 of the present invention. The guidewire 46 is preferably provided with a configuration to enable it to guide, in a controlled manner, a removal mechanism 54 at and along the location of the occluding material for separating and removing portions of the occluding material, so as to create a series of sculpted conduits through an obstructed vessel lumen. The resulting passageway created through the obstruction would be diametrically larger than the outer diameter of the removal mechanism 54 and the catheter 32.

Referring to Figs. 8, 8A, and 8C, the guidewire 46 is provided with a generally helical distal guide section 200 adjacent its distal end 202. As shown in Fig. 8A, the helical distal guide section 200 has a three-dimensional configuration that approximates the configuration of a luminal wall. The distal end 202 of the guidewire 46 is generally straight and preferably has an atraumatic distal tip 206. The remainder of the guidewire 46, and in particular, the proximal section 204, is generally straight, as with conventional guidewires. The distal section 202 and the proximal section 204 are axially coplanar with each other, and are preferably coaxial with respect to each other. In other words, the distal section 202 and the proximal section 204 are oriented along the same longitudinal axis. In addition, the distal section 202 and the proximal section 204 are concentric, and can also be eccentric, with respect to the guide section 200. The proximal and distal extremities of the guide section 200, or the entire helical section, are preferably provided with sufficient radiopacity so that the guide section 200 can be clearly viewed during fluoroscopic visualization. The radiopacity can be provided by the use of a radiopaque wire 201, as shown in Fig. 8C, which can be made of platinum or gold alloys

or other radiopaque wires, and which is wound around the core 199 forming the helical turns of the guide section 200.

The guidewire 46 is intended to allow the catheter 32 and the removal mechanism 54 carried thereon to follow the helical configuration of the helical guide section 200 so as to bring the removal mechanism 54 in contact with the inner luminal wall of the blood vessel to be treated. After sequential passes with the catheter 32 and removal mechanism 54 along the helical guide section 200, and sequential axial translations of the guidewire 46, a passageway in the lumen of the blood vessel is formed whose diameter is generally equal to the sum of the diameter of the helical guide section 200 and twice the depth of the cuts, shears or slices of the occluding material taken by the removal mechanism 54.

The core 199 of the guidewire 46, and in particular, its guide section 200, are preferably formed using materials of a composition, processing regimen, shape and dimension that operate over a range within the material's elastic limit. Specifically, the materials used for the guide section 200 preferably operate within a range defined by a lower boundary of yield stress and an upper boundary of the elastic limit of the material, and in particular, a material having a sufficiently wide range of deformation (e.g., approximately up to 8%) upon which full recovery can still be achieved. "Yield stress" as used herein means the stress level at which a finite strain is first observable. "Stress" can be defined as an applied force or system of forces that tends to strain or deform a body. "Strain" can be defined as a deformation produced by stress. "Elastic limit" as used herein means the stress level at which permanent or plastic deformation takes place.

Thus, a guide section 200 that is provided with a material operating within the material's yield stress and elastic limit will have a preformed shape that is adaptable to essentially any inner open space of a generally tubular or duct-like passageway, and in particular, to lumen shapes varying from true cylindrical to substantially non-cylindrical. Such a guide section 200 is capable of being elastically (but not plastically) deformed in order to pass it through the guidewire lumen 62 of the torque member 52, and is capable of recovering its full configuration inside the passageway of the stenosis or lumen.

As a result, the pitch (i.e., wavelength) and the helical diameter HD (i.e., amplitude) of the helical guide section 200 are preferably dynamically adaptable to the changing geometries of a passageway within a stenosis or body lumen. For example, the pitch to diameter ratio preferably in the range from 0.1:1 to 5:1, and in one embodiment is

1:1. The pitch and the helical diameter HD of the helical section are preferably changed as the volume of the occluding material is reduced. Specifically, the pitch is looser, and helical diameter HD is smaller, when the volume of the occluding material is greatest (i.e., the passageway through the occluding material is smallest). As the volume of the occluding material is reduced, the pitch preferably becomes tighter and the helical diameter HD greater.

In addition, the maximum diameter HD of the helix in the helical guide section 200 is preferably chosen to be equal to or slightly larger than the body lumen in which it is to be deployed for treatment although, as explained below, varying diameters can be provided depending on the mode of operation utilized. The helical angles for the helical guide section 200 are also chosen such that the rigid length of the removal mechanism 54 has minimal impact on elastically deforming the helical turns of the helical guide section 200 as the removal mechanism 54 traverses the helical guide section 200. The overall length HL of the helical guide section 200 is preferably chosen to be slightly longer than the length of the occluding material to be traversed.

One example of a material that can be used for the guide section 200 is a shape memory alloy such as nickel-titanium (NiTi). NiTi exhibits superelastic properties and increased flexibility over conventional stainless steel which will ease the insertion of the helical guide section 200 through the guidewire lumen 62. NiTi allows for more precise axial positioning adjacent to an already removed helical conduit or track by conforming more readily to the body lumen being treated.

Examples of superelastic metal alloys, including NiTi, which are usable to form the core 199 of the guidewire 46 of the present invention are described in detail in United States Patent No. 4,665,906. The disclosure of United States Patent No. 4,665,906 is expressly incorporated herein by reference insofar as it describes the compositions, properties, chemistries, and behavior of specific metal alloys which are superelastic within the temperature range at which the guide section 200 of the guidewire 46 of the present invention operates, any and all of which superelastic metal alloys may be usable to form the core 199 of the guide section 200 of the guidewire 46.

When NiTi is used to form the core 199 of the helical guide section 200 of the guidewire 46, the helical guide section 200 of the guidewire 46 is provided in its original helical configuration having its maximum helical diameter. The guidewire 46 is then mechanically deformed to a generally straight configuration so that it can be easily

inserted through the guidewire lumen 62. After the guidewire 46 has been introduced into a blood vessel for use according to the methods described hereinbelow, the helical guide section 200 is caused to return to its original helical configuration, at either its maximum helical diameter or at varying helical diameters. Depending on the operation mode employed, as described below, this can be accomplished by thermally inducing the helical guide section 200 to cause it to return to its helical configuration (either its maximum diameter or at varying helical diameters), or by releasing the forces that hold the helical guide section 200 in the generally straight configuration.

A helical guide section 200 having at least a core made from NiTi can be employed in one of the following modes: superelastic, constrained recovery without proportional control, and constrained recovery with proportional control. These terms are now defined.

The term "superelasticity" means the property of certain alloys to return to their original shape upon unloading after a substantial deformation. Superelastic alloys such as NiTi can be strained ten times more than ordinary spring materials without being plastically deformed. With respect to the guidewire 46, the "superelastic" mode means a NiTi core helical guide section 200 that has an original helical configuration, is deformed when it is held in a generally straight configuration, and which returns to its original helical configuration when it is released from the forces that have held it in the generally straight configuration.

"Constrained recovery" means a NiTi core helical guide section 200 having a maximum diameter that is greater than or equal to the diameter of the luminal passageway in which it is deployed when it is returned to its original helical configuration at its maximum helical diameter. Again, this luminal passageway can be the passageway created through the occluding material. In other words, the helical guide section 200 is "constrained" in that it contacts the luminal passageway when it "recovers" its original helical configuration.

"Proportional control" means that the recovery of the helical guide section's 200 original helical configuration is proportionally controlled so that the helical guide section 200 is induced to proportionally progress from the straight configuration to its maximum and full helical diameter over a continuum.

Proportional control can be accomplished by titrating the amount of thermal energy applied to the helical guide section 200. For example, heat can be applied

to the helical guide section 200 by bathing the helical guide section 200 in a physiologically inert fluid (e.g., saline, Ringer's Solution, etc.) that is introduced via the lumen of a guide catheter (not shown) through which the catheter 32 is introduced. Alternatively, heat can be applied to the helical guide section 200 by passing current through the guidewire 46 from its proximal end 204. This can be accomplished by attaching one or two leads to the helical guide section 200. For example, referring to Fig. 8B, a lead pair 203 is connected to a source of heat, such as a resistance heater RH. The lead pair 203 has a distal lead attachment 205 and a proximal lead attachment 207 provided on the distal and proximal extremities, respectively, of the helical guide section 200.

In addition, temperature sensors (e.g., thermocouples or thermistors) can be provided integrally with or in the vicinity of the helical guide section 200 for closed loop feedback to an appropriate electrical circuit during energy titration. One possible arrangement would be to place a distal temperature sensor 208 and a proximal temperature sensor 209 on the distal and proximal extremities, respectively, of the helical guide section 200 (see Fig. 8B). Each temperature sensor can be either a thermocouple or a thermistor. Distal temperature sensor 208 is coupled to a first thermocouple or thermistor thermometry circuit via a first lead pair 211, and proximal temperature sensor 209 is coupled to a second thermocouple or thermistor thermometry circuit via a second lead pair 213. The temperature sensing elements 208, 209 measure the temperature gradient across the helix of the helical guide section 200. This temperature sensing placement approach takes advantage of the available space within a 0.014 inch or other conventional size guidewire diameter and the temperatures measured would accurately represent the phase transformation correlation with the helical diameter of the helical guide section 200. Proportional control would reduce the number of guidewires 46 required for the procedure, as will become more evident in the description of the methods of the present invention hereinbelow.

Any of the NiTi wires used as the guidewire core 199 described above (i.e., superelastic, constrained recovery without proportional control, and constrained recovery with proportional control) are available in the market and can be obtained, for example, from Raychem Corp. of Menlo Park, California.

The helical guide section 200 of the guidewire 46 can be modified so that it has a generally tapered or stepped, or both tapered and stepped, configuration. For

example, the helix of the guide section 200 can be tapered from the proximal extremity to the distal extremity thereof so that the helical diameter decreases from the proximal extremity to the distal extremity. The helix can also be stepped at certain discrete locations of the guide section 200. In addition, although the helical guide section 200 of the guidewire 46 is illustrated as having uniformly configured helixes, it is also possible to provide the helixes in a manner that they are non-uniform to each other across the helical length HL.

As a further alternative, the guide section 200 need not be provided in a helical configuration. Referring to Fig. 8C, the guide section 200a has a polygonal configuration in three-dimensional space.

As yet another alternative, a plurality of guide sections 200 can be provided in spaced-apart manner at the distal end of the guidewire 46. For example, two spaced-apart guide sections 200 would be helpful in treating body lumens where restenosis has occurred at the locations of two spaced-apart implanted stents.

The curved three dimensional profile has a longitudinal dimension and a radial dimension with the longitudinal dimension capable of increasing inversely proportional to the radial dimension. The curved three dimensional profile is capable of axial elongation such that the radial dimension approaches the same diameter as the proximal section of the guidewire when a pull force (as measured by an Instron or tensile testing equipment) between 0.02 lbf (0.0045 N) and 2.0 lbf (0.45 N) is exerted on the guide section. The pull force is typically generated by a catheter being advanced over the guide section. The guide section is capable of repetitive expansion and contraction to a plurality of radial dimensions. These expansions and contractions can be generated by mechanical, thermal or electrical energy.

The test methodology for the tensile testing involves: First a wire with a radial expansible guide section is pulled through a glass tube of a 0.016" internal diameter. When the radial expansible guide section is completely stretched out in the glass tube, a measurement is taken of the distance between the beginning and end of the radial expansible guide section. The wire is then marked at those points (generally by withdrawing the wire slightly, or cutting the glass tube at the point to be marked. Then the wire is withdrawn from the glass tube and allowed to relax back into a curved three dimensional profile. The distance between the relaxed points is then measured. The wire is then fitted in an Instron with a ten pound load cell so the clamps of the Instron attach at

the points previously marked on the wire. The jaws are spaced apart the same length as the relaxed distance between the marked points and the pull distance is set to the extended distance of the wire measured in the glass tube less the relaxed distance. The wire is then drawn slowly (about 2.54 cm per minute) and the force required to pull the wire to approximate the extension in the glass tube is measured. Currently this test represents the preferred embodiment of evaluating the force on the wire in operation. Care must be taken to avoid problems in orthogonal alignment which may skew the results.

4. Mandrel for use in Making the Guidewire 46.

Figure 8M illustrates a mandrel for making a guide section 200 of the present invention. Figure 8M shows a mandrel 8000 having a channel 8004 for receiving the guidewire 46. The mandrel 8000 has a proximal receptacle 8012 for receiving the guide wire 46 and a means for securing the guidewire 46 to the mandrel 8000. The distal section of the guidewire 46 is formed by threading it through the receptacle 8008. Figure 8Ma shows the guidewire 46 wrapped around the mandrel 8000 with the distal and proximal ends properly threaded through the receptacles 8008 and 8012. Figure 8Mb shows the entire mandrel assembly 8050 which is heated between 300 and 800 degrees Celsius to heat set the guidewire 46. The guidewire 46 is secured by a device for locking the wire in place such as a screw 8016. Any locking means that prevents the guidewire 46 from slipping during the temperature setting phase will do. Figure 8Mc shows the final shape of the guide section 200 after the shape setting procedure. Note the period between minor dimensions on the mandrel 8055 match the distance between helical winds 8055' in the guide section 200.

5. Alternative Removal Mechanisms

A number of alternative removal mechanisms 54 are illustrated in Figs. 9A-9D. Fig. 9A illustrates another helical cutter 54a which is similar to the helical cutter 54 illustrated in Figs. 2 and 3, except that helical cutter 54a has a shallower helix angle while the helical cutter 54 has a steeper helix angle. As a result, helical cutter 54a has fewer helical turns 74a. The helical turns 74a likewise have a proximal cutting edge 76a that is adapted to cut occluding material during clockwise rotation of the helical cutter

54a. If the helical cutter 54a is to be rotated counter-clockwise, then the helical turns 74a will need to be wound in the opposite direction. The helical cutter 54a is secured to the exposed distal length 84 of the inner coil 56 according to the same method described above. A bearing assembly, such as bearing assembly 100, described above, is also preferably provided at the connection between the catheter body 34 and the helical cutter 54a.

Fig. 9B illustrates a Forstner cutter 230 that can be used to core a passageway through the occluding material. The Forstner cutter 230 is defined by a cylindrical shaft 232 having a widened annular coring blade or cutting edge 234 provided at the distal end. A plurality of scraping surfaces 236 are positioned about 180 degrees apart to break apart the occluding material that has been cored by the coring blade 234. The cutter 230 is connected to the inner coil 56 of the torque member 52 by sliding the distal end 72 of the inner coil 56 through the hollow lumen of the cylindrical shaft 232, and securing the proximal end 238 of the cylindrical shaft 232 to the distal ends 86 and 88 of the middle and outer coils 58 and 60, respectively. A helical turn 240 is provided at the proximal end 238 of the cylindrical shaft 232 to facilitate the transportion of occluding material from the cutter 230 to the conveyor defined by the outer coil 60 and the inner surface 66 of the catheter body 34. The cutter 230 is housed inside a cutter housing 242, which is provided in the form of a tapered cylindrical body having a proximal cylindrical section 246 inside which the cutter 230 is housed, and a tapered distal section 248. The proximal end of the proximal cylindrical section 246 is affixed to the distal end 38 of the catheter body 34 by adhesive bonding, a barbed-hose connection 247 (see Fig. 9B), or other similar affixation means, or the proximal cylindrical section 246 can be provided with the catheter body 34 in one piece. A side window 250 is provided between the proximal cylindrical section 246 and the tapered distal section 248, and through which a portion of the annular coring blade 234 extends to cut occluding material. The cutter housing 242 does not rotate together with the cutter 230. In use, the cutter 230 is rotated and dislodged occluding material is received through side window 250 to be transported through the flute defined by the helical turn 240 of the cylindrical shaft 232 and the helical turns of the outer coil 60. A bearing assembly 251 is also preferably provided at the interface between the distal end 72 of the torque member 52 and the distal tapered section 248 of the cutter housing 242.

Fig. 9C illustrates a rotary cutter 260 that can be used to remove a small amount of occluding material. The rotary cutter 260 has a cylindrical shaft 262 with a spherical rotary burr 264 provided at the distal end. The burr 264 has a plurality of circumferential fluted blades 266 provided on the surface of the burr 264 for dislodging occluding material. The cutter 260 is connected to the inner coil 56 of the torque member 52 by sliding the distal end 72 of the inner coil 56 through the hollow lumen of the cylindrical shaft 262, and securing the proximal end 268 of the cylindrical shaft 262 to the distal ends 86 and 88 of the middle and outer coils 58 and 60, respectively. The cutter 260 is provided in, and extends through, a circumferential side window 276 of a two-part cutter housing. The cutter housing has a proximal cylindrical section 272 which is affixed to the distal end 38 of the catheter body 34 by hose-barbed connection, adhesive bonding or other similar affixation means, and a tapered distal section 274 which is affixed to the distal end 72 of the torque member 52 by welding, soldering or other similar affixation means. In use, the distal tapered section 274 rotates together with the burr 264, and dislodged occluding material can be either aspirated through the use of the "screw-pump", or allowed to escape through the patient's blood flow since only a small amount of occluding material is being dislodged and removed. A bearing assembly, such as bearing assembly 100, described above, is also preferably provided at the connection between the catheter body 34 and the rotary cutter 260. In the embodiment illustrated in Fig. 9C, the proximal cylindrical section 272 can actually be part of the shell 104 of the bearing assembly 100.

Fig. 9D illustrates a sidecutter 290 that can be used to remove occluding material. The sidecutter 290 is provided in the form of a distal housing 292 for the distal end 72 of the torque member 52. The distal housing 292 has a tapered cylindrical body having a proximal cylindrical section 294 and a tapered distal section 296 which is affixed to the distal end 72 of the torque member 52 by welding, soldering or other similar affixation means. A side window 298 is provided at one side of the distal end 300 of the distal housing 292. The side window 298 defines a tapered cutting edge 302, and a lateral cutting edge 304. In use, the distal housing 292 rotates together with the torque member 52, with the cutting edges 302 and 304 operating to dislodge occluding material. The occluding material is received through side window 298 to be transported along the flutes defined by the helical turns of the outer coil 60. A bearing assembly, similar to

bearing assembly 100 described above, can also be provided at the interface between the proximal cylindrical section 294 and the distal section 38 of the catheter body 34.

During use of the cutters 260 and 290 described hereinabove, the cutters 260 and 290, and their housings 274 and 292 are rotated together with the torque member 52 to dislodge occluding material. However, during the rotation of the cutter 230, its housing 242 is not rotated.

6.A First Method of Use

Figs. 10A-10M illustrate one method of using the system 30 of the present invention, including certain alternatives and variations.

Fig. 10A illustrates a segment of a blood vessel BV that has been partially occluded by occluding material OM at the region where a stent S had previously been implanted. A small occlusion passageway OP is defined between the occluding material OM, and has a diameter which is significantly smaller than the luminal passageway LP of the blood vessel BV. Although Figs. 10A-10M illustrate the use of the system 30 in connection with a blood vessel BV that has been partially occluded by occluding material OM at the region where a stent S had previously been implanted, the system 30 can also be used with a non-stented blood vessel BV that has been partially occluded (i.e., stenosed) by occluding material OM. The system 30 can also be used in a completely occluded blood vessel, if an initial pilot guidewire, such as the guidewire GW described below, can be passed through the occlusion.

a. First Step -- Introduction of Guidewire

In the first step illustrated in Fig. 10B, a straight guidewire GW is percutaneously introduced into the luminal passageway LP using conventional guidewire introduction techniques, and traverses the occluding material OM through the occlusion passageway OP. As part of the conventional guidewire introduction techniques, a guide catheter (not shown) is first introduced into the patient's vasculature through a puncture wound, and the guidewire GW and catheter 32 are subsequently introduced through the lumen of the guide catheter. The guidewire GW can be a conventional stainless steel guidewire. Alternatively, the guidewire GW can be a NiTi guidewire 46 according to the present invention that has been mechanically deformed from its original helical configuration to a generally straight configuration, and which requires thermal

inducement to recover its original helical configuration (i.e., does not include a NiTi guidewire operating in superelastic mode). At this time, the physician will assess the location and dimensional characteristics of the occluded segment of the blood vessel BV using conventional angiographic techniques. If a stent S has been implanted adjacent the occluded segment of the blood vessel BV, the length and deployed diameter of the stent S will also be assessed.

b. Second Step -- Formation Of Initial Pilot Lumen

After the guidewire GW has been positioned inside and extended through the occlusion passageway OP, the catheter 32 is advanced along the guidewire GW in an "over-the-wire" manner inside the luminal passageway LP to the proximal extent of the occluding material OM. See Fig. 10C. The hand-held device 42 is actuated to cause the removal mechanism 54 to rotate to separate, remove and extract portions of the occluding material OM in the path of the removal mechanism 54 as it is advanced through the occluding material OM. As the catheter 32 is advanced distally over the guidewire GW, the catheter body 34 is not rotated during the rotation of the removal mechanism 54, but will "self-center" itself over the guidewire GW, which has a generally straight configuration within the occluding material OM. When the removal mechanism 54 has reached the distal extent of the occluding material OM, as shown in Fig. 10D, an initial pilot lumen PL will have been formed. This pilot lumen PL will have a diameter which is about the same as the outer diameter or outer dimension of the removal mechanism 54.

c. Third Step -- Removal of Guidewire GW

With the initial pilot lumen PL formed in the occluding material OM, the axial position of the catheter 32 is maintained at the distal extent of the occluding material OM and the guidewire GW is removed. See Fig. 10E. The removal of the guidewire GW in this step can be omitted if the guidewire GW is a NiTi guidewire 46 according to the present invention that has been mechanically deformed from its original helical configuration to a generally straight configuration, and which requires thermal inducement to recover its original helical configuration.

d. Fourth Step -- Introduction of Guidewire 46

A guidewire 46 according to the present invention is now chosen by the physician. The guidewire 46 can be a superelastic guidewire or a constrained recovery NiTi guidewire. The maximum helical diameter of the helical guide section 200 is chosen to be greater than or equal to the diameter of the pilot lumen PL. The guidewire 46 is also chosen so that the length HL of the helical guide section 200 is greater than or equal to the length of the occluding material OM and the implanted stent S, if applicable. Additionally, the helical guide section 200 is deformed from its original helical configuration to a generally straight configuration so that the subsequent front-loading operation is not impeded by the resistance encountered while advancing the helical guide section 200 through the guidewire lumen 62 in the inner coil 56 of the torque member 52. The deformation is accomplished by elastically deforming the helical guide section 200 without plastically deforming it. If the guidewire is a superelastic guidewire, this deformation is accomplished by front loading the guidewire 46 through the guidewire lumen 62. If the guidewire 46 is a constrained recovery NiTi guidewire, this deformation can be accomplished by, for example, applying sufficient tension to the helical guide section 200 and drawing it through a makeshift die created by a user's thumb and forefinger which simultaneously apply a compressive force to straighten the helical guide section 200. In other words, the twinned martensite which is similar in shape to the parent austenite (i.e., helical) is converted into a deformed martensite which is generally straight.

The selected guidewire 46 is then front-loaded into the proximal end 40 of the catheter 32 and advanced until the straight distal end 202 exits from the distal end 72 of the torque member 52. See Fig. 10F. This front-loading step can also be omitted if the initial pilot guidewire GW is a NiTi guidewire 46 according to the present invention that has been mechanically deformed from its original helical configuration to a generally straight configuration, and which requires thermal inducement to recover its original helical configuration. During the front-loading step, the helical guide section 200 is generally straightened-out inside the guidewire lumen 62, as shown in Fig. 10F. Although the helical guide section 200 is not entirely straight when it extends inside the torque member 52, its pitch is significantly looser, and its diameter is significantly smaller, inside the torque member 52 than when it is deployed for use inside the blood vessel BV while lying outside the torque member 52.

e. Fifth Step -- Retraction of Catheter 32

The catheter 32 is now retracted until its distal end 38 is at the proximal extent of the occluding material OM. See Fig. 10G. At this time, if the guidewire 46 is a superelastic guidewire, the helical guide section 200 will have naturally assumed its maximum helical configuration, as constrained by the luminal wall of the pilot lumen PL. If the guidewire 46 is a constrained recovery NiTi guidewire, the helical guide section 200 is then heated above its austenite finish temperature Af so that it returns to its helical shape and diameter as constrained by the pilot lumen PL. The heating can be accomplished by bathing the helical guide section 200 in a physiologically inert fluid (e.g., saline, Ringer's Solution, etc.) that is introduced via the lumen of the guide catheter, or by passing current through the guidewire 46 from its proximal end 204 according to one of the techniques described above.

In either case, the helical guide section 200 now assumes a helical diameter which is defined by the diameter of the pilot lumen PL, in which the helical turns of the helical guide section 200 will be adjacent to, or abut, the occluding material OM. Thus, as shown in Fig. 10G, the helical guide section 200 adapts to the diameter of the pilot lumen PL and the nature (e.g., configuration) of the occluding material OM by positioning its helical turns adjacent to, or abutting, the occluding material OM.

f. Sixth Step - First Pass of Removal Mechanism 54

The distal end 38 of the catheter 32, and the removal mechanism 54, are now advanced over the helical guide section 200. The removal mechanism 54 is rotated during the advancement of the catheter 32 while the guidewire 46 is maintained at the same axial position in the luminal passageway LP. The helical guide section 200 guides the removal mechanism 54 along a helical path that will cause the removal mechanism 54 to engage the occluding material OM. Referring to Fig. 10H, the ability of the helical guide section 200 to conform to the dimensions and nature of the pilot lumen PL and the occluding material OM positions and maintains the removal mechanism 54 in apposition with the luminal wall of pilot lumen PL. Therefore, the removal mechanism 54 is held off-axis with respect to the pilot lumen PL, and at any given axial position within a single wavelength along the helical guide section 200, the removal mechanism 54 is not coplanar with any previous or subsequent axial position along the helical guide section 200. In addition, the pitch of the helical guide section 200 will be looser, and the diameter of the helical guide section 200 will be smaller since the diameter of the pilot lumen PL constrains the guidewire GW and is relatively small compared to the subsequent lumens that are to be created.

The removal mechanism 54 follows the helical path of the helical guide section 200 as it is guided therealong. However, the portions of the helical guide section 200 that are proximal to the removal mechanism 54 become straightened, as best illustrated in Fig. 10H. When the distal end 38 of the catheter 32 reaches the distal-most extent of the occluding material OM, a helical channel HC of occluding material OM will have been removed. See Fig. 10I.

g. Seventh Step - Retract the Removal Mechanism 54 and Axially Translate the Guidewire 46

At this point, the catheter 32 and its removal mechanism 54 are retracted proximally, while the guidewire 46 is maintained at the same axial position in the luminal passageway LP, until the distal end 38 of the catheter 32 is proximal to the occluding material OM. At this time, the helical guide section 200 will again conform itself to the dimension and nature of the existing lumen (which now has one helical channel cut into the occluding material OM and the occluding material.

The guidewire 46 is then repositioned by retracting or advancing it axially by a distance approximate to the width of the helical channel HC, which is equivalent to the axial length of the shearing or cutting aspect of the removal mechanism 54 defined by the proximal cutting edges 76. Again, the helical guide section 200 will conform itself to the dimension and nature of the existing lumen and the occluding material with respect to its new axial position inside the lumen. See Fig. 10J.

h. Eighth Step - Subsequent Passes of Removal Mechanism 54 To Create a Larger Occlusion Passageway OP

The removal mechanism 54 is now rotatably advanced again over the helical guide section 200 according to the manner described in the Sixth Step above, to cut another helical channel HC that is confluent with the previously-removed helical channel HC. See Fig. 10K. The seventh and eighth steps are continually repeated until all the removed helical channel HC coalesce and create a larger occlusion passageway OP whose diameter is approximately the same as the maximum helical diameter of the helical guide section 200.

i. Ninth Step - Create One or More Larger Occlusion Passageways OP

If necessary, it is possible to create one or more progressively-larger occlusion passageways. If the existing guidewire 46 is a superelastic guidewire or a constrained NiTi guidewire (without proportional control), then this existing guidewire 46 may be exchanged for another guidewire 46 having a larger-diameter helical guide section 200. The larger-diameter helical guide section 200 of the new guidewire 46 will conform itself to the dimension and nature of the existing lumen OP (which now has a greater diameter than the pilot lumen PL) and the occluding material OM. Again, the ability of the helical guide section 200 to conform to the dimensions and nature of the occlusion passageway OP and the occluding material OM positions and maintains the removal mechanism 54 in apposition with the luminal wall of occlusion passageway OP. The third through eighth steps described above may be repeated to create a larger occlusion passageway OP. See Fig. 10L.

Subsequent guidewires 46 having larger-diameter helical guide sections 200 can be exchanged, and the third through eighth steps described above may be

repeated to create increasingly larger occlusion passageways OP, until it is determined that a sufficiently large treated passageway TP has been created. See Fig. 10M. As part of this determination, the physician will consider achieving a treated passageway TP size that is approximately equal to the size of the luminal passageway LP, as well as the relative position and diameter of an implanted stent S, if applicable. The procedure can now be terminated by withdrawing the catheter 32, the guidewire 46, and the guide catheter.

In carrying out the steps of this method, the system 30 and the described method of the present invention are well-suited to protecting the integrity of any stent S that may be implanted in the treated region of the blood vessel BV. This is due in part to the fact that a guidewire 46 can be selected with a helical guide section 200 that is matched to the inner diameter of the stent S to avoid cutting or damaging the stent S.

The ability of the helical guide section 200 to conform to the dimensions and nature of the luminal passageway LP and the occluding material OM allow the removal mechanism 54 to be used safely with occluding material OM that is not consistent in nature. For example, the forces or stress exerted by the helical guide section 200 on the luminal wall are highest in the most constrained cross-sections (i.e., in the passageways having the smallest diameters). In the immediate areas of the constrained cross-section (or areas with a greater volume of occluding material OM), the removal mechanism 54 is more forcibly directed (by the helical guide section 200) in an outward direction and therefore takes a deeper cut of the occluding material OM. The deeper cut allows that portion of the cross-section to "catch up" with the other less constraining portions (or areas with a smaller volume of occluding material OM) to generally create a neolumen which gradually takes on a more regular and circularly symmetrical shape. As the lumen is enlarged by subsequent passes of the removal mechanism 54, a progressively lesser force will be exerted by the helical guide section 200 against the luminal wall.

7. A Second Method of Use

The method of use illustrated in connection with Figs. 10A-10M can be modified if the guidewire 46 is a constrained recovery NiTi guidewire with proportional control.

According to this modified method, in the First step, the guidewire GW initially introduced is a constrained recovery NiTi guidewire with proportional control

that has already been deformed from its original helical configuration to a generally straight configuration according to the methods disclosed in connection with the Fourth step above. As a result, the Third and Fourth steps are omitted. In the Fifth step, the heat applied to the helical guide section 200 is titrated to cause the helical guide section 200 to re-acquire a helical configuration, but not the maximum helical diameter. Finally, in the Ninth step, instead of exchanging the existing guidewire 46 with other guidewires 46 having progressively larger helical sections 200, the heat applied to the helical guide section 200 is carefully titrated to cause the helical guide section 200 to progressively re-acquire (i.e., in a step-wise manner) its maximum helical configuration. Thus, only one guidewire 46 is needed for the procedure.

Thus, the present invention provides a system 30 and methods that are effective in separating, removing and extracting occluding material from a body lumen. The helical guide section 200 of the guidewire 46 allows the removal mechanism 54 to create a passageway in occluding material OM that is diametrically larger than the dimension of the removal mechanism 54. The provision of the guidewire 46 and its helical guide section 200 also allows the physician to carefully select a helical guide section 200 with the optimum size (or diameter) to avoid injuring the luminal wall of the vessel, or damaging an implanted stent. This ability to select the size of the luminal passageway to be created allows the system 30 and methods of the present invention to be used in a wide variety of applications, patients and conditions. The system 30 and methods of the present invention are also simple to use.

Although the guidewire 46 of the present invention, and its guide section 200, has been described for use with a removal mechanism, it is also possible to use the guidewire 46 and its guide section 200 together with catheters or probes in other applications, such as but not limited to diagnostic (e.g., intravascular ultrasound imaging, angioscopy, fluoroscopy), energy delivery (e.g., laser, cryogenics, radiation, photodynamic therapy, brachytherapy, ultrasound angioplasty), cutting (e.g., directional coronary atherectomy catheters, transluminal extraction catheters), ablation (e.g., rotational atherectomy catheters), thrombectomy, selective biopsy, and drug delivery. In this regard, the guide section 200 can provide effective stabilization for an associated device when used, for example, in angioscopy, ultrasound imaging, and monitoring arteries in critical care applications (e.g., measuring pressure and flow measurements, and oximetry).

The present invention further provides kits for performing the methods of the present invention, as illustrated in Fig. 11. The kits comprise catheters 300 having cutting tips 302, guidewires 304 as described above, and instructions for use 306 setting forth the methods for using the catheters in combination with the guidewires. the kit components will usually be packaged together in a conventional package 310, such as a pouch, box, tube, tray, or the like, which will usually be sterilized. The instructions 306 may be in the form of a package insert (as illustrated), or may be printed in whole or in part on the package 310 itself.

While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention.

WHAT IS CLAIMED IS:

1. A guidewire for use in guiding another device to desired locations within a body lumen, the guidewire comprising:

a generally straight proximal section, and a guide section which defines a curved three-dimensional profile that is diametrically larger than the diameter of the proximal section, the guide section providing a curved path along which another device can be advanced, the guide section being made from a shape memory material having sufficient flexibility to assume a generally straightened configuration when the guide section is extended through a lumen of a guiding member associated with the another device or catheter.

2. The guidewire of claim 1, wherein the guide section is made from a material that remains in its elastic or superelastic state when the guide section extends through a lumen of a guiding member associated with the another device or catheter.

3. The guidewire of claim 1 or 2, further including a generally straight distal section extending distally from the guide section, wherein the straight proximal section extends proximally from the guide section, and wherein the distal and proximal sections of the guidewire extend along the same longitudinal axis.

4. The guidewire of claim as described in all preceding claims, wherein the guide section is expandable, or can be configured to exert a radially outward force against a luminal wall of a lumen into which it is positioned.

5. The guidewire as described in all proceeding claims wherein the guide section is expandable to a diameter between 0.5 mm and 20 mm, with a preferable operating diameter between 1 mm and 6 mm.

6. The guidewire as described in all proceeding claims wherein the guide section has either a helical configuration or a polygonal configuration to provide a helical or polygonal path for a catheter tracking over it.

7. The guidewire as described in all proceeding claims wherein the guidewire has a taper, being wider in diameter at its proximal end, and narrower in

diameter at its distal end, the taper being either gradual and continuous from any one point along the length of the guide wire to the distal end, or a plurality of steps starting at any one point along the length of the guidewire to the distal end.

8. The guidewire as described in all proceeding claims wherein the guide section has a core which is made of a superelastic material having a tensile strength of at least X, and the core being between 0.002" and 0.01" in diameter.

9. The guidewire as described in all proceeding claims wherein the guide section has a core which is made primarily of nickel-titanium or a super elastic material.

10. The guidewire as described in all proceeding claims wherein the guide section of the guidewire is provided with lead attachments for delivering heat to the guide section and a means for measuring the temperature gradient across the guide section, such as thermisters or thermocouples.

11. The guidewire as described in all proceeding claims wherein the guide section has a tapered helical configuration or a uniform helix throughout, or a step between adjacent helixes, or a stepped configuration.

12. The guidewire as described in all the proceeding claims wherein the outward radial force of the guide section can be increased by any combination of the following; increasing the diameter of the core wire of the guide section, increasing the unconstrained radial diameter of the guide section, reducing the spacing between the helical winds of the guide section, or adjusting the alloying constituents of the shape memory material used in the guide section.

13. The guidewire of all the preceding claims wherein the shape memory material of the guide section has a transition temperature above 10 degrees centigrade and exists in the austenite phase of the shape memory material when the guide section is at zero percent (0%) induced strain.

14. A system, comprising:

a catheter having a distal end, a proximal end, and a lumen extending longitudinally there through;

a torque member extending longitudinally through the lumen of the catheter, and having a lumen and a distal end;

a removal mechanism secured to the distal end of the torque member; and

a first guidewire.

15. The system of claim 14, further including:

a second guidewire defines a curved three-dimensional profile that is diametrically larger than the dimension of the guide section of the first guidewire.

16. The system of claim 14, wherein the torque member comprises a three layer composite of PTFE wrapped in a wire braid under a polyimide layer, the three layer composite being wrapped by an inner coil, a middle coil secured over the inner coil, and an outer coil secured over the middle coil.

17. The system of claim 16, wherein the inner, middle and outer coils all have helical configurations, with the inner coil having a helical winding direction that is different from the helical winding direction of the middle coil, and the outer coil has a helical winding direction that is different from the helical winding direction of the middle coil so that the inner coil has a helical winding direction that is substantially opposite from the helical winding direction of the middle coil so that when the torque member is rotated in one direction, the middle coil attempts to become diametrically smaller and the inner coil attempts to become diametrically larger, thereby creating a rotational engagement between the middle and inner coils.

18. The system of claim 16, wherein the torque member has a distal end, and the removal mechanism is secured to the distal end of the torque member.

19. The system of claim 16, wherein the lumen of the catheter has a luminal wall, and wherein the luminal wall and the outer coil define a conveyor mechanism for extracting separated occluding material, the outer coil forming a plurality of helical flutes which operate as a screw pump to remove occluding material.

20. The system of claim 19, further including a collection reservoir coupled to the proximal end of the catheter and communicating with the lumen of the catheter to receive occluding material that has been extracted by the conveyor

mechanism, alternatively a suction pump may be coupled to the collection reservoir for aspirating occluding material.

21. The system of claim 14, further including a hand-held device coupled to the proximal end of the catheter and having a lumen communicating with the lumen of the catheter, with the torque member extending longitudinally through the lumen of the hand-held device, the hand-held device further including a motor for rotating the torque member.

22. The system of claim 14, wherein the removal mechanism comprises at least one helical turn wrapped around the torque member, the helical turn having a leading cutting edge and extending beyond the distal end of the catheter.

23. The system of claim 14, wherein the removal mechanism comprises a cylindrical shaft having a distal end and a lumen, with the torque member received inside the lumen of the shaft, the removal mechanism having a widened annular cutting edge provided at the distal end of the shaft, and a plurality of scraping surfaces communicating with the annular cutting edge for breaking up excised occluding material.

24. The system of claim 23, wherein the removal mechanism is housed inside a housing, the housing having a proximal end affixed to the distal end of the catheter, and a cutting window through which a portion of the annular cutting edge extends to cut occluding material.

25. The system of claim 14, wherein the removal mechanism comprises a cylindrical shaft having a distal end and a lumen, with the torque member received inside the lumen of the shaft, the removal mechanism having a rotary burr provided at the distal end of the shaft.

26. The system of claim 14, wherein the removal mechanism comprises a cutter housing inside which the torque member is housed, with the distal end of the torque member affixed to the housing, the cutter housing having a side window which defines at least one cutting edge.

27. The system of claim 14, further including a bearing assembly for coupling the removal mechanism to the distal end of the catheter, the bearing assembly

coupled to the distal end of the catheter and to the removal mechanism to allow for rotation of the removal mechanism, and to prevent axial translation of the removal mechanism relative to the catheter.

28. The system of claim 27, wherein the bearing assembly has a shell member coupled to the distal end of the catheter and a snap ring coupled to the removal mechanism to allow for rotation of the removal mechanism, and with the snap ring fitted inside the shell member to prevent axial translation of the snap ring and the removal mechanism.

29. The system of claim 28, wherein the shell member has a cylindrical body having an annular distal lip that extends radially inwardly, and a proximal ramp that ramps radially inwardly to form a cylindrical barbed section which has a diameter that is smaller than the diameter of the cylindrical body.

30. The system of claim 29, wherein the snap ring has a cylindrical body having an inner surface, and a rib extending circumferentially about the inner surface, the snap ring further including a longitudinal slit provided along the cylindrical body to allow the cylindrical body to be compressed and radially expanded.

31. The system of claim 30, wherein the removal mechanism has a circumferential groove, and wherein the rib is fitted inside the circumferential groove.

32. The system of claim 28, wherein the snap ring is seated inside the shell between the distal lip and the ramp.

33. The system of claim 14, wherein the guide section of the guidewire is provided with a lead attachment for delivering heat to the guide section, and either thermocouples or thermistors for measuring the temperature gradient across the guide section.

34. A system, comprising:

a catheter having a distal end, a proximal end, and a lumen extending longitudinally there through;

a torque member extending longitudinally through the lumen of the catheter, and having a distal end;

a removal mechanism secured to the distal end of the torque member, the removal mechanism defining a lumen;

a first guidewire having a guide section that extends through the lumen of the removal mechanism, and which defines a curved profile that is diametrically larger than the dimension of the removal mechanism, the guide section providing a curved path along which the removal mechanism can be advanced; and

a second guidewire that can be used in place of the first guidewire, the second guidewire having a guide section that extends through the lumen of the removal mechanism, and which defines a curved profile that is diametrically larger than the dimension of the guide section of the first guidewire, the guide section of the second guidewire providing a curved path along which the removal mechanism can be advanced.

35. The system of claim 34, wherein each of the guide sections of the first and second guidewires is configured to exert a radially outward force against a luminal wall of a lumen into which it is positioned.

36. The system of claim 35, wherein each of the guide sections of the first and second guidewires has a helical configuration to provide a helical path for the removal mechanism.

37. A method of treating a region of occluding material in a body lumen, comprising:

a. introducing a guidewire into the body lumen and through the region of occluding material;

b. introducing a catheter over the guidewire, the catheter having a removal mechanism disposed at its distal end;

c. creating an initial pilot lumen through the occluding material;

d. retracting the catheter and removal mechanism to a position along the guidewire that is proximal to the occluding material;

e. providing a guide section in the guidewire having a curved profile that is diametrically larger than the dimension of the removal mechanism;

f. advancing the removal mechanism along the guide section to separate occluding material leaving a curved channel therein;

g. retracting the catheter and removal mechanism to a position along the guidewire that is proximal to the occluding material;

h. axially translating the guide section of the guidewire within the occluding material; and

i. advancing the removal mechanism along the guide section to separate occluding material that is confluent with the first curved channel in the occluding material.

38. The method of claim 37, further including the steps of:

j. retracting the catheter and removal mechanism to a position along the guidewire that is proximal to the occluding material;

k. axially translating the guide section of the guidewire within the occluding material;

l. advancing the removal mechanism along the guide section to separate and remove a third curved channel in the occluding material that is confluent with the first and second curved channels in occluding material; and

m. repeating steps (j) through (l) until all confluent channels in the occluding material have been removed to create a new larger-diameter luminal passageway.

39. The method of claim 37, further including the steps of:

j. retracting the catheter and removal mechanism to a position along the guidewire that is proximal to the occluding material;

k. increasing the dimension of the guide section of the guidewire; and

l. advancing the removal mechanism along the guide section to separate and remove a third curved channel of occluding material which has a larger diameter than the first curved channel in the occluding material.

40. The method of claim 39, wherein step (k) includes the step of applying heat to the guide section of the guidewire.

41. The method of claim 37, further including the steps of:

j. advancing the catheter and removal mechanism to a position along the guidewire that is distal to the occluding material;

k. exchanging the guidewire with a second guidewire having a guide section with a larger dimension than the guide section of the removed guidewire;

l. retracting the catheter and removal mechanism to a position along the guidewire that is proximal to the occluding material; and

m. advancing the removal mechanism along the guide section of the second guidewire to separate and remove a third curved channel in the occluding material which has a larger diameter than the first curved channel in the occluding material.

42. The method of claim 37, wherein step (e) includes the step of providing the guide section with a helical configuration.

43. The method of claim 42, wherein step (e) further includes the step of providing the guide section of the guidewire in the form of a nickel-titanium alloy.

44. The method of claim 37, wherein step (e) further includes the step of causing the guide section to exert a radially outward force against the pilot lumen.

45. The method of claim 37, wherein step (e) further includes the step of providing the guide section from a shape memory material having sufficient flexibility to assume a generally straightened configuration when the guide section extends through a lumen of the torque member.

46. The method of claim 37, wherein step (e) further includes the step of providing the guide section from a material that remains in its elastic state when the guide section extends through a lumen of the torque member.

47. A method of treating a region of occluding material in a body lumen, comprising the steps of:

a. introducing a first guidewire into the body lumen and through the region of occluding material;

b. introducing a catheter over the first guidewire, the catheter having a removal mechanism disposed at its distal end;

c. creating an initial pilot lumen through the occluding material;

d. removing the first guidewire;

e. introducing a second guidewire through a lumen of the catheter, the second guidewire having a guide section with a curved profile that is diametrically larger than the dimension of the removal mechanism;

f. retracting the catheter and removal mechanism to a position along the second guidewire that is proximal to the occluding material;

g. advancing the removal mechanism along the guide section to separate and remove a first curved channel in the occluding material;

h. retracting the catheter and removal mechanism to a position along the second guidewire that is proximal to the occluding material;

i. axially translating the guide section of the second guidewire within the occluding material; and

j. advancing the removal mechanism along the guide section to separate and remove a second curved channel in the occluding material that is confluent with the first curved channel in the occluding material.

48. The method of claim 47, further including the steps of:

k. axially translating the guide section of the second guidewire within the occluding material; and

l. advancing the removal mechanism along the guide section to separate and remove a third curved channel in the occluding material that is confluent with the first and second curved channels in the occluding material.

49. The method of claim 47, further including the steps of:

k. retracting the catheter and removal mechanism to a position along the second guidewire that is proximal to the occluding material;

l. increasing the dimension of the guide section of the second guidewire; and

m. advancing the removal mechanism along the guide section to separate and remove a third curved channel in the occluding material which has a larger diameter than the first curved channel in the occluding material.

50. The method of claim 49, wherein step (l) includes the step of applying heat to the guide section of the second guidewire.

51. The method of claim 47, further including the steps of:

k. retracting the catheter and removal mechanism to a position along the second guidewire that is proximal to the occluding material;

l. exchanging the second guidewire with a third guidewire having a guide section with a larger dimension than the guide section of the second guidewire; and

m. advancing the removal mechanism along the guide section of the third guidewire to separate and remove a third curved channel of occluding material which has a larger diameter than the first curved channel of occluding material.

52. The method of claim 47, wherein step (e) includes the step of providing the guide section with a helical configuration.

53. The method of claim 52, wherein step (e) further includes the step of providing the guide section of the second guidewire in the form of a nickel-titanium alloy.

54. The method of claim 52, wherein step (e) further includes the step of providing the guide section of the second guidewire in the form of a superelastic material.

55. The method of claim 47, wherein step (f) further includes the step of causing the guide section to exert a radially outward force against the pilot lumen.

56. The method of claim 47, wherein step (e) further includes the step of providing the guide section from a shape memory material having sufficient flexibility to assume a generally straightened configuration when the guide section extends through a lumen of the torque member.

57. The method of claim 47, wherein step (e) further includes the step of providing the guide section from a material that remains in its elastic state when the guide section extends through a lumen of the torque member.

58. A method of treating a region of occluding material in a body lumen, comprising the steps of:

a. creating an initial pilot lumen through the occluding material;

b. introducing into the pilot lumen a guide mechanism having a curved profile which positions portions of the guide mechanism adjacent the occluding material; and

c. advancing a removal mechanism along the guide mechanism to separate and remove a first plurality of generally confluent curved channels to form a first passageway through the occluding material which is diametrically larger than the pilot lumen.

59. The method of claim 58, further including the step of:

d. further advancing a removal mechanism along the guide mechanism to separate and remove a second plurality of generally confluent curved channels to form a second passageway through the occluding material which is diametrically larger than the first passageway.

60. The method of claim 59, wherein step (d) further includes the step of:

d1. increasing the dimension of the curved profile of the guide mechanism to position portions of the guide mechanism adjacent the occluding material.

61. The method of claim 58, wherein step (c) further includes the steps of:

c1. advancing a removal mechanism along the guide mechanism to separate and remove a first curved channel;

c2. axially translating the guide mechanism within the pilot lumen; and

c3. advancing a removal mechanism along the guide mechanism to separate and remove a second curved channel which is confluent with the first curved channel.

62. The method of claim 58, wherein step (b) further includes the step of providing the curved profile with a helical configuration.

63. The method of claim 58, wherein step (b) further includes the step of causing the guide mechanism to exert a radially outward force against the pilot lumen.

64. The method of claim 58, wherein step (b) further includes the step of providing the guide mechanism from a shape memory material having sufficient flexibility to assume a generally straightened configuration when the guide mechanism extends through a lumen of a torque member.

65. The method of claim 58, wherein step (e) further includes the step of providing the guide mechanism from a material that remains in its elastic state when the guide mechanism extends through a lumen of a torque member.

66. A system comprising:

(a) a catheter including:

a catheter body having a proximal end, a distal end, and a lumen there through; and

a cutting mechanism at the distal end of the catheter body for excising material and directing it to the lumen; and

(b) a guidewire defining a curved path, wherein the catheter body can be advanced over the guidewire to deflect the cutting mechanism over the curved path.

67. A system as in claim 66, wherein the cutting mechanism has a width which is no more than 1.2 times a width of the catheter body at its distal end.

68. A system as in claim and of claims 66 and 67, wherein the cutting mechanism comprises a helical blade and a torque member disposed in the lumen of the catheter body.

69. A system as in claim 91, wherein the helical blade has a diameter no larger than 1.5 times a width of the catheter at its distal end.

70. A system as in claim 92, wherein the helical blade comprises a pair of blades arranged as a double helix and tapered toward the distal end.

71. An atherectomy catheter comprising:

a catheter body having a proximal end, a distal end, and a lumen there through;

a torque member having a proximal end, a distal end, and a lumen there through, said torque member being rotatably disposed in the catheter body lumen with an annular lumen between the torque member and catheter body lumen;

a helical blade assembly attached to the distal end of the torque member said assembly being tapered in the distal direction and having an interior which is open to the annular lumen in the catheter body.

72. An atherectomy catheter as in claim 71, wherein the helical blade assembly comprises at least two parallel helical blades.

73. An atherectomy catheter as in claim 72, further comprising a helical screw formed over at least a distal portion of the torque member.

74. An atherectomy catheter as in any of claims 71-73, further comprising means for applying a vacuum to the annular lumen and collecting material drawn proximally through said lumen.

75. A method for treating a region of the occluding material in a body lumen, said method comprising:

positioning a guidewire having at least one curve within the region, wherein the curve resiliently engages a peripheral portion of the region;

advancing a cutting blade over the guidewire to excise occluding material from the lumen.

76. A method as in claim 75, wherein positioning the guidewire comprises advancing a straight guidewire in the region and thereafter inducing the straight guidewire to assume a geometry having at least one curve.

77. A method as in claim 76, wherein the guidewire is heated to induce a phase change which causes the guidewire to assume a helical configuration.

78. A method as in claim 75, wherein advancing the cutting blade comprises rotating a helical blade.

79. A method as in claim 78, further comprising collecting excised material from an interior volume within the helical blade and removing the collected material from the body lumen.

80. A method for treating a region of occluding material in a body lumen, said method comprising:

introducing a guidewire through the region;

heating the guidewire to induce at least one curve; and

advancing a removal mechanism over the guidewire, wherein the curve engages the removal mechanism against a peripheral portion of the region.

81. A method as in claim 80, wherein the guidewire is a shape memory alloy and the heating step induces a phase change from martensitic to austenitic, wherein the austenitic phase has a curved shape.

82. A method as in claim 80, wherein the curve is a helix.

83. A method as in claim 80, wherein the advancing the removal mechanism comprises rotating a cutting blade.

84. A method as in claim 83, wherein rotating the cutting blade comprises rotating a tapered helical cutting blade.

85. A method for removing hyperplastic material from the interior of a stent within an artery, said method comprising:

positioning a helical guidewire within the stented region of the artery;

advancing a removal mechanism over the guidewire to create a helical channel in the hyperplastic material;

over the guidewire to create a helical channel in the hyperplastic material;

repeating the advancement of the removal mechanism over the guidewire a number of times sufficient to expose at least a portion of the stent.

86. A method as in claim 85, wherein positioning the guidewire comprises advancing a straight guidewire into the stented region and thereafter inducing the straight guidewire to assume a geometry having at least one curve.

87. A method as in claim 86, wherein the guidewire is heated to induce a phase change which causes the guidewire to assume a helical configuration.

88. A method as in claim 85, wherein advancing the removal mechanism comprises rotating a cutting blade.

89. A method as in claim 88, wherein rotating the cutting blade comprises rotating a tapered helical cutting blade.

90. A method as in claim 85, wherein the advancement step is repeated at least 2 times.

91. A method as in claim 85, wherein energy is transferred to the guidewire to increase its width between successive advancements of the removal mechanism.

92. A method of manufacturing a guidewire with a radially expansible guide section comprising the steps of:

(a) wrapping a core wire around a mandrel;

(b) securing the core wire about the mandrel;

(c) heating the mandrel assembly to a temperature between 300 degrees C and 800 degrees C;

(d) stopping the heating;

(e) cooling the mandrel assembly to room temperature; and

(f) unwrapping the core wire from the mandrel.

93. The method of manufacturing a guidewire as in claim 92 further comprising at least one of the steps of:

(g) coating the core wire with a biocompatible material;

(h) attaching a coil wire to the core wire; and

(i) providing an atraumatic tip at the distal end.

94. The method of claim 92, wherein said core wire has a tapered profile having a larger diameter at said proximal section and a narrower profile at said distal section.

95. The method of claim 92, wherein step (a) comprises a core wire composed at least partially of a shape memory material or shape memory alloy.

96. The method of claim 92, wherein step (a) comprises a core wire composed of nickel-titanium, or stainless steel with a shape memory material laminate coating, or stainless steel with a shape memory sandwich.

97. The method of claim 92, wherein step (a) comprises a core wire composed of at least one wire within a shape memory material matrix, said shape memory matrix being formed in particular to operate as a guidewire.

98. The method of claim 92, wherein step (a) further comprises said core wire segment wound around said mandrel having a diameter between 0.0005" and 0.020".

99. The method of claim 92, wherein step (a) further comprises winding the core wire about the mandrel such that the spacing between each wind is 1 to 3 mm.

100. The method of claim 92, wherein the mandrel of step (a) further comprises a helical channel about the mandrel for providing a predetermined shape setting, said channel having spacings between each wind from 1 mm to 3 mm with a mandrel minor diameter between 0.5 mm and 20 mm, and wherein the mandrel minor diameter is preferably 1 mm to 6 mm.

101. The method of claim 92, wherein step (a) further comprises ensuring the core wire is wound such that there is no slack in the wire coils.

102. The method of claim 92, wherein step (b) further comprises a means for securing the wire about the mandrel to assure the core wire does not unravel or slip.

103. The method of claim 92, wherein step (c) further comprises heating the mandrel assembly to a temperature between 450 and 550 degrees C.

104. The method of claim 103, wherein the mandrel assembly remains at temperature from 1 to 2 minutes.

105. The method of claim 92, wherein step (e) further comprises quenching the mandrel assembly.

106. The method of claim 92, further comprising coating the core wire with a laminate material for reducing the core wire's coefficient of friction.

107. The method of claim 92, further comprising attaching an atraumatic element to the core wire or the filament wire.

108. A mandrel for shape setting a wire having a radial expansible guide section comprising a temperature stable core, at least one screw thread having spaced apart roots capable of mechanically receiving a wire, said mandrel having at least one retaining device for securing said wire within said spaced apart roots and preventing said wire form slipping or shifting.

109. The mandrel of claim 108, wherein said mandrel has either a uniform or nonuniform minor diameter between 0.5 and 20 mm.

110. The mandrel of claim 108, wherein said mandrel has either a uniform or a nonuniform linear geometry.

111. The mandrel of claim 108, wherein the mandrel has a plurality of cross section geometry's.

112. The mandrel of claim 108, wherein said cross section geometry's are any combination of regular and irregular shapes.

113. The mandrel of claim 108, wherein the mandrel further comprises a minor diameter of 0.5 mm to 20 mm.

114. The mandrel of claim 108, wherein the pitch is between 0.001" and 0.5".

115. The mandrel of claim 108, wherein said mandrel is hollow.

116. The mandrel of claim 108, wherein said mandrel is either brass, stainless steel or a ceramic.

117. The mandrel of claim 108, wherein the retaining device is a screw or a tube slidably fit over said mandrel.

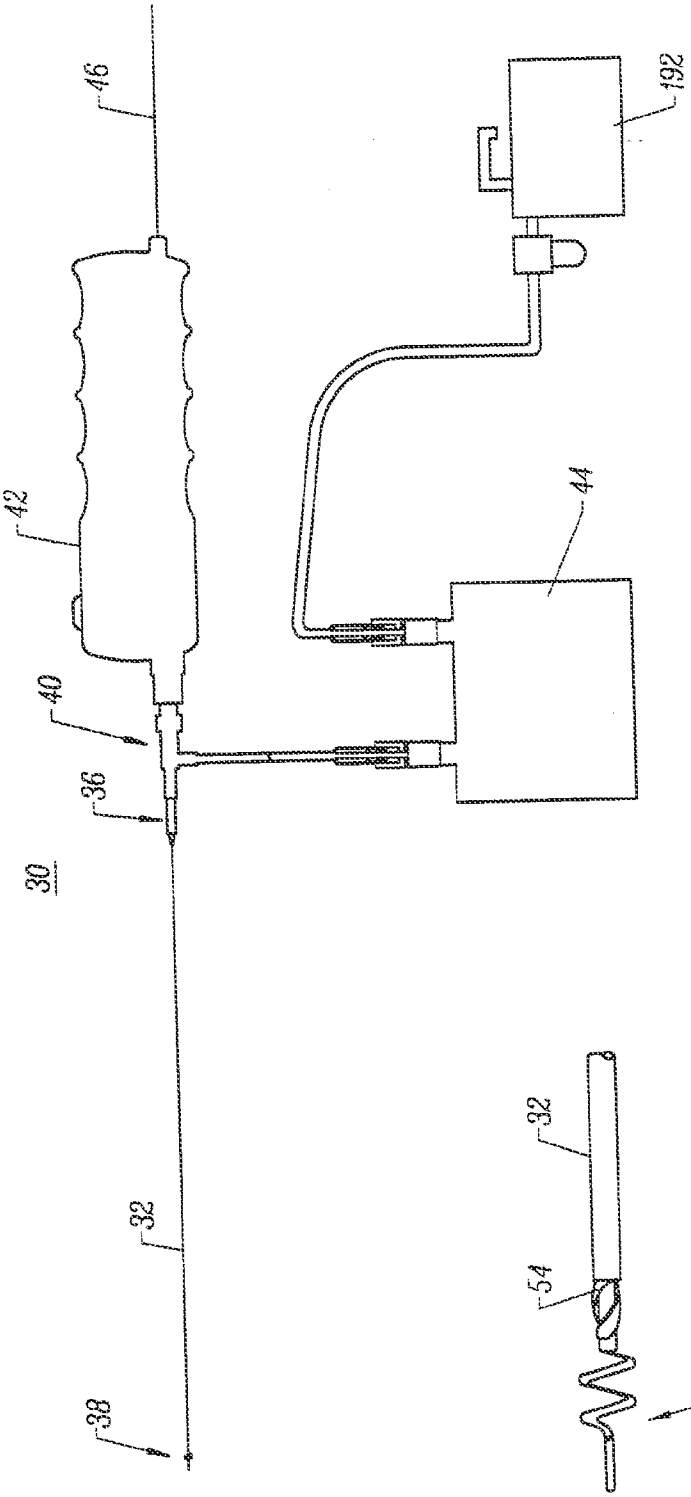

FIG. 1

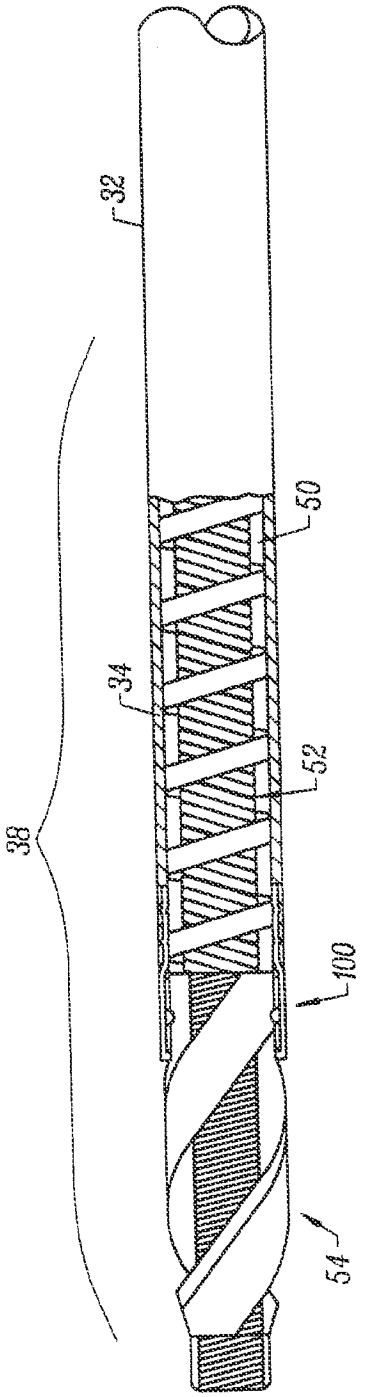

FIG. 2

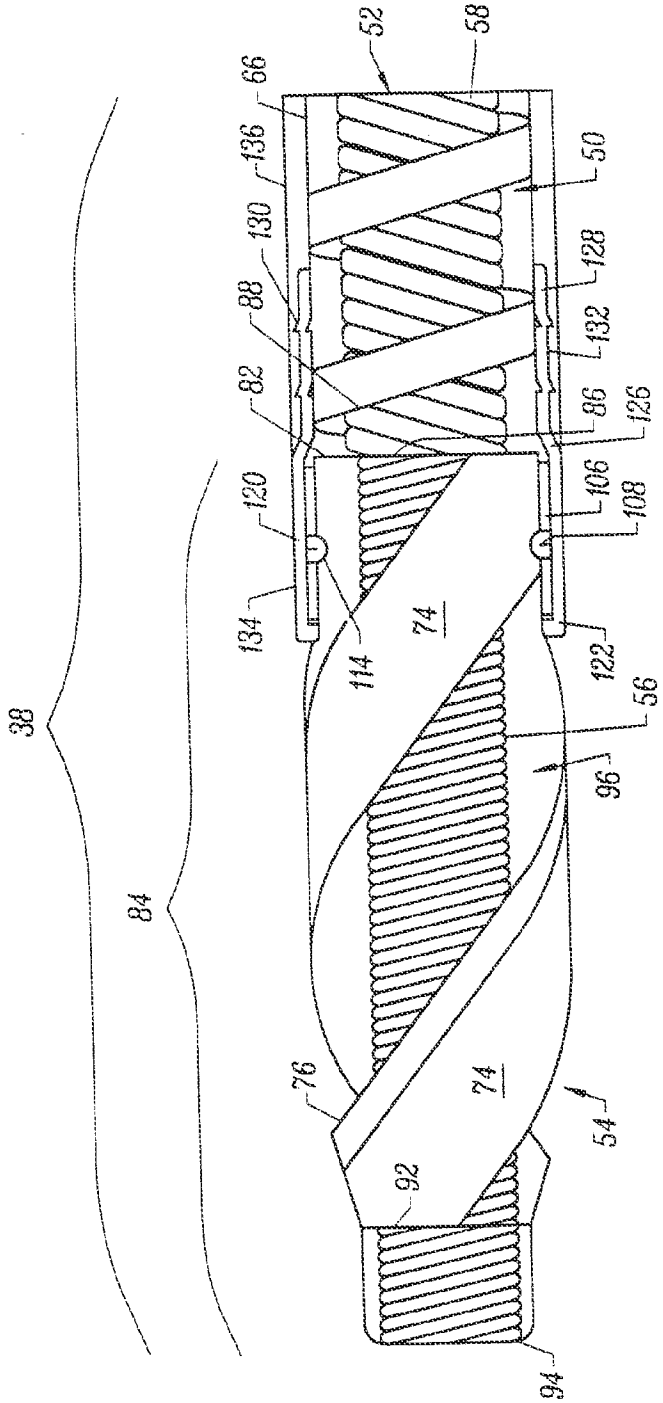
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FIG. 3

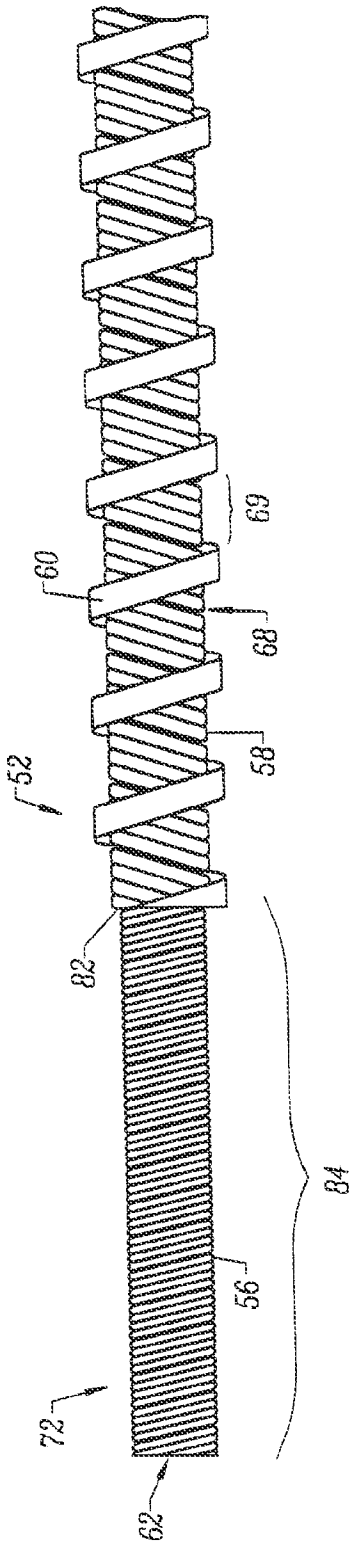

FIG. 4

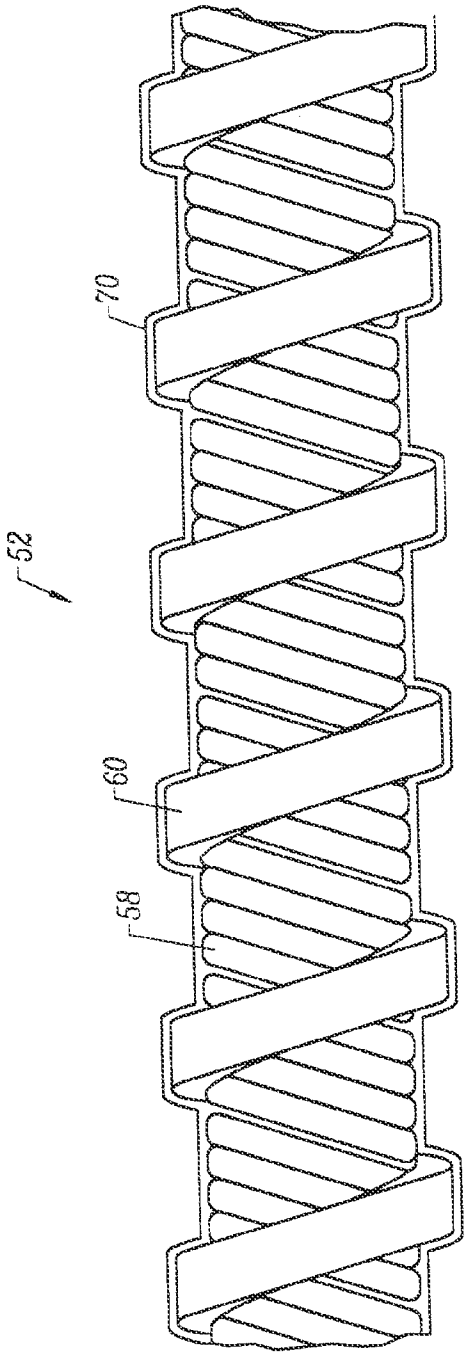

FIG. 4A

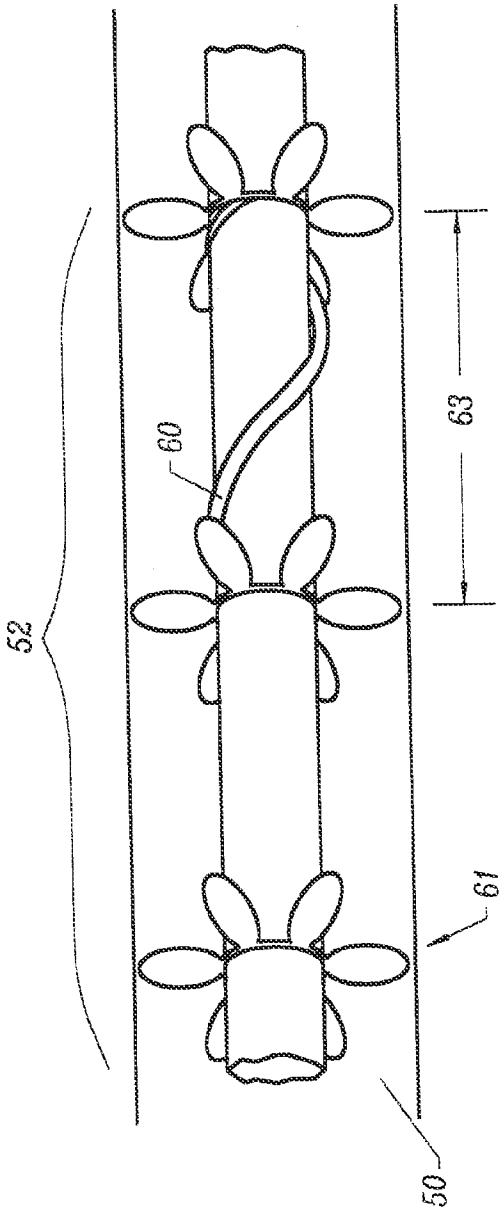

FIG. 4B

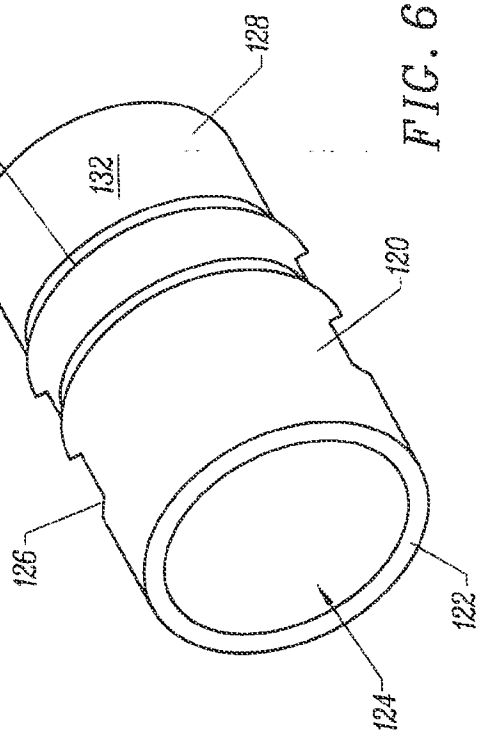

FIG. 6

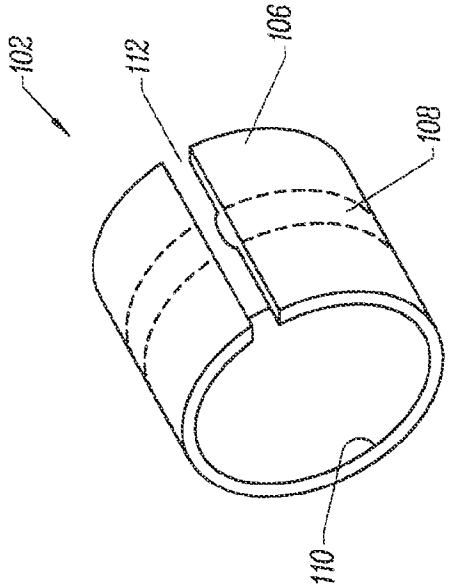

FIG. 5

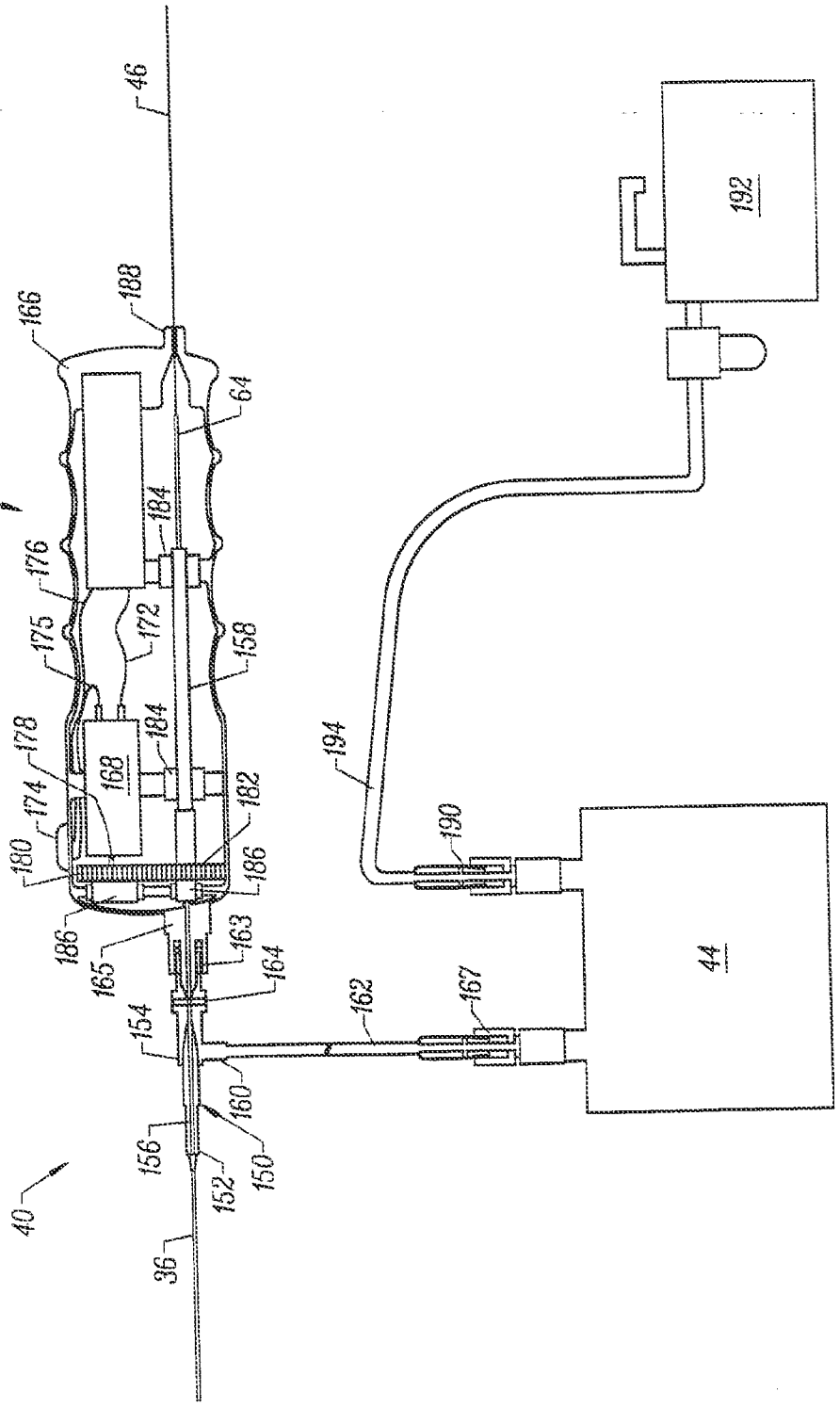
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FIG. 7

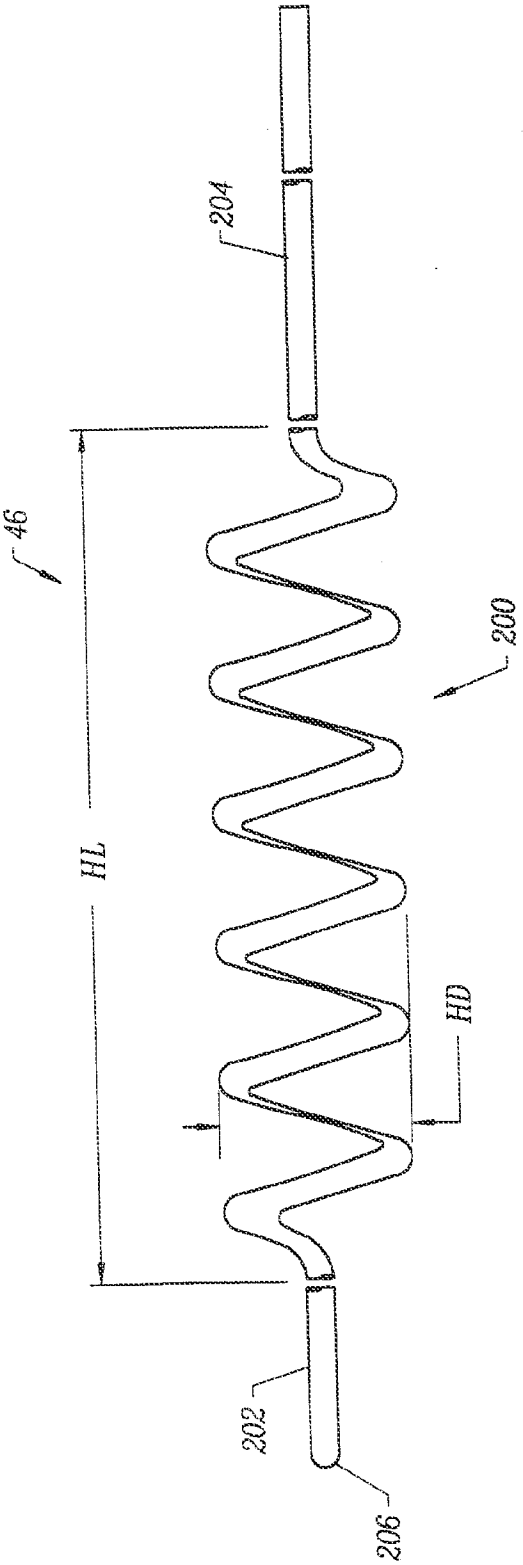

FIG. 8

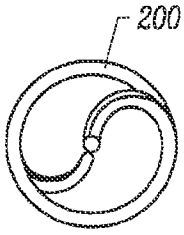

FIG. 8A

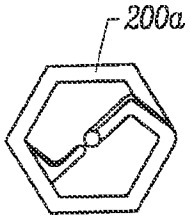

FIG. 8D

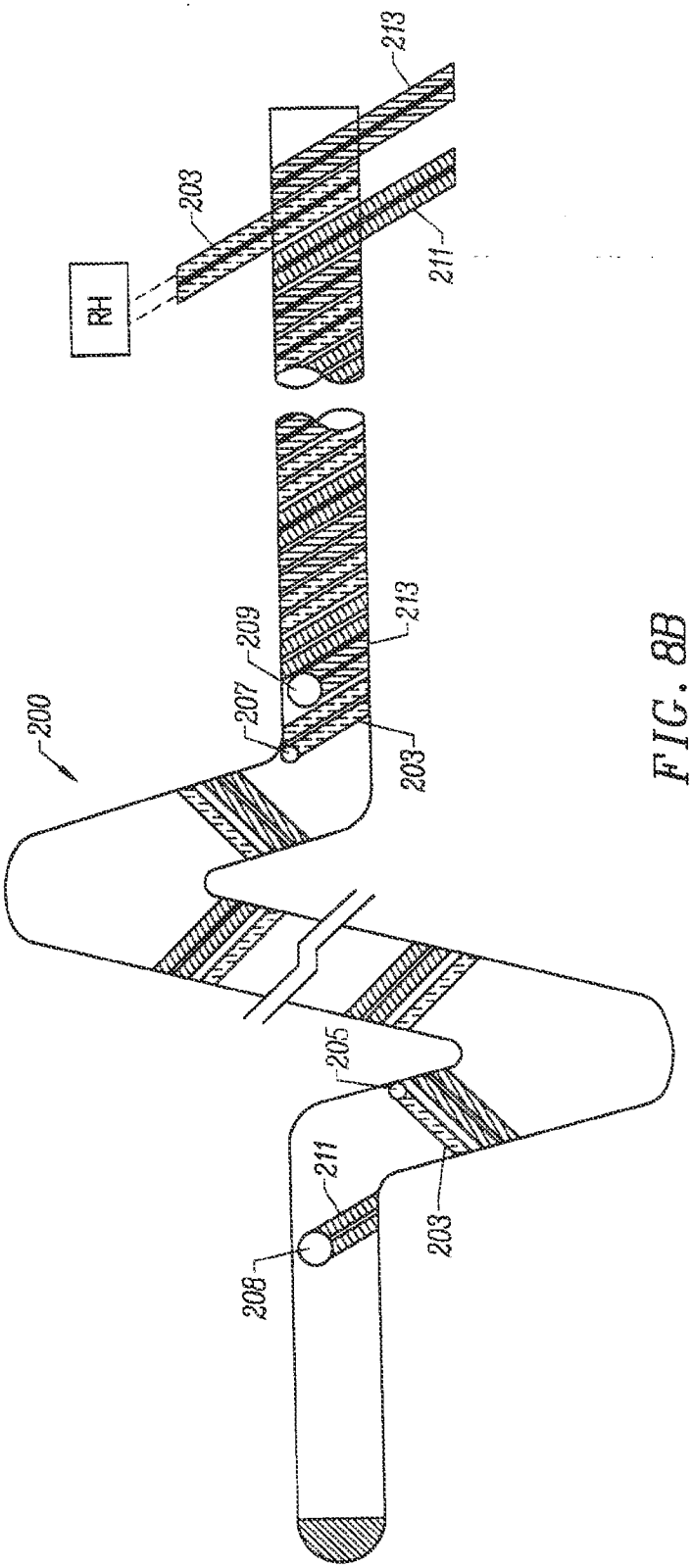

FIG. 8B

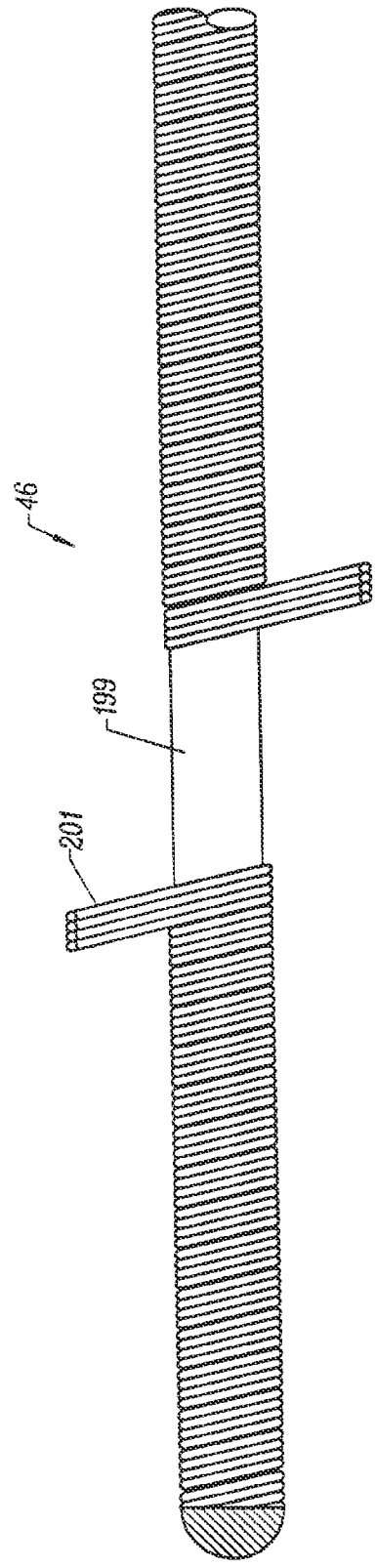

FIG. 8C

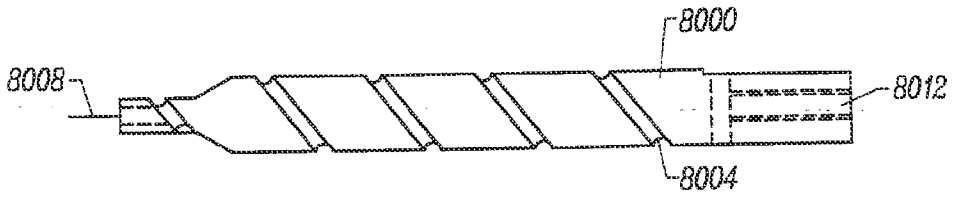

FIG. 8E

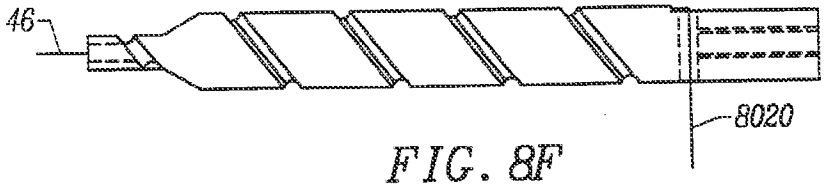

FIG. 8F

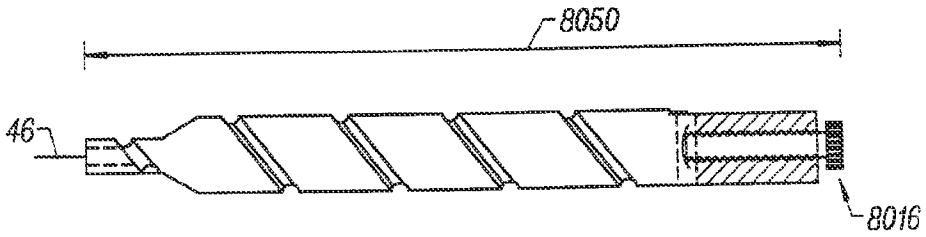

FIG. 8G

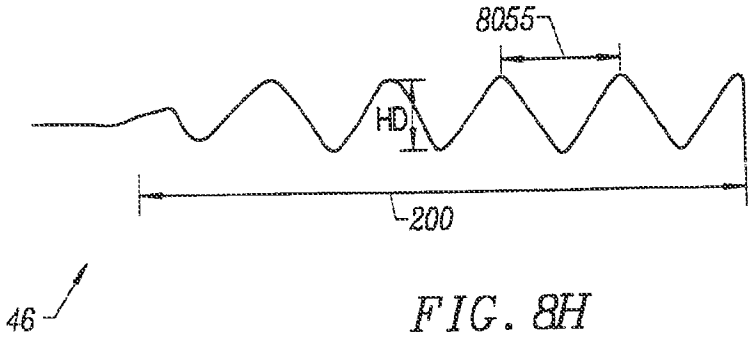

FIG. 8H

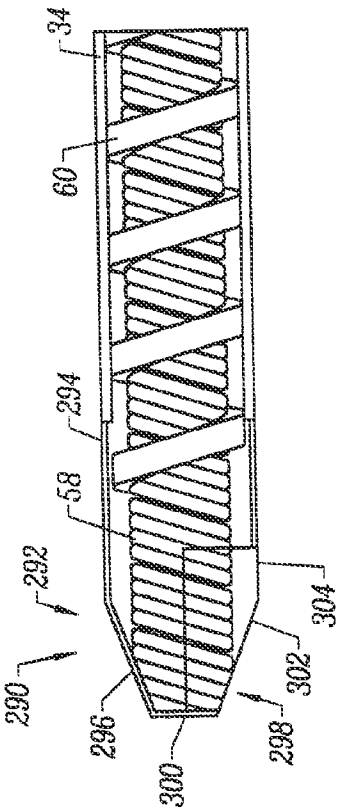

FIG. 9D

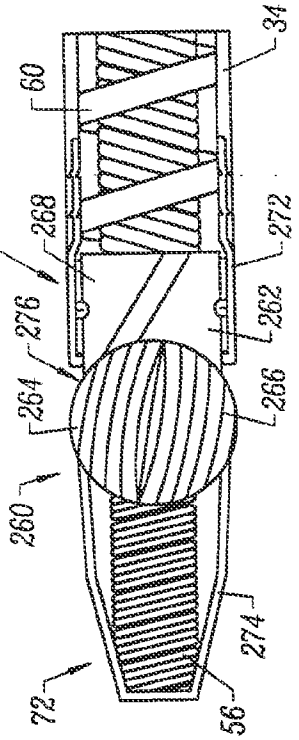

FIG. 9C

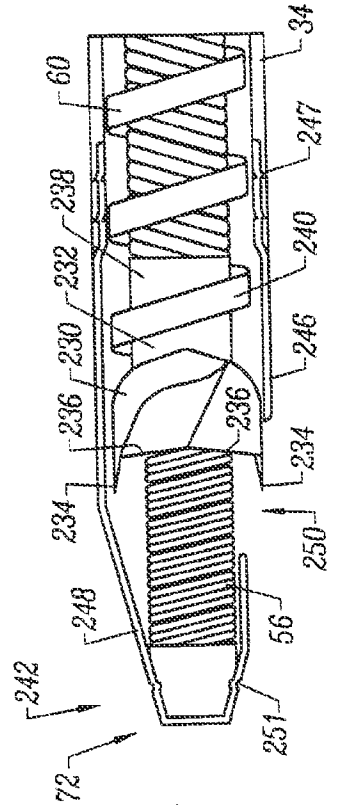

FIG. 9B

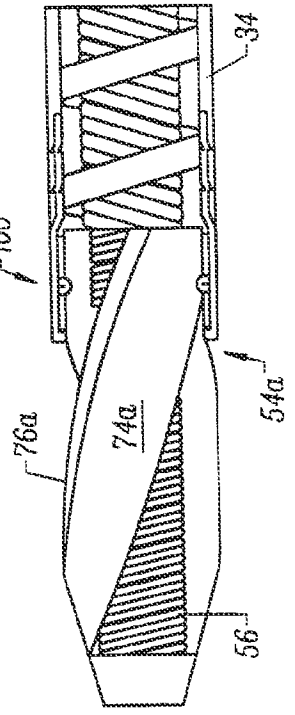

FIG. 9A

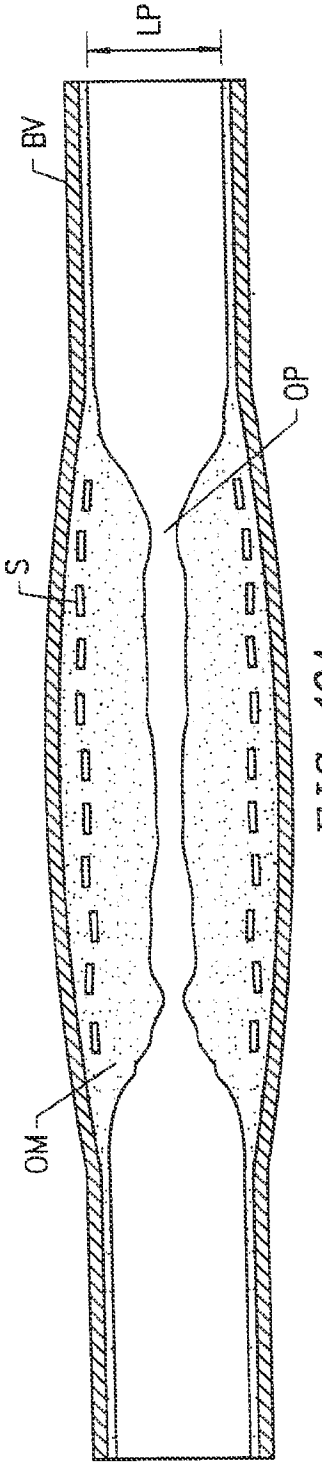

FIG. 10A

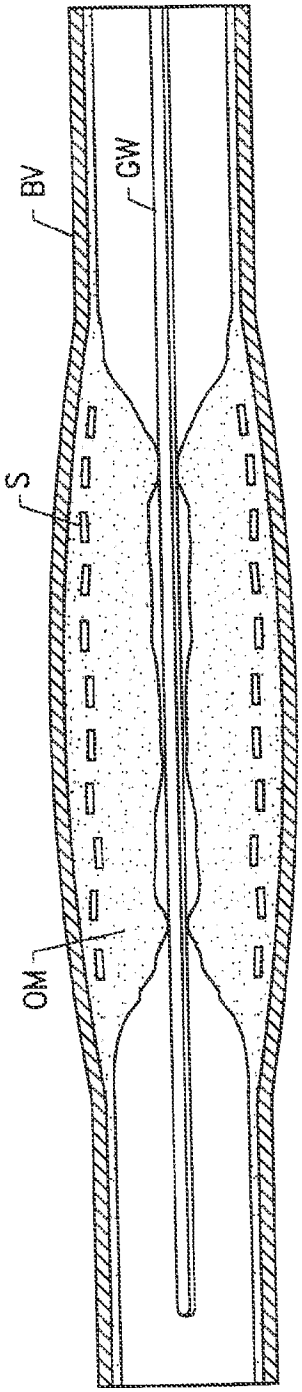

FIG. 10B

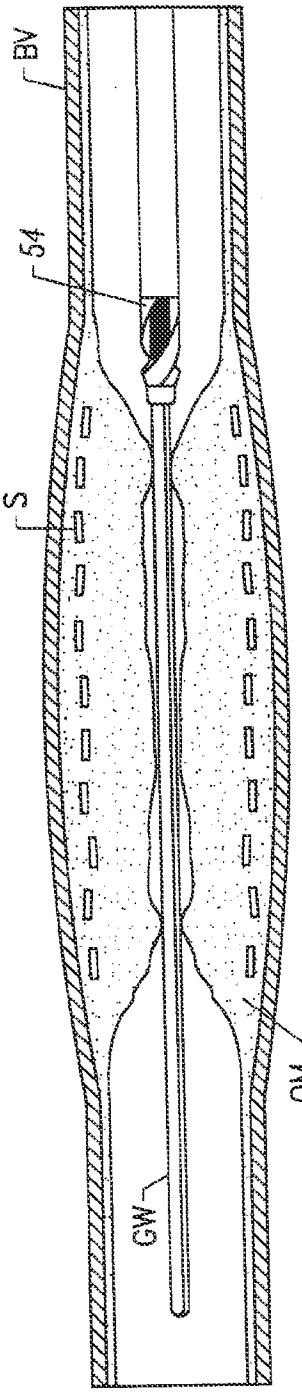

FIG. 10C

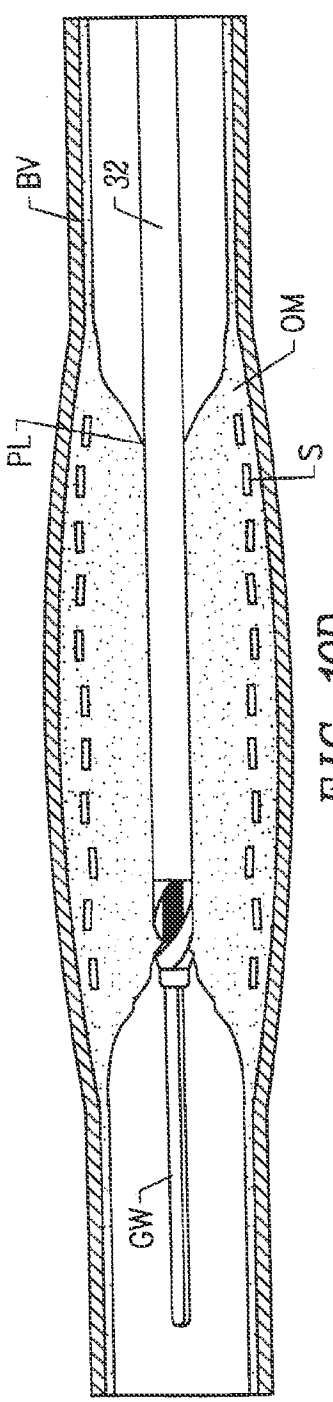

FIG. 10D

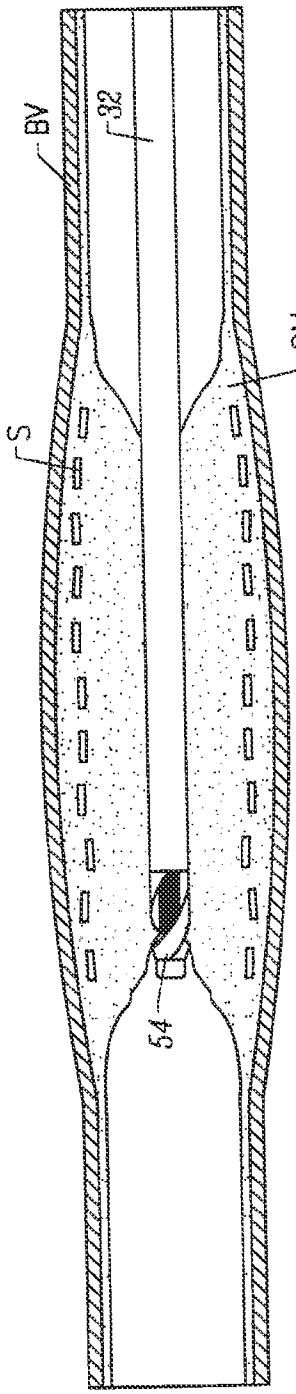

FIG. 10E

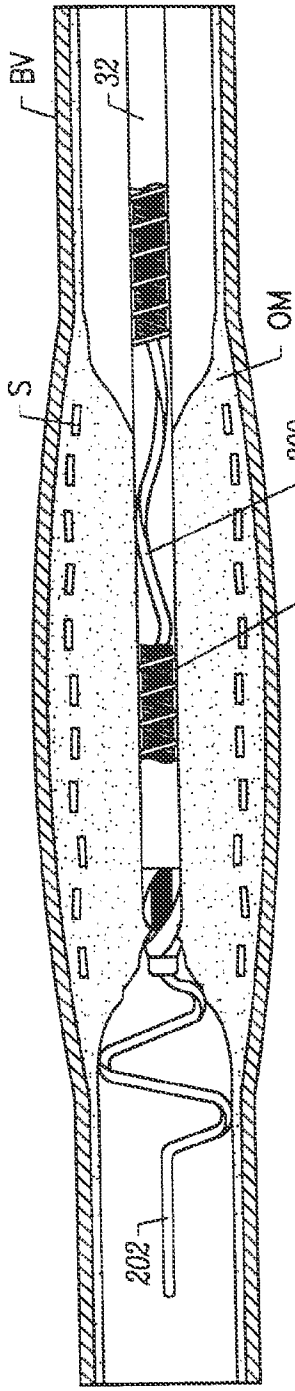

FIG. 10F

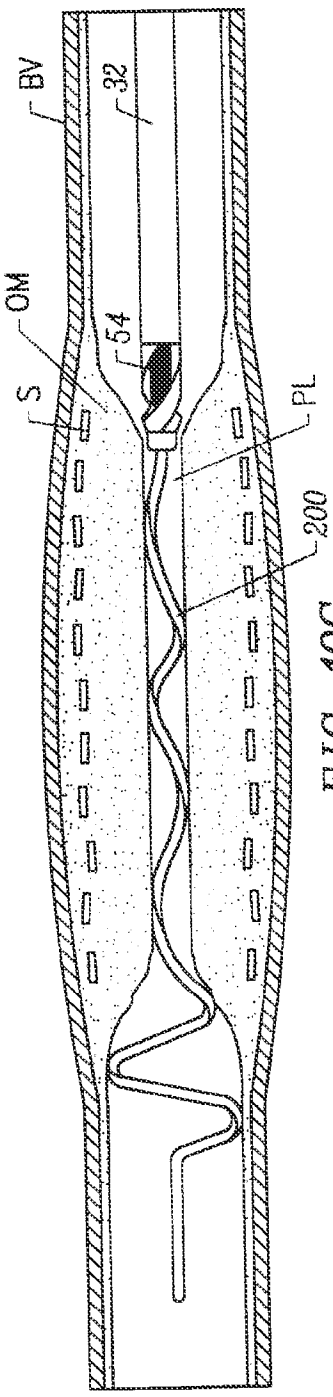

FIG. 10G

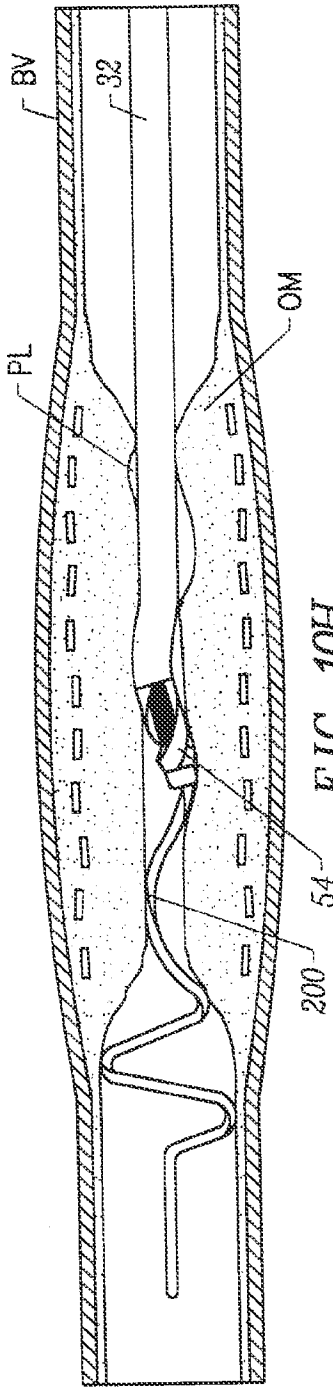

FIG. 10H

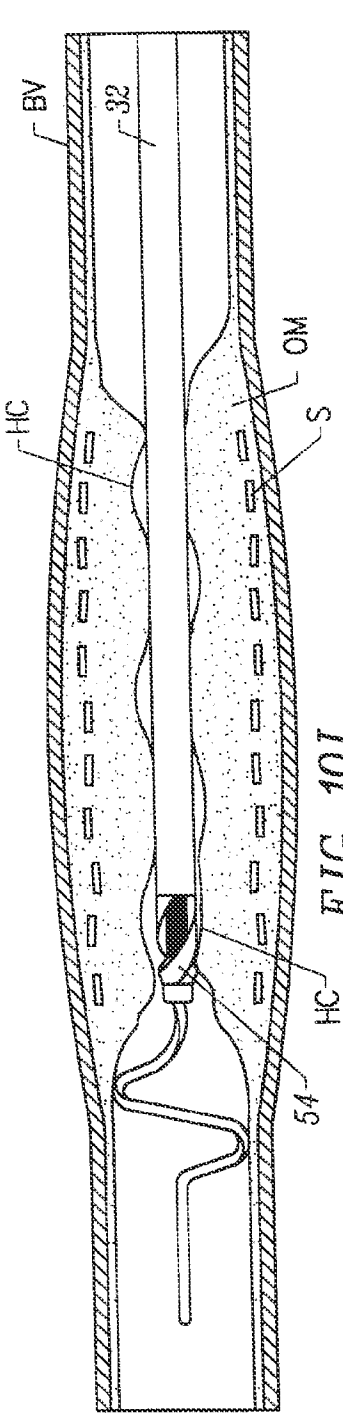

FIG. 10I

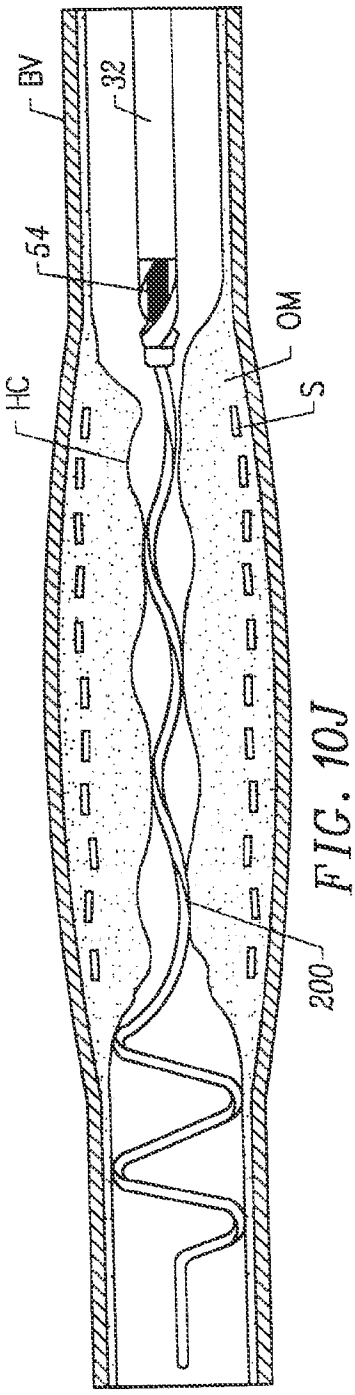

FIG. 10J

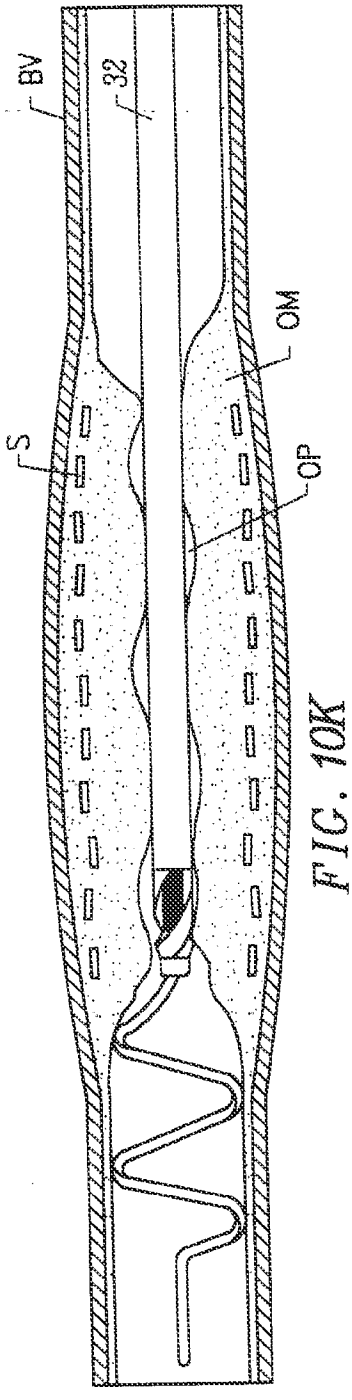

FIG. 10K

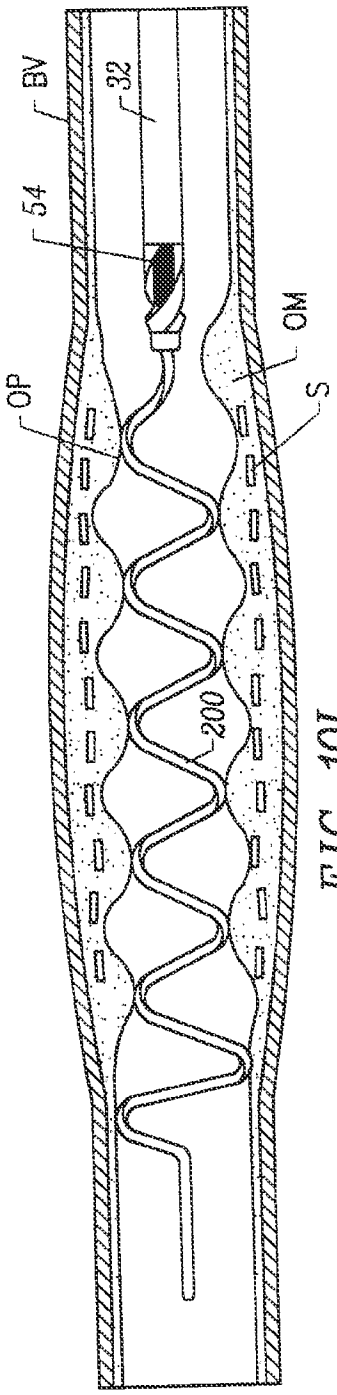

FIG. 10L

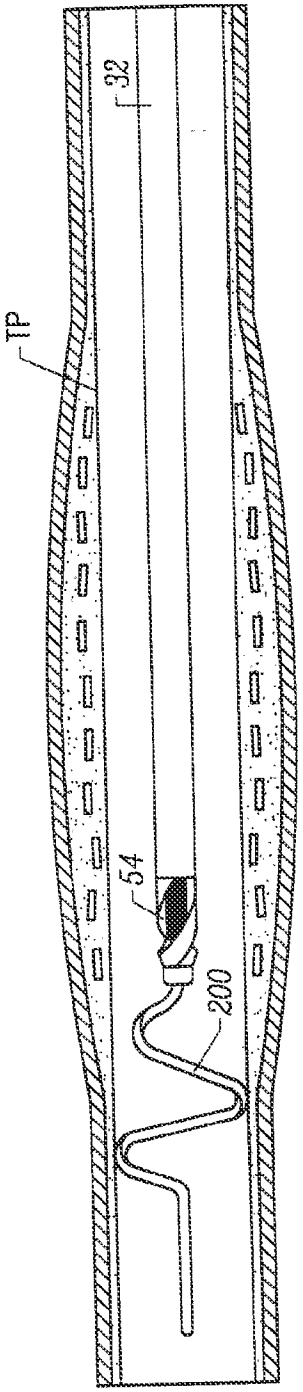

FIG. 10M

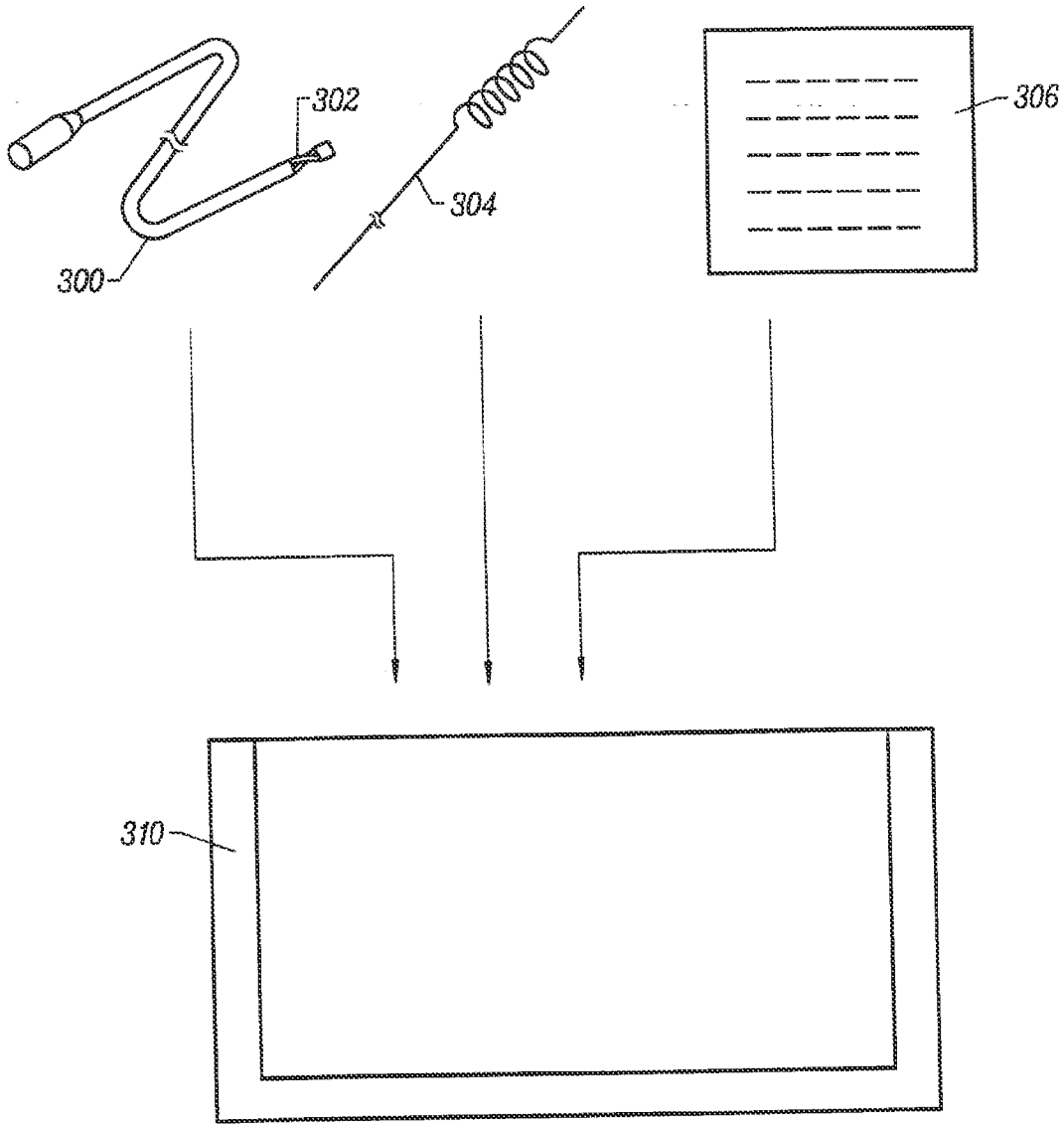

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/23832

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/22
US CL :606/159, 170, 180

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/159, 170, 180

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,527,326 A (HERMANN et al) 18 June 1996, entire document.	1-117
X,E	US 5,843,103 A (WULFMAN) 01 December 1998, entire document.	1-117

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 24 JANUARY 1999	Date of mailing of the international search report 08 FEB 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer KEVIN TRUONG Telephone No. (703) 308-3767

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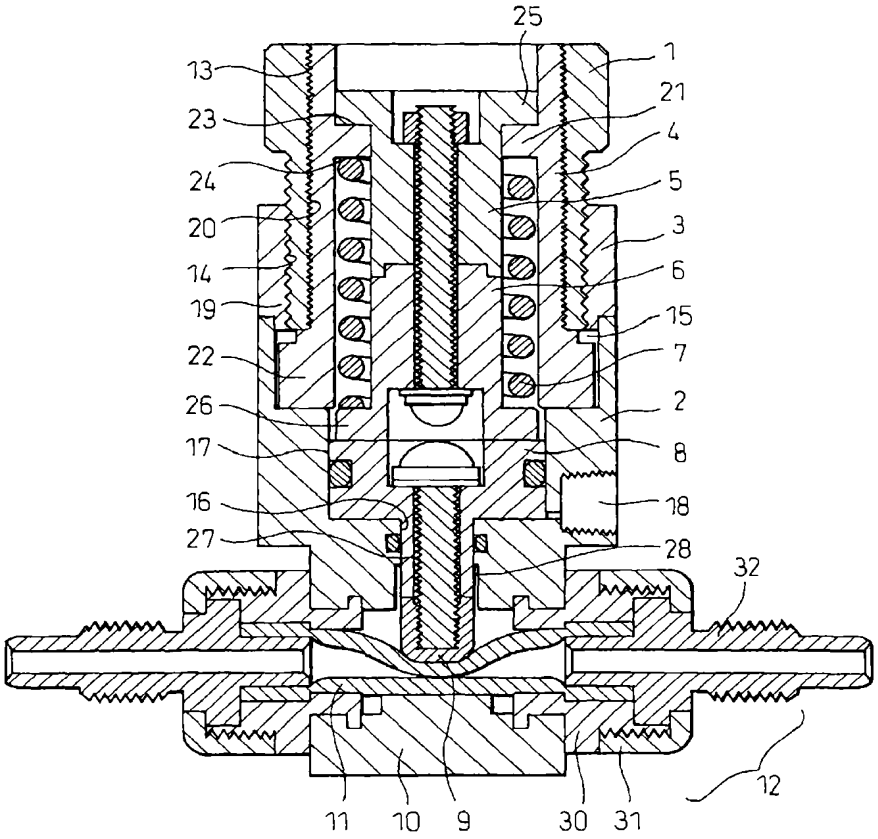
[続葉有]

(54) Title: PINCH VALVE

(54) 発明の名称: ピンチバルブ



(57) Abstract: A pinch valve, comprising a body (10) accepting a pipe body (11), a cylinder body (2) having an upper cylinder part (17) and a lower handle support part (3), a piston stored in the cylinder part, a pressing element (9) fixed to the piston to press the pipe body, a cylindrical handle (1), a hollow stem (4), and piston retainers (5, 6), the handle further comprising a female thread part and a male thread part having pitches larger than those of the female thread part, wherein the male thread part is threaded to the female thread part formed on the handle support part, the stem having the male thread part threaded to the female thread part of the handle on the outer peripheral surface thereof is stored in the cylinder body, and the piston retainers are inserted into the stem so that the bottom end face comes into contact with the top end part of the piston and energized to the piston side by a spring.

(57) 要約: ピンチバルブは、管体（１１）を受容する本体（１０）と、上側シリンダー部（１７）と下側ハンドル支持部（３）とを有するシリンダー本体（２）と、シリンダー部に収容されたピストンと、管体を押圧するためにピストンに固定された挟圧

[続葉有]

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(81) 指定国 (国内): CN, KR, US.

添付公開書類:
— 国際調査報告書

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子（９）と、円筒状ハンドル（１）と、中空ステム（４）と、ピストン押さえ（５，６）とを具備する。ハンドルは、雌ネジ部と、雌ネジ部のピッチより大きいピッチの雄ネジ部とを有し、雄ネジ部がハンドル支持部に形成された雌ネジ部に螺合する。ステムは、外周面にハンドルの雌ネジ部に螺合される雄ネジ部を有し、シリンダー本体内に収容されている。ピストン押さえは、下端面がピストンの上端部と接触するようにステム内に嵌挿され、バネによりピストン側へ付勢されている。

明　細　書

ピンチバルブ

技術分野

本発明は、化学工場、半導体製造、食品、バイオテクノロジーなどの各種産業分野における流体輸送配管に用いられるピンチバルブに関するものであり、更に詳しくは、開度調整をより精密かつ容易に行うことができる開度調整機構を有したピンチバルブに関するものである。

背景技術

本出願人は従来のピンチバルブを改良した、非常にコンパクトで、バルブの開閉運転における内部に配管された管体の耐久性を向上させ、微少流量の調整が可能なピンチバルブを発明し、先に出願した（特願２００１－１７９０２７号）。その構造を図８を参照して説明すると、上部内周面に開度調節用の雌ネジ部６０を有するシリンダー部６１とシリンダー部６１の下端部に連通するエアー口６２とを有するシリンダー本体５２と、下部外周面にシリンダー本体５２の開度調節用の雌ネジ部６０に螺合される雄ネジ部６３を有する筒状のハンドル５４と、ハンドル５４の凹部６４の上端面とでバネ５３を挟持する円盤形状のバネ受け５５と、ハンドル５４の上部に係合され、且つ下端面がバネ受け５５と接合されることによりバネ５３をハンドル５４とバネ受け５５との間に挟持するようにした接続棒５６と、シリンダー部６１の内周面に上下動可能且つ密封状態で摺接され、且つシリンダー本体５２の下面中央に設けられた貫通孔６５を密封状態で貫通するように中央より垂下して設けられた連

結部６６を有するピストン５７と、ピストン５７の連結部６６の下端部に固定された挟圧子５８と、本体５１内に保持され挟圧子５８に押圧された弾性体からなる管体５９とを具備するものであった。

このピンチバルブの作動は以下に記載の通りである。図８に示すようにバルブ全閉状態において、ハンドル５４を開方向に回動させると、接続棒５６を介してバネ受け５５の下端面が上昇する。これに伴い、管体５９の内部を流れる流体の流体圧と管体５９の弾性力とにより挟圧子５８が押し上げられ、その結果、ピストン５７が上昇し、管体５９は中間開度となる。一方、中間開度に調整した状態でエアー口６２から第１空間部６７に圧縮空気を供給圧入すると、その圧縮空気の圧力により、ピストン５７が周側面をシリンダー部６１の内周面に摺接させながら上昇し始める。それに伴って、ピストン５７の上端部がバネ受け５５を介してバネ５３を圧縮させながら上昇すると共に、ピストン５７より垂下して設けられた連結部６６を介して挟圧子５８が上昇する。そして、ついには、挟圧子５８の上端面がシリンダー本体５２の下端面に設けられた長円状スリットの上端面に到達してピストン５７及び挟圧子５８の上昇は止まり、ピンチバルブは全開状態となる。

また、全開状態において、エアー口６２から第１空間部６７へのエアー供給を止め、大気開放すると、バネ５３に当接しているバネ受け５５を介してピストン５７がバネの反発力により下降し始め、それに伴ってピストン５７より垂下して設けられた連結部６６を介して挟圧子５８も下降する。そして、ついには、接続棒５６の鍔部６８の下面がハンドル５４の上部に設けられた凹部６４の底面に到達して、ピストン７及び挟圧子５８の下降は止まり、該ピンチバルブは中間開度に調整された状態となる。このように、ハンドル５４の開度を調整することにより流量を微調整することが可能であった

。

ところで、上記構成のピンチバルブでは、管体の開度を調整する挟圧子のストローク量の調整はハンドル５４の回転量に比例し、その比例定数はハンドルの雄ネジ部のピッチによって決定される。従って、より精密なストローク量の調整を行うためには非常に小さな回転角度で調整する必要があり、操作誤差が大きく微調整が困難であった。より微細な調整を可能とさせるためには、ハンドル１の雄ネジ部のピッチをより小さくすれば可能であるが、ピッチを小さくすることには、強度的な面や加工精度面に問題があり、限度があった。

発明の開示

本発明は以上のような従来技術の問題点に鑑みなされたものであり、従来のピンチバルブにおいて、開度の微調整すなわち流量の微調整をより精密かつ容易に行うことが可能なピンチバルブを提供することを目的とする。

上記目的を達成するために、流体の流路の一部をなす弾性の管体を受容する溝を有した本体と；内周面に雌ネジ部を備えたハンドル支持部と、ハンドル支持部の下方に位置し且つ底部中央に貫通孔が形成されているシリンダー部と、周側面にシリンダー部の下端部に連通するエアーロとを有し、本体上に固定された有底筒形状のシリンダー本体と；シリンダー部の内周面に上下動可能且つ密封状態で摺接され、シリンダー部の貫通孔を密封状態で貫通するように中央より垂下して設けられた連結部を有するピストンと；ピストンが下降したときに管体を押圧するように、ピストンの連結部の下端部に固定された挟圧子と、内周面に形成された雌ネジ部と；下部外周面に形成され且つ雌ネジ部のピッチより大きいピッチの雄ネジ部とを

有し、雄ネジ部をハンドル支持部の雌ネジ部に螺合させる円筒状のハンドルと；上部内周面に環状突起部が形成され、外周面にハンドルの雌ネジ部に螺合される雄ネジ部が形成されており、上下動可能且つ回動不能にシリンダー本体内に収容されている中空ステムと；上端部に上側鍔部を、下端部に下側鍔部を有し、下端面がピストンの上端部と接触するように中空ステム内に上下に移動自在に嵌挿され、上側鍔部を前記中空ステムの環状突起部の上面に係合させ、下側鍔部と中空ステムの環状突起部の下面との間でバネを支承するようになっているピストン押さえとを具備するピンチバルブが提供される。

発明の特徴は、１つの円筒状のハンドルの内周面及び外周面下部にそれぞれネジ部を設け、内周面に設けられた雌ネジ部のピッチより、外周面下部に設けられた雄ネジ部のピッチを大きくした点である。これにより、ハンドルを１回転分回動させると、ハンドルはその外周の雄ネジ部と螺合するハンドル支持部及びそれと接合されているシリンダー本体に対して雄ネジ部のピッチ分だけ上昇又は下降する一方、ハンドルの内周の雌ネジ部と螺合する中空ステムはハンドルに対して雌ネジ部のピッチ分だけハンドルと逆方向に移動する。すなわち、中空ステムは、ハンドルの１回転により、ハンドルの雌ネジ部のピッチと雄ネジ部のピッチ差分だけハンドル支持部及びシリンダー本体に対して移動し、中空ステム位置を微少量だけ変化させることが可能となる。一方、中空ステムの環状突起部、バネ及びピストン押さえの両鍔部との相互作用により、中空ステムの上下方向位置はピストン押さえの上下方向位置を規定し、ピストンを介して挟圧子による管体の開度を規定する。したがって、本発明のピンチバルブの構造によれば、中空ステムの上下方向位置の微調整ができ、ピストンを介して挟圧子による管体の開度（すなわち、弁開

度）の微調整が可能となる。

また、ピストン押さえの下側鍔部と中空ステムの環状突起部との間にバネが配置された状態で、ピストン押さえが中空ステム内に上下に移動自在に嵌挿されているので、エアー口を通してシリンダー部に空気を供給することにより、シリンダー本体に対する中空ステムの上下方向位置に関わらず、ピストン押さえがバネの力に抗して中空ステムに対して上昇できる。したがって、シリンダー部に対する空気の供給又は開放により、ハンドルを回転させることによる中空ステムの位置の変更を伴わずに、中間開度状態と全開状態との間での移行が可能である。

好ましくは、雄ネジ部と雌ネジ部のピッチ差を雄ネジ部のピッチの２０分の１から５分の１の範囲になるように設けるのが良い。ピッチ差が雄ネジ部のピッチの２０分の１より小さいと、ハンドルのストローク量が大きくなり過ぎて弁高が大きくなる。また、ピッチ差が雄ネジ部のピッチの５分の１より大きいと、弁開度の微調整ができなくなる。上記範囲内で雄ネジ部と雌ネジ部のピッチ差を選択することにより、希望するハンドルのストローク量を調整することができるため、幅広い開度の微調整が可能となる。

また、好ましくは、シリンダー本体のハンドル支持部とシリンダー部の中間部の内周面に凹部が形成されており、中空ステムがその下端部にシリンダー本体の凹部に収容される鍔部を有する。このようにシリンダー本体の凹部に中空ステムの鍔部を収容することにより、ハンドルの回動により、中空ステムが上下動できる一方で、シリンダー本体に対して回動できないようにする。

また、好ましくは、挟圧子は、シリンダー本体の下端部に流路軸線と直交する方向に延びる長円状スリット内に収容される。このように挟圧子が長円状スリット内に収容されることにより、挟圧子の

回転が妨げられるようになる。

また、好ましくは、本体の両側に管体と他のチューブとを接続する接続部が設けられる。これにより、ピンチバルブを外部流路と接続することが容易になる。

また、本発明のピンチバルブの管体の材料はＥＰＤＭ、フッ素ゴム、シリコンゴム、フッ素系樹脂、またはフッ素ゴムとシリコンゴムとの複合体などであれば良く特に限定されるものではないが、フッ素系樹脂とシリコンゴムとの複合体が特に好適な材料として挙げられる。

また、ハンドル、シリンダー本体、ハンドル支持部、中空ステム及び本体の材料は金属、プラスチックなどの剛性のあるものであれば特に限定されるものではないが、ＰＶＣ又は、ＰＶＤＦ等のフッ素系樹脂のプラスチックが特に好適な材料として挙げられる。

また、接続部を構成する連結体の材料はプラスチックなどの耐薬品性を有するものであれば特に限定されるものではないが、ＰＴＦＥ、ＰＶＤＦ、ＰＦＡ等のフッ素系樹脂のプラスチックが特に好適な材料として挙げられる。

図面の簡単な説明

本発明の上述の目的及びその他の目的、特徴、利点を以下、添付図面を参照して本発明の実施形態に基づいてさらに詳細に説明する。

図１は、本発明ピンチバルブの実施態様に係る閉状態を示す縦断面図である。

図２は、図１のピンチバルブを側面（流路方向）から見た縦断面図である。

図３は、ハンドル、中空ステム、ストッパー、バネ受け、及びバ

ネの分解斜視図である。

図４は、図１のピンチバルブの開状態を示す縦断面図である。

図５は、図４のピンチバルブを側面（流路方向）から見た縦断面図である。

図６は、図１におけるシリンダー本体の底面図である。

図７は、図１のピンチバルブの中間開度状態を示す縦断面図である。

図８は、従来技術の縦断面図である。

発明を実施するための最良の形態

以下、本発明の実施態様について図面を参照して説明するが、本発明が本実施態様に限定されないことは言うまでもない。

図面に基づいて本発明のＰＶＤＦ製ピンチバルブを説明する。

１は円筒状のハンドルであり、その内周面には雌ネジ部１３が設けられ、また、その下部外周面には、上端部より縮径して雄ネジ部１４が雌ネジ部１３のピッチより大きいピッチで設けられている。（図１、図３参照）

２は有底筒形状のシリンダー本体であり、その上部内周面には凹部１５が設けられ、凹部１５の下方にはそれより縮径され且つ底部中央に貫通孔１６を有したシリンダー部１７が設けられている。

また、シリンダー本体２の下部側面にはシリンダー部１７の下方部に連通するエアロ１８が設けられ、同下端面中央には上記貫通孔１６を中心にして、長円状スリット２８が設けられている。（図６参照）。

３はハンドル１の支持体であり、内周面に設けられた雌ネジ部１９がハンドル１の雄ネジ部１４と螺合されており、下端部はシリンダー本体２の凹部１５の上端部に接合固定され、シリンダー本体２

の一部を構成している。

４は中空ステムであり、外周面に設けられた雄ネジ部２０はハンドル１の雌ネジ部１３と螺合されており、上部内周面には環状突起部２１が、また、下端部側面にはシリンダー本体２の凹部１５に収容される鍔部２２が設けられている。図示されていないが、中空ステム４は、ハンドル１の回動により上下動はするが、シリンダー本体２に対して回動はできないようにシリンダー本体２の凹部１５に収容されている。（図１、図３参照）

５は円筒状のストッパーであり、中空ステム４の環状突起部２１の内周面で支承されており、上端部には環状突起部２１の上面と係合すなわち接触あるいは離間される鍔部２５が設けられている。（図１、図３参照）

６はストッパー５の下端部に接合される円筒状のバネ受けであり、下端部側面にはピストン８の上面と係合する鍔部２６が設けられている。（図１、図３参照）

本実施態様では、ストッパー５とバネ受け６は両者を貫通して挿入されたボルトとナットで接合固定されているが、固定方法はこれに限定されず、螺着あるいは溶着などによる固定でもよい。このようにストッパー５とバネ受け６とを接合固定することにより、１つのピストン押さえを構成する。

７はバネであり、バネ受け６の鍔部２６の上面と中空ステム４の環状突起部２１の下面とに接触した状態で挟持されている。本実施態様では、１本のバネ７が装着されているが、必要とする付勢力に応じて２本以上のバネ７を装着しても良い。

ピストン８は円盤状で、外周面にＯ－リングが装着されており、常に上端面がバネ受け６の下端面と接触し、且つ、シリンダー本体２のシリンダー部１７に上下動可能且つ密封状態で収納されている

。ピストン８の中央底部には、そこから垂下した筒状の連結部２７が設けられている。この連結部２７はシリンダー本体２の底部中央に設けられた貫通孔１６を密封状態で貫通しており、その先端部には挟圧子９が固定されている。本実施態様では、連結部２７を貫通して挿入された固定ボルトの先端部に螺着により、挟圧子９が固定されている。

挟圧子９は、管体１１を押圧する部分が断面半円柱状で全体棒状に形成され、流路軸線と直交して管体１１を横切るようにピストン８の連結部２７に固定されており、弁全開時にはシリンダー本体２の下端面に流路軸線と直交して設けられた長円状スリット２８内に収納されるようになっている。（図４、図５参照）

１０はシリンダー本体２の下端面にボルト・ナットなど（図示せず）で接合固定されている本体であり、流路軸線上には管体１１を受容する断面矩形状の溝２９が設けられている。

管体１１はシリコンゴムが含浸されたＰＴＦＥシートを何層も積層して構成されたＰＴＦＥとシリコンゴムの複合体からなり、本体１０内に流路を形成している。本実施態様では管体の材質はＰＴＦＥとシリコンゴムの複合体になっているが、ＥＰＤＭ、シリコンゴム、フッ素ゴム及びこれらの複合体などでも良く特に限定されるものではない。

１２はＰＴＦＥ製の接続部であり、本体１０の溝部２９とシリンダー本体２の底部に係合してシリンダー本体２と本体１０の各両側側面に固定される連結体受け３０と、連結体受け３０と係合し且つ管体１１と接続される連結体３２と、連結体受け３０の外周面に螺合することにより連結体３２を連結体受け３０に固定しているキャップナット３１とから形成されている。尚、接続部１２の構造は本実施態様に限定されず、配管ラインのチューブと管体１１を接続す

る構造のものであればいずれのタイプのものでも良い。

上記構成からなる本実施態様のピンチバルブの作動は次の通りである。

今、図１、図２に示されているピンチバルブが全閉の状態において、エアー口１８からシリンダー本体２のシリンダー部１７内に圧縮空気を供給圧入すると、該圧縮空気の圧力により、ピストン８が外周面をシリンダー部１７の内周面に摺接させながら上昇し始める。それに伴って、ピストン８の上端面がバネ受け６を介してバネ７を圧縮させながら上昇すると共に、ピストン８より垂下して設けられた連結部２７を介して挟圧子９が上昇する。そして、ついには、挟圧子９の上端部がシリンダー本体２の下端部に設けられた長円状スリット２８の上端面に到達し、ピストン８及び挟圧子９の上昇は止まり、管体１１は全開状態となる（図４，５の状態）。

次に、図４，５に示されているピンチバルブが全開の状態において、エアー口１８からシリンダー本体２のシリンダー部１７への圧縮空気の供給を止め、シリンダー部１７内の空気を大気開放すると、バネ７に当接しているバネ受け６を介してピストン８がバネ７の反発力により、下降し始め、それに伴ってピストン８より垂下して設けられた連結部２７を介して挟圧子９も下降する。そして、ついには、ピストン８の下端面がシリンダー部１７の底面に到達し、ピストン８及び挟圧子９の下降は止まり、管体１１は全閉状態となる（図１，２の状態）。この時、挟圧子９の回り防止のため、挟圧子９の上端面はシリンダー本体２の長円状スリット２８内に位置するようになっている。

次に、本実施態様のピンチバルブを中間開度に調整する方法について説明する。

図１の状態、即ちピンチバルブが全閉の状態において、ハンドル

１を開方向に１回転分だけ回動させると、ハンドル１はハンドル１の外周面の雄ネジ部１４のピッチ分だけ上昇し、逆にハンドル１の雄ネジ部１４より小さいピッチを有するハンドル１の内周面の雌ネジ部１３に螺合された中空ステム４はハンドル１の雌ネジ部１３のピッチ分だけ下降し、全体的には両者のピッチ差分だけ中空ステム４は上昇する。例えば、ハンドル１の内周面の雌ネジ部１３および中空ステム４の雄ネジ部２０のピッチを１．８ｍｍにするとともに、ハンドル１の外周面の雄ネジ部１４およびハンドル支持体３の内周面の雌ネジ部１９のピッチを２．０ｍｍとした場合、ハンドルを１回転させることによって中空ステム４は０．２ｍｍ上昇することとなる。すなわち、ハンドル１の外周面の雄ネジ部１４のネジピッチの１０分の１だけ上昇する。これに伴って、バネ受け６の下端面がストッパー５を介して上昇し、管体１１の内部を流れる流体の流体圧と管体１１の弾性力とにより挟圧子９が押し上げられ、その結果、ピストン８が上昇し、管体１１は中間開度に調整される（図７の状態）。

一方、ピンチバルブにおける中間開度に調整した状態から全開状態へ、あるいは全開状態から中間開度の状態への移行は、エアー口１８から空気の供給あるいは圧入空気の開放により上記説明と同じ動作で行えば良い。

以上説明したごとく、本実施態様のピンチバルブは、流体の流れを開閉するのみならず、中間開度で流体を流すことができる。従って、例えば半導体製造装置などの装置内閉ループ配管において背圧弁として使用することができる。

本発明のピンチバルブは以上のような構造を有しており、これを使用することにより従来品に比較して開度調整がより精密かつ容易に行え、広い範囲の流量の微調整を早く行うことができる。

以上、本発明を添付図面に示す実施態様について説明したが、この実施態様はもっぱら説明上のものであり、制限を意味するものではない。したがって、本発明の範囲は、請求の範囲によって限定されるものであり、請求の範囲から逸脱することなく本発明の実施態様を修正及び変更することが可能である。

請　求　の　範　囲

１．流体の流路の一部をなす弾性の管体を受容する溝を有した本体と、

内周面に雌ネジ部を備えたハンドル支持部と、該ハンドル支持部の下方に位置し且つ底部中央に貫通孔が形成されているシリンダー部と、周側面に該シリンダー部の下端部に連通するエアー口とを有し、前記本体上に固定された有底筒形状のシリンダー本体と、

前記シリンダー部の内周面に上下動可能且つ密封状態で摺接され、前記シリンダー部の貫通孔を密封状態で貫通するように中央より垂下して設けられた連結部を有するピストンと、

前記ピストンが下降したときに管体を押圧するように、該ピストンの連結部の下端部に固定された挟圧子と、

内周面に形成された雌ネジ部と、下部外周面に形成され且つ該雌ネジ部のピッチより大きいピッチの雄ネジ部とを有し、該雄ネジ部を前記ハンドル支持部の雌ネジ部に螺合させる円筒状のハンドルと、

上部内周面に環状突起部が形成され、外周面に前記ハンドルの雌ネジ部に螺合される雄ネジ部が形成されており、上下動可能且つ回動不能に前記シリンダー本体内に収容されている中空ステムと、

上端部に上側鍔部を、下端部に下側鍔部を有し、下端面が前記ピストンの上端部と接触するように前記中空ステム内に上下に移動自在に嵌挿され、前記上側鍔部を前記中空ステムの環状突起部の上面に係合させ、前記下側鍔部と前記中空ステムの環状突起部の下面との間でバネを支承するようになっているピストン押さえと、

を具備することを特徴とするピンチバルブ。

２．前記ハンドルの雌ネジ部と雄ネジ部のピッチ差が該ハンドル

の雄ネジのピッチの２０分の１から５分の１である請求項１に記載のピンチバルブ。

３．前記シリンダー本体の前記ハンドル支持部と前記シリンダー部の中間部の内周面に凹部が形成されており、前記中空ステムがその下端部に前記シリンダー本体の凹部に収容される鍔部を有する請求項１に記載のピンチバルブ。

４．前記ハンドルの雌ネジ部と雄ネジ部のピッチ差が該ハンドルの雄ネジのピッチの２０分の１から５分の１である請求項３に記載のピンチバルブ。

５．前記挟圧子は、前記シリンダー本体の下端部に前記流路軸線と直交する方向に延びる長円状スリット内に収容される請求項１に記載のピンチバルブ。

６．前記ハンドルの雌ネジ部と雄ネジ部のピッチ差が該ハンドルの雄ネジのピッチの２０分の１から５分の１である請求項５に記載のピンチバルブ。

７．前記本体の両側に前記管体と他のチューブとを接続する接続部が設けられている請求項１に記載のピンチバルブ。

８．前記ハンドルの雌ネジ部と雄ネジ部のピッチ差が該ハンドルの雄ネジのピッチの２０分の１から５分の１である請求項７に記載のピンチバルブ。

９．前記管体の材料が、ＥＰＤＭ、フッ素ゴム、シリコンゴム、フッ素系樹脂、又はこれらの複合体である請求項１に記載のピンチバルブ。

10．前記ハンドルの雌ネジ部と雄ネジ部のピッチ差が該ハンドルの雄ネジのピッチの２０分の１から５分の１である請求項９に記載のピンチバルブ。

11．前記管体がフッ素系樹脂とシリコンゴムの複合体からなる請

求項９に記載のピンチバルブ。

12．前記ハンドルの雌ネジ部と雄ネジ部のピッチ差が該ハンドルの雄ネジのピッチの２０分の１から５分の１である請求項11に記載のピンチバルブ。

Fig. 1

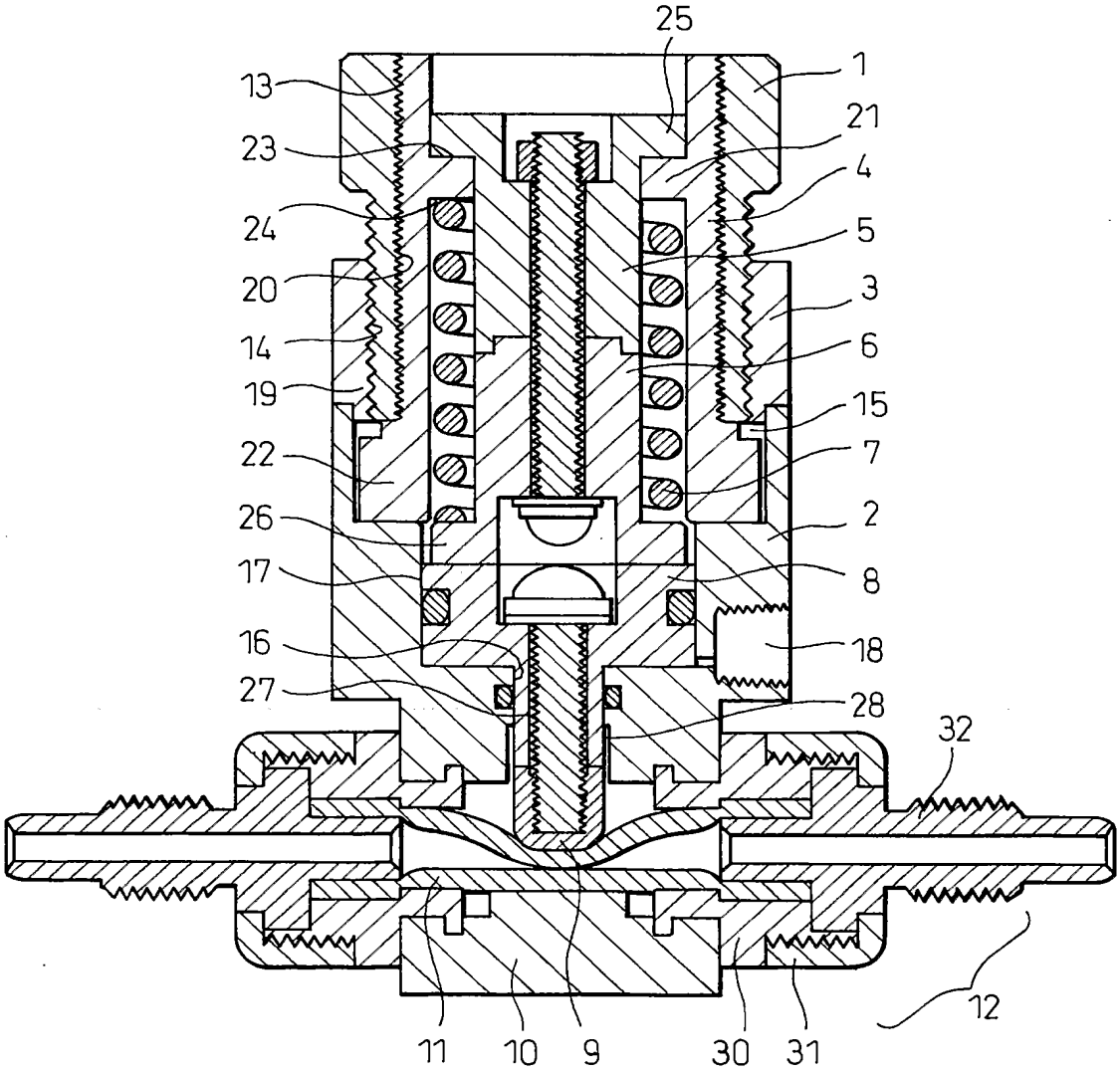
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Fig.2

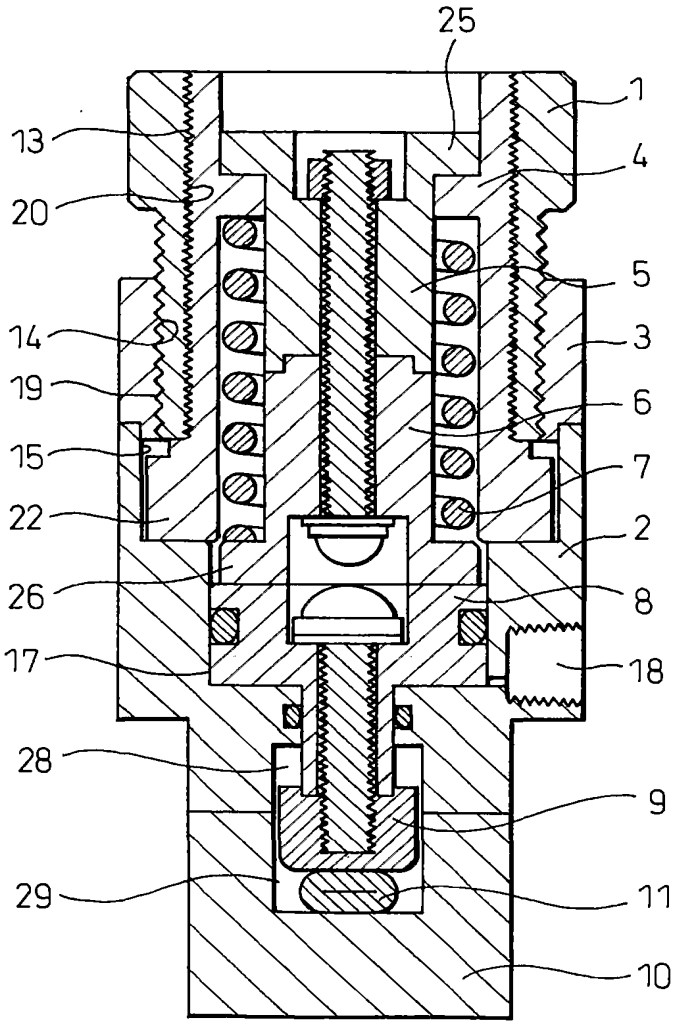


Fig. 3

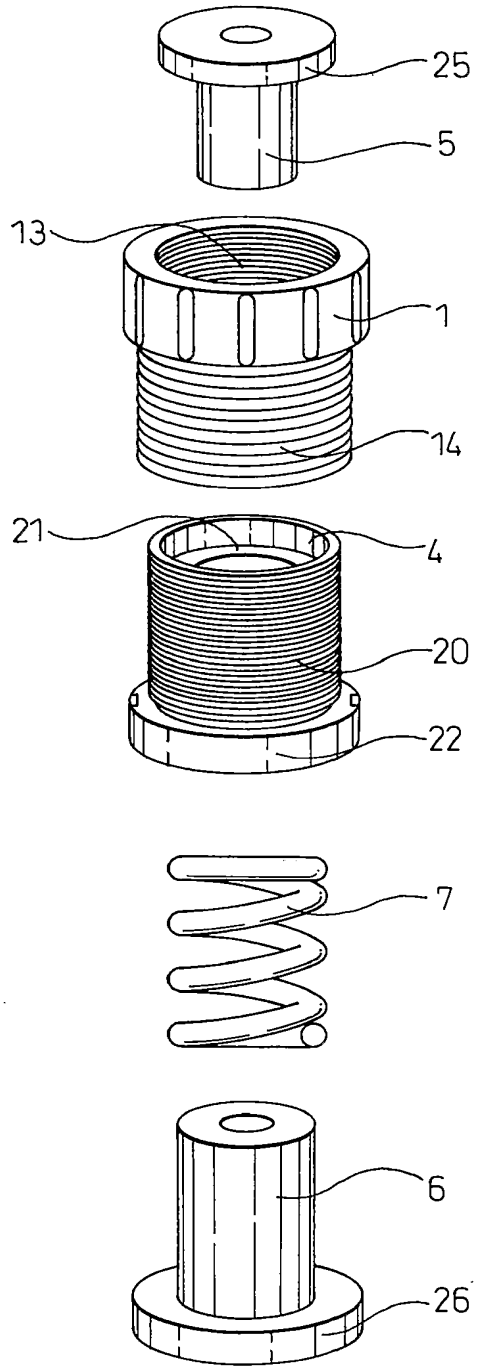


Fig. 4

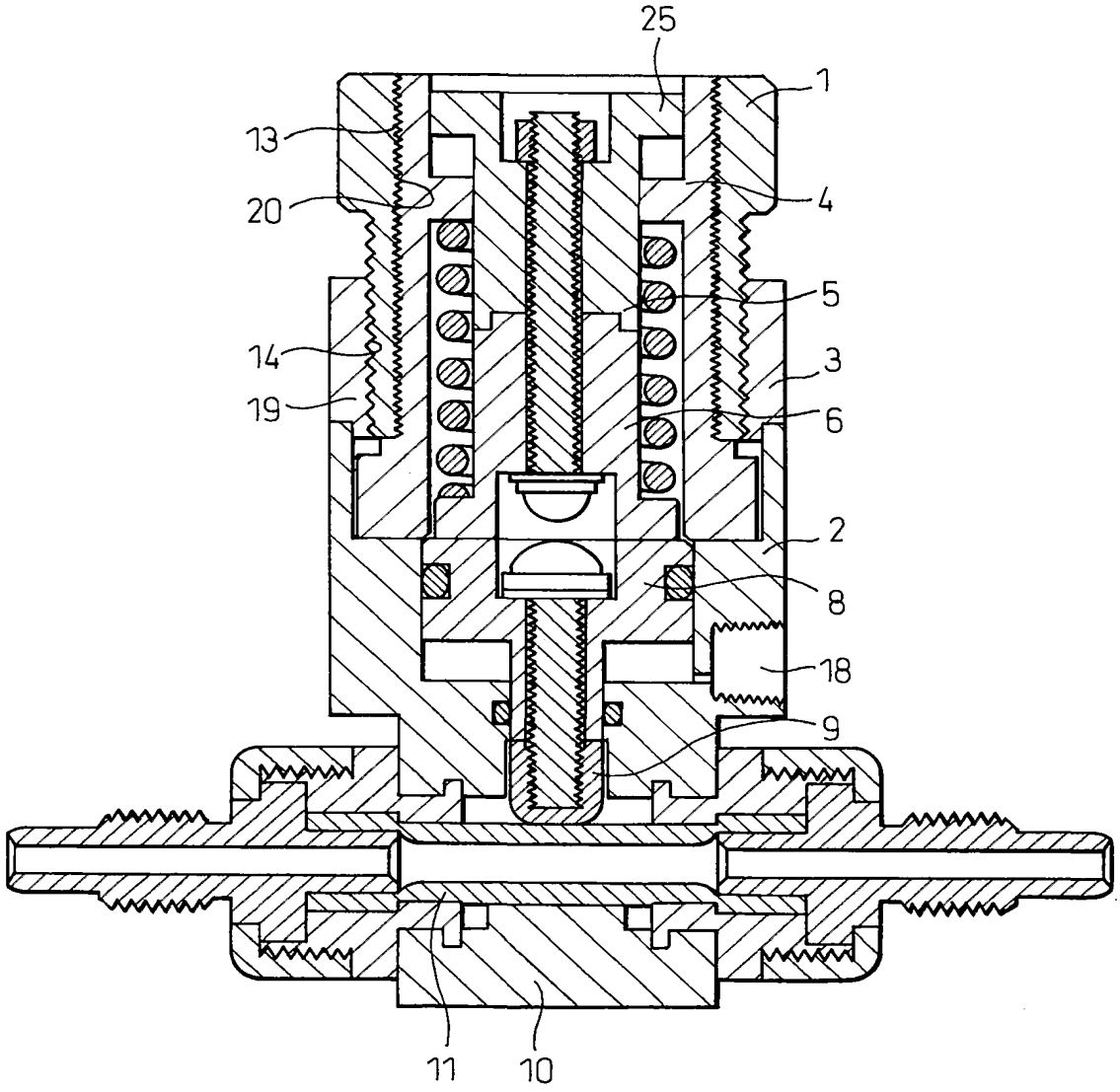


Fig.5

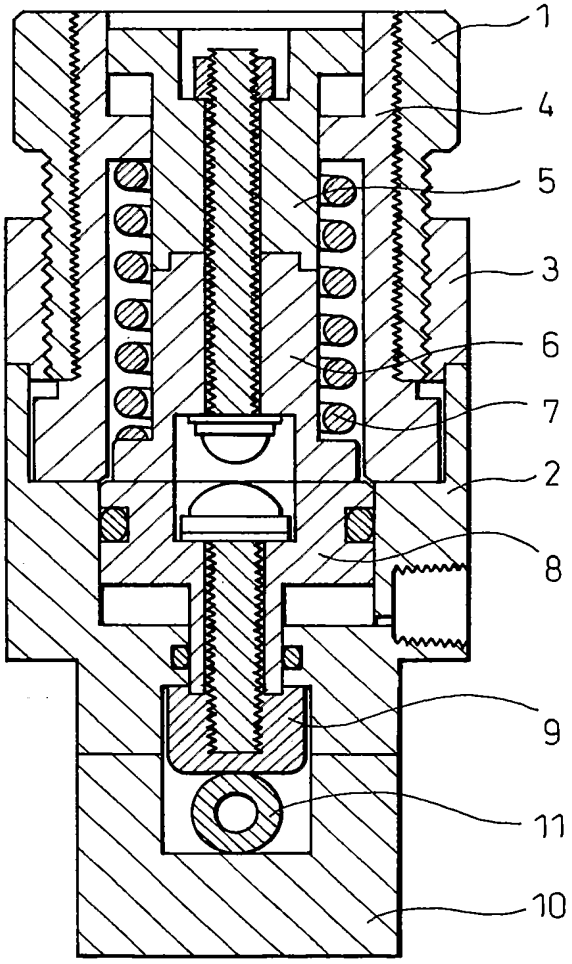


Fig.6

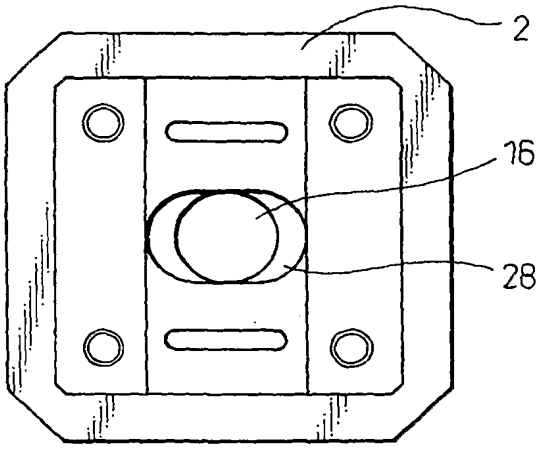


Fig.7

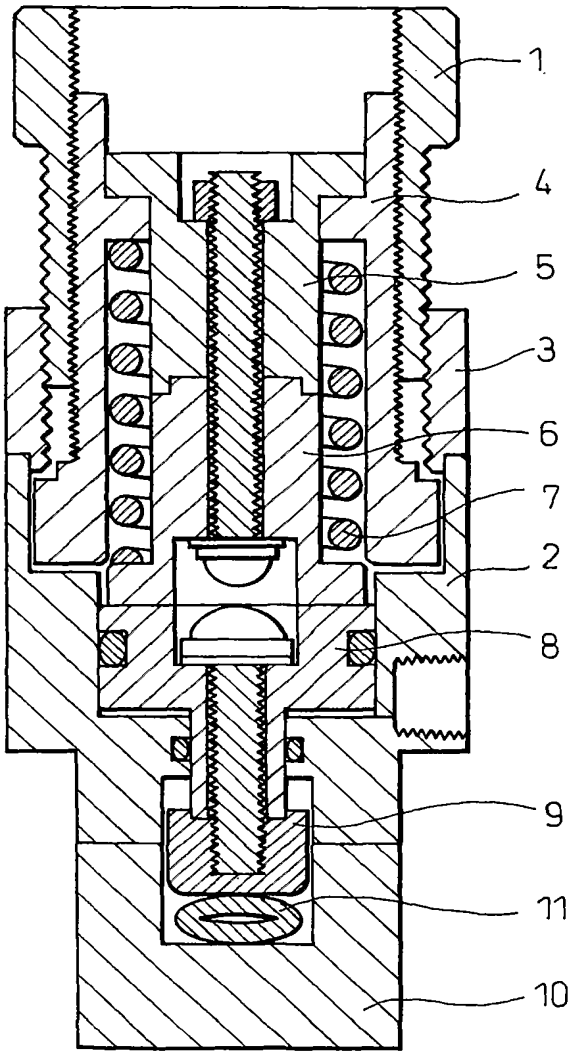
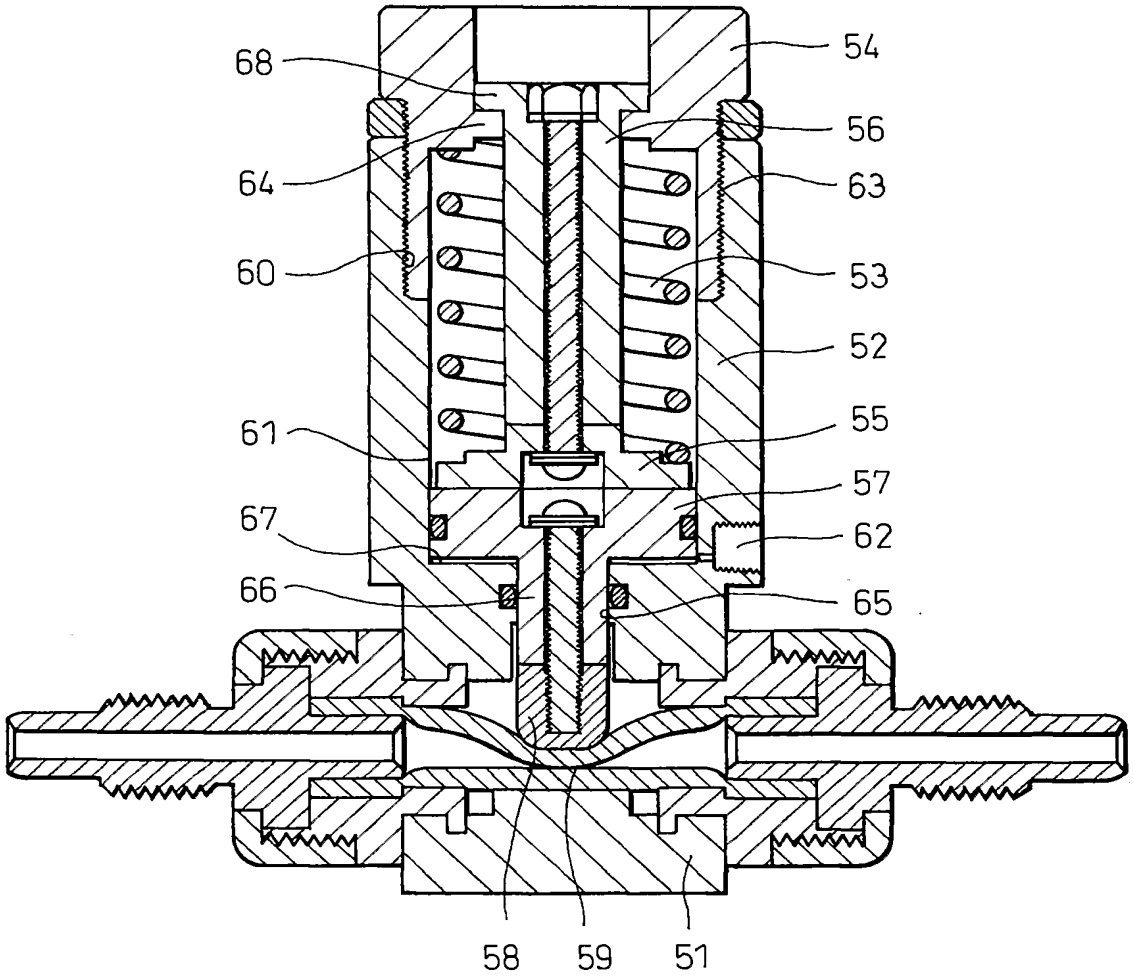


Fig.8



従来技術

参照番号・事項の一覧表

１…ハンドル

２…シリンダー本体

３…ハンドル支持体

４…中空ステム

５…ストッパー

６…バネ受け

７…バネ

８…ピストン

９…挟圧子

１０…本体

１１…管体

１２…接続部

１３…雌ねじ部

１４…雄ねじ部

１５…凹部

１６…貫通孔

１７…シリンダー部

１８…エアー口

１９…雌ネジ部

２０…雄ネジ部

２１…環状突起部

２２…鍔部

２３…上面

２４…下面

２５…鍔部

２６…鍔部

２７…連結部

２８…長円状スリット

２９…溝

３０…連結体受け

３１…キャップナット

３２…連結体

５１…本体

５２…シリンダー本体

５３…バネ

５４…ハンドル

５５…バネ受け

５６…接続棒

５７…ピストン

５８…挟圧子

５９…管体

６０…雌ネジ

６１…シリンダー部

６２…エアー口

６３…雄ネジ

６４…凹部

６５…貫通孔

６６…連結部

６７…第１空間部

６８…鍔部

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP03/10525

A. CLASSIFICATION OF SUBJECT MATTER
Int.Cl[7] F16K7/07

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Int.Cl[7] F16K7/07

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1926-1996 Toroku Jitsuyo Shinan Koho 1994-2003
Kokai Jitsuyo Shinan Koho 1971-2003 Jitsuyo Shinan Toroku Koho 1996-2003

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 02/46648 A1 (Asahi Organic Chemicals Industry Co., Ltd.), 13 June, 2002 (13.06.02), Figs. 15 to 20 & EP 1253360 A1 & JP 2002-372159 A	1-12
P,A	JP 2002-372159 A (Asahi Organic Chemicals Industry Co., Ltd.), 26 December, 2002 (26.12.02), Figs. 1 to 6 & WO 02/103230 A1 & EP 1253360 A1	1-12
A	JP 45-3264 Y1 (T.V. Valve Co., Ltd.), 13 February, 1970 (13.02.70), Full text (Family: none)	1-12

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 November, 2003 (18.11.03)	02 December, 2003 (02.12.03)
Name and mailing address of the ISA/ Japanese Patent Office	Authorized officer
Facsimile No.	Telephone No.

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP03/10525

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 7-103396 A (SMC Corp.), 18 April, 1995 (18.04.95), Full text (Family: none)	1-12

Form PCT/ISA/210 (continuation of second sheet) (July 1998)

国際調査報告	国際出願番号　ＰＣＴ／ＪＰ０３／１０５２５

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））
Ｉｎｔ．　Ｃｌ．[7]　Ｆ１６Ｋ７／０７

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））
Ｉｎｔ．　Ｃｌ．[7]　Ｆ１６Ｋ７／０７

最小限資料以外の資料で調査を行った分野に含まれるもの
日本国実用新案公報　　１９２６－１９９６年
日本国公開実用新案公報　　１９７１－２００３年
日本国登録実用新案公報　　１９９４－２００３年
日本国実用新案登録公報　　１９９６－２００３年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求の範囲の番号
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ＰＡ	ＪＰ　２００２－３７２１５９　Ａ（旭有機材工業株式会社）　２００２．１２．２６　第１－６図　＆ＷＯ　０２／１０３２３０　Ａ１＆ＥＰ　１２５３３６０　Ａ１	１－１２
Ａ	ＪＰ　４５－３２６４　Ｙ１（テイヴイバルブ株式会社）　１９７０．０２．１３　全文（ファミリーなし）	１－１２
Ａ	ＪＰ　７－１０３３９６　Ａ（エスエムシー株式会社）　１９９５．０４．１８　全文（ファミリーなし）	１－１２

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国際調査を完了した日	国際調査報告の発送日
１８．１１．０３	02.12.03

国際調査機関の名称及びあて先	特許庁審査官（権限のある職員）	３Ｑ	９８２７
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	電話番号　０３－３５８１－１１０１　内線　３３８１		

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(54) **Title**: APPARATUS AND METHODS FOR REMOVING OBSTRUCTIVE MATERIAL FROM BODY LUMENS

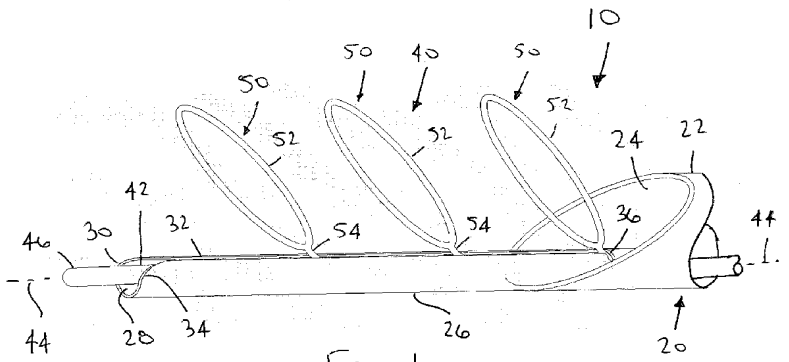

FIG. 1

(57) **Abstract**: An apparatus is provided for removing material within a body lumen that includes a catheter including a proximal end, a distal end for introduction into a body lumen, and an aspiration lumen extending therebetween; a guide member extending from the distal end and terminating in a distal tip, the guide member comprising a track adjacent a track lumen extending from the distal tip into the aspiration lumen; and an obstruction clearing device deployable from the guide member and retractable along the track. In addition or alternatively, the apparatus includes a cutting head reciprocable within the aspiration lumen adjacent the distal end for macerating material being aspirated into the aspiration lumen.

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APPARATUS AND METHODS FOR REMOVING OBSTRUCTIVE MATERIAL FROM BODY LUMENS

FIELD OF THE INVENTION

The present invention relates generally to apparatus for removing material within a body lumen of a patient. More particularly, the present invention relates to apparatus for removing or otherwise capturing thrombus or other obstructive material from within a tubular graft, blood vessel, or other body lumen, e.g., by cutting, separating, and/or aspiration of material, and to methods for making and using such apparatus.

BACKGROUND

Flow within a blood vessel or other body lumen within a patient's vasculature may become constricted or ultimately interrupted for a variety of reasons. For example, a vessel may gradually narrow due to inflammation and/or cell proliferation. In addition, thrombus may form due to such narrowing or other flow problems within a vessel.

For example, an aorto-venous graft may be implanted in an arm of a patient experiencing kidney failure, e.g., to facilitate dialysis treatment. Such grafts may be a fistula formed directly in the patient's body, e.g., through tissue between an adjacent artery and vein or other vessels, may be a xenograft implanted between two vessels, or may be a synthetic graft. Such grafts only have a limited life cycle due to inflammation, thrombus formation, and the like. Once such a graft becomes sufficiently occluded or otherwise deteriorates, a new graft must be implanted at a new location for subsequent treatment.

Some medical procedures involve aspirating material from within a body lumen. Although it may be desirable to provide a relatively large aspiration lumen in a catheter or other device to facilitate aspiration, many procedures require the device to maintain a relatively small profile, e.g., to provide desired tracking performance and/or avoid damaging the passages through which the device is directed. In such devices, relatively large particles may obstruct the aspiration lumen of the device, preventing further aspiration.

Accordingly, apparatus and methods for removing material from aorto-venous grafts, blood vessels, or other body lumens would be useful.

SUMMARY

The present invention is directed to apparatus for removing material within a body lumen of a patient. More particularly, the present invention is directed to apparatus for removing or otherwise capturing thrombus or other obstructive material within a tubular graft, blood vessel, or other body lumen, e.g., by cutting, separating, and/or aspiration the material, and to methods for making and using such apparatus.

In accordance with a first embodiment, an apparatus is provided for removing material within a body lumen that includes an elongate tubular member including a proximal end, a distal end sized for introduction into a body lumen, and an aspiration lumen extending between the proximal and distal ends; a guide member extending from the distal end and terminating in a distal tip, the guide member comprising a track adjacent a track lumen extending from the distal tip into the aspiration lumen; and an obstruction clearing device deployable from the guide member and retractable along the track.

In an exemplary embodiment, the obstruction clearing member includes a core wire slidable within the track lumen and one or more lumen clearing elements deployable from the distal tip of the guide member when the core wire is advanced relative to the guide member. The lumen clearing element(s) may include an expandable structure that is expanded from a contracted condition within the guide member to an expanded condition when deployed from the guide member, e.g., for engaging material within a body lumen. The expandable structure may be directable proximally along the track in the expanded condition, e.g., when the core wire is subsequently retracted relative to the guide member, for drawing the lumen clearing element(s) and any captured material into the aspiration lumen of the tubular member.

In addition, the guide member may include an orifice, e.g., in a side wall thereof, communicating with the track lumen, the orifice located within the aspiration lumen such that, when the core wire is retracted relative to the guide member, the expandable structure is compressed inwardly towards the contracted condition and the lumen clearing element(s) are drawn through the orifice into the track lumen. For example, the lumen clearing element(s) may be oriented substantially axially within the track lumen when the one or more lumen clearing elements are drawn through the orifice into the track lumen. When the core wire is subsequently advanced relative to the guide member, the lumen clearing element(s) may be directed through the track lumen in the contracted condition until the lumen clearing element(s) are redeployed from the distal tip of the guide member.

In accordance with another embodiment, a method is provided for removing material within a body lumen of a patient. A distal end of a tubular member may be introduced into a body lumen, the tubular member having a guide member extending distally from the distal end. The tubular member may be positioned such that the distal end is disposed adjacent material to be removed and a distal tip of the guide member is disposed beyond the material. One or more lumen clearing elements may be deployed from the distal tip of the guide member, each lumen clearing element including an expandable structure that expands from a contracted condition within the guide member to an expanded condition when deployed from the distal tip. The deployed lumen clearing element(s) may be retracted along a track of the guide member to engage material within the body lumen and draw the material into a lumen of the tubular member.

When the lumen clearing element(s) are retracted along the track of the guide member, the lumen clearing element(s) may be retracted through an orifice into the guide member to compress and/or draw the expandable structure(s) into the guide member. If desired, the lumen clearing element(s) may be redeployed from the distal tip of the guide member after retracting the one or more lumen clearing elements through the orifice into the guide member. This process may be repeated as often as desired to remove material from the body lumen.

Optionally, the material may be aspirated before or while being drawn into the lumen of the tubular member, e.g., to facilitate removing the material from the body lumen. In addition or alternatively, the material engaged by the lumen clearing elements may be separated by the expandable structure into multiple pieces, e.g., as the expandable structure is directed into the tubular member lumen and/or compressed back towards the contracted condition.

In accordance with still another embodiment, an apparatus is provided for removing material within a body lumen that includes an elongate tubular member including a proximal end, a distal end sized for introduction into a body lumen, and an aspiration lumen extending between the proximal and distal ends; and a cutting head disposed within the aspiration lumen adjacent the distal end. The cutting head is reciprocable axially or otherwise movable within the aspiration lumen for breaking up material being aspirated into the aspiration lumen.

In accordance with yet another embodiment, a method is provided for removing material within a body lumen of a patient. A distal end of a tubular member may be

introduced into a body lumen, the tubular member including an aspiration lumen and a cutting head disposed within the aspiration lumen near the distal end. The tubular member may be positioned such that the distal end is disposed adjacent material to be removed and/or vacuum pressure may be applied to the aspiration lumen to draw material within the body lumen towards the distal end of the tubular member. The cutting head may be activated, e.g., before, after, or when the vacuum pressure is applied, to cause the cutting head to reciprocate relative to the distal end to macerate material drawn to the distal end of the tubular member. The cutting head may break the material into pieces sufficiently small to be aspirated into the aspiration lumen by the vacuum pressure.

Other aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

It will be appreciated that the exemplary apparatus shown in the drawings are not necessarily drawn to scale, with emphasis instead being placed on illustrating the various aspects and features of the illustrated embodiments.

FIG. 1 is a side view of a distal end of an exemplary embodiment of an apparatus for capturing material within a body lumen, the apparatus including a plurality of lumen clearing elements deployable along a track of a catheter.

FIG. 2 is a cross-sectional view of a body lumen, showing the apparatus of FIG. 1 positioned therein with the lumen clearing elements deployed from the track within the body lumen.

FIGS. 3A-3G are cross-sectional views of a body lumen showing a method for capturing material from the body lumen using the apparatus of FIGS. 1 and 2.

FIG. 4 is a side view of a distal end of another exemplary embodiment of an apparatus for capturing material from within a body lumen that includes an alternate configuration for a lumen clearing element.

FIG. 5 is a side of an exemplary embodiment of another apparatus for capturing material within a body lumen that includes a reciprocating cutting head deployable from a catheter.

FIGS. 6A-6D are cross-sectional views of a body lumen showing a method for capturing material within the body lumen using the apparatus of FIG. 5.

FIGS. 7A-7D are side views of alternative embodiments of cutting heads that may be included in the apparatus of FIG. 5.

FIGS. 8A-8D are perspective details of the cutting heads of FIGS. 7A-7D, respectively, being deployed from a distal end of a catheter.

FIG. 9 is a cross-sectional view of a body lumen showing an exemplary embodiment of a system for capturing material from the body lumen that includes the apparatus of FIG. 5 and an expandable device for directing material within the body lumen towards the apparatus.

FIG. 10 is a side view of another exemplary system for capturing material from a body lumen including a sheath and a cutting assembly.

FIG. 11 is a cross-sectional view of a body lumen showing a method for removing material from a body lumen using the system of FIG. 10.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

Turning to the drawings, FIGS. 1 and 2 show an exemplary embodiment of an apparatus 10 for removing, retrieving, and/or otherwise capturing thrombus, objects, and/or obstructive material from within a body lumen 90, such as a blood vessel, aorto-venous fistula, tubular graft, and the like. Generally, the apparatus 10 includes a catheter, sheath, or other tubular member 20, and an obstruction clearing or retrieval device 40 including one or more lumen clearing appendages or elements 50 carried by a core wire, shaft, or other elongate member 42.

In the embodiment shown, the catheter 20 includes a proximal end (not shown), a distal end 22, and a lumen 24 extending therebetween. In addition, the catheter 20 includes a guide member 26 extending distally from the distal end 22, e.g., attached to or integrally formed with the distal end 24 of the catheter 20. Alternatively, the guide member 26 may be movable relative to the catheter 20, e.g., to allow the guide member 26 to be advanced from and/or retracted into the lumen 24 of the catheter 20 during use.

The guide member 26 includes a track lumen 28 that extends at least partially from within the catheter 20, e.g., from within the lumen 24 to a distal tip 30 of the guide member 26. The guide member 26 may terminate within the distal end 24 of the catheter 20, e.g., at a predetermined length therein corresponding to the length of the lumen clearing element(s) 50 and/or the region of the shaft 42 carrying the lumen clearing

element(s) 50. Alternatively, the guide member 26 may extend substantially to the proximal end of the catheter 20 (not shown).

The guide member 26 may allow the lumen clearing element(s) 50 to be deployed from and/or drawn into the guide member 26 during use, as described further below. For example, the guide member 26 may include a track or other feature for guiding the lumen clearing element(s) 50 along the guide member. In the embodiment show, the guide member 26 includes a slit 32 that extends from the catheter 20, e.g., from within or adjacent the distal end 22, to the distal tip 30 of the guide member 26. The slit 32 may be oriented inwardly towards the lumen 24 of the catheter 20, e.g., to guide the lumen clearing element(s) 50 into the lumen 24 of the catheter, as described further below.

The distal tip 30 of the guide member 26 may be substantially atraumatic, e.g., rounded or otherwise shaped to reduce risk of damaging walls of body lumens within which the apparatus 10 is introduced. In addition, the distal tip 30 may include a tapered entrance 34 communicating with the slit 32, e.g., to guide the lumen clearing element(s) 50 into the slit 32, as described further below. The guide member 26 also includes an orifice 36, e.g., at an end of the slit 32 opposite the tapered entrance 34, e.g., within the lumen 24 of the catheter 20. The orifice 36 may be sized and/or shaped to allow the lumen clearing element(s) 50 to be drawn into the track lumen 28 of the guide member 26, e.g., as described further below.

Optionally, the catheter 20 may include one or more additional lumens (not shown) extending between the proximal end and the distal end 22, e.g., for delivering and/or aspirating fluid, for receiving a guidewire or other rail (not shown), and the like. For example, in some applications, it may be desirable to advance the entire apparatus 10 over a guidewire or other rail (not shown), e.g., by loading the guidewire through a guidewire lumen (also not shown) disposed adjacent the lumen 24, or through the lumen 24 itself. In addition, or alternatively, a source of fluid, e.g., one or more solvents or other therapeutic agents, a source of vacuum, e.g., a syringe, a vacuum line, and the like, may be coupled to the catheter 20, e.g., for delivering or aspirating material through the lumen 24 or other lumen (not shown) in the catheter 20.

For example, the apparatus 10 may include a handle (not shown) coupled to or otherwise on the proximal end of the catheter 20, e.g., for manipulating the catheter 20 and/or the entire apparatus 10. The handle may include one or more controls or actuators (also not shown) for actuating the obstruction clearing device 40 and/or other components

of the apparatus 10. In addition, the handle may include one or more ports (not shown) for coupling to a source of fluid and/or vacuum. For example, one of the ports may communicate with the lumen 24 and a vacuum line, syringe, or other source of vacuum may be coupled to the port to allow aspiration of material within or adjacent the lumen 24, e.g., as described further below. Exemplary embodiments of handles that may be provided on the apparatus 10 are disclosed in provisional application Serial No. 61/078,330, filed July 3, 2008.

With continued reference to FIGS. 1 and 2, the core wire 42 of the obstruction clearing device 40 generally includes a proximal end, e.g., within the proximal end of the catheter 20 (not shown), and a distal end terminating in a distal tip 46, e.g., defining a longitudinal axis 44 for the apparatus 10. The core wire 42 may be a substantially flexible elongate member, e.g., a solid or hollow wire structure, having sufficient length to extend from the proximal end of the catheter 20 through and beyond the guide member 26.

For example, the core wire 42 may have sufficient length to extend from a target site within a patient's body through the catheter 20 to a location outside the patient's body. Alternatively, the core wire 42 may extend to and be coupled to other components of the apparatus 10 spaced apart proximally from the lumen clearing element(s) 50. The core wire 42 may have sufficient column strength to allow advancement of the core wire 42 through the catheter 20 without substantial risk of buckling or kinking. For example, a distal region of the core wire 42 may be relatively flexible and a proximal region may be substantially rigid or semi-rigid to facilitate advancement of the distal region from the proximal end of the catheter 20. The core wire 42 may be formed from a single wire strand, multiple strands, a coiled wire structure, and the like having a sufficiently small profile to be slidably received in the catheter 20 and/or guide member 26.

In an exemplary embodiment, the proximal end of the core wire 42 may be received within and/or otherwise coupled to a handle (not shown). The handle may be mounted or otherwise provided on the proximal end of the catheter 20, as described above, and may include an actuator, e.g., a slider control, button, and the like (not shown) for directing the core wire 42 axially relative to the catheter 20, e.g., to deploy and/or retract the lumen clearing element(s) 50 from the guide member 26, as explained further below.

The distal tip 46 of the core wire 42 may be substantially atraumatic, e.g., rounded or otherwise shaped to minimize risk of perforation and/or catching during advancement from the guide member 26 within a patient's body. Optionally, the distal tip 46 may be

covered by a coiled wire and/or a polymeric covering, and/or may include a "J" or other curved tip (not shown).

With particular reference to FIG. 1, as shown, the obstruction clearing device 40 includes a plurality of the lumen clearing elements 50 for capturing material within a body lumen. Although three lumen clearing elements 50 are shown, it will be appreciated that the apparatus may include fewer or more elements, e.g., only one or two, or four or more, as desired. Each lumen clearing element 50 may include an expandable structure that may be compressed to allow advancement through the track lumen 28 of the guide member 26 and expanded to extend at least partially across a body lumen.

In the exemplary embodiment shown in FIGS. 1 and 2, each lumen clearing element 50 includes an enclosed hoop 52 coupled to an arm 54 extending from the core wire 42. Each respective hoop 52 and arm 54 may be integrally formed together, for example, by forming the hoop 52 and arm 54 from a flat sheet, e.g., by laser cutting, die cutting, stamping, and the like, by bending or otherwise forming a wire into the hoop shape with one end of the wire providing the arm 54 and the other end attached to the arm 52 to enclose the hoop 52, and the like. Each arm 54 may be attached at predetermined locations on the core wire 42, e.g., spaced apart from one another by a desired spacing, e.g., by bonding, welding, soldering, and the like. For example, one end of each arm 54 by attached to a side of the core wire 42 such that the arms 54 are aligned axially with one another. The arms 54 may be spaced apart by a distance such that the hoops 52 do not substantially overlap one another when compressed to the contracted condition, e.g., to reduce an overall profile of the lumen clearing elements 50 when compressed into the track lumen 28 of the guide member 26.

One of each arm 54 may be attached directly to the core wire 42. Alternatively, a portion of each arm 54 may be wrapped at least partially around the core wire 54 and/or each arm 54 may be attached to a collar or sleeve (not shown) that may be attached to the core wire 54 such that the arms 54 are spaced apart and axially aligned with one another.

In an exemplary embodiment, the hoops 52 and/or arms 54 may be formed from elastic or superelastic material. Thus, the hoops 52 may be compressed radially inwardly to a contracted condition (not shown) sufficiently small to be directed into and along the track lumen 28 of the guide member 26, yet resiliently expandable towards an expanded, relaxed condition, as shown, in which the hoops 52 extend transversely from the core wire 42. Exemplary materials for the lumen clearing element(s) 50 include metals, such as

Nitinol or stainless steel, polymers or other plastics, or composite materials. The hoops 52 and/or arms 54 may be heat treated or otherwise set to biased to the expanded condition yet resiliently compressible to the contracted condition.

In the relaxed condition, the hoops 52 may have a circular or elliptical shape, e.g., approximating a desired range of diameters of body lumens to be treated using the apparatus 10. For example, the hoops 52 may have a size sufficient to extend substantially across a body lumen 90 in the expanded condition, e.g., having a diameter or minor elliptical axis between about two and ten millimeters (2-10 mm) and/or a circumference or other perimeter length between about six and thirty millimeters (6-30 mm). In the relaxed condition, the arms 54 may be biased to extend transversely relative to the core wire 42 and longitudinal axis 44 at a desired angle, e.g., between about thirty and ninety degrees (30-90°). As shown, in the relaxed condition, the arms 54 and hoops 52 may extend away from the distal end 22 of the catheter 20, although, alternatively, they may extend substantially perpendicular to or towards the distal end 22, if desired.

The arms 54 may have a length relatively smaller than the size of the hoops 52, e.g., between about half to two millimeters (0.5-2.0 mm). Thus, the arms 54 may simply provide flexible hinges to allow the hoops 52 to be deployed from and retracted into the track lumen 28 of the guide member 26.

In the contracted condition, each hoop 52 may be compressible inwardly, e.g., such that side regions of the hoops 52 between the arm 52 and the outer region opposite the arm 52 are directed towards one another. Thus, in the contracted condition, the hoops 52 may have a cross-section smaller than the diameter of the track lumen 28 of the guide member 26, e.g., between about half to two millimeters (0.5-2.0 mm), as described further below. Also in the contracted condition, the arms 54 may be bendable inwardly towards the core wire 42, e.g., such that the hoops 52 extend substantially parallel to the longitudinal axis 44 to facilitate the hoops 52 being received in and directed along the track lumen 28 of the guide member 26, as described further below.

The hoops 52 may have a variety of cross-sections or thicknesses, e.g., a circular cross-section, which may provide a substantially atraumatic shape to prevent damaging the wall of a body lumen within which the element(s) 50 are deployed. Alternatively, other cross-sections may be provided along the entire perimeter of the hoops 52 or only at desired regions, e.g., between the side and outer regions, to provide one or more cutting edges, e.g., to facilitate removing adherent material from the wall of a body lumen within

which the element(s) 50 are deployed. For example, a single cutting edge may be provided on each of the hoops 52 or multiple cutting edges, e.g., extending along an outer or leading edge of the hoops 52 or spirally around the hoops 52, as desired. In addition or alternatively, the thickness of the hoops 52 may be varied around their perimeter to provide a variable flexibility to different regions of the hoops 52, if desired.

Optionally, if desired, the lumen clearing element(s) may include one or more additional features, e.g., to facilitate capturing material therein and/or removing adherent material from a wall of a body lumen being treated. For example, FIG. 4 shows an alternative embodiment of an lumen clearing element 50' that includes a hoop 52' coupled to an arm 54' extending from a core wire 42, similar to the previous embodiment. However, unlike the previous embodiment, additional loops 56' are provided on the hoop 52,' e.g., that extend from side regions of the hoop 52.' The loops 56' may be substantially symmetrical relative to the outer region of the hoop 52,' e.g., with one loop 56' on either side of the outer region of the hoop 52,' as shown. Thus, in this embodiment, the lumen clearing element 50' splits into three separate loops around a midpoint of the hoops 52,' which may reduce spacing between the loops. This embodiment may facilitate breaking up thrombus or other material as it is contacted by the lumen clearing element(s) 50' and/or drawn into the catheter 20, e.g., as described further below.

During manufacturing assembly or during preparation immediately before use, the apparatus 10 is provided with the obstruction clearing device 40 loaded into the catheter 20, e.g., such that the lumen clearing elements 50 are compressed into the contracted condition within the track lumen 28 of the guide member 26 (not shown, see generally FIGS. 3A-3B).

For example, during manufacturing, the guide member 26 may be attached to the catheter 20 such that the guide member 26 extends from the proximal end of the catheter 20 beyond the distal end 22 of the catheter 20, as described above. Alternatively, the guide member 26 may extend only a short distance into the distal end 22 of the catheter 20. The catheter 20 may include a co-extrusion or other tubular body that includes both the lumen 24 and a guide lumen (not shown), and the guide member 26 may be coupled to the catheter 20 such that the track lumen 28 of the guide member 26 communicates with the guide lumen. The catheter 20 and/or guide member 26 may be constructed as a single tubular component along their length or may be formed from multiple tubular components

attached together, e.g., to provide a desired rigidity and/or flexibility at difference regions along the length of the catheter 20 and/or guide member 26. For example, the proximal regions may be relatively rigid or semi-rigid to facilitate advancement of the catheter 20 and/or guide member 26, while the distal regions may be relatively flexible to facilitate advancement through tortuous anatomy.

To make the obstruction clearing device 40, the lumen clearing elements 50 may be formed and attached to the core wire 42, e.g., as described above. The core wire 42 may be backloaded into the lumen 28 of the guide member 26, e.g., until a proximal end of the core wire 42 extends towards or to the proximal end of the catheter 20. The proximal end of the core wire 42 may be coupled to an actuator, e.g., on a handle on the proximal end of the catheter 20. The core wire 42 may be directed proximally, e.g., using the actuator on the handle or before coupling to the actuator, to draw the lumen clearing elements 50 into the lumen 28 of the guide member 26, thereby compressing the lumen clearing elements 50 into the contracted condition, similar to the method described below for retracting the lumen clearing elements 50 during use.

Optionally, if desired, the apparatus 10 may include one or more markers to facilitate positioning and/or advancement of the apparatus 10 during use. For example, one or more radiopaque markers may be placed on the obstruction clearing device 40, e.g., on the core wire 42, hoops 52, and/or arms 54. Alternatively, the lumen clearing elements 50 or components thereof may be formed from radiopaque or other materials that may facilitate imaging the apparatus 10 during use. For example, radiopaque markers and/or materials may facilitate positioning or otherwise imaging the apparatus 10 using fluoroscopy or other x-ray imaging, e.g., when deploying and/or actuating the basket device 40. Alternatively, echogenic markers and/or materials may be provided to facilitate imaging using ultrasound or similar imaging techniques.

Turning to FIGS. 3A-3G, an exemplary method is shown for retrieving, removing, or otherwise capturing material 92 within a body lumen 90, e.g., using an apparatus 10, which may be any of the embodiments described herein, and not necessarily limited to the embodiment shown and described below with reference to FIGS. 1 and 2. The body lumen 90 may be a blood vessel, e.g., a vein or artery, a graft, e.g., an aorto-venous fistula, tubular xenograft, or synthetic tubular graft, and the like. For example, the body lumen 90 may be a passage communicating between an adjacent artery and vein (not shown), e.g., in an arm or other region of a dialysis patient. Alternatively, the body lumen 90 may be a

blood vessel within a patient's vasculature, e.g., a peripheral vessel in a patient's leg, a cerebral vessel, and the like. In a further alternative, the material 92 may be a stone within a patient's urinary tract or other foreign object to be removed from the patient's body.

Optionally, the body lumen 90 may be accessed using one or more additional instruments (not shown), which may be part of a system or kit including the apparatus 10. For example, an introducer sheath, guide catheter, or other tubular member (not shown) may be introduced adjacent the target site where the material is to be removed, or may be introduced elsewhere in the patient's body to provide access to the patient's vasculature or other passages communicating with the body lumen 90. If the body lumen 90 is located in a peripheral vessel of the patient, a percutaneous puncture or cut-down may be created using a needle or other instrument (not shown) at a peripheral location (also not shown), such as a femoral artery, carotid artery, or other entry site, and an introducer sheath may be placed through the puncture at the peripheral location to provide access. The apparatus 10 may be advanced through the patient's vasculature from the entry site, e.g., alone or with the aid of a guide catheter, guidewire, and the like (not shown).

For example, to facilitate directing the apparatus 10 from an entry site to the target body lumen 90, a guide catheter, micro-catheter, or other tubular body may be placed from the entry site to the body lumen 90 using conventional methods. In addition or alternatively, a guidewire (not shown) may be placed from the entry site to the body lumen 90 if desired, e.g., if the apparatus 10 includes a guidewire lumen in the catheter 20 or core wire 42.

Initially, as shown in FIG. 3A, the apparatus 10 has been advanced into the body lumen 90 such that the guide member 26 extends through or otherwise beyond the material 90 being captured. Optionally, one or more fluids may be delivered into the body lumen 90, e.g., to facilitate imaging and/or positioning the apparatus 10. For example, radiopaque fluid may be delivered into the body lumen 90 via the lumen 24 of the catheter 20 (or via a lumen in the core wire 42 or the track lumen 28 of the guide member 26) to facilitate locating and/or measuring the size of the material 92 using fluoroscopy. Markers (not shown) on the apparatus 10 may facilitate positioning the guide member 26 and/or distal end of the catheter 20 relative to the material 92 before the obstruction clearing device 40 is deployed, e.g., to facilitate verifying that the distal tip 30 of the guide member 26 is positioned distal to the material 92.

Optionally, at this point or any time hereafter, a source of vacuum communicating with the lumen 24 of the catheter 20 may be activated to aspirate the material 92 or segments thereof and/or fluid into the lumen 24. In addition or alternatively, the vacuum may be applied to maintain the material 92 adjacent the distal end 22 of the catheter 20, e.g., to prevent migration of the material 92 during subsequent steps of the procedure.

Turning to FIG. 3B, the obstruction clearing device 40 may then be deployed within the body lumen 90, e.g., such that the lumen clearing elements 50 are disposed distally beyond the material 92. As shown, the core wire 42 may emerge first from the track lumen 28 beyond the distal tip 30 of the guide member 26, and then the lumen clearing elements 50 may become exposed, whereupon the lumen clearing elements 50 may resiliently and automatically expand to the expanded condition within the body lumen 90, as shown in FIG. 3C. Because the distal tip 30 of the guide member 26 is positioned distally beyond the material 92, the lumen clearing elements 50 are deployed well beyond the material 92, which may reduce the risk of deploying the lumen clearing elements 50 within or adjacent the material 92 and dislodging the material 92 or segments prematurely.

With further reference to FIG. 3D, the obstruction clearing device 40 may then be retracted relative to the catheter 20 and guide member 26. As shown, as the core wire 42 is withdrawn back into the track lumen 28 of the guide member 26, the arms 54 of each successive lumen clearing element 50 may contact the distal tip 30 and be guided by the tapered entrance 34 into the slit 32. The slot 32 may be sufficiently wide that the arms 54 pass freely into and along the slot 32 with the hoops 52 remaining deployed substantially in the expanded condition, as shown. Thus, the hoops 52 may substantially surround, engage, and/or otherwise capture the material 92 within one or more of the hoops 52, e.g., depending on the length and/or size of the material 92.

As shown in FIG. 3E, as the obstruction clearing device 40 is retracted further, the hoops 52 of the lumen clearing elements 50 are pulled through the distal end 22 of the catheter 20 into the lumen 24. As the outer region of the hoops 52 enter the lumen 24, the material 92 may be cut or otherwise separated if it is too large to be drawn into the lumen 24 in a single piece. The smaller pieces may be drawn into the lumen 24 due to aspiration provided by the vacuum within the lumen 24 and/or pulled in by the hoop 52 entering the distal end 22. If remaining pieces of the material 92 are too large to be drawn into the lumen 22, they may remain immediately outside the distal end 22, e.g., due to the aspiration pressure, until the next hoop 52 engages and/or cuts the material 92 further.

Thus, multiple successive lumen clearing elements 50 may facilitate breaking the material 92 into pieces sufficiently small to be drawn into the lumen 24 by aspiration.

If desired, the material 92 may be treated, e.g., at least partially dissolved, macerated, and the like before, during, or after withdrawal of the lumen clearing elements 50 into the catheter 20. For example, a therapeutic agent may be delivered into the body lumen 90 via the catheter 20 (e.g., through lumen 24 or another infusion lumen, not shown), e.g., to at least partially dissolve or separate thrombus or other relatively soft material before being drawn into the lumen 24 of the catheter 20.

Optionally, the hoops 52 of the lumen clearing elements 50 may include one or more cutting edges (not shown), which may facilitate separating the material 92 into multiple pieces. In addition or alternatively, such cutting edge(s) may facilitate scraping a wall of the body lumen 90, e.g., to remove adherent material from the wall of the body lumen 90 and facilitate capturing the material.

As shown in FIG. 3F, the final lumen clearing element 50 has been drawn into the lumen 24, along with the captured material 92. As the lumen clearing elements 50 enter the lumen 24, the hoops 52 may be compressed inwardly towards the contracted condition and/or the arms 54 may be bent to accommodate receiving the hoops 52 within the lumen 24. As can be seen in FIG. 3G (and FIG.1), the slit 32 in the guide member 26 communicates with the orifice 36 within the distal end 22 of the catheter 20. The orifice 36 may be sufficiently large, e.g., wide to receive the hoops 52 therethrough, thereby allowing the hoops 52 to be drawn through the orifice 36 into the track lumen 28. As this occurs, the lumen clearing elements 50 may be compressed into the contracted condition, e.g., oriented substantially axially within the track lumen 28 of the guide member 26.

In this orientation, if desired, the obstruction clearing device 40 may be advanced distally again to direct the lumen clearing elements 50 distally through the track lumen 28 of the guide member 26, e.g., until the lumen clearing elements 50 are deployed from the distal tip of the guide member 26, as shown in FIGS. 3B and 3C. Thus, the steps shown in FIGS. 3B-3G may be repeated as many times as desired, e.g., to capture additional pieces of material 92 within the body lumen 90. Optionally, the catheter 20 may be repositioned within the body lumen 90, e.g., advanced distally further into the body lumen 90 to capture additional material (not shown) therein.

Because the lumen clearing elements may be retracted and redeployed as often as desired, the obstruction clearing device may include any number of lumen clearing

elements. For example, as shown in FIG. 4, the obstruction clearing device 40' includes only one lumen clearing element 50, which may be deployed and then retracted repeatedly to break up and/or capture material within a body lumen. The material may be easily broken into pieces small enough to be drawn into the lumen 24 of the catheter 20 by aspiration or otherwise. Once all of the desired material has been removed, the apparatus 10 (e.g., with the lumen clearing element(s) withdrawn into the guide member 26) may be withdrawn from the body lumen and/or the patient's body.

The process may be repeated, as desired, using the same apparatus 10 or a different apparatus (not shown). For example, the obstruction clearing device 40 may be withdrawn into the catheter 20 and then directed to another location within the body lumen 90 or other elsewhere in the patient's body, and then redeployed to capture additional material, and the process may be repeated as often as desired.

Turning to FIG. 5, another embodiment of an apparatus 110 is shown for removing material from a body lumen. Generally, the apparatus 110 includes a catheter, sheath, or other tubular member 120 and a cutting assembly 140 disposed within the catheter 110. In addition, the apparatus 110 includes a control system 160, e.g., for moving the cutting element 140 relative to the catheter 120, and a vacuum source 170, which may be disposed within a handle 180 of the apparatus 110. Optionally, the apparatus 110 may include a guide member and obstruction clearing device (not shown), if desired, which may be used in combination with the cutting assembly 140, e.g., with the obstruction clearing device drawing material into the catheter 120 and the cutting assembly 140 breaking the material up to facilitate aspiration, as described further below.

The catheter generally 120 includes a proximal end 121, a distal end sized for introduction into a body lumen 122, and one or more lumens, e.g., an aspiration lumen 124, extending between the proximal and distal ends 121, 122. Optionally, the catheter 120 may include one or more additional lumens (not shown), e.g., a guidewire lumen, a shaft lumen, and the like, if desired. The catheter 120 may be constructed similar to the previous embodiments, e.g., having a desired length and/or flexibility for accessing a body lumen within a patient's body to be treated. The relative size of the catheter 120 and handle 180 shown in FIG. 5 are not to scale, but are merely intended to illustrate the various components of the apparatus 110. In particular, the handle 180 has been shown substantially larger than its actual size relative to the catheter 120 to facilitate identification of the components within the handle 180.

The cutting assembly 140 generally includes a cutting head 142 disposed adjacent the distal end 122 of the catheter 120 and a drive shaft 144 extending proximally from the cutting head 142, e.g., to the proximal end 121 of the catheter 120, as shown. The cutting head 142 terminates in a rounded tip 146 and includes one or more teeth 148, e.g., along a side edge of the cutting head 142. The cutting head 142 has a width smaller than the diameter of the aspiration lumen 124, e.g., slightly smaller than the aspiration lumen 124 such that the cutting head 142 is free to move axially within the aspiration lumen 124 with minimal lateral movement. Alternatively, the cutting head 142 may have a width substantially smaller than the aspiration lumen 124 and may be movable along one side of the catheter wall, e.g., with the teeth 148 oriented inwardly towards the center of the aspiration lumen 124.

FIGS. 7A-7D are side views of alternative embodiments of cutting heads 142 that may be provided for the cutting assembly 140 of FIG. 5. For example, the cutting head 142a of FIG. 7A includes a rounded tip 146a and a plurality of teeth 148a along opposite side edges of the cutting head 142a. FIG. 7B shows a similar cutting head 142b that includes four sets of teeth 148b spaced apart ninety degrees from one another, each set of teeth 148b extending axially along a cutting length of the cutting head 142b. The cutting head 142c of FIG. 7C terminates in a sharpened tip 146c and includes a set of teeth 148c tapering to the tip 146c. FIG. 7D shows a cutting head 142d that includes a rounded tip 146d and one set of teeth 148d, similar to that shown in FIG. 5, except that the teeth 148d are angled diagonally, e.g., proximally away from the tip 146d. Such angled teeth 148d may facilitate cutting, tearing, breaking up, or otherwise macerating material engaged by the teeth 148d and pulling the material into the aspiration lumen 124, as described further below. Similar to the cutting head 142 of FIG. 5, the cutting heads 142a-142d may be movable within the aspiration lumen 124 of a catheter 120, as shown in FIGS. 8A-8D, respectively, and described further below.

Returning to FIG. 5, the cutting head 142 (or any of the alternatives shown in FIGS. 7A-7D) may be formed from a substantially rigid sheet, bar, or other base material, e.g., by machining, laser cutting, stamping, casting, molding, and the like, thereby providing the desired shape for the tip 146 and teeth 148. The cutting head 142 may be integrally formed with the shaft 144 or may be attached to the shaft 144 subsequent to forming the cutting head 142, e.g., by welding, soldering, bonding, mating connectors (not shown), and the like. The shaft 144 may be formed from a substantially rigid or semi-

rigid solid or hollow wire, rod, or other material, e.g., having sufficient column strength to allow the cutting head 142 to be reciprocated or otherwise moved from the proximal end 121 of the catheter 120. The cutting head 142 and/or shaft 144 may be formed from a variety of materials, e.g., metals, such as stainless steel, plastic, or composite materials.

The shaft 144 may have a relatively small diameter or other cross-section compared to the cutting head 144, e.g., such that the shaft 144 occupies minimal space within the aspiration lumen 124 of the catheter 120. Thus, material aspirated into the aspiration lumen 124 of the catheter 120 may be free to pass along the aspiration lumen 124 with minimal resistance caused by the shaft 144. Alternatively, the shaft 144 may enter and travel along a separate shaft lumen (not shown) in the catheter 120, e.g., extending from a location adjacent the distal end 122 to the proximal end 121, e.g., if it is desired to separate the shaft 144 substantially from material traveling through the aspiration lumen 124.

Returning to FIG. 5, the proximal end 121 of the catheter 120 may be coupled to the handle 180 such that the shaft 144 extends into the handle 180, e.g., through one or more seals 182. In exemplary embodiments, the seal(s) 182 may include a piston/cylinder arrangement, a bellows, and the like. The shaft 144 may be coupled to the control system 160, e.g., such that the shaft 144 may be reciprocated or otherwise moved relative to the catheter 120. For example, the control system 160 may include a motor for driving the shaft 144, e.g., by coupling the shaft 144 to an output 163 of the motor 162. The control system 160 may also include a power source 164, e.g., a battery pack, rechargeable battery, a cable for connecting to an electrical outlet (not shown), and the like, coupled to the motor 162 and an electrical switch 166 for selectively supplying power from the power source 164 to the motor 162 for turning the motor 162 off and on.

The vacuum source 170 is coupled to the aspiration lumen 124 of the catheter 120, e.g., via line 172 that communicates with the aspiration lumen 124. In the exemplary embodiment shown, the vacuum source 170 may be a syringe 176 including a plunger 178, which may be drawn to create a vacuum within the syringe 176 and then locked in position to maintain the vacuum. Alternatively, the vacuum source may be an external vacuum source, e.g., house vacuum in a facility, an external pump, and the like.

A fluid valve 174 is provided in the line 172 that may be actuated by a user to selectively open and close the line 172, e.g., to supply a vacuum pressure to the aspiration lumen 124 from the syringe 176. The fluid valve 174 may be coupled to the switch 166

such that, when a user activates the fluid valve 174 to aspirate the aspiration lumen 124, the switch 166 turns on the motor 162, causing the cutting head 142 to reciprocate. Alternatively, there may be a delay between opening the fluid valve 174 and turning on the motor 162 or the motor 162 may be turned on independently of the vacuum source 160. When the fluid valve 174 is deactivated to close the line 172, the switch 166 turns the motor 162 off, or the motor 162 may be turned off independently, either before or after turning off the vacuum source 160.

Turning to FIGS. 6A-6D, an exemplary method is shown for using the apparatus 110 of FIG. 5 to remove material 92 from a body lumen 90. The body lumen 90 may be a tubular graft, blood vessel, or other location within a patient's body accessed similar to the previous embodiments described above. As shown in FIG. 6A, the distal end 122 of the catheter 120 is positioned within the body lumen 90, e.g., from a percutaneous or other entry site, with the cutting assembly 140 and aspiration deactivated. Turning to FIG. 6B, a vacuum may be applied to the aspiration lumen 124, thereby drawing the material 92 within the lumen 90 towards the distal end 122 of the catheter 120. For example, as described above with additional reference to FIG. 5, the plunger 178 may be drawn to create a vacuum within syringe 176 and then locked or otherwise secured to maintain the vacuum within the syringe 176. Alternatively, an external source of vacuum (not shown) may be coupled to the handle 180 to apply a vacuum to the line 172. The fluid valve 174 may be opened to apply the vacuum to the aspiration lumen 124 of the catheter 120.

As shown, the material 92 may be too large to be drawn into the aspiration lumen 124 despite the vacuum. Turning to FIG. 6C, however, when the fluid valve 172 is opened, the switch 166 is substantially simultaneously activated to turn on the motor 162 and begin reciprocation of the cutting head 142. Alternatively, the switch 166 may be activated independently of the fluid valve 172, e.g., before or after opening the fluid valve 172. Once the motor 162 is activated, the cutting head 142 may reciprocate from a proximal or first position within the distal end 122 of the catheter 120 (shown in FIGS. 5 and 6B) to a distal or second position extending at least partially from the distal end 122 (shown in FIG. 6C).

When the cutting head 142 moves to the distal position, the tip 146 of the cutting head 142 may initially contact the material 92, e.g., to being breaking the material 92 up into smaller particles or pieces. The teeth 148 may also contact the material 92, e.g., to push the material upwardly and/or pull the material 92 proximally, which may cut, break,

or otherwise separate the material 92 into smaller pieces 92a. As shown in FIG. 6D, the smaller pieces 92a may be sufficiently small to pass freely into the aspiration lumen 124 due to the vacuum being applied, thereby removing the pieces 92a from the body lumen 90 into the catheter 110, e.g., into the syringe 176 or other storage chamber (not shown) in the handle 180. It may take several reciprocations to fully macerate and aspirate the material 92 within the body lumen 90. The proximal oriented teeth, such as the teeth 148a-148d shown in FIGS. 7A-7D, may facilitate tearing off pieces 92a of the material 92, e.g., when the cutting head 142a-142d is withdrawn back into the distal end 122 of the catheter 120.

The motor 162 and consequently the cutting head 142 may be operated at speeds sufficiently fast to minimize the chance of the material 92 deforming and moving out of the way of the teeth 148 during reciprocation. For example, it may be desirable to operate the cutting head 142 at speeds of about 3,600-60,000 cycles per minute, e.g., about ten thousand cycles per minute or more. Such speeds may substantially prevent the material 92 from moving out of the way of the cutting head 142, which may result in a more complete and quick maceration and aspiration of the material 92.

Turning to FIG. 9, in an alternative embodiment, the apparatus 110 of FIG. 5 may be used in cooperation with an expandable flow restoration device 190, e.g., to provide a system for removing material 92 from a body lumen 90. The flow restoration device 190 may include an expandable member 192 on a distal end 194 of a shaft 196, e.g., a catheter, sheath, or other tubular body. The expandable member 192 may be a balloon, a mechanically expandable structure, and the like. In the embodiment shown, the expandable member 192 may be a helical device, such as those disclosed in co-pending provisional application Serial No. 61/153,620, filed February 18, 2009.

The shaft 196 of the flow restoration device 190 may be slidably received within a lumen of the catheter 120, e.g., the aspiration lumen 124 or another lumen provided within the catheter 120. In one embodiment, the distal end 194 of the flow restoration device 190 (with the expandable member 192 collapsed, not shown) may be inserted into a port in the proximal end of the catheter 120 and advanced through the catheter 120 after the catheter 120 has been positioned in the body lumen 90. The distal end 194 of the flow restoration device 190 may be advanced completely through the material 92 obstructing the body lumen 90, whereupon the expandable member 192 may be expanded, as shown.

Alternatively, a guidewire or other rail (not shown) may be placed in the body lumen 90 before the apparatus 110 and/or flow restoration device 190. The flow restoration device 190 may be advanced over the guidewire into the body lumen 90 and positioned as desired. The catheter 120 may then be advanced over the shaft 196 of the flow restoration device 190 or over a separate guidewire (not shown), e.g., until the catheter 120 is positioned relative to the flow restoration device 190 as shown in FIG. 9.

The flow restoration device 190 may then be retracted proximally towards the distal end 122 of the catheter 120, e.g., with the cutting head 142 and vacuum activated to facilitate pulling material 92 towards the distal end 122 and cutting head 142. The expandable member 192 may sufficiently engage the wall of the body lumen 90 to scrape or otherwise remove adherent material from the wall of the body lumen 90 and direct the material towards the distal 122 of the catheter 120.

Alternatively, the shaft 196 of the flow restoration device 190 may be coupled to an axial clutch device (not shown) within the handle 180 of the apparatus 110. In this alternative, the clutch device may be activated before, after, or when the motor 162 and/or vacuum source 160 are activated. During use, the clutch device is free to pass over the shaft 196 in a distal direction, e.g., during the outstroke of the cutting head 142, but engages the shaft 196 during the instroke of the cutting head 142, thereby directing the shaft 196 and expandable member 192 proximally within the body lumen 90. Thus, each stroke of the cutting head 142 may pull the expandable member 192 proximally a predetermined distance to automatically pull material 92 within the body lumen 90 towards the cutting head 142 and distal end 122 of the catheter 120. The location of the expandable member 192 may be set at a minimum distance from the distal end 122 of the catheter 120 before activation to ensure that a desired section of the body lumen 90 is scraped as the material 92 is macerated and aspirated by the apparatus 110.

Turning to FIGS. 10 and 11, another embodiment of an apparatus 210 is shown that includes a catheter, sheath, or other tubular member 220 and a cutting assembly 240. Similar to the previous embodiments, the catheter 220 includes a proximal end 221, a distal end 222, and an aspiration lumen 224 extending therebetween. Unlike the previous embodiments, the catheter 220 includes a balloon or other expandable member 228 adjacent the distal end 222. For example, if the distal end 222 is beveled, the balloon 228 may be provided on an outer wall of the catheter 220 opposite the leading edge of beveled tip 223, as shown.

The balloon 228 may be formed from compliant or semi-compliant material, e.g., such that the balloon 228 conforms to surrounding anatomy when the balloon 228 is expanded. Thus, the balloon 228 may expand to substantially occlude a body lumen within which the catheter 220 is disposed, which may prevent escape of material past the catheter 220 during use, as described further below.

As shown, the balloon 228 may be bonded or otherwise attached on only one side of the distal end 222 of the catheter 220. Alternatively, a balloon may be provided that extends partially or entirely around the circumference of the distal end 222 of the catheter 220. In this alternative, the balloon may be biased or otherwise constructed to expand primarily or exclusively in one direction, e.g., radially outwardly opposite from the beveled tip 223.

Alternatively, the balloon 228 may be formed from noncompliant material, e.g., such that the balloon 228 expands to a predetermined shape, which may press the catheter 220 against the wall of the body lumen opposite the balloon 228 without necessarily sealing the body lumen. In a further alternative, other expandable members may be provided instead of the balloon 228. For example, an expandable mesh or frame (not shown) may be provided on the catheter 220, which may be expanded by activating an actuator on a handle 230 of the catheter 220. The mesh or frame may include a membrane such that, when the mesh or frame is expanded within a body lumen, the expandable member may be substantially nonporous to reduce migration of material past the catheter 220. Alternatively, the mesh or frame may be porous, if desired, e.g., to allow continued flow along the body lumen 90.

The cutting assembly 240 includes a cutting head 242 (which may be any of the embodiments described herein) and a shaft 244, which may also be generally similar to the previous embodiments. However, in this embodiment, the cutting assembly 240 is separate from the catheter 220 but may be selectively inserted into and/or removed from the catheter 220 during use.

A handle 230 is provided on the proximal end 221 of the catheter 220 that includes a plurality of ports 232. One or more of the ports 232 may include a hemostatic seal (not shown), a Luer or other connector (also not shown), and the like. For example, a first port 232a may include one or more hemostatic seals and a female Luer connector (not shown), which may accommodate receiving the cutting assembly 240 therein. For example, the cutting head 242 may be sufficiently small to be received through the first port 232a and

into the aspiration lumen 224 of the catheter 220. The proximal end 246 of the cutting assembly 240 may include a male Luer or other connector that corresponds to a connector on the first port 232a. The catheter 220 and shaft 244 may have relative lengths such that, when the connectors are engaged, the cutting head 242 is disposed within the aspiration lumen 224 immediately adjacent the distal end 222, similar to the previous embodiments.

If the distal end 222 of the catheter 220 includes the beveled tip 223, the cutting assembly 240 and/or catheter 220 connectors may including features to ensure that the cutting assembly 240 is coupled to the catheter in a predetermined radial orientation, e.g., to ensure that the cutting head 242 is positioned radially within the distal end of the catheter 220 with the teeth 248 oriented away from the beveled tip 223. For example, the connectors on the first port 232a and the proximal end 246 of the cutting assembly 240 may including mating tabs and slots, or other features (not shown) that permit the cutting assembly 240 to be secured to the catheter 220 only in the predetermined orientation. Alternatively, the catheter 220 may include a channel or other track (not shown) within the aspiration lumen 224 that the cutting head 242 and/or shaft 244 may be advanced along within the aspiration lumen 224 to ensure that the cutting head 242 is maintained in the desired orientation relative to the beveled tip 223.

A second port 232b on the handle 230 may communicate with an interior of the balloon 228 via an inflation lumen (not shown) in the catheter 220. Thus, a source of inflation media (not shown) may be coupled to the port 232b and used to selectively expand and collapse the balloon 228. Finally, a third port 232c on the handle 230 may communicate with the aspiration lumen 224 and may allow a vacuum source to be coupled to the third port 232c for aspirating material from the distal end 222 of the catheter 220, similar to the previous embodiments.

Alternatively, an internal vacuum source may be provided within the handle 230, e.g., a syringe device (not shown), similar to that described above. In addition, the handle 230 may include a control system (also not shown) that may be coupled to the shaft 244 of the cutting assembly 240 when it is received through the handle 230 into the aspiration lumen 224.

Turning to FIG. 11, during use, the catheter 220 may be positioned within a body lumen 90 having material 92 therein that is to be removed. The catheter 220 may be introduced simply to remove the material 92. Alternatively, the catheter 220 may be placed in the body lumen 90 to perform a diagnostic and/or therapeutic procedure therein.

For example, one or more instruments, e.g., guidewires, catheters, embolectomy devices, flow restoration devices, and the like (not shown), may be inserted into the first port 232a, through the aspiration lumen 224 and beyond the distal end 222 of the catheter 220 to perform a procedure within or beyond the body lumen 90. Once the procedure is complete, any instruments may be removed, and then the cutting assembly 240 may inserted into the first port 232a and through the aspiration port 224 to position the cutting head adjacent the distal end 222. The cutting assembly 240 may be locked relative to the catheter 220 with the cutting head 242 within the distal end 222, e.g., using the mating connectors on the first port 232a and proximal end 246 of the cutting assembly 240, as described above.

After the catheter 220 is positioned to a desired location within the body lumen 90, the balloon 228 may be inflated to press against the wall of the body lumen 90, thereby pushing the catheter 220 against the opposite side of the body lumen 90. Thus, the beveled tip 223 of the distal end 222 may be pushed against or adjacent the wall of the body lumen 90. The cutting assembly 240 and/or vacuum source may then be activated to macerate and/or aspirate the material 92 into the catheter 220. As the cutting head 242 reciprocates relative to the distal end 222 of the catheter 220, the cutting head 242 may move between a proximal position fully within the aspiration lumen 242 and a distal position wherein the cutting head 242 does not extend beyond the beveled tip 223. This may reduce the risk of the cutting head 242 contacting the wall of the body lumen 90 and/or otherwise damaging the body lumen 90.

In addition, the balloon 228 may ensure that the teeth 248 of the cutting head 242 are oriented towards the center of the body lumen 90, thereby also reducing the risk of the teeth 248 or other features of the cutting head contacting the wall of the body lumen 90. In addition or alternatively, the balloon 228 may also press the distal end 222 against the body lumen 90 to reduce the risk of material 92 breaking free and escaping beyond the distal end 222 of the catheter 220.

After sufficient material 92 has been macerated and aspirated from the body lumen 90, the cutting head 242 may be turned off, the vacuum source deactivated, and the balloon 228 deflated. The cutting assembly 240 may be removed from the catheter 220 before the catheter 220 is removed, or alternatively, both the cutting assembly 240 and catheter 220 may be removed at the same time.

It will be appreciated that elements or components shown with any embodiment herein are exemplary for the specific embodiment and may be used on or in combination with other embodiments disclosed herein.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the appended claims.

We claim:

1. An apparatus for removing material within a body lumen, comprising:

an elongate tubular member including a proximal end, a distal end sized for introduction into a body lumen, and an aspiration lumen extending between the proximal and distal ends;

a guide member extending from the distal end and terminating in a distal tip, the guide member comprising a track adjacent a track lumen extending from the distal tip into the aspiration lumen; and

an obstruction clearing device comprising a core wire slidable within the track lumen and one or more lumen clearing elements deployable from the distal tip of the guide member when the core wire is advanced relative to the guide member, the lumen clearing elements comprising an expandable structure that is expanded from a contracted condition within the guide member to an expanded condition when deployed from the guide member for engaging material within a body lumen, the expandable structure directable proximally along the track in the expanded condition when the core wire is subsequently retracted relative to the guide member for drawing the one or more lumen clearing elements and any captured material into the aspiration lumen of the tubular member.

2. The apparatus of claim 1, wherein the guide member comprises an orifice in a side wall thereof communicating with the track lumen, the orifice located within the aspiration lumen such that, when the core wire is retracted relative to the guide member, the expandable structure is compressed inwardly towards the contracted condition and the one or more lumen clearing elements are drawn through the orifice into the track lumen.

3. The apparatus of claim 2, wherein the one or more lumen clearing elements are oriented substantially axially within the track lumen when the one or more lumen clearing elements are drawn through the orifice into the track lumen such that, when the core wire is advanced relative to the guide member, the one or more lumen clearing elements are directed through the track lumen in the contracted condition until the one or more lumen clearing elements are redeployed from the distal tip of the guide member.

4. The apparatus of claim 1, wherein the one or more lumen clearing elements comprise a flexible arm coupled to the expandable structure.

5. The apparatus of claim 1, wherein the expandable structure comprises a hoop.

6. The apparatus of claim 1, wherein the expandable structure comprises a plurality of loops.

7. The apparatus of claim 1, wherein the expandable structure comprises one or more cutting edges.

8. The apparatus of claim 1, wherein the track comprises a longitudinal slit in the guide member.

9. The apparatus of claim 1, wherein the one or more lumen clearing elements comprise a plurality of expandable structures spaced apart axially along the core wire such that the expandable structures are deployed successively from the distal tip of the guide member.

10. The apparatus of claim 1, further comprising a handle on the tubular member proximal end and an actuator on the handle coupled to the core wire for directing the core wire axially relative to the guide member for deploying and retracting the one or lumen clearing elements.

11. A method for removing material within a body lumen of a patient, comprising:

introducing a distal end of a tubular member into a body lumen, the tubular member having a guide member extending distally from the distal end;

positioning the tubular member such that the distal end is disposed adjacent material to be removed and a distal tip of the guide member is disposed beyond the material;

deploying one or more lumen clearing elements from the distal tip of the guide member, each lumen clearing element comprising an expandable structure that expands

from a contracted condition within the guide member to an expanded condition when deployed from the distal tip; and

retracting the deployed one or more lumen clearing elements along a track of the guide member to engage the material disposed adjacent the distal end of the tubular member and draw the material into a lumen of the tubular member.

12. The method of claim 11, further comprising aspirating the material drawn into the lumen of the tubular member to remove the material from the body lumen.

13. The method of claim 11, wherein, as the deployed one or more lumen clearing elements are retracted along a track, the expandable structure is directed into the tubular member lumen and compressed towards the contracted condition.

14. The method of claim 13, wherein the material engaged by the lumen clearing elements is separated into multiple pieces as the expandable structure is directed into the tubular member lumen and compressed towards the contracted condition.

15. The method of claim 11, wherein retracting the deployed one or more lumen clearing elements along the track of the guide member comprises retracting the one or more lumen clearing elements through an orifice into the guide member to compress and draw the one or more lumen clearing elements into the guide member.

16. The method of claim 15, further comprising redeploying the one or more lumen clearing elements from the distal tip of the guide member after retracting the one or more lumen clearing elements through the orifice into the guide member.

17. The method of claim 11, wherein the expandable structure comprises a hoop that extends substantially across the body lumen in the expanded condition when deployed from the distal tip.

18. The method of claim 17, wherein the expandable structure further comprises a flexible arm coupled to the hoop, the flexible arm sliding along the track when the deployed one or more lumen clearing elements are retracted along the track.

19. The method of claim 11, wherein the one or more lumen clearing elements comprise a plurality of expandable structures spaced apart from one another such that the expandable structures are deployed successively from the distal tip of the guide member.

20. The method of claim 11, wherein the expandable structure is aligned axially within the guide member in the contracted condition, and wherein the expandable structure resiliently extends transversely relative to the guide member when deployed in the expanded condition.

21. An apparatus for removing material within a body lumen, comprising:

an elongate tubular member including a proximal end, a distal end sized for introduction into a body lumen, and an aspiration lumen extending between the proximal and distal ends; and

a cutting head disposed within the aspiration lumen adjacent the distal end, the cutting head being reciprocable axially within the aspiration lumen for macerating material being aspirated into the aspiration lumen.

22. The apparatus of claim 21, further comprising a vacuum source communicating with the aspiration lumen for selectively applying vacuum to the aspiration lumen to aspirate material into the distal end of the tubular member.

23. The apparatus of claim 21, further comprising a control system carried within a handle on the proximal end of the tubular member, the control system controlling reciprocation of the cutting head within the aspiration lumen.

24. The apparatus of claim 23, further comprising a drive shaft extending from the cutting head to the proximal end of the tubular member, the control system comprising a motor coupled to the drive shaft for reciprocating the drive shaft axially, thereby reciprocating the cutting head axially within the aspiration lumen.

25. The apparatus of claim 21, wherein the cutting head comprises a rounded tip that is exposed from the distal end of the tubular member and a plurality of teeth extending along a side edge of the cutting head.

26. The apparatus of claim 21, wherein the distal end of the tubular member terminates in a beveled tip, the tubular member further comprising an expandable member on an outer wall of the tubular member opposite the beveled tip.

27. The apparatus of claim 26, wherein the cutting head is reciprocable relative to the distal end of the tubular member such that the cutting head moves between a proximal position fully within the aspiration lumen and a distal position wherein the cutting head does not extend beyond the beveled tip.

28. The apparatus of claim 21, further comprising a flow restoration device extending distally beyond the distal end of the tubular member, the flow restoration device comprising an expandable member on a distal tip thereof.

29. The apparatus of claim 28, further comprising a clutch device within a handle on the proximal end of the tubular member, the clutch device coupled to the flow restoration device such that, when the cutting head is activated, the clutch device causes the expandable member on the flow restoration device to move proximally towards the distal end of the tubular member.

30. The apparatus of claim 28, wherein the expandable member of the flow restoration device comprises one or more cutting elements for removing adherent material from a wall of a body lumen within which the apparatus is disposed.

31. A method for removing material within a body lumen of a patient, comprising:

introducing a distal end of a tubular member into a body lumen, the tubular member comprising an aspiration lumen and a cutting head disposed within the aspiration lumen near the distal end;

positioning the tubular member such that the distal end is disposed adjacent material to be removed;

applying a vacuum pressure to the aspiration lumen to draw material within the body lumen towards the distal end of the tubular member; and

activating the cutting head to cause the cutting head to reciprocate axially relative to the distal end to macerate material drawn to the distal end of the tubular member to break the material into pieces sufficiently small to be aspirated into the aspiration lumen by the vacuum pressure.

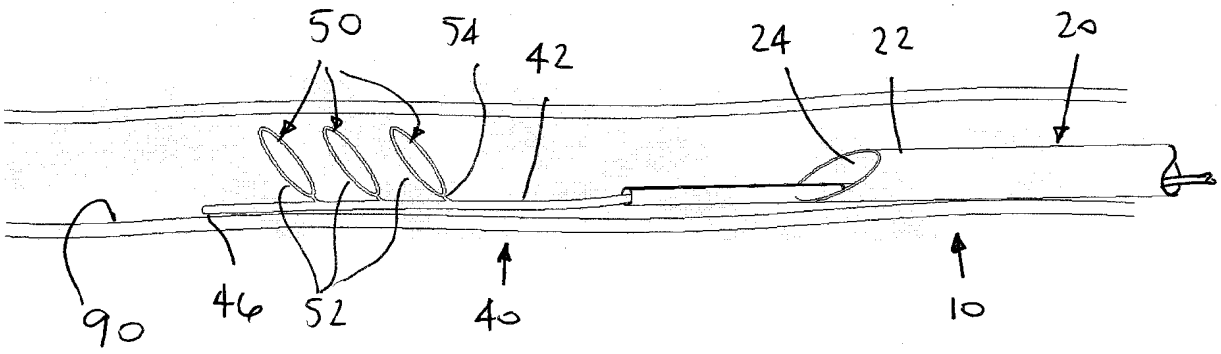
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FIG. 2

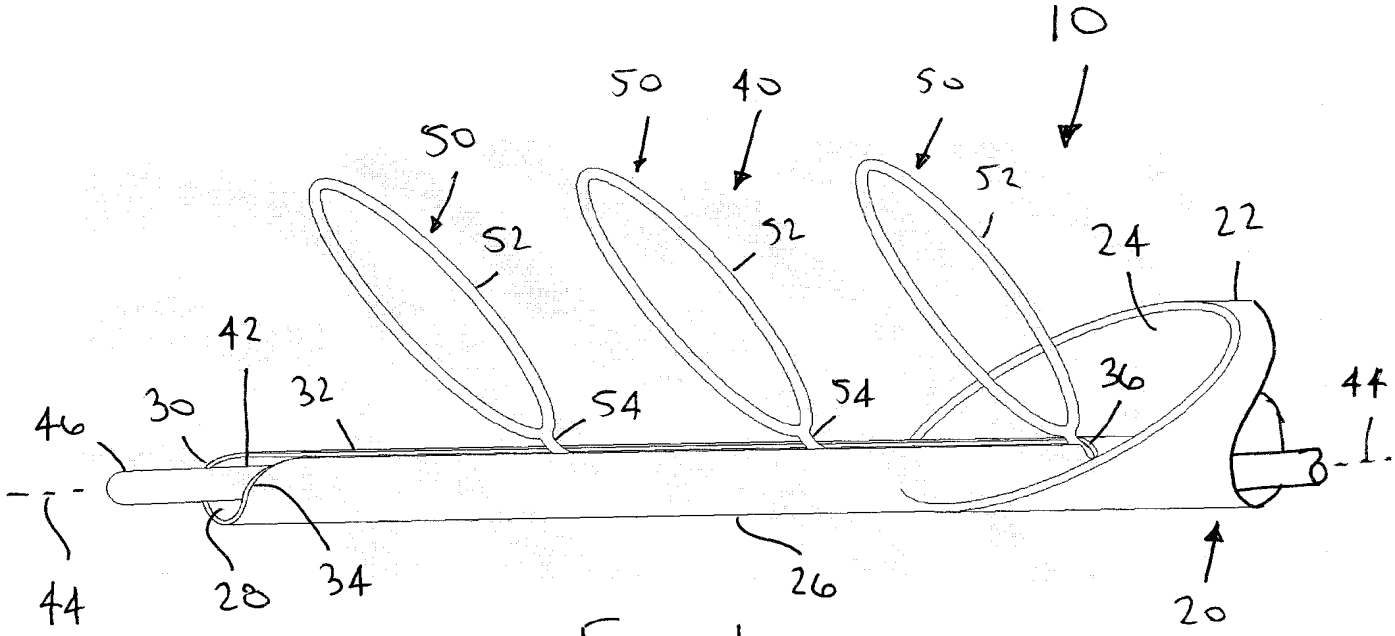
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FIG. 1

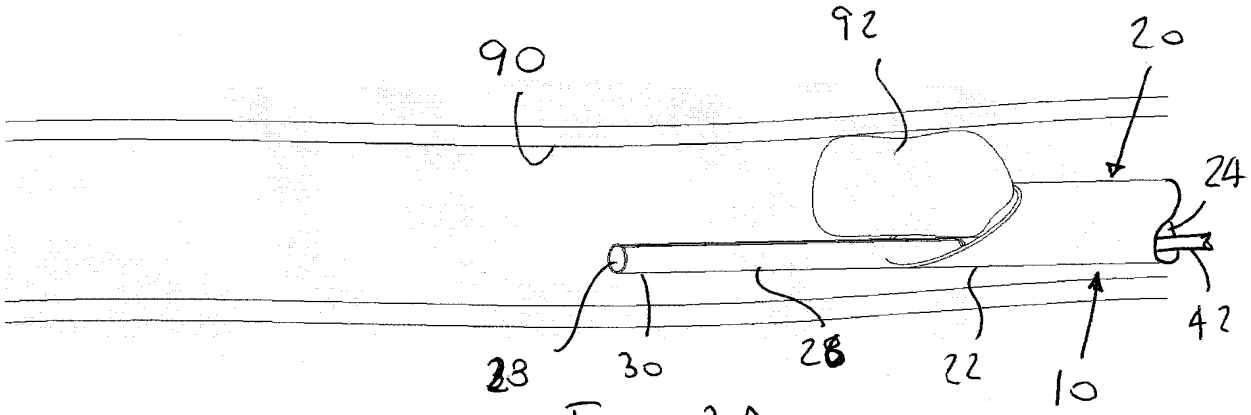

FIG. 3A

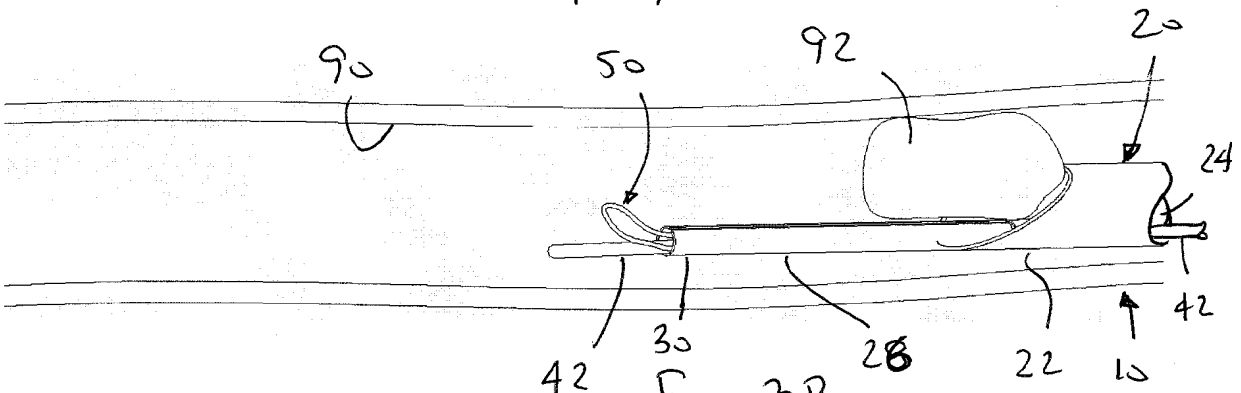

FIG. 3B

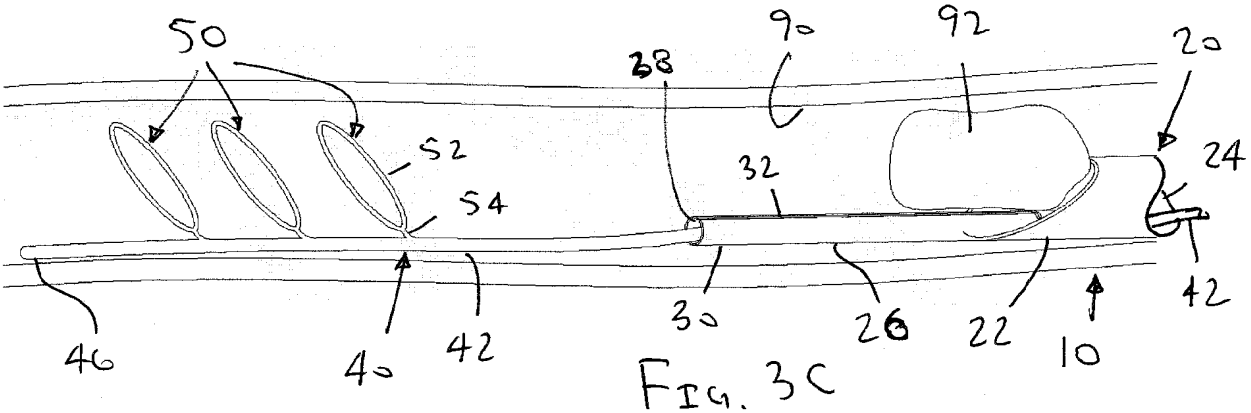

FIG. 3C

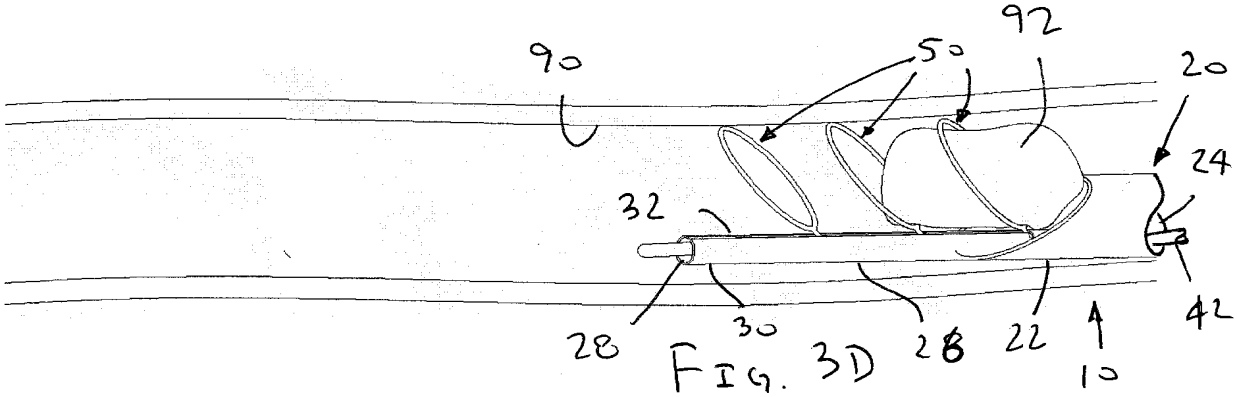

FIG. 3D

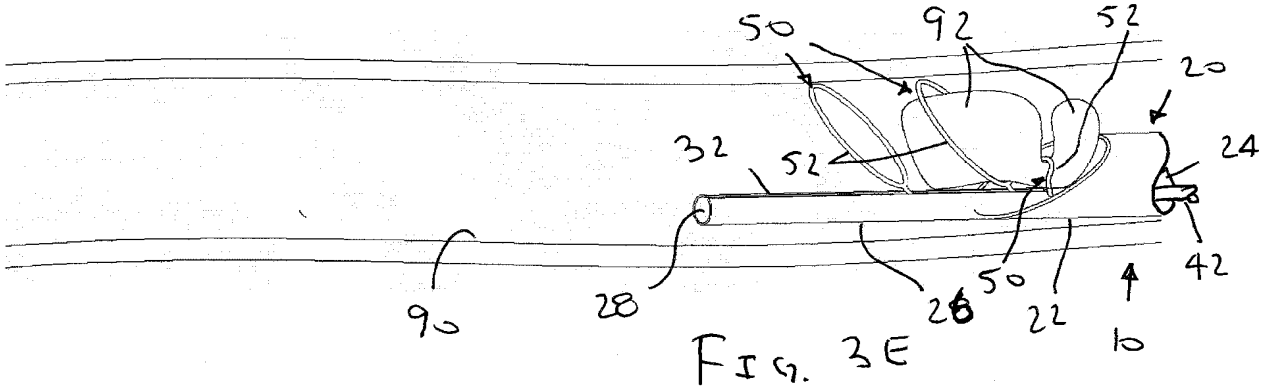

FIG. 3E

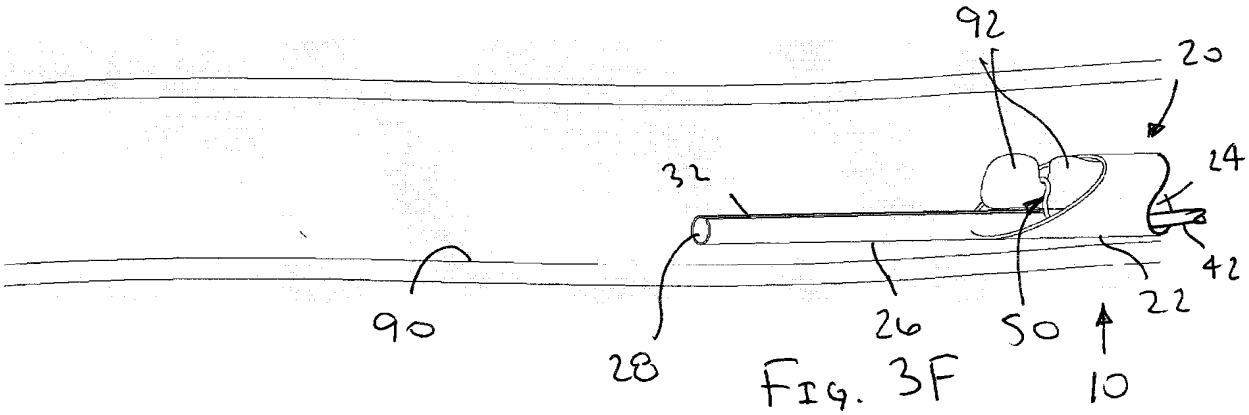

FIG. 3F

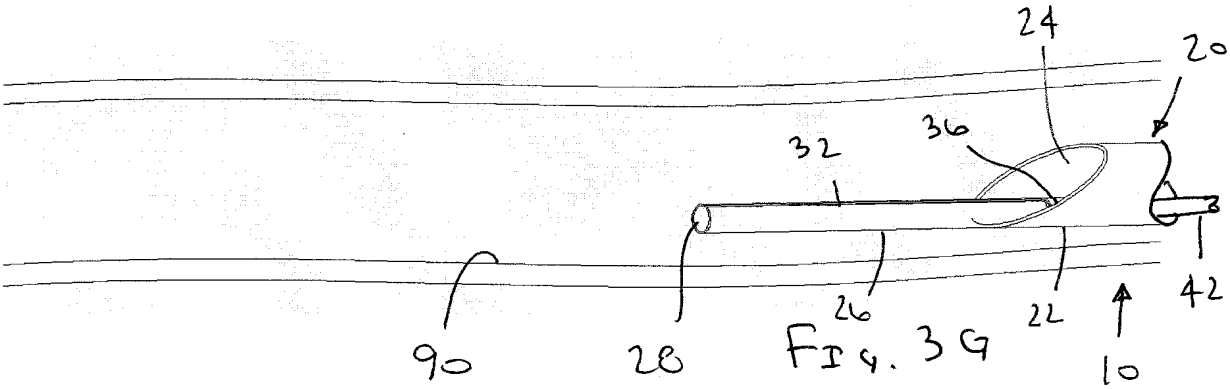

FIG. 3G

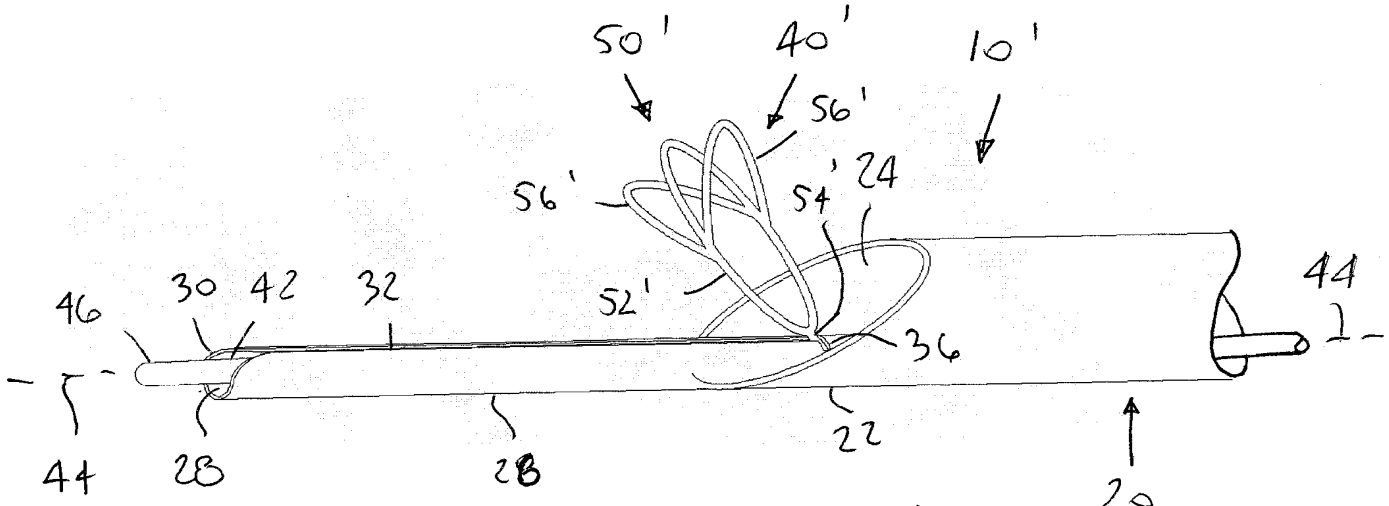

FIG. 4

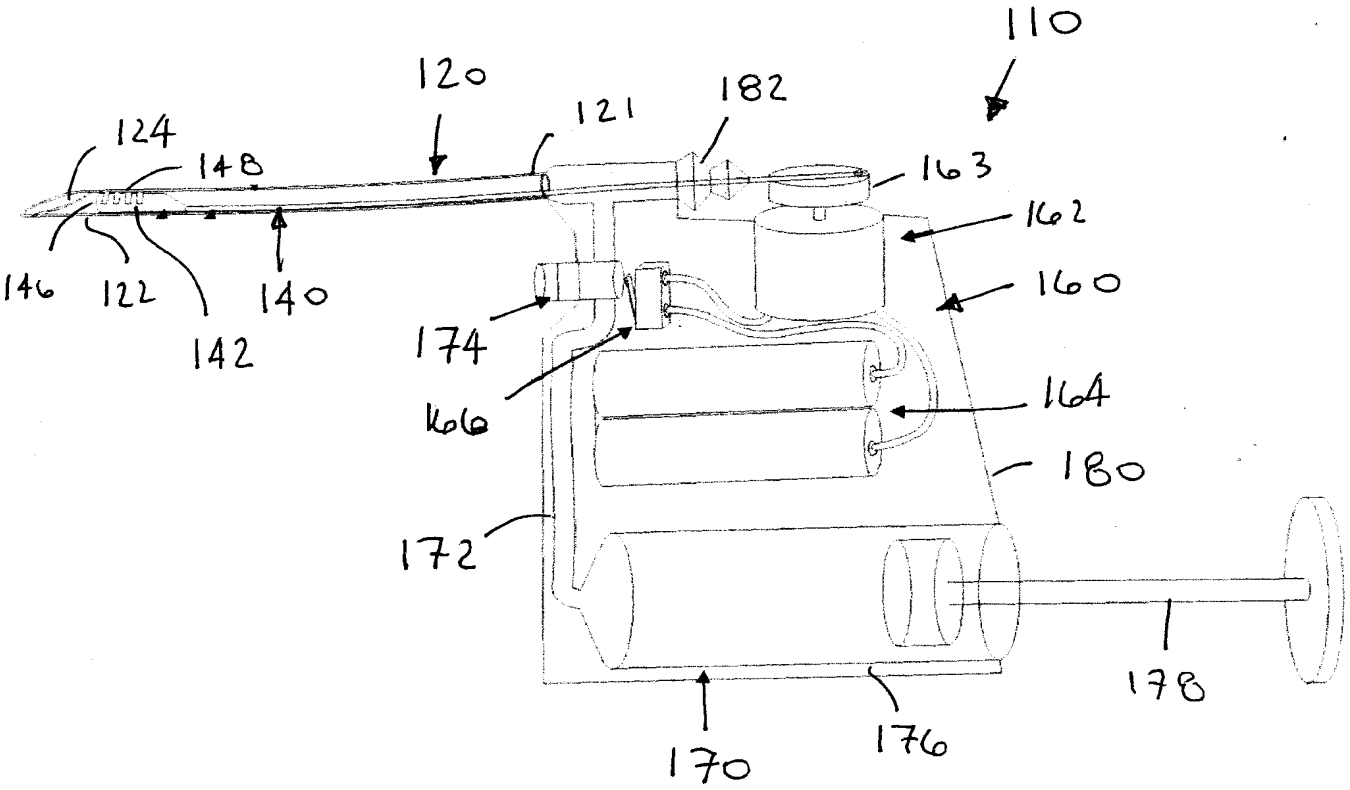
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FIG. 5

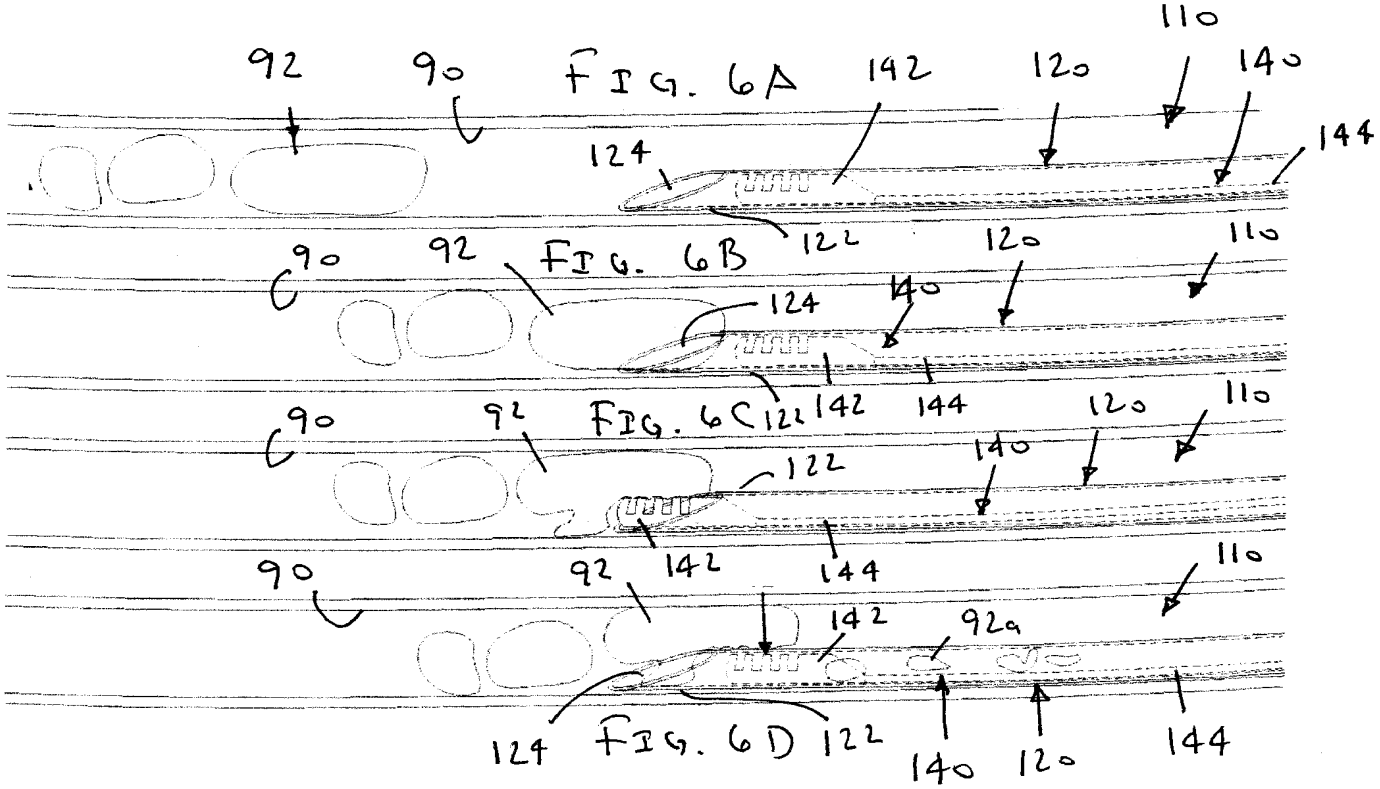
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FIG. 6A
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FIG. 6B
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FIG. 6C
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FIG. 6D

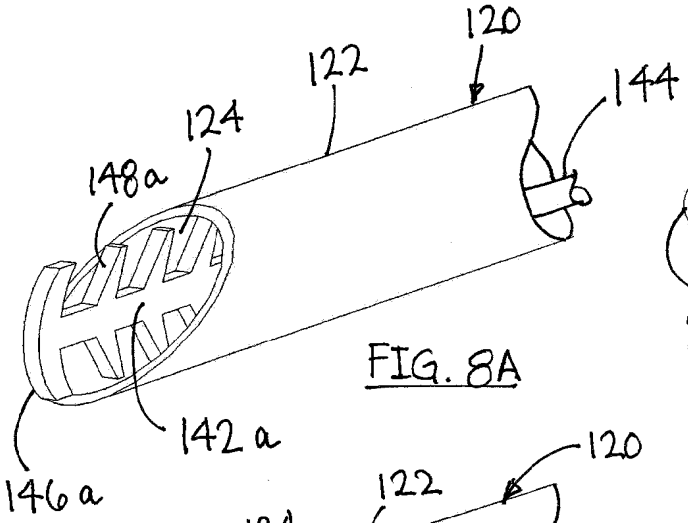

FIG. 8A

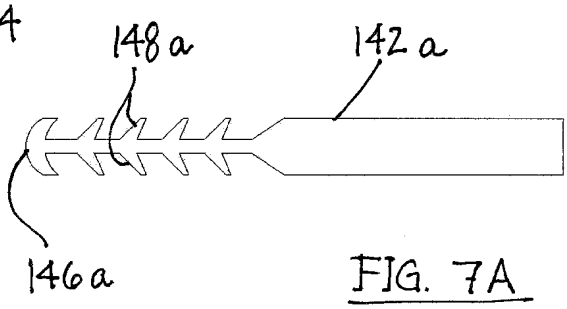

FIG. 7A

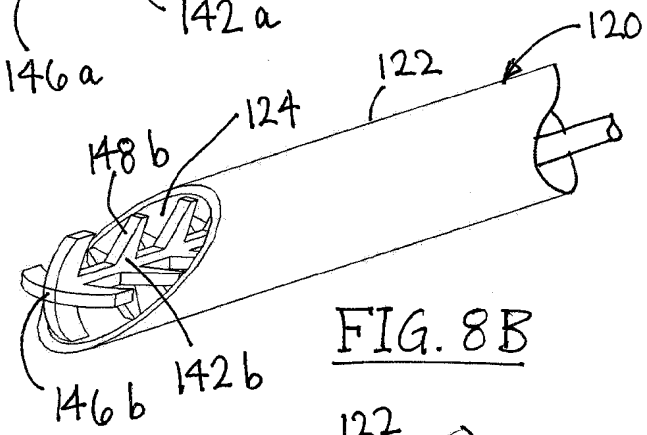

FIG. 8B

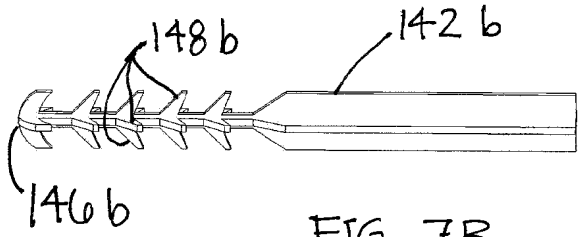

FIG. 7B

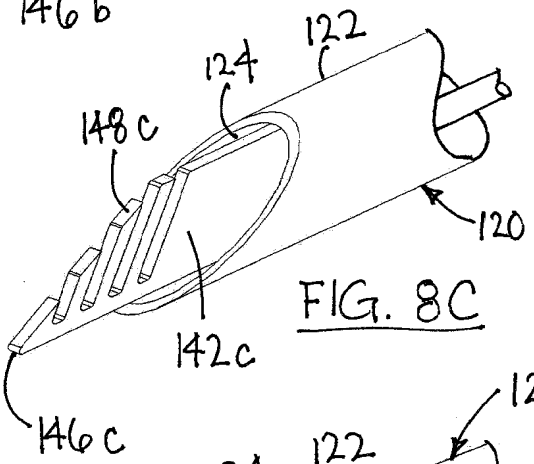

FIG. 8C

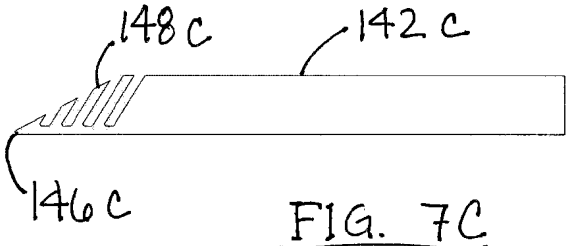

FIG. 7C

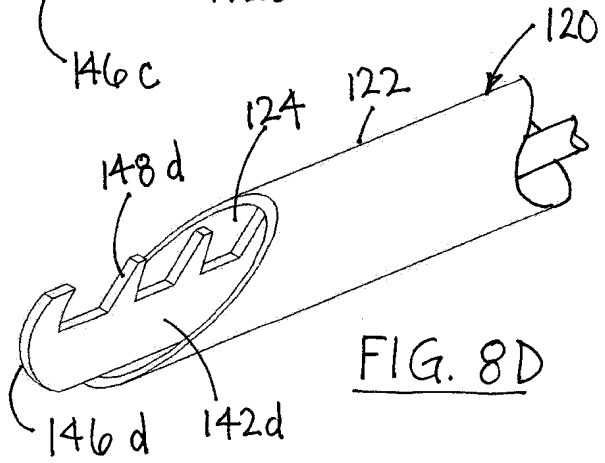

FIG. 8D

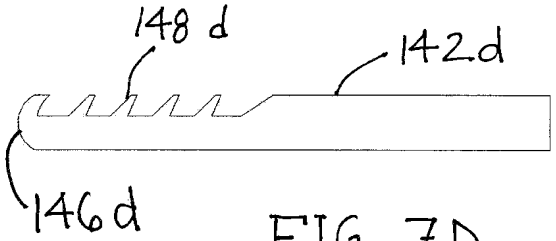

FIG. 7D

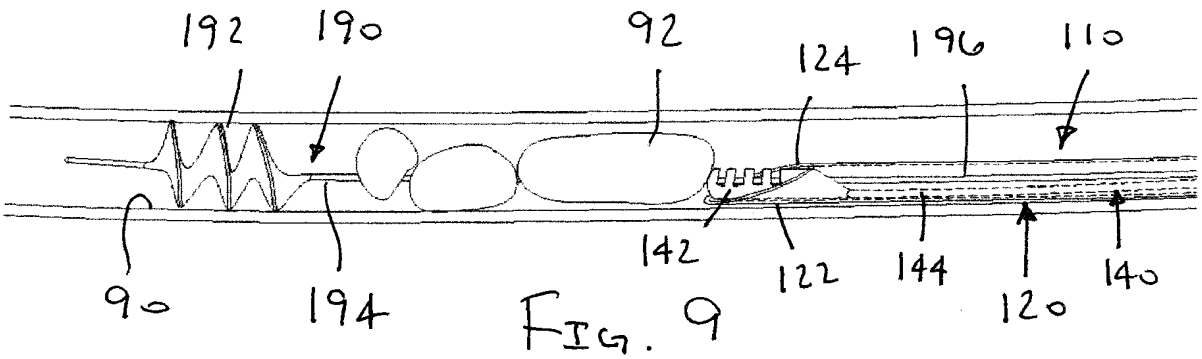

FIG. 9

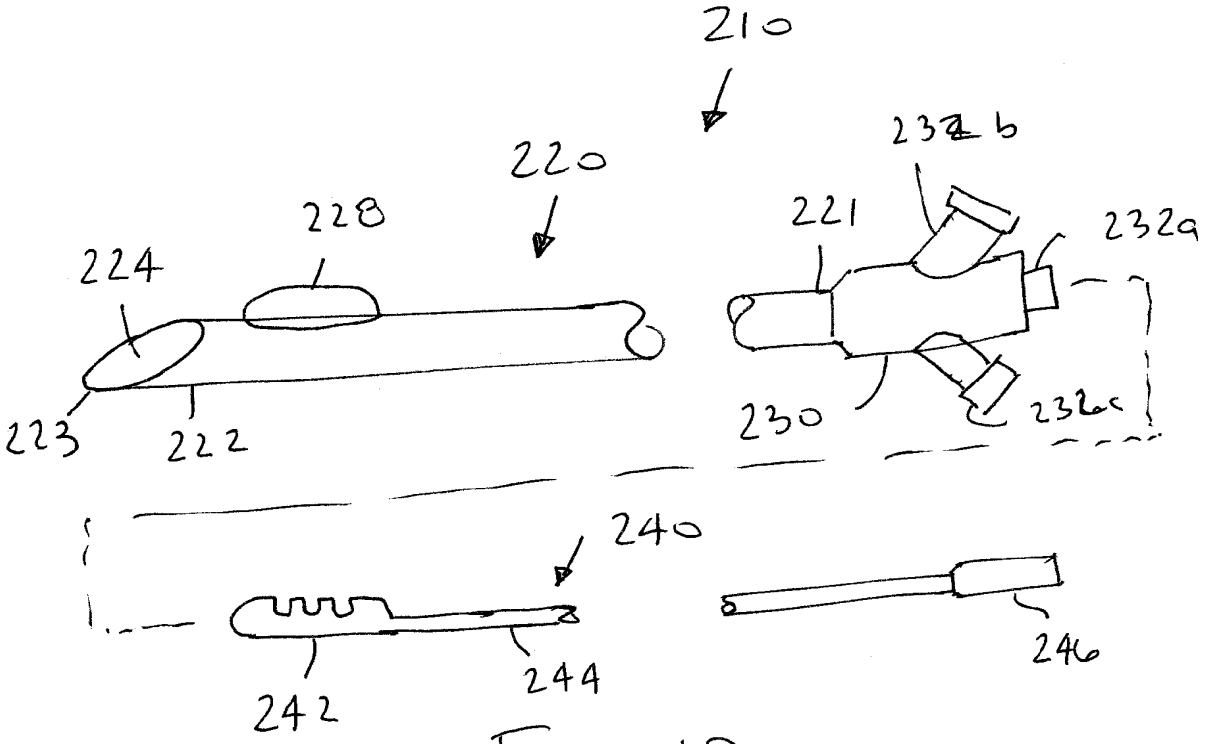
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FIG. 10

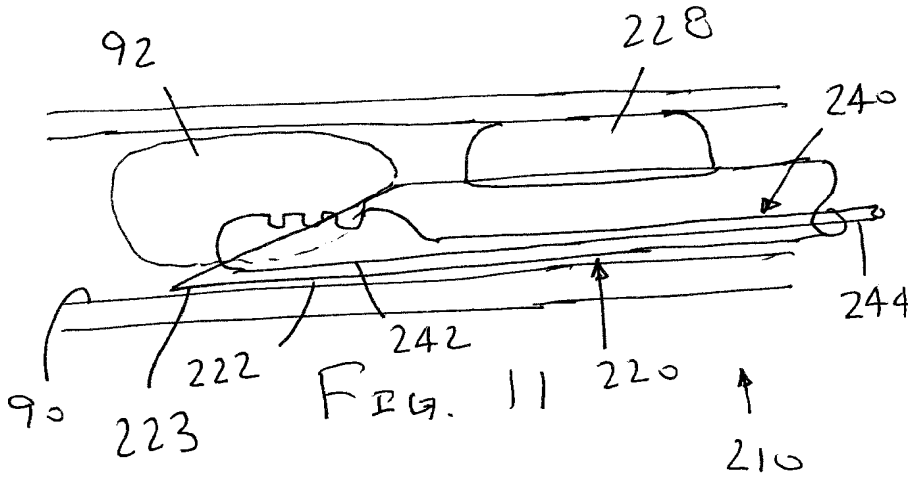
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FIG. 11

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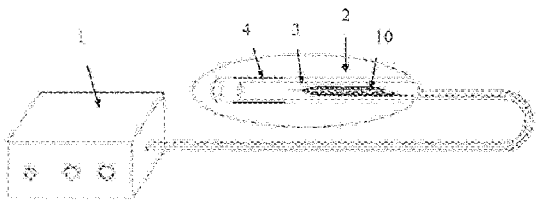
权利要求书1页 说明书4页 附图5页

(54)发明名称

血管取栓系统

(57)摘要

本发明提供一种血管取栓系统。所述取栓系统包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和取栓器，导引导丝穿过内管，内管则被套在外鞘管内，且内管能够沿着导引导丝移动，该取栓器与推拉导丝相连，安装好的推拉导丝和取栓器被压握入内管内，且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换，在收回位置，取栓器被回收到内管内，在展开位置，取栓器被推出内管。所述取栓系统还包括抽吸装置，该抽吸装置与内管相连通，且内管上设有抽吸孔。根据本发明的取栓系统，既可以方便的捕捉大块血栓，又可以通过抽吸防止小块血栓的脱落，解决了血管远端血管再次栓塞的问题，同时有效减少了取栓后并发症的概率。



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1. 一种取栓系统，其特征在于，其包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和取栓器，导引导丝穿过内管，内管则被套在外鞘管内，且内管能够沿着导引导丝移动，该取栓器与推拉导丝相连，安装好的推拉导丝和取栓器被压握入内管内，且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换，在收回位置，取栓器被回收到内管内，在展开位置，取栓器被推出内管，所述取栓系统还包括抽吸装置，该抽吸装置与内管相连通，且内管上设有抽吸孔。

2. 根据权利要求 1 所述的取栓系统，其中取栓器包括外层支架和内层支架，内外层支架均构成为网状，且外层支架包覆在内层支架外，两者之间形成间隙。

3. 根据权利要求 2 所述的取栓系统，其中外层支架与内层支架在近端相连接或在近端和远端均相连接。

4. 根据权利要求 2 或 3 所述的取栓系统，其中内外层支架的近端和 / 或远端具有椭圆形开口或圆形开口，或为封闭的。

5. 根据权利要求 1-3 中任一项所述的取栓系统，其中推拉导丝与取栓器的牵引连接点布置成在展开位置贴近血管壁。

6. 根据权利要求 1-3 中任一项所述的取栓系统，其中取栓器在展开位置整体呈近似圆柱形。

7. 根据权利要求 1-3 中任一项所述的取栓系统，其中取栓器被构造有内凹和 / 或外凸的结构。

血管取栓系统

技术领域

[0001] 本发明涉及医疗器械，具体涉及一种介入血管的医疗器械，特别涉及一种血管取栓系统。

背景技术

[0002] 血管内血栓是临床上的常见病和多发病，而颅内血栓又是重中之重，它造成脑栓塞，具有发病率高、致残率高、死亡率高和复发率高的特点，是中老年人致死和致残的主要疾病。而随着老年人口的不断增加和生活水平的提高，脑血管病的发病率在不断升高。根据调查，我国目前每年有 300 万的新增脑血栓群体，而急性脑血栓占脑卒中的比例也由 55.8% 上升到 81.6%，成为脑部第一大疾病。

[0003] 血管的再通是治疗急性缺血性脑卒中的关键。目前颅内血栓的治疗方法主要有两种：药物溶栓和机械取栓。

[0004] 药物溶栓治疗是把溶栓剂注入病变所在的血管内的病灶附近，在病灶局部瞬间地形成很高的溶栓剂浓度，加快血栓溶解速度，进而增加血管再通的机会。但是，根据美国国立神经疾病与卒中研究院(NINDS)的研究结果，静脉溶栓应在发病 3 小时内进行，动脉溶栓时间窗为 6 小时之内。由于药物溶栓治疗时间窗较短，而且溶栓治疗只适用于体积较小的血栓，其对大体积血栓栓塞的治疗效果并不理想，所以最终大约只有 3 ～ 5% 的患者适合做药物溶栓治疗。

[0005] 机械取栓是将取栓器输送至病变位置，然后通过鞘管将血栓取出至体外。机械取栓包括以下几种方法：捕捉取栓、抽吸取栓、旋切取栓等。捕捉取栓在取人块血栓时效果最好，但是容易造成血管壁上的斑块和破碎的血栓块脱落后流向远端血管造成新的栓塞；抽吸取栓在取小块栓子时效果较好，在取大块血栓时为了防止堵塞抽吸管需要反复捣碎血栓后再抽吸，过程麻烦而且很容易伤到血管；旋切取栓对血管壁造成的损伤较大，很容易引起并发症。

[0006] 中国实用新型专利 CN201020104685.1 公开了一种用于人体血管内血栓抽吸导管，其包括依次连接的管座、加强管、单腔管、双腔管、尖端管和显影标记。该取栓系统在抽吸腔的远端有 1-4 个开孔，增加了导管的通过性和血栓抽吸能力，并减小在手术过程中对人体血管的损伤，同时提高导管的跟踪性和推送性。

[0007] 中国发明专利申请 CN201110222609.X 和中国实用新型专利 CN201120281795.X 公开了一种血栓抽吸导管，其包括抽吸管，所述抽吸管包括管座，所述管座连接导管，所述抽吸管的外壁上可活动的套设有套管，所述套管包括 Y 型连接头、双腔管及球囊，所述 Y 型连接头连接双腔管，球囊设置于双腔管的远端外壁上，所述抽吸管内可插入干扰金属丝，所述干扰金属丝的远端可伸出抽吸管的远端外。该取栓系统可以快速清除散布在血管广泛区域的血栓及处理冠脉末梢微血管的栓塞，而且当遇到体积大及高黏稠的血栓时，可利用干扰金属丝打散血栓后再进行抽吸。

[0008] 美国专利申请 US2010/0049147A1 公开了另外一种血栓抽吸导管。美国专利申请

US2007/0161963A1 也公开了一种血栓切除术抽吸导管系统。

[0009] 上述抽吸取栓系统在取小块栓子时效果较好，但是在取大块血栓时为了防止堵塞抽吸管需要反复捣碎血栓后再抽吸，过程麻烦而且很容易伤到血管。

[0010] 中国发明专利申请 01114889.6 公开了一种可用于颅内血管的可回收血栓临时滤器，其由过滤器、导向头、导引杆、连接件和外鞘组成，其中过滤器由形状记忆合金丝编织而成。美国专利申请 2011/0160763 也公开了一种可用于颅内血管的取栓装置，其包括骨架，骨架可由形状记忆合金丝编织而成，以捕获血栓。

[0011] 上述取栓系统在捕获血栓之后回收时，血栓固定不牢固、容易脱落，而且结构复杂。

[0012] 此外，利用目前的取栓装置，在取栓过程中血管壁上的斑块和破碎的血栓块很容易脱落，流向远端血管，造成新的栓塞。据报道，约有 70% 的血管介入取栓手术中观察到了有血栓碎片和碎块流向远端血管，这增加了患者血管再栓塞的风险。

[0013] 因此，需要一种改进的血管取栓装置，这种装置应满足以下几个条件：1）取栓过程简单、方便；2）柔顺性好，捕获率高，支撑力适中，取栓过程中不会损伤血管内壁；3）在捕获血栓之后回收时，血栓固定牢固、不易脱落。总之，既要具有良好的取栓效果，又要能够有效防止小血栓的脱落同时又不会损伤血管造成严重的并发症。

发明内容

[0014] 有鉴于此，本发明提供了一种改进的取栓系统，该系统解决了现有技术中存在的血管壁斑块和碎血栓块容易脱落而造成远端血管再次栓塞的问题，而且柔顺性好、捕获率高。

[0015] 根据本发明的一方面，本发明提出一种血管取栓系统，其包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和网状取栓器，导引导丝穿过内管，内管则被套在外鞘管内，且内管能够沿着导引导丝移动，该取栓器与推拉导丝相连，安装好的推拉导丝和取栓器被压握入内管内，且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换，在收回位置，取栓器被回收到内管内，在展开位置，取栓器被推出内管，所示取栓系统还包括抽吸装置，该抽吸装置与内管相连通，且内管上设有抽吸孔。本发明的取栓系统将捕捉取栓与抽吸取栓相结合，既可以方便的捕捉大块血栓，又可以通过抽吸防止小块血栓的脱落，解决了血管远端血管再次栓塞的问题，同时有效减少了取栓后并发症的概率。

[0016] 根据本发明的优选实施例，外鞘管在远端还设有可膨胀封堵球囊。

[0017] 根据本发明的优选实施例，内管上设有 1 ～ 4 个抽吸孔，这些抽吸孔可以是导管远端的开口，也可以是导管侧壁上的开孔。开口和开孔的形状可以是圆形、椭圆形或其他形状。开孔可以对称分布、间隔分布或随机分布。

[0018] 根据本发明的优选实施例，取栓器既可以通过激光切割金属管材、片材而获得，也可以通过金属丝编织而获得，其中金属管、片、丝材可以是镍钛合金、钴镍合金、不锈钢等。这样使取栓器的柔顺性和贴壁性良好。

[0019] 另外，优选地，取栓器的近端和远端均可以是开口的或封闭的。取栓器整体还可以是近似圆柱状、内凹状或外凸状等。取栓器还可以是单层结构，或是双层或多层结构。

[0020] 根据本发明的优选实施例，取栓器整体长度为 15 ～ 60mm，直径为 2 ～ 6mm，壁厚为

0.04 ～ 0.12mm。

[0021] 优选地，推拉导丝与取栓器的牵引连接点布置成在展开位置贴近血管壁。这样可提高大体积血栓的有效捕获率。

[0022] 优选地，取栓器在展开位置整体呈近似圆柱形。这样使取栓器具有良好的径向支撑力，从内管中释放到血管后具有较好的血管贴壁性。

[0023] 取栓时，通过血管造影确定血栓的位置，然后把内管输送至栓塞处远端，回撤内管，将取栓器从血栓中间释放，利用封堵球囊在远端封堵住血管，然后先回撤取栓器进入内管中，之后再打开抽吸装置进行抽吸。然后，关闭抽吸装置，将内管向远端移动 5 ～ 20mm，之后再次打开抽吸装置抽吸剩余小块血栓，然后关闭抽吸装置。最后，将内管收进外鞘管内，撤出体外。

[0024] 根据本发明的血管取栓系统，可以有效捕获斑块和血栓碎片，增加了血栓捕获稳定性，防止了血栓脱落，从而降低再栓塞的风险。另外，本发明的血管取栓系统结构简单，取栓过程方便容易。

附图说明

[0025] 通过下面参照附图对本发明实施例进行的详细描述，本发明的特征及其优点将是显而易见的。在图中：

[0026] 图 1 是本发明实施例的取栓系统的总体示意图。

[0027] 图 2-9 是本发明的内管的实施例的示意图。

[0028] 图 10-20 显示了本发明的取栓器的实施例的示意图。

具体实施方式

[0029] 下面参照图 1-20 详细描述本发明的实施例。

[0030] 为了便于描述，以下描述使用了术语“近端”和“远端”，其中“近端”指的是离操作端近的一端，远端指的是远离操作端的一端。

[0031] 如图 1 所示，取栓系统包括抽吸装置 1、外鞘管 2、内管 3 和取栓器 10 组成。取栓器 10 为网状并与取栓系统的推拉导丝（未示出）相连，安装好的推拉导丝和取栓器 10 被压握入内管 3 内。取栓器 10 可通过推拉导丝的推拉而在收回位置和展开位置之间转换，在收回位置，取栓器 10 收回到内管 3 内，在展开位置，取栓器 10 被推出到内管 3 外。另外，取栓系统还包括导引导丝（未示出），导引导丝穿过内管 3，用以在血管内引导取栓系统。外鞘管 2 在远端处设有可膨胀封堵球囊 4。

[0032] 此外，取栓器 10 上还设有显影标记（未示出），以帮助定位取栓器 10。可以理解的是，内管 3 和外鞘管 2 上也可以设有显影标记。

[0033] 内管上设有 1 ～ 4 个抽吸孔，这些抽吸孔可以仅是内管远端的开口，如图 2 和 6 所示，也可以是在远端开口基础上在导管侧壁上再开一些抽吸孔，如图 3 ～ 5 和图 7 ～ 9 所示。开口和开孔可以是圆形、椭圆形或其他形状，可以单独、对称、间隔或随机分布。

[0034] 取栓器可以是单层结构，如图 10 ～ 14 的取栓器 10 所示。取栓器 10 的近端和远端均可以是封闭的或开口的。另外，如图 14 所示，取栓器 10 可以构造有外凸和内凹结构。

[0035] 取栓器也可以是双层结构。如图 15 ～ 20 所示。取栓器 10’ 为支架套支架结构，

整体呈近似圆柱形，其包括两部分，即内层支架 20 和外层支架 30，其中内外层支架均构成为网状，外层支架包覆在内层支架外，且两者之间留有间隙。取栓器 10' 的内外层的近端远端可以是只近端连接，如图 16、17、19 和 20 所示，也可以是近远端都连接，如图 15 和 18 所示。连接可以是焊接连接、利用金属套管连接或利用金属丝缠绕连接等。

[0036] 当然，取栓器也可以是多层结构。

[0037] 取栓器通过激光切割具有形状记忆效应的金属管材（如镍铁合金等）而形成并经热处理定型。当然，取栓器也可以通过切割具有形状记忆效应的金属片材，然后卷曲，热处理定型而形成。取栓器的合适尺寸如下：长度为 15 ～ 60mm，直径为 2 ～ 6mm，壁厚为 0.04 ～ 0.12mm。也可以用高弹性的高分子材料来代替金属材料。上述合适的材料是本领域技术人员所熟知的，在此不再详细描述。

[0038] 推拉导丝与取栓器的牵引连接点布置为在展开位置贴近血管壁。这样可提高大体积血栓的有效捕获率。

[0039] 本发明的取栓系统的使用方法如下。

[0040] 介入治疗时，首先通过血管造影确定血管病变位置，然后将取栓装置 1 导入血管内，使导引导丝穿过病变位置，再使内管 3 沿导引导丝穿过病变位置并通过内管 3 上的显影标记（未示出）定位，期间取栓器 10 一直位于内管 3 内，处于收回位置。然后，回撤导引导丝，通过推拉导丝将取栓器 10 推到内管 3 远端，回撤内管 3 至病变位置，将取栓器 10 释放，通过取栓器 10 上的显影标记可定位取栓器 10。由于形状记忆金属的形状记忆效应或高弹性高分子材料的弹性作用，取栓器 10 在血液温度的作用下转换到展开位置，贴靠血管壁。然后，利用封堵球囊 4 在远端封堵住血管，拉动推拉导丝，回撤取栓器 10 捕获血栓，直至将取栓器 10 收回到内管 3 内。然后，打开抽吸装置 1 进行抽吸，之后关闭抽吸装置，接着将内管向远端移动 5 ～ 20mm，之后再次打开抽吸装置抽吸剩余小块血栓，然后关闭抽吸装置。再将内管 3 收回到外鞘管 2 中。最后，将取栓装置 1 整体撤出人体外，完成取栓过程。

[0041] 采用目前的取栓系统取栓时，血管壁上的斑块和破碎的的血栓块很容易因外力作用破碎脱落，流向远端血管而造成新的栓塞，增加患者的手术风险。本发明的设计将捕捉取栓与抽吸取栓这两种方式相结合，在取栓时可以通过抽吸将脱落的小块血栓吸入抽吸管，同时通过捕获可以将大体积的血栓拉入抽吸管，避免了捕获取栓时小块血栓易脱落和抽吸取栓时不易捕获大块血栓的缺点，且操作方便，再通率高。

[0042] 本发明的取栓系统可适合于颅内血管取栓，也可以适合于其它血管内取栓。本领域技术人员可以理解，以上描述只是示例性的。在不背离本发明的思想和范围的情况下，本领域技术人员仍可以对本发明作出多种修改和变化。

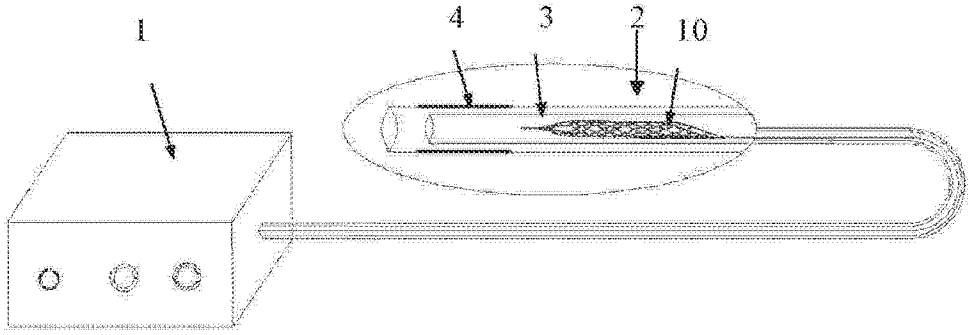
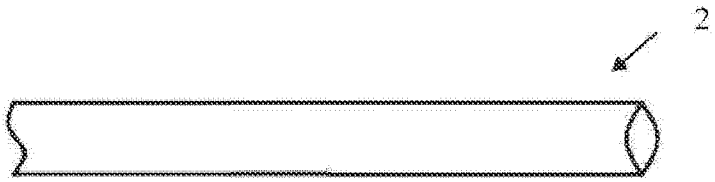


图 1



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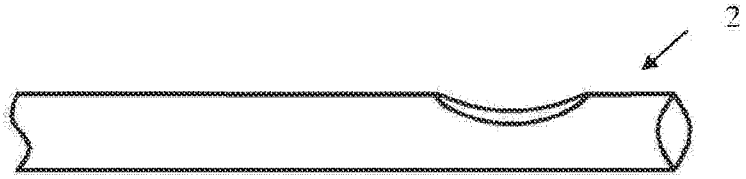
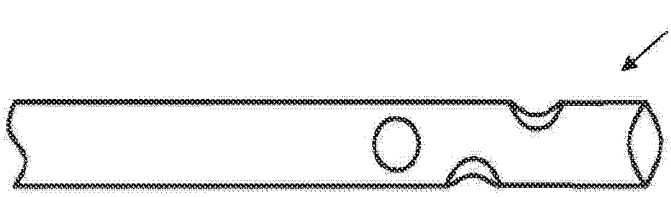


图 3

图 4



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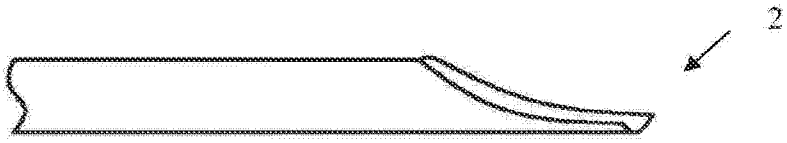

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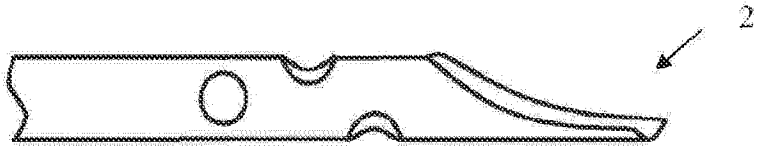


图 7

图 8

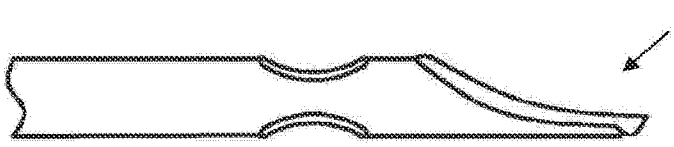
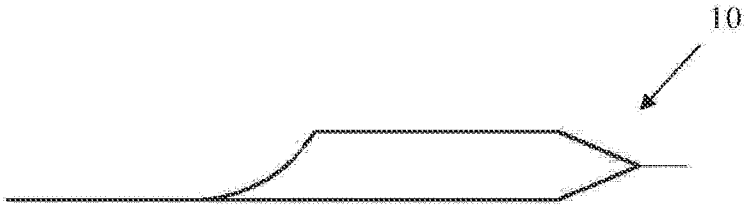


图 9



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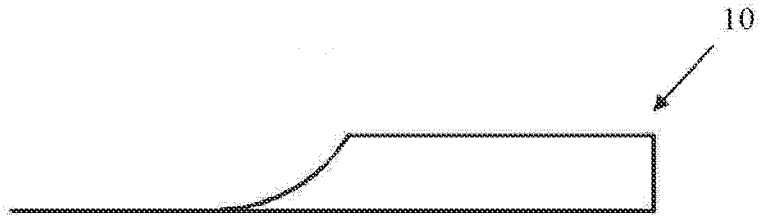

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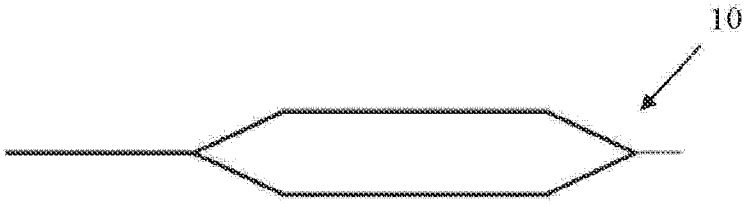
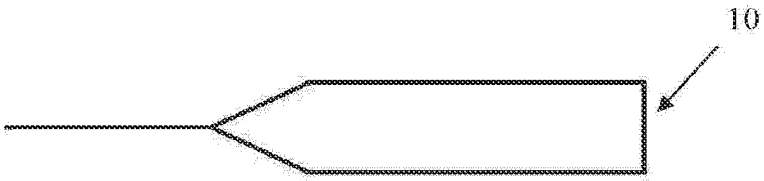


图 12



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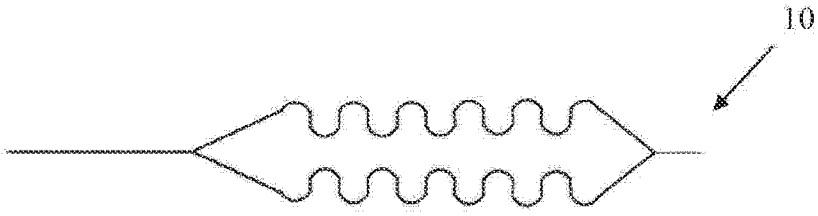
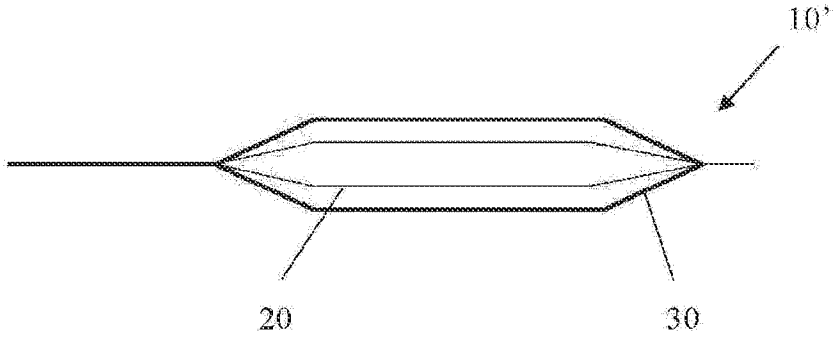


图 14



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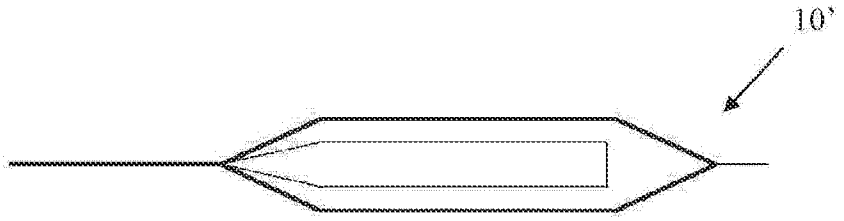


图 16

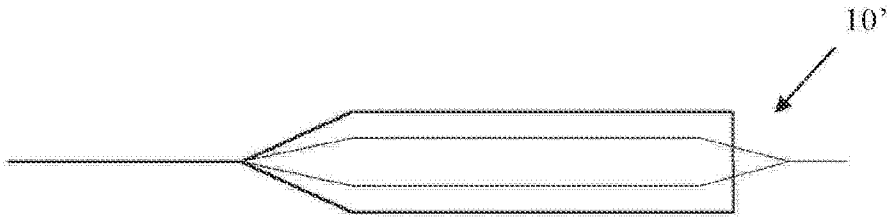
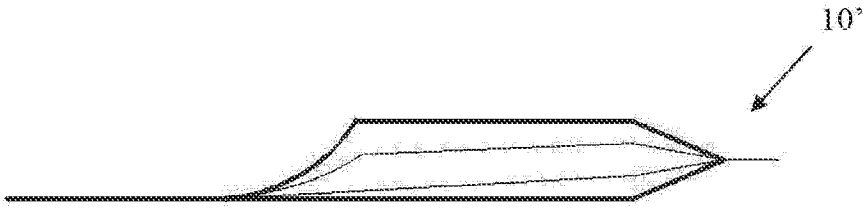


图 17



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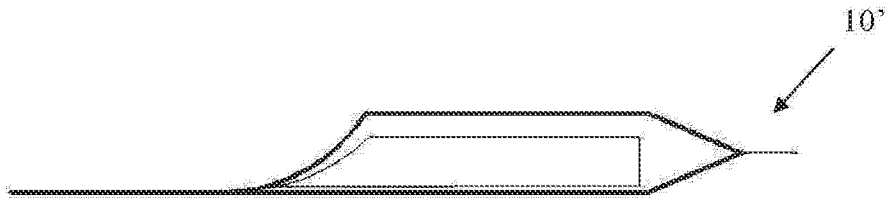

图 19

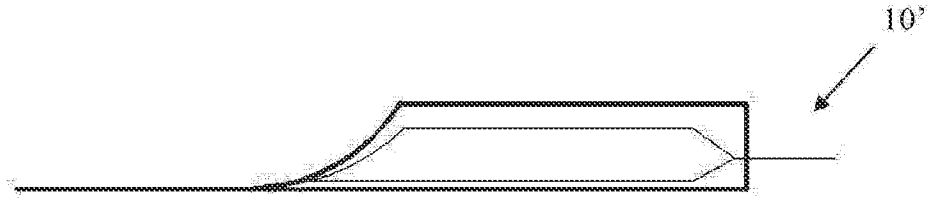

图 20

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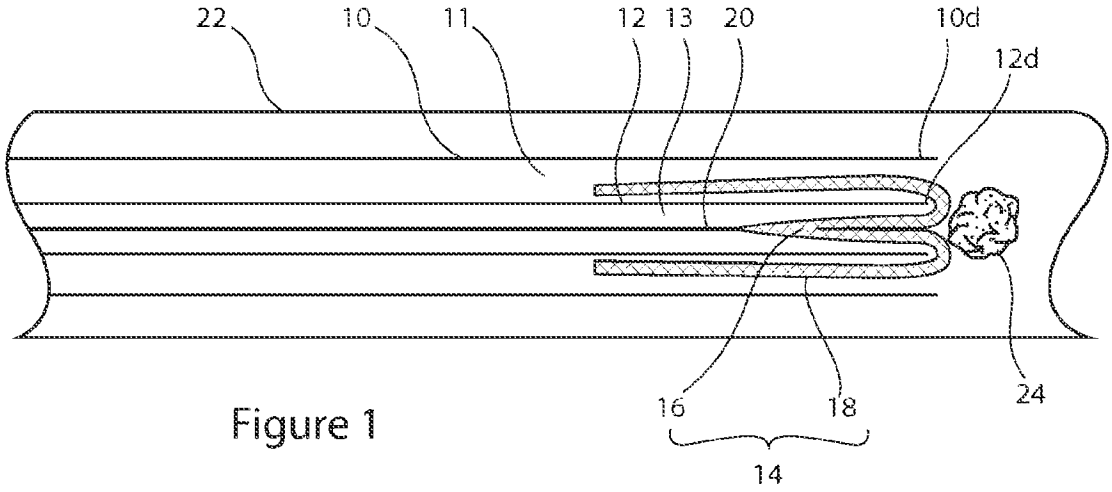

Figure 1

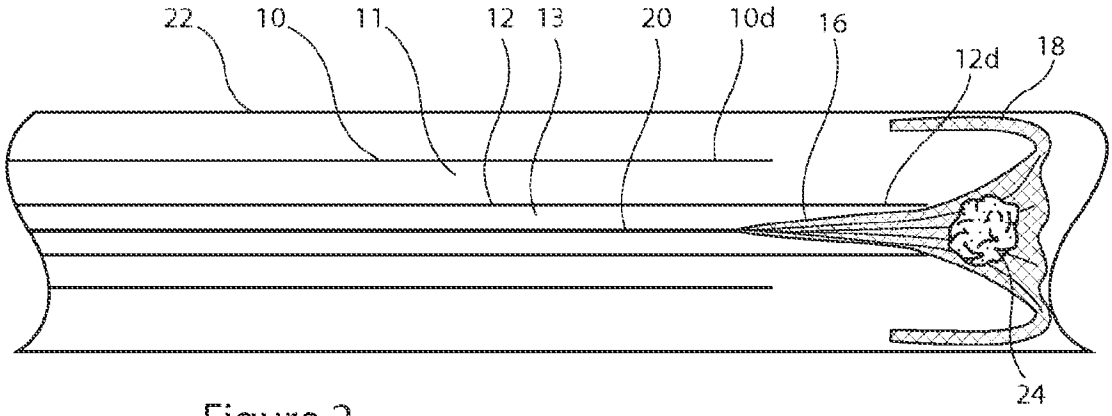

Figure 2

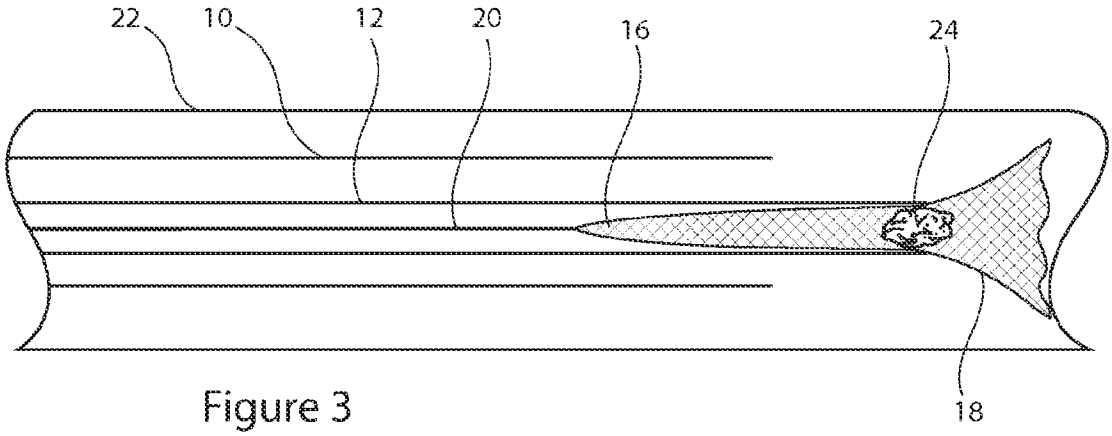

Figure 3

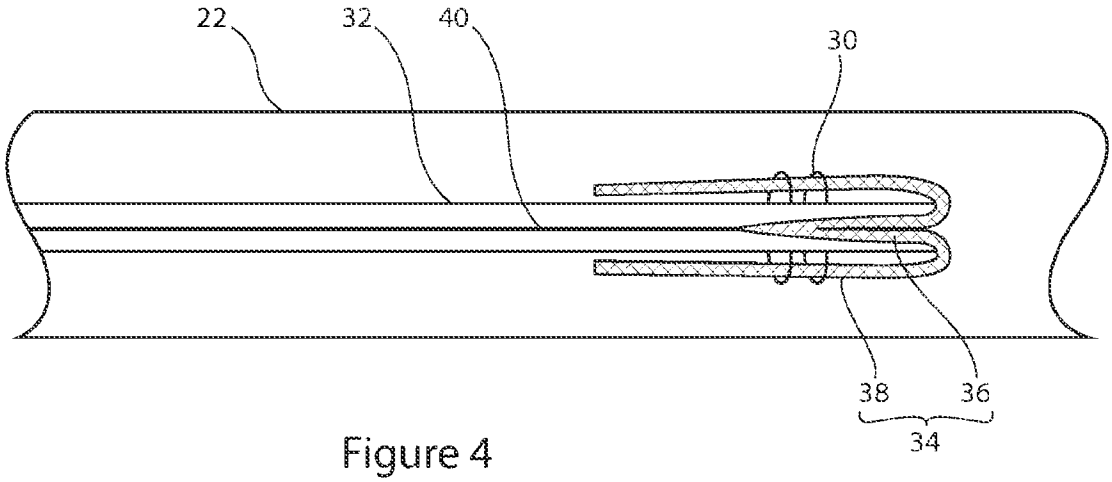

Figure 4

OBJECT CAPTURE DEVICE

Description

Technical Field

The present invention relates to an object capture device as well as to a method of capturing objects from a body lumen, particularly for the capture of thrombi in a patient's vasculature.

Background Art

It is known that material may form or build up in vessels of the circulatory system; such material may seriously compromise the health of the patient. For example, thrombi or blood clots may form and may partially or completely occlude a blood vessel, decreasing or even completely cutting off blood flow through the vessel. The thrombus may adhere to the vessel wall or may be dislodged, becoming free floating in the vessel. A free floating thrombus, also known as an embolus, may travel along a vessel and eventually cause a blockage in a distant part of the body, such as the heart or the brain, with potentially lethal consequences.

Various devices are known for capturing and removing thrombi and other objects from a patient's blood system. Such devices typically involve the use of a plurality of different tools which are deployed in different stages of the capture and removal procedure. For example, a first medical device may be introduced to break the thrombus into pieces so as to prevent it from blocking a vessel. However, breaking the thrombus into pieces can be harmful to the patient as dislodged parts may travel through the circulatory system and eventually block another vessel elsewhere. In order to avoid this, blocking and/or suction means are required to ensure that the dislodged parts are safely collected. For example, a filter may be positioned distal of the thrombus so as to catch the dislodged parts after the thrombus has been broken up by the first medical device. The material trapped by the filter can remain in place until removed using yet further apparatus

such as an aspirator. Various prior art thrombus capturing devices are disclosed in US2010/0249815, US 7,621,870, US 2007/0149996 and US 7,780,696.

Disclosure of the Invention

The present invention seeks to provide an improved object capture device and method, particularly for removing objects such as thrombi from a patient's vasculature.

The preferred embodiment provides a single tool for capturing and removing thrombi. This tool can be used in a single stage, thus facilitating the medical procedure quickly and easily. There is also disclosed a method for capturing and removing thrombi. In particular the invention provides a mechanism for pulling a thrombus away from a vessel wall. The device comprises an object collecting member, hereinafter referred to as a basket.

According to an aspect of the present invention there is provided a medical device for collecting objects from a body vessel, including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a closed first end and an open second end; and an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, and a second configuration in which the first end of the basket is withdrawn into the catheter and the everted second end is at least partially inverted; and wherein, the medical device is operable so as to relatively move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

The second end may be constrained in the first position and free from attachment or constraint in the second position.

The actuator may be, for example, a wire, rod or cable, hereinafter referred to as a wire.

In the second configuration at least part of the second end of the basket may be withdrawn into the catheter.

Also described is a medical device for collecting objects from a body vessel, including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a first end and a second end; and an actuator connected to the first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, the second end being constrained in position, and a second configuration in which the first end is withdrawn into the catheter and the everted second end is at least partially inverted, the second end being free from constraint; and wherein, the medical device is operable so as to release the second end from constraint, and move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

The basket may be provided with a closed first end and an open second end. By providing a basket having a closed first end, the basket is able to pull, as if sucking, an object such as a thrombus into the basket.

Preferably the basket is made of spring steel, or shape memory material such as, for example, Nitinol, hereinafter referred to as shape memory material. Where the remembered shape is a generally tubular basket, on release of the second end of the basket the basket may spring radially outwardly and distally of the catheter to surround a thrombus. By providing a rolling basket which rolls outwardly during its deployment so as to position itself between a thrombus and the vessel wall in which the thrombus lies, the basket may surround

the thrombus such that when the basket is withdrawn into the catheter the thrombus is withdrawn into the basket.

The everted portion of the basket may scrape against the vessel wall thus dragging any plaque or thrombus adhered thereto into the basket as the basket is reverted or inverted by withdrawal of the member into the catheter. As the basket is withdrawn into the catheter a pulling or suction effect is created, pulling an end of the thrombus or other object or material into the basket and pulling the rest of the thrombus through the vessel towards the catheter so that it too can be captured by the basket. The pulling or suction effect may be best achieved when the basket is positioned up against the object in the vessel before pulling the basket into the catheter.

The actuator may be actuatable so as to draw the basket into the catheter and so move the catheter and the basket from said first configuration to said second configuration. The medical device may be operable so as to advance the catheter over the basket and so move the catheter and the basket from said first configuration to said second configuration. The medical device may be operable so as to advance the catheter over the basket and so as to draw the basket into the catheter. Thus the basket may be withdrawn into the catheter and the catheter may be advanced over the basket at the same time. In use the movement between the catheter and the basket may cause objects in a body lumen to be drawn into the basket.

In the second configuration the first end and substantially the whole of the second end of the basket may be withdrawn into the catheter. If the thombus is appropriately sized, the basket containing the thrombus may be withdrawn through the catheter lumen and out of the patient.

The thombus may be broken down in the patient's lumen by a lytic agent, before being removed from the patient. The lytic agent may be delivered to the site of the thrombus through the catheter lumen, or through a lumen external to the catheter, for example though a lumen in an outer sheath.

The basket can, in the first configuration, have a first end inside the catheter and second end everted over the distal end of the catheter. In the first

configuration the second end of the basket may extend radially out of the catheter and be everted over the first end of the basket and over the distal end of the catheter.

The basket may be made from wire or filamentary material. The basket may be made from braided material such as braided wire. The braiding of the basket may be tight. In other words the wires may be packed closely together, such that the spaces between the wires, if any, are small. The wires may be tightly braided so as to prevent bodily fluid such as blood from passing through the basket. For example the basket may be similar to that found in a flow diverter. The basket may have an impermeable covering to prevent fluid from passing through the basket.

The basket may be constructed so as to allow fluid to pass through the closed first end of the basket. For example the basket may comprise apertures through which fluid can pass. However, the closed first end of the basket may prevent captured objects, such as fibres from a thrombus, from passing through.

The basket may be sized so as to collect a substantially entire thrombus or other object or material. Thombi can be very large. As such the second end of the basket may be, for example from approximately 10 mm to 200mm in length.

The medical device may comprise an outer catheter, also known as an outer sheath. The outer sheath may be provided with a proximal and a distal end and a lumen therethrough. The catheter may be disposed within the lumen of the outer catheter, thereby to be configured as an inner catheter. An annular space may be provided between the inner and the outer catheters. Where an outer catheter is provided, the second end of the basket may be located in the annular space between the inner and outer catheters in the first configuration, so as to constrain the second end during delivery.

The inner and outer catheters may be moveable relative to one another so as to release the second end of the basket from between the outer catheter and the inner catheter. The second end of the basket may be free from constraint in the second configuration. The second end of the basket may be free from attachment in both the first and second configurations.

The second end may be attached to the catheter in the first configuration. Such attachment may be with ties. The ties may be releasable using a trigger wire, for example.

Where the basket is made of shape memory material, releasing the second end may allow the basket to assume its memory shape.

Also described is a method of collecting objects from a body vessel, including: providing a medical device comprising a catheter provided with proximal end, a distal end and a lumen therethrough, and an elongate basket provided with a closed first end and an open second end; and an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are moveable relative to one another between a first configuration and a second configuration, wherein in the first configuration the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, and in the second configuration the first end of the basket is withdrawn into the catheter and the everted second end is at least partially inverted; inserting the medical device into a body vessel; and operating the medical device so as to move the catheter and the basket from said first configuration to said second configuration thereby causing objects in a body vessel to be drawn into the basket.

The method may comprise the step of withdrawing the medical device from the body lumen, the medical device containing objects from the body vessel. In particular the basket may contain objects from the body vessel. The object containing portion of the basket may be contained within the catheter.

Where the medical device comprises an outer sheath, and where the second of the basket is held between the sheath and the inner catheter, the method may comprise the step of withdrawing the outer sheath so as to release the basket. After operating the medical device so as to capture a thrombus or other object or material in the basket, the method may comprise advancing the outer

sheath distally relative to the catheter and basket, such that the outer sheath surrounds an object containing portion of the basket, before removing the device from the patient's lumen. In this case the object containing portion of the basket may be contained within the outer sheath. Where the second end of the basket is held in the first position by ties, for example, the method may comprise the step of releasing the ties so as to release the basket.

The device described may be in the first configuration whilst tracking through the vasculature. On reaching a location proximate to the thrombus or other object, the site of interest, the device may be activated so as to move to the second configuration.

Also described is a method of collecting objects from a body vessel, including: providing a medical device for collecting objects from a body vessel, the medical device including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a first end and a second end; and a wire connected to the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, the second end being constrained in position, and a second configuration in which the first end is withdrawn into the catheter and the second end is at least partially inverted, the second end being free from constraint; inserting the medical device into a body vessel; and operating the medical device so as to release the second end from constraint, and so as to move the catheter and the basket from said first configuration to said second configuration, such that an object in a body vessel is drawn into the basket.

Brief Description of the Drawings

Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 shows an embodiment of a medical device for collecting objects from a body lumen, the medical device comprising a catheter and a basket arranged in a first configuration;

Figure 2 shows the medical device of Figure 1 after the outer sheath has been withdrawn from around the basket;

Figure 3 shows the medical device of Figures 1 and 2, the catheter and the basket arranged in the second configuration; and

Figure 4 shows another embodiment of a medical device for collecting objects from a body lumen.

Description of the Preferred Embodiments

Referring to Figure 1, there is shown in schematic form an embodiment of a medical device for collecting objects from a body lumen 22. The medical device is shown inside a patient's vessel 22; within which there is also a thrombus 24. The medical device comprises an outer catheter 10 disposed concentrically around an inner catheter 12, and an object collecting member 14, hereafter called a basket 14.

The inner 12 and outer 10 catheters are in the form of elongate tubes having proximal (not shown) and distal 10d,12d ends. In use the distal ends 10d,12d of the catheters are positioned proximate the thrombus or object or material to be removed and the proximal ends are outside of the patient. The outer catheter 10 comprises a lumen in which the inner catheter 12 is disposed. The catheters are arranged such that an annular gap 11 is provided between the inner 12 and outer 10 catheters. The inner catheter 12 also comprises a lumen 13, into which the basket 14 may be withdrawn.

The basket comprises a first end portion 16 and a second end portion 18. The first end portion 16 of the basket 14 is connected to an actuator wire 20. The wire 20 is disposed inside the lumen of the inner catheter 12 and extends through the lumen to an actuating portion of the medical device which in use is external to the patient's body. The first end portion 16 of the basket 14 is, in a first configuration, housed within the lumen of the inner catheter 12. The basket

14 extends, from the first end portion 16, out of the end of the inner catheter 12 and is everted so as to extend backwardly over itself around the inner catheter and inside the outer catheter 10 such that the second end portion 18 of the basket 14 is housed in the annular gap 11 between the inner catheter 12 and the outer catheter 10.

In this case the distal ends of the catheters are aligned with one another and are positioned such that the basket abuts the thrombus 24. The basket surrounds part of the thrombus when it is moved up against the thrombus, giving it a grip on the thrombus and thus aiding withdrawal/pulling of the thrombus into the basket when the device is used.

The basket 14 comprises a braided wire basket made of shape memory material, or of spring steel, for example. Such a basket may be flexible so as to fit around thrombi of various shapes and sizes, and so as to be able to be withdrawn into the narrow lumen of the inner catheter. The braiding of the basket is tight, such that the spaces between the wires, if any, are small. It is not necessary for the basket to allow blood or other fluid to pass through it. The thrombus removal process may be carried out very quickly and as such preventing blood flow through the vessel whilst the procedure is carried out does not harm the patient.

Figure 2 shows the medical device of Figure 1 after the outer catheter 10 has been withdrawn relative to the inner catheter 12. The outer catheter is provided so as to cover the basket and prevent it from springing open during introduction of the device. Once the outer catheter has been withdrawn the second end portion 18 of the basket 14 is no longer constricted and is able to spring open outwardly. The basket opens until it comes into contact with the internal walls of the vessel, scraping along the sides of the lumen so as to surround the thrombus 24. The second end portion 18 of the basket 14 remains everted, backwards over itself, and contacts the sides of the vessel 22.

Figure 3 shows the medical device of Figures 1 and 2 in a second configuration, in which the first end portion 16 of the basket 14 and part of the second end portion 18 are withdrawn into the inner catheter 12 such that the basket 14, and the thrombus 24 inside it, is substantially contained within the

inner lumen 12. The basket 14 can be from 10 to 200mm long, depending on the length and size of the material/thrombus to be captured. The basket 14 is designed to be long enough to trap the entirety of the thrombus. In particular, the everted second portion 18 of the basket 14 is designed to be long enough to trap the entirety of the thrombus. In one mode movement of the basket 14, from the first configuration shown in Figure 1 to the second configuration shown in Figure 3, is actuated by pulling on the actuating element 20. By pulling back on the actuating element 20 the second end portion 18, the open end of the basket, is pulled into the distal end 12d of the inner catheter 12. This action causes the second end portion 18 of the basket to roll inwardly, thus drawing, as if pulling or sucking, the thrombus into the closing basket. The thrombus is thus trapped bit-by-bit in the basket and withdrawn into the inner catheter 12. As a result of the relative movement between the inner catheter 12 and the basket 14 from the first configuration to the second configuration the thrombus 24 is thus drawn into the inner catheter 12, inside the basket 14.

Where the thrombus is small enough to be withdrawn through the lumen of the inner catheter continued retraction of the actuating element 20 allows withdrawal of the basket, in which the thrombus is held, through the lumen 13 of the inner catheter 12. The basket 14 containing the thrombus 24 may thus be completely removed from the patient's vessel through the lumen 13 of the inner catheter 12. As such this embodiment provides a single tool which is used in a single stage to remove the thrombus from a patient's vessel.

Where the thrombus is too large to be pulled into the lumen of the inner catheter, the outer catheter or sheath may be advanced over the thrombus. In this manner the thrombus can be held within the basket and also within the outer catheter so that it can then be removed from the patient.

In some instances, instead of pulling back on the actuator wire 20, the inner catheter 12 may be advanced over the basket 14. This movement from the first configuration to the second configuration will have the same effect of withdrawing the basket 14 into the inner catheter 12.

The apparatus may be operated by advancing the inner catheter 12 over the basket 14 as the actuator wire 20 is basket 14 withdrawn into the catheter 12. A combination of the two movements may be performed together so that as the basket 14 is withdrawn in the catheter 12 the catheter is also advanced over the basket.

Figure 4 shows another embodiment of a medical device for collecting objects from a body vessel. The medical device comprises an inner catheter 32, and a basket 34 having first 36 and second 38 end portions.

In this device ties 30 are provided to secure the second end portion 38 of the basket 34 in its everted position around the outside of the inner catheter 32. In this embodiment the outer catheter is not required to secure the basket 34 in its first configuration. Trigger wires (not shown) may be used to release the ties 30 so as to enable the basket to open outwardly as a result of its shape memory characteristics, and to be withdrawn into the inner catheter 32. An outer catheter (not shown) may be provided for use in delivery of the medical device to a location adjacent a thrombus inside a vessel.

It is to be understood that the different features of the various embodiments described herein can be combined together; as such the features described in the dependent claims may be combined with the embodiments described in each of the independent claims.

CLAIMS

1. A medical device for collecting objects from a body vessel, including:

a catheter provided with a proximal end, a distal end and a lumen therethrough;

an elongate basket provided with a closed first end and an open second end; and

an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter;

wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over at least part of the first end of the basket, and a second configuration in which the first end is withdrawn into the catheter and the everted second end is at least partially inverted; and

wherein, the medical device is operable so as to move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

2. A medical device according to claim 1, wherein the basket is made of shape memory material.

3. A medical device according to claim 1, wherein the basket is made of wire or filamentary material.

4. A medical device according to claim 3, wherein the basket is made of braided wire or filamentary material.

5. A medical device according to claim 4, wherein the wire or filamentary material is tightly braided so as to prevent fluid from passing through the basket.

6. A medical device according to claim 5, wherein the basket has an impermeable covering.

7. A medical device according to claim 1, wherein the actuator is a wire.

8. A medical device according to claim 1, wherein the basket comprises apertures sized to allow fluid to pass through the closed first end of the basket but prevent the captured objects from passing therethrough.

9. A medical device according to claim 1, wherein the actuator is actuatable so as to draw the basket into the catheter and so move the catheter and the basket from said first configuration to said second configuration.

10. A medical device according to claim 1 wherein, the medical device is operable so as to advance the catheter over the basket and so move the catheter and the basket from said first configuration to said second configuration.

11. A medical device according to claim 1, wherein in the second configuration the first end and substantially the whole of the second end of the basket may be withdrawn into the catheter.

12. A medical device according to claim 1 wherein the basket is from 10 to 200mm in length.

13. A medical device according to claim 1 wherein the second end is constrained in the first position and free from constraint in the second position.

14. A medical device according to claim 1 comprising an outer sheath provided with a proximal and a distal end and a lumen therethrough, wherein the catheter is disposed within the lumen of the outer sheath, thereby to be configured as an inner catheter, an annular space being provided between the inner catheter and the outer

sheath, and wherein in said first configuration the second end of the basket is located in the annular space between the inner catheter and outer sheath.

15. A medical device according to claim 14 wherein the second end of the basket is free from attachment and wherein the inner catheter and outer sheath are moveable relative to one another so as to release the second end of the basket from between the outer sheath and the inner catheter.

16. A medical device according to claim 13 wherein, the medical device is operable so as to release the second end from constraint.

17. A medical device according to claim 16, wherein the basket is made of shape memory material, said material having a memory shape, and wherein releasing the second end portion allows the basket to assume its memory shape.

Espacenet

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THROMBOSIS REMOVAL CATHETER

No documents available for this priority number.

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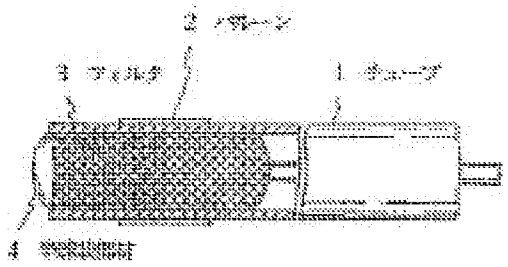
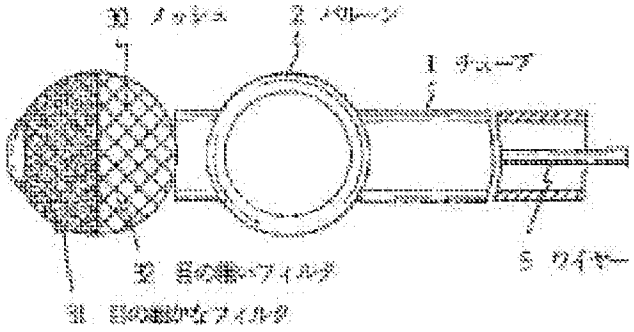
- cooperative:

Application number: JP19920237565 19920722

Priority number(s): JP19920237565 19920722

Abstract of JPH06190049 (A)





PURPOSE: To capture/dispose of a thrombosis piece leaked out of between a balloon and blood vessel inner walls, by advancing a wire referred to a tube to pushed out/expand a self-expandable filter out of the tube head to hit the blood vessel inner walls, under the state of which the thrombus removing catheter is moved back. CONSTITUTION: In a state as a filter 3 is accommodated into a tube 1, it is put into a blood vessel so that a semispherical member 4 closes the tube head to prevent the blood from leaking out of the tube 1 outside the body. Advancing the wire 5 pushes out a filter 3 up to the tube 1 head to expand this self- expandable filter 3 to hit the blood vessel inner walls. The balloon 2 is then expanded to get a contact with the blood vessel inner walls. Under this state, slowly drawing back the thrombus removing catheter then has the balloon 2 remove the thrombosis out outside the body. A little amount of thrombus piece leaked out of between the balloon 2 and the blood vessel inner walls is captured and discharged out outside the body by sliding between the maximum diameter part of the fine-mesh filter 31 and the blood vessel inner walls.

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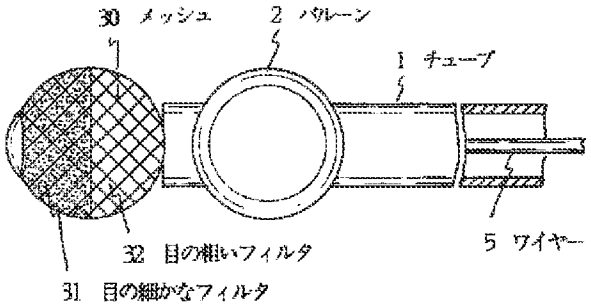
(54)【発明の名称】　血栓除去カテーテル

(57)【要約】
【目的】バルーンと血管内壁との間から漏出した血栓片を捕集して体外に排出する。
【構成】バルーンカテーテルに膨張可能フィルタを追加してバルーン周辺から漏出した血栓片を捕集して体外に排出する。



【特許請求の範囲】
【請求項１】　フレキシブルなチューブと、該チューブの先端部付近の外面に設けられた膨張収縮自在なバルーンとよりなるバルーンカテーテルにおいて、該チューブの内部に収容可能な自己膨張性フィルタが設けられ、該フィルタの先端部は、該チューブの内径と同じ最大直径の外方に向かう半球状部材と接続し、該フィルタの後端部は該チューブに内挿されたフレキシブルなワイヤーと接続し、該フィルタは先端部に向かって凸状となった目の細かなフィルタと、該目の細かなフィルタの基端の最大径部と接続する目の粗いフィルタとよりなり、該チューブを基準とした該ワイヤーの前進により、該自己膨張性フィルタが該チューブの先端部から押し出されて膨張し、血管内壁と当接することを特徴とする血栓除去カテーテル。
【請求項２】　該自己膨張性のフィルタが球状の目の粗い弾性メッシュをベースとし、該メッシュの前半部が目の細かなフィルタ材料により充填され、該メッシュの後半部自体が該目の粗いフィルタであることを特徴とする請求項１記載の血栓除去カテーテル。
【発明の詳細な説明】
【０００１】
【産業上の利用分野】本発明は血栓除去カテーテルに関する。詳しくは、血管内に挿入し、バルーンを膨張させてからチューブを後退させて血栓を体外に排出するのに使用されるバルーンカテーテルの改良に関するものであり、該チューブの後退時に該バルーンの周辺から血流方向に漏出する血栓片を捕集して体外に排出する血栓除去カテーテルに関する。
【０００２】
【従来の技術】従来のバルーンカテーテルは内壁に血栓が付着した血管内に挿入してからバルーンを膨張させ、血管内壁と当接させた状態で該カテーテルを引き出すことにより血栓を除去していた。
【０００３】
【発明が解決しようとする課題】上記のバルーンカテーテルによる血栓除去に際して、少量の血栓片が膨張したバルーンの周辺から漏出して血管内の下流方向に流れることがあった。特に静脈からの血栓除去時に少量であっても剥離した血栓片が血管の下流方向に流れると、心臓を経て肺動脈塞栓を生じる危険性があり、場合によって患者が死亡することがあった。
【０００４】
【課題を解決するための手段】上記の課題を解決するために、本発明の血栓除去カテーテルはフレキシブルなチューブと、該チューブの先端部付近の外面に設けられた膨張収縮自在なバルーンとよりなるバルーンカテーテルにおいて、該チューブの内部に収容可能な自己膨張性フィルタが設けられる。該フィルタの先端部は該チューブの内径と同じ最大直径の外方に向かう半球状部材と接続し、該フィルタの後端部は該チューブに内挿されたフレキシブルなワイヤーと接続する。該フィルタは先端部に向かって凸状となった目の細かなフィルタと、該目の細かなフィルタの基端の最大径部と接続する目の粗いフィルタとよりなる。該チューブを基準とした該ワイヤーの前進により、該自己膨張性フィルタが該チューブの先端部から押し出されて膨張して血管内壁と当接する。
【０００５】
【作用】本発明の該自己膨張性のフィルタを内挿した血栓除去カテーテルを内壁に血栓が付着した血管内に挿入してバルーンを膨張させてからワイヤー前進させて該自己膨張性フィルタを該バルーンカテーテルの前端から離脱させるか、あるいは該自己膨張性フィルタを離脱させてから該バルーンを膨張させると、該バルーンと該自己膨張性フィルタが該血管の内壁に当接する。該バルーンと、該自己膨張性フィルタが該血管の内壁に当接した状態で本発明の血栓除去カテーテルを後退させると血栓は該バルーンによって体外に除去され、該バルーンから漏出した少量の血栓片は該目の粗いフィルタを通過して該目の細かなフィルタによって捕集されて体外に排出される。あるいは、血管の状態に応じて自己膨張性フィルタを血管内壁に当接させた状態で留置して、該チューブのみを後退させると血管内壁に付着している血栓が該バルーンによって体外に除去される。該血栓除去時に該バルーンと血管内壁との間から漏出して下流方向に流れた血栓片は該目の粗いフィルタを通過して該目の粗いフィルタによって捕捉される。該バルーンによって血栓が体外に除去されたら、該バルーンを収縮させてから該チューブを前進させて該フィルタと当接させ、該ワイヤーを引っ張って該フィルタを該チューブ内に収容し、該チューブを体外に取り出すと、該フィルタによって捕捉された血栓片も除去される。
【０００６】
【実施例】以下、本発明の血栓除去カテーテルの実施例を図面を参照して説明する。第１図は該チューブ内に該フィルタを収容し、該バルーンが収縮した状態を示す該血栓除去カテーテルの要部の一部切欠側面図、第２図は該フィルタを該チューブから前方に押し出し、該バルーンを膨張させた状態を示す該血栓除去カテーテルの要部の一部切欠側面図である。第１図において、該血栓除去カテーテルは、フレキシブルなチューブ１と、該チューブの先端部付近の外面に設けられた膨張収縮自在なバルーン２とよりなるバルーンカテーテルにおいて、該チューブ１の内部に収容可能な自己膨張性フィルタ３が設けられる。該フィルタ３の先端部は該チューブ１の内径と同じ最大直径の外方に向かう半球状部材４と接続し、該フィルタ３の後端部は該チューブに内挿されたフレキシブルなワイヤー５と接続する。該フィルタ３は、先端部に向かって凸状となった目の細かなフィルタ３１と、該目の細かなフィルタ３２の基端部の最大径部と接続す

る目の粗いフィルタ３２とよりなり、該チューブ１を基準とした該ワイヤー５の前進により、該自己膨張性フィルタ３は該チューブ１の先端部から押し出され、膨張して図２に示されるように図示されない血管内壁と当接する。該フレキシブルチューブ１は例えば一般のカテーテルに使用されているプラスチック製である。該膨張収縮自在なバルーン２は例えば生体適合性に優れた天然ゴム製であって、該チューブ１の肉厚内の図示されないルーメンを経て該チューブの基端部に設けられた図示されないポートに連通し、該ポートからの例えば生食の注入によって膨張可能であり、また該生食の排出によって収縮可能である。該チューブ１の内径と同じ最大直径の外方に向かう半球状部材４は血液適合性に優れたプラスチック材料、例えばシリコーンによって構成される。該自己膨張性のフィルタ３のベース材料は、好ましくは全体が球状ないし楕円状になった弾性メッシュ３０、例えばナイロンメッシュによって構成される。該目の細かなフィルタ３１は、該メッシュ３０の先端側の内面の半分に、例えば極細の生体適合性に優れたプラスチック製ファイバ、例えばポリエステルファイバを充填するか、あるいは該メッシュ３０の前半部をポリマー溶液に浸漬し、硬化させて該前半部にメンブレンフィルタを形成させたものであってもよい。該目の粗いフィルタ３２は該目の粗いメッシュ３０の後半部自体によって構成される。該フレキシブルなワイヤー５は例えばステンレス鋼製である。本発明の血栓除去カテーテルは第１図に示されるように該フィルタ３を該チューブ１内に収容した状態で血管内に挿入される。該挿入時に、該半球状部材４は該チューブ１の先端部を閉じて、血液が該チューブ１から体外に漏出するのを防止する。第２図は該ワイヤー５の前進によって該フィルタ３が該チューブ１の先端部に押し出され、該バルーンが膨張した状態を示し、該フィルタ３は自己膨張性のため膨張して図示されない血管内壁と当接し、該バルーン２は前記のとおり生食注入によって膨張し血管内壁と当接している。該フィルタ３の押し出しと該バルーン２の膨張はいずれが先であってもよい。本発明の該自己膨張性のフィルタ３を内挿した血栓除去カテーテルを内壁に血栓が付着した血管内に挿入してバルーン２を膨張させてからワイヤー前進させて該自己膨張性フィルタを該バルーンカテーテルの前端から離脱させるか、あるいは該自己膨張性フィルタ３を離脱させてから該バルーン２を膨張させると、該バルーン２と該自己膨張性フィルタ３が該血管の内壁に当接する。該バルーン２と該自己膨張性フィルタ３が該血管の内壁に当接した状態で本発明の血栓除去カテーテルを徐々に後退させると血栓は該バルーン２によって体外に除去され、該バルーン３と血管内壁との間から漏出した少量の血栓片は該目の粗いフィルタ３２を通過して該目の細かなフィルタ３１の最大径部と血管内壁との摺動によって捕集されて体外に排出される。あるいは、血管内壁の状態に応じて自己膨張性フィルタ３を血管内壁に当接させた状態で留置して、該チューブ１を後退させると血管内壁に付着している血栓が該バルーン３によって体外に除去される。該血栓除去時に該バルーン３と血管内壁との間から漏出して下流方向に流れた血栓片は該目の粗いフィルタ３２を通過して該目の細かなフィルタ３１によって捕捉される。該バルーンによって血栓が体外に除去されたら、該バルーン３を収縮させてから該チューブ１を前進させて該フィルタ３と当接させ、該ワイヤー５を引っ張って該フィルタ３を該カテーテル内に収容し、該チューブ１を体外に取り出すと、該フィルタ３によって捕捉された血栓片も除去される。

【０００７】

【発明の効果】本発明の血栓除去カテーテルは上記のような構成となっているので、バルーンの周辺から漏出した血栓片を完全に捕集して体外に除去することができる。

【図面の簡単な説明】

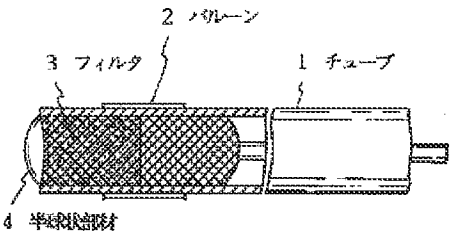
【図１】チューブ内にフィルタを収容した状態を示す血栓除去カテーテルの要部の一部切欠側面図

【図２】フィルタをチューブから前方に押し出し、バルーンを膨張させた状態を示す血栓除去カテーテルの要部の一部切欠側面図

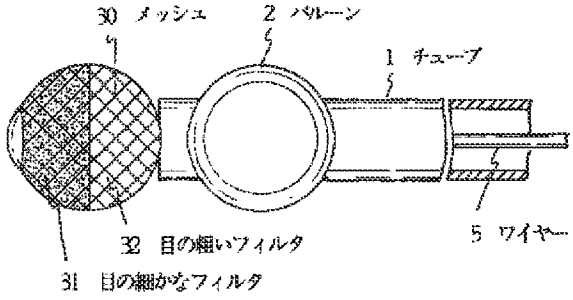
【符号の説明】

１はチューブ、２はバルーン、３はフィルタ、４は半球状部材、５はワイヤー、３０はメッシュ、３１は目の細かなフィルタ、３２は目の粗いフィルタ。

【図１】



【図２】



JPH06190049A - ABSTRACT

PURPOSE: To capture/dispose of a thrombosis piece leaked out of between a balloon and blood vessel inner walls, by advancing a wire referred to a tube to pushed out/expand a self-expandable filter out of the tube head to hit the blood vessel inner walls, under the state of which the thrombus removing catheter is moved back. CONSTITUTION: In a state as a filter 3 is accommodated into a tube 1, it is put into a blood vessel so that a semispherical member 4 closes the tube head to prevent the blood from leaking out of the tube 1 outside the body. Advancing the wire 5 pushes out a filter 3 up to the tube 1 head to expand this self- expandable filter 3 to hit the blood vessel inner walls. The balloon 2 is then expanded to get a contact with the blood vessel inner walls. Under this state, slowly drawing back the thrombus removing catheter then has the balloon 2 remove the thrombosis out outside the body. A little amount of thrombus piece leaked out of between the balloon 2 and the blood vessel inner walls is captured and discharged out outside the body by sliding between the maximum diameter part of the fine-mesh filter 31 and the blood vessel inner walls.

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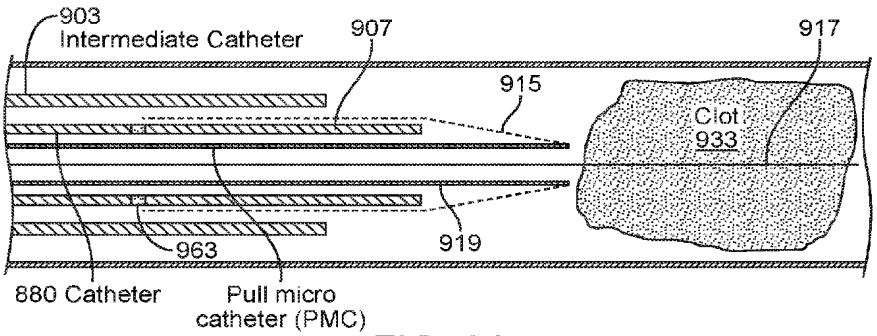

FIG. 9A

(57) Abstract: Mechanical thrombectomy apparatuses, and particularly knitted rolling tube mechanical thrombectomy apparatuses configured to have improved tracking for delivery through tortious vessels are described herein.

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INVERTING THROMBECTOMY APPARATUSES HAVING ENHANCED TRACKING

FIELD

[0001] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0002] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient quality of life.

[0003] Mechanical thrombectomy devices may be particularly advantageous. There is a definite need for thrombectomy devices, and particularly a mechanical thrombectomy devices that can be easily and accurately delivered through the, often tortious, anatomy in the peripheral and central vasculature, then reliably deployed to remove clot material. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY

[0004] Described herein are inverting tractor mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them.

[0005] In particular, described herein are inverting tractor mechanical thrombectomy apparatuses that are configured to have improved tracking within even the most tortious vessels of the anatomy. These inverting tractor mechanical thrombectomy apparatuses may be referred to herein as mechanical thrombectomy apparatuses. The method and apparatuses described herein may include the use of a deliver catheter (e.g., "intermediate catheter") that

is pre-loaded with the mechanical thrombectomy apparatus in a specific arrangement that provides enhances tracking, and methods of using them to reach, and remove, clot.

[0006] Also described herein are adaptations to mechanical thrombectomy apparatuses that allow them to remove particularly large clots without breaking or disrupting the clot, even if the rolling tractor portion of the mechanical thrombectomy apparatus is not able to pull additional clot into the apparatus.

[0007] Typically, the mechanical thrombectomy apparatuses described herein are inverting thrombectomy apparatuses (also referred to herein as inverting tractor thrombectomy apparatuses and inverting tube thrombectomy apparatuses) that include a flexible tube (e.g., tractor tube, tractor region, tractor portion, etc.) and an elongate inversion support catheter. The tractor tube generally comprises a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The flexible tube may be formed of a knitted material, and may be configured (e.g., sized, oriented, etc.) to roll smoothly over the distal end opening of the elongate inversion support catheter.

[0008] The flexible tube may be configured so that it is doubly biased, in order to prevent jamming and to grab and compress relatively large clots as it rolls and inverts into the elongate inversion support catheter at the distal end opening of the elongate inversion support catheter; the flexible tube may be biased so that it has an expanded (e.g., relaxed) un-inverted configuration having an outer diameter that is approximately the same or slightly larger than the inner diameter of the elongate inversion support catheter, which may be referred to as a second configuration of the flexible tube. The flexible tube may also be further biased so that it has an expanded (e.g., relaxed) inverted configuration (which may be referred to as a first configuration) having an inner and outer diameter that is larger than the outer diameter of the elongate inversion support catheter. The inner diameter in this first configuration may be greater than 1.2x (e.g., between 1.2x and 10x, between 1.2x and 8x, between 1.2x and 6x, between 1.2x and 5x, between 1.2x and 3x, etc.) the outer diameter of the inversion support catheter. Thus, when the flexible tube is placed in and over the distal end of the inversion support catheter, a first (inner) portion of the tractor tube is within the distal end of the elongate inversion support catheter in the un-inverted configuration and it is biased to expand towards (and in some configuration against) the inner diameter of the inversion support catheter; the region of the flexible tube that is inverted over the distal end opening of the inversion support catheter and extends proximally down the outside of the inversion support catheter is in an inverted configuration in which the inner diameter of the flexible tube is biased to be larger than the outer diameter of the inversion support catheter. This double-

biased configuration may be a result of the weave pattern (e.g., knitting), and/or a shape setting of the material forming the tractor tube, which may be a shape memory material. As a result, the inverting portion of the flexible tube, where it rolls and inverts over itself at the distal end of the inversion support catheter may be prevented from collapsing on itself as the tractor tube is rolled and pulled into the inversion support catheter. In some variations this configuration may also result in a somewhat flattened (e.g., and in some cases "trumpet shaped") distal end face that is rolling over the distal end opening of the elongate inversion support catheter. The trumpet-shaped distal end may have a teardrop-shaped cross-section. In some variations, the distal end face of the flexible tube may be T-shaped.

[0009] Also described herein are variations in which the first configuration of the flexible tube on the outside of the inversion support catheter (which may be referred to herein as an elongate inversion support catheter) maybe flush or nearly flush with the outer diameter of the inversion support catheter, e.g., within 50%, 40%, 30%, 20%, etc. of the outer diameter of the inversion support catheter.

[00010] The flexible tube may be coupled to a puller that is within the lumen of the inversion support. The puller may be a wire, filament, rod or more preferably a catheter or tube (and may be referred to herein as a pull micro catheter or "PMC" for convenience). A guidewire may be passed through the flexible tube, and therefore through the inversion support and the tractor tube. As will be described herein, this may be used for positioning.

[00011] The inversion support catheter may be configured as a catheter having a distal end opening into which the tractor inverts. The flexible tube may invert and rolls back into itself and may be drawn into the inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the inversion support catheter. The rolling motion may thus draw a clot or other object within a vessel into the inversion support. The inversion support catheter may be shaped or configured to have a sufficient column strength to withstand the compressive pulling force of the flexible tube as it is drawn (and rolled, inverting) into the distal end of the inversion support catheter. The inversion support catheter may be slotted (e.g., may include a plurality of slots or openings) to provide increased flexibility as well as column strength. However, as will be described herein, many inversion support catheters may become less flexible (e.g., more rigid) when a compressive force is applied to the flexible tube, either as a result of pulling the flexible tube proximally, either from within the inversion support catheter, or from the outside of the inversion support catheter as the flexible tube brushes against the vessel and/or a delivery catheter when being driven distally towards a clot.

[00012] Thus, described herein are mechanical inverting thrombectomy apparatuses that are adapted to enhance tracking as the apparatus is positioned within the vessel by pushing it distally away from an insertion point into the body to the site of the thrombus. These apparatuses and methods may include pre-loading the apparatus within an intermediate catheter in a particular configuration allowing it to track more easily, as well as variations in which the flexible tube is held within the inversion support catheter and deployed near the clot. Finally, described herein are apparatus in which the flexible tube (e.g., mesh, weave, knit) to limit or prevent the application of a compressive force on the inversion support catheter that may otherwise reduce flexibility and maneuverability of the inversion support catheter.

[00013] Also described herein are apparatuses for removing extensive clots, even when the flexible tube portion of the apparatus has been completely inverted, without breaking the clot and risking release of the clot back into the bloodstream where it could cause further harm.

[00014] For example, described herein are apparatuses that use one or more vacuum sources that may be applied either or both when initially contacting a clot and/or when removing the clot after being completely or partially engulfed by the flexible tube (tractor) portion of the apparatuses described herein. For example, the inverting tube apparatus (e.g., a mechanical thrombectomy apparatus) is configured to be inserted through a vessel such as a blood vessel, artery, etc., until a distal end, or a distal-most end, of the inverting tube apparatus is proximate to a clot. The clot may be immediately adjacent to the end of the apparatus, or it may be within a few cm (e.g., within 1 cm, within 2 cm, within 3 cm, within 4 cm, etc.). This may be detected by visualization, such as fluoroscopy. Thus, the apparatuses described herein may include one or more markers for visualization. Contrast may be used to visualize the clot and/or may be released from the apparatus. The apparatus may be deployed in a pre-loaded/pre-assembled configuration, as will be described in more detail below.

[00015] The flexible tube may be knitted and/or the apparatus may be configured with the opening into the vacuum lumen (e.g., through the puller catheter) at the distal-most end of the device, so that the flexible tube extends behind (proximal) the distal-facing end of the puller catheter. For example, the method of removing a clot from a vessel may include: advancing an inverting tube apparatus through a vessel until a distal end of the inverting tube apparatus is proximate to a clot, wherein the inverting tube apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller catheter within a lumen of the elongate support catheter, and a knitted tube having a first end coupled at a distal end region of the puller catheter, wherein knitted tube inverts over a distal

end of the inversion support catheter and extends proximally between the intermediate catheter and the inversion support catheter, further wherein the knitted tube comprises a filament that is knitted to form a plurality of interlocking loop stitches; advancing the puller catheter distally so that a distal face of puller catheter extends distally from the inverting tube apparatus further than the knitted tube; applying a vacuum through the puller catheter to engage the clot with the distal face of the puller catheter; and pulling the puller catheter proximally to roll the knitted tube over a distal end of the inversion support catheter so that the knitted tube inverts over the distal end of the inversion support catheter, captures the clot, and pulls the clot proximally into the inversion support catheter.

[00016] A large clot may be a clot that is typically longer than the capacity of the apparatus to hold within the flexible tube. This is described in greater detail herein, but may be, e.g., a 12:1 ratio (where, for every 12 cm of, e.g., woven, flexible tube, 1 cm of length of clot may be contained within the woven flexible tube). In general, large clots may have a large diameter and/or a long length. Longer clots may include clots having a length that is about 0.5 m or longer (e.g., about 1 cm or longer, about 2 cm or longer, about 3 cm or longer, about 4 cm or longer, about 5 cm or longer, etc.).

[00017] With respect to removing larger clots, the second end may reach the distal end of the inversion support catheter while a portion of the clot extends distally from the inversion support catheter so that at least a portion of the clot extends out of the flexible tube. The second end of the flexible tube may be prevented (stopped) from inverting over the end of the inversion support catheter, or it may be inverted and flipped (e.g., by advancing the intermediate catheter) in a non-traumatic way that prevents or limits the risk of breaking/tearing/disrupting the clot.

[00018] In any of these variations, suction may be applied through the inverting tube apparatus (e.g., through the intermediate catheter and/or the inversion support catheter) when withdrawing the inversion support catheter and puller with the clot attached proximally into the intermediate catheter.

[00019] The second end of the flexible tube may comprise a cuff that is less flexible that a region of the tube adjacent to the cuff. As will be described in more detail below, the cuff may be formed as a material attached to or applied onto/over the end of the flexible tube. For example, the second end of the flexible tube may comprise a cuff formed of a polymeric material applied onto/over the knitted tube. The cuff may be slit or cut (e.g., all or partially along its length) to provide some flexibility when pulling over or around the end of the tube. For example, the cuff may include longitudinal slits along its length. The cuff may have a

durometer that is greater than the durometer of the flexible tube (e.g., knitted tube). The cuff, in some variations, is thicker than the flexible tube. In any of the variations described herein, the cuff may be radiopaque (e.g., by including a radiopaque material, such as platinum) on or within the cuff.

[00020] As mentioned, the apparatus may be configured so that the end (e.g., the second end) of the flexible tube may be prevented from inverting and rolling over the distal end of the inversion support catheter by simply pulling proximally on the puller. Thus, in any of these variations, the intermediate catheter may be configured to push the cuff over the distal end of the inversion support catheter when the intermediate catheter is advanced distally past the cuff

[00021] Specifically described herein are apparatuses using flexible knitted tubes (tractors) as part of any of the mechanical thrombectomy apparatuses described herein. For example, the knitted flexible tubes may be configured to have stitch lengths that assist in capturing of clot within the vessel, even where the vessel has a larger inner diameter than the outer diameter of the flexible tube in an expanded configuration outside of the inversion support catheter. In particular, apparatuses in which the stich length is within a range of lengths that may be set by the dimension of the vessel (e.g., blood vessel, artery, peripheral vessel, etc.) and/or the outer diameter of the inversion support catheter. For example, a stitch length may be between about 0.5mm and 10 mm and/or may be selected based on the dimension of the vessel into which the apparatus is to be operated to remove a clot.

[00022] For example, described herein are method of removing a clot from a vessel having an inner diameter (ID), the method comprising: advancing an inverting tube apparatus through the vessel until a distal end of the inverting tube apparatus is proximate to a clot, wherein the inverting tube apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the support catheter, and a knitted tube having a first end coupled at a distal end region of the puller and a second end, wherein the knitted tube extends between the intermediate catheter and the inversion support catheter; further wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between the difference of 25% of the ID and one half the outer diameter (OD) of the inversion support catheter and 65% of the ID and one half of the OD of the inversion support catheter; pulling the puller proximally to roll the knitted tube over the distal end of the inversion support catheter so that the knitted tube inverts over a distal end of the inversion

support catheter driving the loop stitches outward, captures the clot, and pulls the clot proximally into the inversion support catheter.

[00023] Any of these methods may be used in particular with apparatuses in which the flexible tube is configured to remain relative snug on the inversion support catheter (e.g., within 50% (e.g., 40%, 30%, 25%, 20%, 15%, 10%, etc.) of the outer diameter of the inversion support catheter in the expanded (unconstrained) first configuration. In general, these apparatuses may expand at or near the distal-facing ends of the flexible tube, where the tube is inverting over itself, but may not be expanded at more proximal regions. This may form the T-shaped, Y-shaped, and/or trumpet-shaped distal end faces of the flexible tubes described herein. For example, in some variations, the knitted tube extends over the inversion support catheter with an inner diameter that is within 20% of the OD the inversion support catheter.

[00024] The second end of the knitted tube may comprise a cuff that is less flexible that a region of the knitted tube adjacent to the cuff, as described above and further herein. Alternatively, or additionally, the knitted tube may be shape-set to have a narrower region at the second end region (near the second end) of the flexible tube.

[00025] As mentioned above, in general, each loop stitch may have a stitch length that is between the difference of 25% of the ID and one half the outer diameter (OD) of the inversion support catheter and 65% of the ID and one half of the OD of the inversion support catheter. For example, each loop stitch may have a stitch length that is between the difference of 30% of the ID and one half the OD of the inversion support catheter and 60% of the ID and one half of the OD of the inversion support catheter (e.g., between the difference of 35% of the ID and one half the OD of the inversion support catheter and 50% of the ID and one half of the OD of the inversion support catheter, between the difference of 40% of the ID and one half the OD of the inversion support catheter and 45% of the ID and one half of the OD of the inversion support catheter, between the difference of 25% of the ID and one half the OD of the inversion support catheter and 45% of the ID and one half of the OD of the inversion support catheter, etc.). The stitch length may refer to the longitudinal (in the proximal-to-distal axis, which may curve or bend) of the knitted tube. The knitted tube may be formed of one or more filaments (or filament bundles) that are knitted into the tube to form interlocking links (loop stitches). The filament material may be relatively stiff, such as a wire, e.g., Nitinol wire, that when knitted has a material flexibility. The knit may be coated with a material (e.g., a lubricious material, etc.). Examples of knits are illustrated in, e.g.,

U.S. app. no. 15/496,570, filed on 4/25/2017 ("Anti-Jamming and Macerating Thrombectomy Apparatuses and methods"), previously incorporated by reference in its entirety.

[00026] For example, an inverting tube apparatus for removing a clot from a vessel may include: an intermediate catheter; an inversion support catheter within a lumen of the intermediate catheter; a puller within a lumen of the elongate support catheter; and a knitted tube extending over the inversion support catheter, the knitted tube having a first end coupled at a distal end region of the puller and a second end that is free, wherein the knitted tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter; further wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between 0.5mm and 10mm.

[00027] As mentioned, the knitted tube may extend over the inversion support catheter with an inner diameter that is within 20% (e.g., within about 10%, 15%, 20%, 25%, 30%, 40%, etc.) of the outer diameter of the inversion support catheter (e.g., relatively snugly to or against the inversion support catheter). The second end of the knitted tube may comprise a cuff that is less flexible that a region of the knitted tube adjacent to the cuff.

[00028] Any of the methods and apparatuses described herein may include an expanded flexible tube portion that expands outward less than the diameter of the vessel over much (e.g., greater than about 50%, about 60%, about 70%, about 75%, about 80%, about 90%, etc.) of its length while having an expanded second end region that has a much smaller diameter near this second end region (e.g., having a diameter that is within about 10%, 15%, 20%, 25%, 30%, 40%, etc. of the inversion support catheter. This configuration may allow even larger-diameter clots (e.g., from the peripheral vasculature) to be engulfed and safely removed with apparatuses having a much narrower diameter than the vessels in which the clots are located.

[00029] For example, described herein are inverting tube apparatus for removing a clot from a vessel, the apparatus comprising: an inversion support catheter; a puller within a lumen of the inversion support catheter; and a knitted tube extending over the inversion support catheter in a first configuration, the knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inserting support catheter, wherein the knitted tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter into a second configuration within the inversion

support catheter; further wherein the knitted tube in the first configuration has an expanded outer diameter that is between 0.5 mm and 12 mm for a first region of the knitted tube that is adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the region of the knitted tube adjacent to the first end and within 20% of an outer diameter of the inversion support catheter.

[00030] As mentioned, the knitted tube in the first configuration may have an expanded outer diameter (unconstrained) that is between 0.5 mm and 12 mm; in some variations this expanded outer diameter is between 0.5 mm and 15 mm, e.g., between about 0.5 mm and about 14 mm, between about 0.5mm and about 13 mm, between about 0.5 mm and about 11 mm, between about 0.5 mm and about 10 mm, between about 0.5 mm and about 9 mm, between about 0.5 mm and about 8 mm, between about 3 mm and about 15 mm, between about 4 mm and about 15 mm, between about 5 mm and about 15 mm, between about 3 mm and about 12 mm, between about 4 mm and about 12 mm, between about 5 mm and about 12 mm, between about 3 mm and about 10 mm, between about 4 mm and about 10 mm, between about 5 mm and about 10 mm, etc.

[00031] Any of the apparatuses described herein may include a cuff at the second end, wherein the cuff has a stiffness that is greater than a region of the knitted tube adjacent to the cuff. Alternatively, or additionally, any of these apparatuses may include a stop configured to limit the travel of the knitted tube so that the second end does not roll and invert over the distal end of the inversion support catheter.

[00032] The knitted tube may be shape set so that the first configuration has the outer diameter between, e.g., 0.5mm and 10 mm for the region of the kitted tube adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than, e.g., about 30 % (e.g., about 40%, about 50%, about 60%, etc.) of the inner diameter of the inversion support catheter.

[00033] The first region of the kitted tube (having the larger expanded diameter) may be any appropriate length (e.g., at least about 0.5 cm, about 1 cm, about 2 cm, about 3 cm, about 4 cm, about 5 cm, about 6 cm, about 7 cm, about 8 cm, about 9 cm, about 10 cm, etc.). Similarly, the second region (having the narrower expanded diameter) may be any appropriate length (e.g., at least about 0.5 cm, about 1 cm, about 2 cm, about 3 cm, about 4 cm, about 5 cm, etc.).

[00034] The knitted tube may comprise a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between a predetermined range (e.g., between about 0.5mm and 8 mm, about 0.5 to 10 mm, about 0.5 mm to 12 mm, about 0.5 to 14 mm, etc.). This may permit, for example, at a region of the knitted tube that is inverting from the first configuration to the second configuration, a sub-set of the plurality of loop stitches forming the knitted tube may extend proud from the long axis of the knitted tube by between 0.5 mm and 10 mm (e.g., between about 0.3 mm and about 8 mm, between about 0.5 mm and about 8 mm, between about 0.5 mm and about 7 mm, between about 0.5 mm and about 6 mm, greater than about 1 mm, greater than about 2 mm, greater than about 3 mm, greater than about 4 mm, greater than about 5 mm, etc.) as the knitted tube inverts.

[00035] Any of these apparatuses may include an intermediate catheter having a lumen as described herein. The inversion support catheter may be within the lumen of the intermediate support catheter and may be extended distally from the intermediate catheter to deploy the knitted tube so that the flexible tube may expand into the first configuration.

[00036] As mentioned, described herein are methods for removing a clot from a vessel a larger diameter (and therefore a larger clot diameter) than even the expanded flexible tube of the apparatus. For example, described herein are methods of removing a clot from a vessel having an inner diameter (ID) comprising: advancing an inverting tube apparatus through the vessel until a distal end of the inverting tube apparatus is proximate to a clot, wherein the inverting tube apparatus comprises an inversion support catheter, a puller within a lumen of the support catheter, and a knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inserting support catheter, wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length; expanding the knitted tube to a first configuration along an outer surface of the inverting tube catheter to an outer diameter that between 10% and 80% of an inner diameter of the vessel for a first region of the knitted tube that is adjacent to the first end, wherein the knitted tube has a second configuration within the inverting tube catheter having an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the first configuration; pulling the puller proximally within the inversion support catheter to roll the knitted tube over the distal end of the inversion support catheter so that the knitted tube inverts over a distal end of the inversion support catheter, driving the loop stitches

outward from the kitted tube by between 0.5 and 10 mm; capturing the clot with the knitted tube; and pulling the clot proximally into the inversion support catheter.

[00037] Expanding of the flexible tube (e.g., knitted tube) may comprise exposing the knitted tube from out of an intermediate catheter, wherein the inversion support catheter is within a lumen of the intermediate support catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[00038] The features and aspects of the various embodiments of the disclosed inventions are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00039] FIG. 1A illustrates one example of a delivery catheter ("intermediate catheter" or I.C.) that may be used with a mechanical thrombectomy apparatus as described herein.

[00040] FIGS. 1B-1C2 illustrate components of a mechanical (e.g., inverting tractor) thrombectomy apparatus; FIG. 1B shows an example of an elongate inversion support catheter that is configured to include a plurality of slots (shown here as transverse slots) arranged along the catheter in order to enhance flexibility of the elongate inversion support catheter while providing sufficient column strength to resist buckling as the tractor tube is drawn proximally to invert. The slot pattem of FIG. 1B is intended as a single example only. Other slot/cut-out patterns may be used. FIGS. 1C1 and 1C2 show a tractor tube inverted (e.g., in an inverted configuration) over a puller; in FIG. 1C1 the puller is a puller catheter (PMC) while in FIG. 1C2 the puller is a guidewire. The tractor tube is shown schematically and may be a knitted, woven, or braided material.

[00041] FIGS. 2A-2C illustrate the operation of an inverting tractor mechanical thrombectomy apparatus as described above. FIG. 2A shows the assembled apparatus in which the tractor tube is coupled to the puller and within the elongate inversion catheter with the tractor tube inverting over the distal end of the elongate inversion catheter. FIG. 2B shows the apparatus of FIG. 2A delivered within a vessel near a clot. FIG. 2C shows the operation of the apparatus to withdraw the clot by pulling proximally on the tractor tube from within the elongate inversion support catheter so that the tractor tube is pulled to roll over and evert from the inverted configuration on the outside of the distal end of the elongate inversion support catheter into the un-inverted configuration within the elongate inversion support catheter, pulling the clot with it.

[00042] FIG. 2D illustrates an example of a tortious path that the inverting tractor mechanical thrombectomy apparatus may have to navigate in order to reach the clot.

[00043] FIG. 3A is an example of a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter that may be used as described in order to deliver an inverting tractor mechanical thrombectomy apparatus though a tortious vessel to a deployment location. In this example, the elongate inversion support catheter is held within the intermediate catheter (and may be locked in position) until deployed, while the pusher (e.g., PMC) and tractor are partially extending distally. A guidewire may also be used. FIG. 3B show a prototype assembly (pre-assembled) similar to that shown in FIG. 3A.

[00044] FIG. 4A is another example of a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter that may be used as described in order to deliver an inverting tractor mechanical thrombectomy apparatus though a tortious vessel to a deployment location. In this example, the elongate inversion support catheter is extended from the intermediate catheter, and extends distally along with the puller (PCM). FIG. 4B show a prototype assembly (pre-assembled) similar to that shown in FIG. 4A. FIG. 4C shows an example of a preloaded assembly such as the one shown in FIG. 4A and 4B navigating through a model of a tortious vessel. FIG. 4D is another example of a prototype pre-assembled assembly (inverting tractor mechanical thrombectomy apparatus) such as the one shown in FIG. 4A.

[00045] FIG. 5A is another example of a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter that may be used to deliver an inverting tractor mechanical thrombectomy apparatus though a tortious vessel to a deployment location. In this example, the elongate inversion support catheter, and the tractor tube are held within the intermediate catheter, and the distal end (extending beyond the attachment to the tractor tube) of the puller extends distally. FIG. 5B show a prototype assembly (pre-assembled) similar to that shown in FIG. 5A.

[00046] FIG. 6 is an example of a non-over-the-wire variation of an inverting tractor mechanical thrombectomy apparatus in which the puller is a guidewire, similar to the variation shown in FIG. 2C2.

[00047] FIGS. 7A-7C illustrate one example of an inverting tractor mechanical thrombectomy apparatus in which the apparatus is configured for delivery of the tractor tube within the elongate inversion support catheter so that it may later be deployed (as illustrated in FIGS. 7A-7C) to move the tractor tube portion so that it is inverted over the elongate inversion support catheter distal end.

[00048] FIGS. 8A-8C illustrate another method of deploying an inverting tractor mechanical thrombectomy apparatus (where the apparatus is configured for delivery of the tractor tube within the elongate inversion support catheter) so that the tractor tube portion is inverted over the elongate inversion support catheter distal end when at the deployment region near the clot. In both FIGS. 7A-7C and 8A-8C, withdrawing the tractor tube into the elongate inversion support catheter may prevent it from applying a compressive force on the elongate inversion support catheter as it is deployed through the vessel, either with an intermediate catheter or without an intermediate catheter.

[00049] FIGS. 9A-9K illustrate one method of delivering and deploying an inverting tractor mechanical thrombectomy apparatus pre-loaded into an intermediate catheter such as the one shown in FIGS. 3A-3B. Similar methods may be employed to deliver the pre-loaded variations shown in FIGS. 4A and 5A.

[00050] FIGS. 10A-10D illustrate another example of a method of delivering and deploying an inverting tractor mechanical thrombectomy apparatus pre-loaded into an intermediate catheter such as the one shown in FIGS. 3A-3B.

[00051] FIGS. 11A-11C illustrate a method of using an inverting tractor mechanical thrombectomy apparatus to remove clot after the tractor tube portion of the inverting tractor mechanical thrombectomy apparatus has been completely withdrawn into the elongate inversion support catheter.

[00052] FIG. 12A illustrates an inverting tractor mechanical thrombectomy apparatus configured to prevent the tractor tube from retracting fully into the elongate inversion support catheter. In FIG. 12A the tractor tube has a distal end region that is non-compliant and configured so that it cannot invert over the distal end of the elongate inversion support catheter.

[00053] FIG. 12B shows an example of a cuff on the distal end of an inverted flexible tube.

[00054] FIGS. 13A shows a knitted tractor tube extending in an inverted configuration over the outside of a distal end of an elongate inversion support catheter. FIG. 13B shows the knitted tractor of FIG. 13A applying compressive force to the elongate inversion support catheter when the apparatus is advanced distally. FIG. 13C illustrates an inverting tractor mechanical thrombectomy apparatus configured to hold the kitted tractor tube in a compressed state (in which the transversely arranged, or approximately transversely arranged loops forming the knit overlap over more than 20% or their longitudinal length).

[00055] FIGS. 14A-14D illustrate examples of inverting tractor mechanical thrombectomy apparatuses (e.g., elongate inversion support catheter portions) including a stop that is configured to hold the knitted tractor tube in a compressed configuration. In FIG. 14 a polymer strop is shown. In FIG. 14B a Nitinol braid stop has exposed filaments ("fingers") that prevent proximal sliding of the tractor tube. FIG. 14C shows another example of a Nitinol braid stop has exposed filaments ("fingers") that prevent proximal sliding of the tractor tube. FIG. 14D shows a Nitinol knit segment configured as a stop to prevent proximal sliding of the tractor tube during delivery.

[00056] FIGS. 15A-15G illustrate examples of finger-like stop elements similar to those shown in FIGS. 14B-14C. The distally-directed prongs, filaments or fingers of the stops shown may be placed anywhere along the length of the outer surface of the elongate inversion support catheter to prevent compression of the knitted tractor tube during delivery and deployment.

[00057] FIGS. 15H is another example of a stop on the outer surface of and elongate inversion support catheter having distally-facing prongs that prevent proximal movement of a woven tractor tube, in order to prevent compressive forces on the elongate inversion support catheter.

[00058] FIGS. 16A and 16B illustrate examples of annular housings ("garages") for the tractor tube on the outer surface of an elongate inversion support catheter that may also maintain the tractor tube in a compressed configuration on an outer surface of the apparatus, preventing it from applying compressive force on the distal end of the elongate inversion support catheter. In FIG. 16A, a 48-end braid forms an annular garage for holding the end of the tractor tube so that it remains in a compressed configuration along the outer surface of the elongate inversion support catheter. In FIG. 16B, the apparatus includes a 10 mm long braided region (similar to that shown in FIG. 15A, housing the end of the knitted tractor tube and preventing it from extending proximally and applying compressive forces on the distal end of the elongate inversion support catheter.

[00059] FIG. 17 is an example of one variations of an elongate inversion support catheter having a high column strength in compression, but a high flexibility when not under compression. In FIG. 17, the elongate inversion support catheter includes a plurality of slots or cut-our regions arranged approximately transverse to the elongate length (e.g., long axis). Any of these devices may also include a marker (e.g., platinum, or other radiopaque material) allowing visualization of the distal end region of the elongate inversion support catheter.

[00060] FIGS. 18A-18J illustrate a method of removing a clot from a vessel as described herein, in which a vacuum (suction) may be applied through the puller to make and confirm initial contact with the clot. In FIG. 18A, the apparatus is distally advanced over a guidewire adjacent to the clot. The apparatus may initially be in a tracking configuration as shown and discussed, in which the outer (inversion support) catheter is retracted into the lumen of the intermediate catheter while the puller (puller catheter) with the attached flexible tube extending proximally from the distal end, is tracked over the guidewire. In FIG. 18B, the apparatus is changed to a clot-grabbing configuration in which the inversion support catheter is extended towards the distal end of the apparatus, though still proximal to the puller distal end. The intermediate catheter may also optionally be withdrawn proximally, as shown in FIG. 18C, which in some variations (not shown in FIG. 18A-18J) may allow the flexible tube to expand outwards. FIG. 18C1 shows an example of a prototype device corresponding to FIG. 18C. Once in position, suction may be applied through the puller catheter, as shown in FIG. 18D. This focal suction may be applied while advancing the apparatus distally to engage the clot, as shown in FIG. 18E. The guidewire may be left in place or optionally removed (as shown in FIGS. 18D-18E). Once engaged with the clot at the distal end of the puller, which may be detected by observing the flow and/or pressure through the puller from the suction, the puller may be drawn proximally and/or the inversion support catheter may be moved distally so that the flexible tube rolls over the distal end opening of the inversion support catheter. In FIG. 18F approximately 30% of the clot has been drawn into the inversion support catheter by rolling the flexible tube; in FIG. 18G, more, but not all (e.g., approximately 70%) of the clot has been ingested, though a substantial amount of clot remains outside of the inversion support catheter and flexible tube. The vacuum may be left on, or it may be turned off while pulling the puller proximally to engulf/grab the clot. Heavy arrows indicate movement of the components of the apparatus, such as the intermediate catheter, which may be advanced distally, the inversion support catheter, which may also be advanced distally, and the puller, which may be withdrawn proximally. These motions may be coordinated by the handle (not shown) and/or performed manually by the user. Once the flexible tube has reached the distal end of the inversion support catheter, it may stop or be stopped, to prevent it from rolling over the distal end. In FIG. 18A-18J the second end of the flexible tube includes a cuff that may prevent the flexible tube from rolling over the distal end when pulling proximally on the puller, as shown in FIG. 18H. In FIG. 18I, the intermediate catheter is shown advancing distally beyond the cuff and distal end of the intermediate support catheter, which inverts the cuff over and against the clot without breaking or

disrupting the clot. A vacuum (suction) through the intermediate catheter is also shown being applied (by the small arrows). As shown in FIG. 18J, the flexible tube, puller and inversion support catheter are then drawn proximally into the intermediate catheter along with the un-engulfed portion of the clot, either by driving the intermediate catheter distally over them, and/or by pulling the inversion support catheter (which may be pulled with the puller) proximally.

[00061] FIG. 19 illustrates an example of a mechanical thrombectomy apparatus having a knitted flexible tube that is configured to operate even in larger-dimeter vessels (having proportionally larger-diameter clots) by configuring the stitch length of the knitted tube to help grab larger-diameter clots.

[00062] FIG. 20A illustrates a larger-dimeter clot (e.g., shown in the top as a 15 mm OD, 5 cm long clot) that was captured using a narrower-diameter mechanical thrombectomy apparatus having a knitted flexible tube portion (shown having an expanded outer diameter of 5 cm with an 8F inversion support catheter). The removed clot is shown on the bottom above the ruler.

[00063] FIG. 20B shows a side view of a distal end region of a similar mechanical thrombectomy apparatus having a knitted flexible tube that inverts into a 3 mm inversion support catheter. The knitted flexible tube has a 6 mm expanded first configuration, but may remove clots having an outer diameter much larger (e.g., a 15 mm outer diameter clot, as shown in FIG. 20A).

[00064] FIG. 21A illustrates and example of a relationship between the length of flexible tube required for a mechanical thrombectomy apparatus as described herein in order to completely engulf ("eat") a clot having an outer diameter of 15 mm and a length of 5 cm. In this example, the flexible tube is a knitted or woven tube formed of heat-set 0.01 inch NiTi wire.

[00065] FIG. 21B shows example of the distal ends of mechanical thrombectomy apparatus tested in FIG. 21A, showing variations with 8 mm expanded outer diameter, 5 mm expanded outer diameter, and 3 mm outer diameter, as well as an 8 French (8F) inversion support catheter.

[00066] FIG. 22A shows another example of a cuff that may be at the second end of a flexible tube of a mechanical thrombectomy apparatus. In FIG. 22A, the cuff includes a plurality of slits that may engage with the intermediate catheter (IC) when it is driven distally past the cuff to drive the cuff to invert over the distal end of an inversion support catheter, as shown in FIG. 18I, controllable preventing inversion when pulling the puller, but allowing

inversion without disrupting the clot when advancing the intermediate catheter, as illustrated in FIG. 22B, showing inversion of the cuff after driving the intermediate catheter distally.

[00067] FIGS. 23A-23B illustrate example of the proximal end of a mechanical thrombectomy apparatus, showing the components of the apparatus (e.g., guidewire, inner/inversion support catheter, puller, and intermediate catheter). FIG. 23B shows another example, of a proximal end of the mechanical thrombectomy apparatus showing manual controls, including vacuum attachment ports, for the different regions.

[00068] FIGS. 24A-24B illustrate another example of a set of proximal end controls for a mechanical thrombectomy apparatus. In FIG. 24A the apparatus control region is shown in a first puller position (prior to pulling the clot in). In FIG. 24B the apparatus control region is shown after pulling the clot (showing the puller hub extended proximally).

[00069] FIG. 25 illustrate an example of a mechanical thrombectomy apparatus in which the flexible tube is configured to cut tissue as it rolls into the inversion support catheter. In this example, the flexible tube is a knitted tube that includes sharp cutting edges that may be used to cut through tissue.

[00070] FIGS. 26A-26B illustrate two exemplary side perspective views of mechanical thrombectomy apparatuses. In FIG. 26A, similar to that shown in FIGS. 18A-18J, the apparatus include a flexible (e.g., knitted) tube that is attached at the first end to a puller catheter and is configured to expand within the inversion support catheter to an outer diameter that is greater than 40% (shown here, it's greater than 90%) of the inner diameter of the inversion support catheter, driving the region of the flexible tube within the inversion support catheter against the walls, even when unloaded by clot. The other region (un-inverted) of the flexible tube along the outer diameter of inversion support catheter is shown as snug with the inversion support catheter in the un-constrained configuration. This results in the Y-shaped distal profile, for the inverting flexible tube, which may help grab even larger diameter clots.

[00071] FIG. 26B illustrates another example of a mechanical thrombectomy apparatus in which the expanded outer profile of the flexible tube is expanded beyond the outer diameter of the inversion support catheter near the first end where it attaches to the puller, but the second end, that is freely sliding over the inversion support catheter, has a much smaller (nearly snug) expanded diameter. This region may also or alternatively include a cuff as described herein.

[00072] FIGS. 27A-27C illustrate operation of a mechanical thrombectomy apparatus having a cuff on one end of the flexible tube.

[00073] FIGS. 28A-28C illustrate one example of a mechanical thrombectomy apparatus that includes a cuff retainer that may aid in re-sheathing the apparatus into an intermediate catheter.

[00074] FIGS. 29A-29C illustrate another example of a mechanical thrombectomy apparatus that includes a cuff retainer.

[00075] FIGS. 30A-30C illustrate another example of a mechanical thrombectomy apparatus that includes a cuff retainer.

[00076] FIGS. 31A-31C illustrate another example of a mechanical thrombectomy apparatus that includes a cuff retainer (configured as a stop).

[00077] FIGS. 32A-32F illustrate examples of mechanical thrombectomy apparatus including a cuff that is adapted at the proximal-facing end to aid in re-sheathing into an intermediate catheter. FIGS. 32A-32C illustrate cuffs having a tapered proximal end region. FIGS. 32D and 32E illustrate cuffs having angled proximal-facing sides. FIG. 32F is an example of a cuff having a proximal stent-like region.

[00078] FIGS. 33A-33E illustrate one example of a re-loading mechanical thrombectomy apparatus in which a single-use sub-assembly (including the puller, cuff and flexible tube) can be withdrawn and a new sub-assembly inserted.

[00079] FIGS. 34A-34C illustrate operation of a re-usable/reloadable mechanical thrombectomy apparatus.

[00080] FIG. 35 schematically illustrates one example of an ejection apparatus that may be used to assist in ejecting captured clot material and/or reloading of a mechanical thrombectomy apparatus.

DETAILED DESCRIPTION

[00081] In general, described herein are inverting tractor mechanical thrombectomy apparatus having a tractor tube, configured as an inverting flexible tractor tube that may be pulled proximally to invert over and into the distal end of an elongate inversion support catheter. An end of the tractor tube may be coupled to a puller (e.g., pull wire, pull catheter, etc.) to provide the proximal pulling force. In particular, described herein are apparatuses and methods of using them that improve or enhance tracking of the apparatus from a patient insertion side (e.g., a femoral region or elsewhere) though a tortious vessel, to a deployment site where the apparatus may be deployed to mechanically remove a clot by rolling the tractor tube into the elongate inversion support catheter and grabbing the clot.

[00082] In general, the apparatus may be adapted to improve tracking by preventing stiffening or loss of flexibility of the elongate inversion support catheter that may otherwise occur when the tractor tube, which may extend along a substantial distance proximally from the distal open end of the elongate inversion support catheter, applies a compressive force on the elongate inversion support catheter. This may occur, for example, when the apparatus is deployed through the vessel and/or through an intermediate catheter. Although the outer surface of the elongate inversion support catheter, and/or the outer surface of the tractor tube may be lubricated to reduce friction, the distal movement of the apparatus may still result in a drag force on and portion of the tractor tube that is on the outside surface of the elongate inversion support catheter. The resulting drag force is transferred to the distal end of the elongate inversion support catheter, resulting in a compressive force on the elongate inversion support catheter. An example of this is illustrated in FIG. 13B, described in greater detail below.

[00083] This issue may be exacerbated when the apparatus includes an elongate inversion support catheter that is configured to have both a high column strength (resisting compression) and an increased flexibility, e.g., by including one or more cut-outs, slots, etc. arranged down the length of the elongate inversion support catheter. For example, metal tubes (e.g., Nitinol tubes, etc.) having transversely arranged slots cut into them along the length of the elongate inversion support catheter may have a high column strength, while remaining sufficiently flexible (at least in an unloaded/un-tensioned configuration).

[00084] In general, an inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support catheter (such as those mentioned above), having a distal end and a distal annulus (distal end opening), and a flexible tractor assembly including a flexible tractor tube coupled to an elongate puller within the elongate inversion support catheter. The flexible tractor tube is configured to roll and invert over the distal end opening of the elongate inversion support catheter. Knitted tractor tubes are of particular interested and described herein, although it should be understood that other tractor tubes, e.g., woven, braided, etc., may be used.

[00085] Tracking of any of the inverting tractor mechanical thrombectomy apparatus described herein may include an intermediate catheter (I.C.) as a delivery catheter along with a guidewire. For example, FIG. 1A illustrates an example of a typical intermediate catheter 101 that may be used. Note that in some variations, as will be illustrated below, an intermediate catheter is not needed or used and the inverting tractor mechanical

thrombectomy apparatus may be delivered to the deployment site near the clot to be removed without the need for an intermediate catheter.

[00086] FIG. 1B illustrates one example of an elongate inversion support catheter. In this example, the elongate inversion support catheter 103 is formed of a normally high column-strength material (such as a metal, e.g. Nitinol) having a number of openings (e.g., cut-out regions) or slots along the length to provide enhanced flexibility. The distal end of the elongate inversion support catheter is open 105. Either the entire length or a portion of the length may be cut/slotted as described. The elongate inversion support catheter includes a catheter body having a distal end region that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm,05 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00087] In FIG. 1B, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of of compressive force is applied (e.g., able to withstand at least about 500g, at least about 700 g, at least about 600 g, at least about 500 g, at least about 400 g, at least about 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1B the catheter 103 of the elongate inversion support catheter may be any appropriate

type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00088] In some variations the distal end 105 of the elongate inversion support catheter is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00089] FIG. 1C1 shows an example of a flexible tractor tube 111 coupled to an elongate puller 113, forming a pullable tractor assembly 140. In this example, the tractor tube 111 is shown integrated with the puller 113 and extending back over the puller. The puller in this example is a catheter (e.g. a micro catheter, also referred to herein as a PMC or pull micro catheter). In this example, the opposite end of the flexible tractor tube 111 is open and free (e.g., not connected to the puller or catheter, e.g. elongate inversion support catheter). As will be described in greater detail below, this open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIGS. 1C1 and 1C2, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor 111 is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 111 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The tractor 111 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1C2, the tractor tube 111 is shown coupled to a guidewire (non-hollow structure) 115. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00090] FIG. 2A illustrates an example of an inverting tractor mechanical thrombectomy apparatus 200 deployed. In FIG. 2B the inverting tractor mechanical thrombectomy apparatus is shown deployed near a clot 209. In the deployed configuration the puller 201 (shown here as a puller micro catheter) is held within the elongate inversion support catheter so that the

flexile tractor tube 203 extends from the end of the puller and expands toward the inner radius of the elongate inversion support catheter 207; at the distal end opening of the elongate inversion support catheter the tractor tube inverts over itself and extends proximally in an inverted configuration over the distal end of the elongate inversion support catheter. As shown in FIG. 2C, by pulling the puller proximally, the tractor tube rolls and everts over the distal end opening of the elongate inversion support catheter, drawing the adjacent clot into the elongate inversion support catheter, as shown.

[00091] FIG. 2A the elongate inversion support catheter is positioned between the tractor tube and the puller so that the tractor tube can be pulled proximally by pulling on the puller and rolling the tractor tube into the elongate inversion support catheter so that it inverts. The portion of the tractor tube that is inverted over the distal end of the elongate inversion support catheter has an outer diameter that is greater than the outer diameter of the elongate inversion support catheter. The tractor is biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, the tractor tube may also be configured (e.g., by heat setting, etc.) so that when the tractor tube is everted and rolled over the distal end opening into the elongate inversion support catheter, the outer diameter of the tractor tube within the elongate inversion support catheter has an outer diameter that is greater than the inner diameter of the elongate inversion support catheter (e.g., greater than 0.1x, 0.5x 0.6x, 0.7x, 0.75x, 0.8x, 0.9x, 1x, etc. the inner diameter, ID, of the elongate inversion support catheter. This combination of an un-inverted diameter of the tractor tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the tractor tube of greater than 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the tractor over the distal end opening of the elongate inversion support catheter to grab a clot. The tractor may be expandable and may be coupled to the puller as shown. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00092] In FIG. 2C the clot may be drawn into the elongate inversion support catheter by pulling the tractor proximally into the distal end of the elongate inversion support catheter, as indicated by the arrows 211, 211' showing pulling of the inner portion of the flexible tractor, resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown

by arrows. The end of the tractor outside of the catheter may be "loose" relative to the outer wall of the catheter.

[00093] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last "y" cm (e.g., the distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00094] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions. Alternatively, it may be advantages to have a hydrophilic coating on 1, 3, 5, 10, or 15 cm of the distal ID or the entire catheter ID. This may even enhance aspiration of the clot without a tractor element.

[00095] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating

axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00096] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00097] In any of the variations described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily side over the catheters distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00098] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.025" radius wall on the catheter, ideally approximately 0.05" radius wall.

[00099] The stiffness of the distal of the elongate inversion support catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the elongate inversion support catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inward ward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[000100] It may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may

be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[000101] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[000102] As mentioned above, any of the apparatuses described herein may be configured to provide enhance delivery of the apparatus though the tortious anatomy of the vessels in order to deploy the apparatuses near the clot. For example, FIG. 2D illustrates an example of a tortious path 250 that may be navigated by the apparatuses (including in particular the apparatuses that are pre-loaded into an intermediate/delivery catheter).

[000103] PRELOADED APPARATUSES

[000104] One solution to the problem with tracking of the inverting mechanical thrombectomy apparatuses such as those described herein, and particularly those having a high flexibility, high column strength elongate inversion support catheter (which may stiffen when placed under even relatively small compressive forces from their distal end by the tractor tube) is to preload the inverting mechanical thrombectomy apparatuses within an intermediate catheter so that a portion of the inverting mechanical thrombectomy apparatus is protected within the body of the intermediate catheter, while the rest of the intermediate catheter portion is advanced over and/or along (with) a guidewire. For example, FIG. 3A illustrate one example of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy. In this example, the apparatus may include an intermediate catheter 303 having a distal end 305. The intermediate catheter (I.C.) may be considered part of the inverting mechanical thrombectomy apparatus, although in other variations it may be considered a separate component that is used with the inverting mechanical thrombectomy apparatus. The apparatus also includes an elongate inversion support catheter 307 (also referred to as push catheter "880 Device" in FIG. 3) within the lumen of the intermediate catheter. The elongate inversion support catheter 307 has a distal end 311 and a distal end opening. The apparatus

also includes a puller 319 extending distally within the elongate inversion support catheter and a flexible tractor tube 315 extending proximally from a distal end region of the puller. The puller extends from the distal end of the intermediate catheter and the distal end opening of the elongate inversion support catheter.

[000105] In the pre-assembled configuration shown in FIG. 3A, the elongate inversion support catheter is held within the lumen of the intermediate catheter so that the distal end opening of the elongate inversion support catheter is proximal to the distal end opening of the intermediate catheter by a first distance 325. This distance may be between about 1mm and about 10 cm (e.g., between about 2 mm and about 10 mm, between about 2 mm and about 20 mm, between about 2mm and about 30 mm, etc.). The elongate inversion support catheter may be fixed in position relative to the intermediate catheter, so that as the two catheters move together, until released. For example, the proximal ends of the intermediate catheter and the elongate inversion support catheter may be removably coupled.

[000106] The tractor tube in the pre-assembled apparatus of FIG. 3 extends between the elongate inversion support catheter and the intermediate catheter for some second distance along the length 323 of the elongate inversion support catheter. Securing the end of the tractor tube between the I.C. and the distal end of the elongate inversion support catheter may help both hold it in place, so that it may be held in compression, as will be described in greater detail below, which may also help prevent it from applying compressive force to the distal end of the elongate inversion support catheter. For example, the second length 323 may be between about 1 mm and about 50 cm (e.g., between about 5 cm and about 10 cm, between about 1 cm and about 20 cm, between about 1 cm and about 10 cm, between about 2 cm and about 20 cm, between about 2 cm and about 10 cm, etc.).

[000107] The portion of the tractor tube 315 and puller 319 (e.g., pull micro catheter, or pmc) in this pre-loaded example may extend distally and ride over the guidewire 317. The tractor tube and puller may also be longitudinally fixed relative to the intermediate catheter 303 (e.g., by releasably locking, e.g., at the distal end region) or they may be somewhat longitudinally slideable (and, in some variations, prevented from exceeding a range of, e.g., between about 1 mm and 20 cm from the distal end opening 305 of the intermediate catheter 303.

[000108] In practice, the portion 327 of the tractor tube 315 that extends outside of the intermediate catheter 303 may be between about 1 mm and about 20 cm (e.g., between about 1 cm and about 7cm, between about 1 cm and about 10 cm, between about 1 cm and about 15 cm, between about 2 cm and about 10 cm, between about 2 cm and about 7 cm, etc.). As

mentioned, this distance may be fixed (e.g., by fixing the puller with respect to the push catheter and/or I.C.), or variable. In any of these variations, the puller may extend some distance 329 beyond the distal attachment site for the flexible tractor tube, or the tractor tube may be attached at the distal end of the puller. The distance from the attachment site of the tractor tube and the distal end of the puller may be between about 0 mm and about 10 cm, for example (e.g., between about 1 mm and about 10 cm, between about 1 mm and about 5 cm, etc.).

[000109] In variations in which the pre-loaded apparatus is configured with the puller (and therefore the tractor tube) and/or the elongate inversion support catheter fixed relative to the intermediate catheter for delivery of the apparatus to the clot (e.g., adjacent to the clot), once in the deployment location, the elongate inversion support catheter and/or puller may be unlocked so that they may move independently of the intermediate catheter. In some variations, the elongate inversion support catheter may be unlocked first, so that it can be advanced distally into the tractor tube and over the puller; once the distal end of the elongate inversion support catheter is near the attachment site for the tractor tube on the puller, the puller may be also be released (manually or automatically).

[000110] FIG. 3B illustrates another example of a pre-loaded apparatus (pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy). In FIG 3B, the tractor tube is a knit 355 that is bonded to the puller near a distal end region, described in FIG. 3A. The distal end region of the puller (pmc) 337 extends from the intermediate catheter 343. The opposite end 345 of the tractor tube, approximately 1 cm) is held between the intermediate catheter and the elongate inversion support catheter 341, which is entirely within the intermediate catheter. Exemplary dimensions are shown by the ruler above the prototype device.

[000111] Another variation of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy is shown in FIGS. 4A-4D. In FIG. 4A, the apparatus contains the same elements shown in FIG. 3A, but they are arranged and interact in a different manner. For example, the pre-loaded apparatus includes an intermediate catheter 403 with an open distal end 405, an inner elongate inversion support catheter 307, a tractor tube 415 and a puller 419. In FIG. 4A, he tractor tube is connected to a distal end region of the puller (e.g., within a fixed distance 425 of the distal end of the puller, e.g., between about 0mm and 10 cm (e.g., about 1 mm to about 10 mm, etc.) as in the example in FIG. 3A. The opposite end of the tractor tube is held between the intermediate catheter 403 and the elongate inversion support catheter 407, as in

FIG. 3A. For example, between about 1 mm and about 50 cm of tractor tube (e.g., between about 5 cm and about 10 cm, between about 1 cm and about 12 cm, etc.) may be between the intermediate catheter and the elongate inversion support catheter; the tractor tube may be held loosely, or it may be held so that the distal end of the tractor tube on the outside of the elongate inversion support catheter is compressed, it from being pulled distally by friction from the vessel walls, resulting in compressive forces on the distal end of the elongate inversion support catheter.

[000112] In FIG. 4A, the elongate inversion support catheter is secured in position relative to the puller so that the distal end opening of the elongate inversion support catheter is near the attachment site for the tractor tube on the puller. For example, the distance between the elongate inversion support catheter distal end opening and the attachment site for the tractor tube 429 may be between about 0 mm and about 10 cm (e.g., between about 0 mm and about 1 mm, between about 0 mm and about 2 mm, between about 1 mm and about 5 mm, between about 1 mm and about 3 mm, etc.). As discussed above for FIG. 3A, the puller, elongate inversion support catheter and intermediate catheter may be releasably locked together so that they move together. The portion of the puller from the attachment site of the tractor tube to the distal end of the puller 425 may, as described for FIG. 3A, above, be between about 0 mm and about 10 cm (e.g., between about 0 mm and about 7 mm, between about 0 mm and about 5mm, etc.).

[000113] In operation, the pre-assembled apparatus shown in FIG. 4A may advance distally (e.g., over a guidewire) towards a clot in a vessel with the slightly more flexible distal end portion consisting of a distal portion of the puller, tractor and elongate inversion support catheter extending distally from the distal opening of the intermediate catheter by a distance 427 that may be, for example,, between about 1 cm and 20 cm (e.g., between about 2 cm and about 7 cm, between about 1 cm and 10 cm, between about 2 cm and about 7.5 cm, etc.). This presents a more flexible distal end region that tapers slightly over the guidewire, allowing the apparatus to navigate tortious vessels, including those having branches. Once the distal end of the apparatus is within the deployment region, near (e.g., adjacent to) the clot to be removed, the apparatus may be deployed by removing the coupling between the intermediate catheter, puller and elongate inversion support catheter, and allowing the intermediate catheter to be withdrawn at least slightly, and for the elongate inversion support catheter to be advanced while withdrawing the tractor tube proximally to roll the tractor tube so that it everts over the distal end opening of the elongate inversion support catheter.

[000114] FIG. 4B illustrates an example of distal end of a prototype pre-assembled apparatus similar to that shown in FIG. 4A. In FIG. 4B the apparatus is shown over a guidewire 417 with the elongate inversion support catheter 407 near the attachment site 433 for the tractor tube onto the distal end region of the puller; a distal end region of the puller 431 extends from the tractor tube attachment site to the distal end opening of the puller.

[000115] FIG. 4C illustrates tracing of an apparatus 460 such as the one shown in FIG. 4B through a tortious model of a blood vessel 455; the flexible distal end leads the device in tracking and navigating through the vessel. FIG. 4D illustrates another example of a distal end region of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel, also showing exemplary dimensions. In FIG. 4D, the apparatus is threaded over a movable guidewire 417, and shows a knitted tractor tube 415' that is attached to the distal end region of a puller 419; an elongate inversion support catheter 407' is between the tractor and the puller, as mentioned above. This is pre-loaded into an intermediate catheter 403'.

[000116] Another example of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy. In FIG. 5A, unlike the variations shown in FIG. 3A and 4A, both the elongate inversion support catheter 507 and the tractor tube 515 are held (e.g., releasably locked) within the intermediate catheter 503. This may prevent the tractor tube from pushing against the vessel wall during tracking, and therefore prevent compressive force on the elongate inversion support catheter that may otherwise result in it stiffening. In this example, a portion 509 of the puller 519 may extend distally out of the intermediate catheter, e.g., between about 0 mm to about 30 cm (e.g., between about 0.5 cm to about 20 cm, between about 1 cm to about 15 cm, between about 1 cm to about 10 cm, between about 1 cm and about 5 cm, etc.). The attachment site of the tractor tube to the puller may be at or near the distal opening of the intermediate catheter, or it may be offset by some predetermined distance 507 (or within a range of distances, e.g., between about 0 mm to about 10 cm, such as between about 1 cm to about 8 cm, between about 0 cm to about 2 cm, etc.). Similarly, the elongate inversion support catheter may be preloaded near the attachment site for the tractor tube to the puller (e.g., with a distance 505 of between about 0 mm to about 20 cm, preferably between about 0 mm and 10 mm). The entire length of the tractor tube 503 may be any appropriate length, e.g., between about 1 cm and about 60 cm (e.g., between about 5 cm and about 30cm, between about 5 cm and about 10 cm, etc.).

[000117] In operation, the apparatus shown in FIG. 5A may be deployed over a guidewire (with the component parts all removably secured together, e.g., at a proximal handle) and advanced distally until it is near the clot. In any of these examples, the guidewire may penetrate the clot or it may stop short of the clot. Thereafter, the intermediate catheter may be withdrawn proximally and/or the elongate inversion support catheter advanced distally so that the tractor tube is everted from over the distal end opening of the elongate inversion support catheter and into the elongate inversion support catheter. Pulling the puller proximally may continue to roll the tractor tube, while advancing the elongate inversion support catheter to pull the clot into the elongate inversion support catheter as the tractor tube everts.

[000118] FIG. 5B illustrates another example of the pre-loaded inverting tractor mechanical thrombectomy apparatus shown in FIG. 5A. IN this example, only the distal end of the puller 519' (referred to herein as the pull micro catheter or PMC), while the tractor tube attached more proximally to the PMC remains in the intermediate catheter (I.C.) 503'. In this example, the puller 519' rides over the guidewire 517, and has a length that is about 2 and 5 cm.

[000119] The examples shown in FIGS. 3A-5B shown above include a puller that is configured as a puller micro catheter than may be driven over a guidewire. Any of the variations described herein may instead by configured so that the puller is a guidewire, as shown in the example in FIG. 6. In this example the puller 619 is a guidewire and the tractor tube 615 is attached at one end to the puller. IN this example, the tractor is attached to the distal end of the puller, but it may be attached more proximally, as described above. The elongate inversion support catheter 607 is interposed between the puller and the tractor tube, and may be extended distally so that the tractor tube rolls over the distal end opening of the elongate inversion support catheter when pulling the puller to capture and remove a clot. In the variations shown in FIG. 6, the puller does not necessarily need to be a movable (i.e., longitudinally slideable) pull wire, but may be a fixed wire.

[000120] As an alternative to the pre-assembled configurations described in FIGS. 3A-5B described above, any of the apparatuses described herein may also or alternatively be configured to be deployed through an intermediate catheter that is first deployed (e.g., using a guidewire and one or more internal catheters), and left in place; the inverting tractor mechanical thrombectomy apparatus may then be delivered through the intermediate catheter.

[000121] Some variations an inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy are configured for delivery and deployment to remove a clot without needing an intermediate catheter. For example, in some variations all, or most of, the tractor tube is withdrawn into

the elongate inversion support catheter portion of the apparatus. Thus, the outer surface of the apparatus is the outer surface of the elongate inversion support catheter, which may be smooth, and/or lubricated, and therefore less likely than the tractor tube to provoke a compressive force on the distal end region that would otherwise stiffen the elongate inversion support catheter and prevent it from navigating a tortious vessel. For example, FIGS. 7A-7C show a first example of an inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy that is configured to deliver the apparatus to the deployment site near the clot with the tractor withdrawn nearly fully into the elongate inversion support catheter.

[000122] In FIG. 7A, the inverting tractor mechanical thrombectomy apparatus does not include (or require) the use of an intermediate catheter, though one may be used with it (not shown). The apparatus includes an outer elongate inversion support catheter 707 that includes a stop 704 at or near the distal end. This stop 704 may be a lip, flange, protrusion, or the like, and may provide a larger diameter region that engages with a complimentary stop 816 on the end of the tractor tube 715. The opposite end of the tractor tube is connected to a puller (puller micro catheter 719) similar to the variations described above. When delivered to the clot region of a vessel the puller is withdrawn (preferably loosely, to avoid compressive forces on the elongate inversion support catheter), so that the tractor tube is withdrawn into the elongate inversion support catheter except for small portion at the distal end that is prevented from rolling into the elongate inversion support catheter by the stop on the tractor tube engaging with the stop on the elongate inversion support catheter. The apparatus may be driven over a guidewire 717, as shown, until it is proximate to the clot. FIGS. 7B and 7C illustrate a two-step method for deploying the apparatus that may be used. In This example, the apparatus may be deployed by advancing the puller distally (e.g., "pushing" the puller 775), as shown in FIG. 7B. Thus, the tractor portion will be inverted over itself, ahead of the distal end of the elongate inversion support catheter. Thereafter, as shown in FIG. 7C, the elongate inversion support catheter may be advanced distally into the pocket 777 formed by the inverted tractor tube. The apparatus is then ready for the puller to be pulled proximally to roll the tractor tube back into the elongate inversion support catheter so that it may capture a clot, and may therefore be positioned against or adjacent to the clot.

[000123] FIGS. 8A-8C show an alternative method of deploying the apparatus shown in FIG. 7A. FIG. 8A is similar to FIG. 7A, showing delivery of the apparatus to the clot over a guidewire 717. The apparatus includes the tractor tube 715 and elongate inversion support catheter 707, which include a stop on one or both of the elongate inversion support catheter

and/or tractor tube to engage the distal end of the elongate inversion support catheter with the end of the tractor tube. The apparatus may be delivered with the tractor tube retracted so that it does not tension the elongate inversion support catheter. As shown in FIGS. 8B and 8C, once near the clot, the tractor tube may be repositioned outside of the elongate inversion support catheter so that it can be rolled and used to capture a clot. In FIG. 8B, the elongate inversion support catheter is pulled proximately 851; since the distal end of the elongate inversion support catheter is engaged with the tractor tube to prevent it from sliding off of the end of the elongate inversion support catheter, when the elongate inversion support catheter is pulled proximally while holding the puller in place (or advancing it distally), the tractor tube will extend out of the elongate inversion support catheter and invert, as shown. Thereafter, as shown in FIG. 8C, the elongate inversion support catheter may be advanced distally between the fold formed by the inverted tractor tube, and the entire apparatus advanced distally back to the clot 833, a shown. Once proximate the clot, the puller may be pulled proximally to capture the clot and remove it.

[000124] FIGS. 9A-9K illustrate one method of removing a clot using a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter, such as the variation shown in FIG. 3A. In general, a method of using any of the preloaded assemblies of inverting tractor mechanical thrombectomy apparatuses described herein (e.g., in FIGS. 3A-5B), may be delivered over a wire, through a guide catheter (or a sheath or balloon guide catheter) to a clot fact, e.g., proximate the clot. The tractor tube may then be aligned so that it warps around and over the distal end of the elongate inversion support catheter and rolls into (everts) the elongate inversion support catheter. Once in positioned (against the face of the clot), the elongate inversion support catheter may be pushed distally while pulling proximally on the puller to ingest the clot, until the full length of the tractor tube is pulled proximally and rolled into the elongate inversion support catheter, unless the apparatus includes a stop to prevent it from entering the elongate inversion support catheter. Aspiration may be applied through the elongate inversion support catheter and/or the puller (when a puller micro catheter is used) to ensure that the clot remains in contact with the distal end of the elongate inversion support catheter and tractor. The intermediate catheter may then be advanced to the distal end of the elongate inversion support catheter (and aspiration may be applied through the intermediate catheter. The elongate inversion support catheter may be withdrawn proximally through the intermediate catheter while applying aspiration, which may both ease retraction of the apparatus within the intermediate catheter and may remove any residual clot portions.

[000125] For example, in FIG. 9A, the apparatus has been delivered to the region adjacent to the clot and deployed out of the intermediate catheter 903. The elongate inversion support catheter 907 and puller 919 are advanced together distally to the clot 933 face over a guidewire 917. The elongate inversion support catheter includes a marking 963 that is visible under, for example, fluoroscopy or other imaging modality. In FIGS. 9A-9K this marking on the elongate inversion support catheter is a band. In FIG. 9B, the elongate inversion support catheter is advanced distally while simultaneously or sequentially pulling the puller proximally so that the tractor tube is rolled over the distal end opening of the elongate inversion support catheter and extends slightly within the elongate inversion support catheter (shown biased against the inner diameter of the elongate inversion support catheter). The tractor extending out of the elongate inversion support catheter is pushed against the clot face. In FIG. 9B, the guidewire has been left in place; alternatively, as shown in FIG. 9C, the guidewire may be removed. Alternatively, or additionally, the intermediate catheter 903 may be withdrawn proximally, which may fully unsheathe the tractor, including the distal end of the tractor. This may permit the tractor tube to roll freely over the distal end of the elongate inversion support catheter. The intermediate catheter may be locked to the elongate inversion support catheter, so that the two catheters move together wile drawing the puller proximally to roll the tractor tube over the elongate inversion support catheter, as shown in FIG. 9D. In this example, aspiration (e.g., vacuum) may also be applied, e.g., from within the puller and/or elongate inversion support catheter, which may help the rolling tractor to engage with the apparatus, even before rolling the tractor into the elongate inversion support catheter by withdrawing the puller proximally.

[000126] As shown in FIG. 9E, the puller 919 (PMC) may be drawn proximally while the elongate inversion support catheter 907 is advanced towards/into the clot. As previously mentioned, the intermediate catheter 903 may optionally be advanced with the elongate inversion support catheter (e.g., the two may be coupled together for this portion of the method. This step may be continued to ingest the clot. FIG. 9F shows the clot 30% ingested while still rolling the tractor tube into the elongate inversion support catheter (e.g., by pulling on the puller and/or pushing on the elongate inversion support catheter). FIG. 9G shows the clot 80% ingested and rolling into the elongate inversion support catheter. By FIG. 9H, the tractor tube has been fully withdrawn into the elongate inversion support catheter. In this example, the marker 963 on the elongate inversion support catheter aligns with either a marker on the puller or the puller itself (if it is visible under imaging). FIG. 17 shows another example of an elongate inversion support catheter (slotted 1709 to have a high column

strength and high flexibility) in which the distal end region 1707 is marked with a platinum material to make it visible when imaging (e.g., with fluoroscopy). In FIGS. 9A-9H, the entire clot (100%) is captured by the tractor tube within the elongate inversion support catheter once the entire tractor tube has been rolled into the elongate inversion support catheter. However, this is not necessarily the case, as will be described below, in some variations additional clot may be drawn into the elongate inversion support catheter and/or the intermediate catheter by applying a combination of mechanical action (e.g., pulling the clot with the portion captured by the tractor and suction. For example, FIG. 9I shows the (optional) use of aspiration through the intermediate catheter (and in some cases, the elongate inversion support catheter). The aspiration may be left on while withdrawing the apparatus proximally, as shown in FIG. 9J. As mentioned, this may remove any remaining clot. Alternatively, or additionally a second apparatus may be installed through the intermediate catheter and delivered to the deployment site (with the intermediate catheter left in position. Finally, as shown in FIG. 9K, an angiogram may be performed through the intermediate catheter to confirm that the vessel is opened. If not, additional procedures (e.g., another preloaded assembly of an inverting tractor mechanical thrombectomy apparatus may be inserted and used to remove clot) may be performed.

[000127] In general, when deploying any of the inverting tractor mechanical thrombectomy apparatuses described herein, and in particular, the pre-loaded inverting tractor mechanical thrombectomy apparatuses, the deployment may include the general steps described below. These steps may be customized as indicated herein. First, obtaining access with sheath to the patient's common carotid or ICA. Inject contrast through the sheath to image the vessel. Before, during or shortly after, on the back table (e.g., where the proximal end of the mechanical thrombectomy apparatus is held/prepared), flush the intermediate catheter (I.C.) and connect it to a first rotating hemostatic valve (RHV A), then introduce the elongate inversion support catheter ("880 Device"), puller and tractor through RHV A, e.g., using a peel-away sheath. The elongate inversion support catheter may then be positioned relative to the I.C., e.g., within about 1 cm proximal to the tip of the I.C., as shown in FIG. 3A, and locked in position relative to the I.C. RHV A may then be tightened. A second RHV (e.g., RHV B) may be coupled to the pusher and flushed, and RHV A may be flushed as well. Flush lines may be connected. A guide wire may be loaded through the apparatus. The puller may be locked in position (e.g., as shown in FIG. 3A, extending approximately 1 cm or more from the distal end opening of the I.C.) for tracking.

[000128] The apparatus may then be tracked to the desired location (e.g., near the clot). Once in position, the apparatus may be used to perform the thrombectomy. For example, RHV A and B may be loosened. The coupling between the elongate inversion support catheter and the I.C. may be released, as may any coupling between the puller and the I.C. and/or elongate inversion support catheter. The elongate inversion support catheter may be advanced over the puller until its distal end meets the distal connection between the tractor tube and the puller. The I.C. may be pulled back to unsheathe the tractor tube. The elongate inversion support catheter and I.C. may again be locked in position relative to each other. RHV A may be tightened, and the elongate inversion support catheter may be advanced to the clot face (possible with aspiration through the puller). With a slight pressure forward (distally) on the pusher (and/or I.C.), the puller may be pulled slowing proximally to ingest the clot. Alignment markers on the elongate inversion support catheter and the tractor (e.g., a region at the end of the tractor tube on the outside of the elongate inversion support catheter, or a region of the puller) may be monitored to indicate when the tractor tube is completely inverted into the elongate inversion support catheter, and the user may stop pulling proximally on the puller. RHV A may be loosened and the IC may be advanced, with aspiration, over the elongate inversion support catheter, which may remove any excess clot or pieces of clot. The elongate inversion support catheter, puller and tractor may then be withdrawn proximally through the I.C. The I.C. may remain in position and contrast applied to again image through the vessel and a TICI score determined.

[000129] Another example of the operation of a pre-loaded assembly of an inverting tractor mechanical thrombectomy apparatus is shown in FIGS. 10A-10D. For example, in FIG. 10A, the pre-assembled apparatus is similar to that shown in FIG. 3A, above. The apparatus includes an intermediate catheter 1003 that entirely houses the elongate inversion support catheter 1007 during the tracking through the tortious vessel 1081. A puller (pull micro catheter 1019) passes through the elongate inversion support catheter, and include a tractor tube (shown as a knit tractor tube 1015) extends from an attachment site 1008 approximately 2 mm proximal to the distal end of the puller. The opposite end of the tractor tube is held between the elongate inversion support catheter and the intermediate catheter (within the intermediate catheter). In FIG. 10A, the guidewire 1017 has been inserted distally to and through a clot 1033, and the pre-loaded assembly of the inverting tractor mechanical thrombectomy apparatus is locked (e.g., so that the puller extends distally a predetermined distance and the elongate inversion support catheter is locked relative to the intermediate catheter) and advanced distally over the guide wire until it reaches the clot face.

[000130] In FIG. 10B, the puller distal end is adjacent to the clot face, and the puller may be locked in position (e.g., at the handle) while the elongate inversion support catheter is unlocked from the intermediate catheter and advanced distally over the puller and between the gap formed by the tractor tube. In this example, as the elongate inversion support catheter is advanced distally, the tractor tube may compress to a compressed/jammed state, particularly when a knit material is used, before the elongate inversion support catheter slides within its inner diameter. In FIG. 10C, the elongate inversion support catheter is advanced distally 1068 over the puller (and under the tractor tube) until the distal end of the elongate inversion support catheter is aligned with the clot, as shown. Finally, as shown in FIG. 10D, the puller may be pulled proximally 1091 while the elongate inversion support catheter is pushed distally 1093 to roll the tractor into the elongate inversion support catheter and capture the clot 1033.

[000131] As discussed above, in some variations the tractor tube may be completely rolled into the elongate inversion support catheter before a clot has been completely removed. In such cases, it may be helpful to ensure that the clot is not ripped or fragmented during the process. In order to prevent this, the apparatus may be adapted to limit the movement of the puller and/or the tractor, in addition to (or instead of) using the vacuum and intermediate catheter, as described above. FIGS. 11A-11C illustrate an example in which the clot is too long for the tractor tube apparatus to fully engulf. In FIG. 11A, similar to FIG. 9H, the clot has been captured by the tractor tube 915, which is shown fully retracted into the elongate inversion support catheter 907. The user may detect that the tractor tube has been fully retracted because either the puller 919 maybe limited to prevent it moving further proximally when the tractor tube is fully retracted into the elongate inversion support catheter. Alternatively, or additionally, the tractor tube may include a first marker 963 that may align with a marker on the puller 965 when the tractor tube is fully retracted, as shown in FIG. 11A. Unlike FIG. 9H, however, in this example, the clot has not been fully captured, and some of it remains outside of the tractor and elongate inversion support catheter.

[000132] If the clot is not fully captured by the apparatus, there is a risk that continuing to pull on the clot may disrupt it, e.g., cutting it into fragments. To avoid this, the apparatus may be configured to prevent the user from continuing to apply force to the clot once the tractor has been fully deployed. As mentioned, the user may be instructed to stop drawing the puller proximally once one or more markers indicate that the tractor tube has been retracted to a predetermined position. In particular, it may be beneficial to prevent the tractor tube from fully inverting over the tractor tube, as described in FIG. 12A, below.

[000133] In some variations, the apparatus may include a stop (e.g., in a handle region) preventing or limiting the puller to prevent it from extending beyond a predefined limit. For example, the limiter or puller stop may be configured as a physical stop on the puller portion of a handle that limits the travel of the puller.

[000134] FIGS. 11B-11C illustrate a method for handling this situation without tearing (and risk harming the patient). In FIG. 11B the elongate inversion support catheter is stopped from advancing any further distally, and instead the intermediate catheter may be advanced distally (with or without aspiration through the intermediate catheter). In FIG. 11C, the clot, including the portion outside of the elongate inversion support catheter, has been fully captured within the intermediate catheter, as shown.

[000135] FIG. 12A illustrates another example of a configuration of the apparatus (and in particular the tractor tube) in which the distal end of the tractor tube is configured with a non-compliant material 1205 (e.g., a cuff) so that it cannot flip or roll over the distal end of the elongate inversion support catheter. This may prevent the user from pulling the tractor all the way around the catheter. In some variations, the cuff is configured to permit the tractor tube to flip over the distal end of the elongate inversion support catheter. For example, a cuff on the outer end of the tractor tube may include one or more slits (e.g., between one and 20 slits or slots) extending along its length configured to permit it to flip and invert, but providing an increase in the stiffness of the tractor tube. In any of these variations, the cuff on the outer end of the tractor tube may include a marker (e.g., radiopaque material); for example, the cuff may be a polymer including a platinum or other radiopaque material suspended in it. FIG. 12B illustrates an example of a cuff 1205' at one end of a flexible tube ('tractor') 1207 that has been inverted over the inversion support catheter 1209.

[000136] As mentioned above, any of these apparatuses may include one or more features that may be used to improve tracking, and in particular, by preventing the elongate inversion support catheter from stiffening. This may be a problem with the high column-strength, highly flexible elongate inversion support catheters that include one or more slot or cut-out regions along their length. One feature that may be included, discussed above, is the use of configurations in which the tractor tube, and particularly knitted tractor tubes, are delivered in a compressed state, rather than a stretched state. As mentioned above, pinning one end of the tractor tube in the intermediate catheter may be configured to do this in some of the preloaded configurations described above. FIGS. 13A-16B illustrate other variations. For example, FIG. 13A shows a knitted tractor tube 1315 over an elongate inversion support catheter 1307 that is stretched. The woven links are connected end-to-end (forming a helical winding pattern

around the elongate inversion support catheter). FIG. 13B illustrates the resulting compressive load on the catheter tip in this configuration; friction loads on the knit during tracking may pull on the distal end of the elongate inversion support catheter, causing it to stiffen in compression. However, such compressive loads may be lessened or eliminated by using a woven material held in a compressed configuration, as shown in FIG. 13C. In this example, the interlocking loops forming the weave are overlapping in a compressed state.

[000137] This compressed state may be maintained by pinning, securing or holding one or more ends or lengths of the tractor tube in place when the tractor tube is compressed. Any appropriate mechanism for holding the compression may be used. For example, the apparatus may include a stop or lock to engage with one or more regions of the tractor tube and hold it in a compressed configuration during tracking. FIGS. 14A-14D illustrate variations of structures (stops) that may be used to hold the woven tractor tube on the outside of the elongate inversion support catheter in a longitudinally compressed state. In FIG. 14A, the elongate inversion support catheter includes a polymeric lip, ridge or rim (stop) 1401 that may secure one end of the woven tractor tube against the elongate inversion support catheter with the tractor tube in compression. Distal force may be applied to pull the tractor tube out of the stop (not shown). FIG. 14B shows a Nitinol (NiTi) braid 1403 that holds the knitted tractor tube in compression along the length of the elongate inversion support catheter. FIGS. 14C shows a similar NiTi braids with exposed ends that engage with the knit of the tractor. FIG. 14D a NiTi knit segment also includes projections that engage with the knit, as shown.

[000138] FIGS. 14A-14G show similar finger-like elements that may be used to engage with the knit (the loops formed by the knit) of the tractor. In FIG. 15A. the loose ends of the woven material form short "fingers" that are exposed and engage with the knitted tractor, as shown in FIG. 15B. In FIG. 15C, as similar construction having longer "fingers" of loose ends is shown, and FIG. 15D shows the fingers engaging with the knitted tractor tube. FIG. 15E shows "fingers" formed by the loose ends of the weave located approximately 1 cm from the tip of the elongate inversion support catheter, and FIG. 15F shows these elements engaging the knitted tractor tube. FIG. 15G is another example of a set of fingers formed of projecting metal wires that may be used to removably hold the tractor tube against the elongate inversion support catheter in compression. FIG. 15H shows an example of a variation formed by a metal wire having very long "fingers", engaged with a knitted tractor tube, holding it in compression.

[000139] Alternatively, or additionally, any of these apparatuses may include a housing or garage that may be used to hold the knitted tractor tube in compression. For example, FIG.

16A and 16B illustrate one example of this configuration, in which a housing ('garage') region 1602 formed of a 48-end braided material, is used to hold the knitted tractor tube 1604 in a compressed state at one of its ends on the elongate inversion support catheter. FIG. 16B shows a similar example of a elongate inversion support catheter having a 10 mm long 'garage' region made of a braided material 1608.

REMOVAL OF LARGE CLOTS

[000140] Any of the mechanical thrombectomy apparatuses described herein may be adapted to remove large clots. In general, a large clot may be large in either or both diameter (outer diameter) and length, and may be large relative to the mechanical thrombectomy apparatus. For example, the clot may have a diameter that is larger than the diameter of the apparatus (e.g., larger than the expanded diameter of the flexible tube which captures the clot). Thus, the apparatus may be configured to capture and compress the clot so that it may be withdrawn from the lumen of the vessel, into the lumen of the intermediate catheter and/or inversion support catheter. The apparatus may also be configured to capture and remove clots that are longer than the ability of the flexible tube to hold.

[000141] In general, FIGS. 18A-18J show a method of removing a clot 1815 from a vessel 1815 as described herein, in which a vacuum (suction) may be applied through the puller to make and confirm initial contact with the clot. For example, FIGS. 18A-18B illustrate an example of an apparatus that is preloaded and configured to both track to the clot and to remove the large-diameter clot 1815. For example, in FIG. 18A, the apparatus (mechanical thrombectomy apparatus or inverting tube apparatus) includes an intermediate catheter (IC) 1801, an inversion support catheter ("outer catheter") 1803 within a lumen of the intermediate catheter, a puller (shown as a puller catheter) 1805 within a lumen of the inversion support catheter, and a flexible tube (e.g., knit tube) 1809 extending over the inversion support catheter. The flexile tube has a first end 1826 coupled at a distal end region of the puller and a second end 1824 comprising a cuff 1825 that is less flexible that a region of the flexible tube adjacent to the cuff, wherein the flexible tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the flexible tube rolls and inverts over a distal end of the inversion support catheter 1823. The apparatus is shown over a guidewire 1807. In this example, multiple regions include markers that may be visualized, e.g., under fluoroscopy. For example, the end of the inversion support catheter includes a marker 1823, as does the distal end of the puller 1826. The puller may

also include an intermediate marker 1821, shown aligned with the cuff 1825; the cuff also includes a marker. The assembly is shown within the vessel 1813.

[000142] The apparatus may be distally advanced over the guidewire and positioned adjacent to the clot 1815. The apparatus may initially be pre-loaded in a tracking configuration, in which the outer (inversion support) catheter 1803 is retracted into the lumen of the intermediate catheter 1801 while the puller (puller catheter 1805) with the attached flexible tube 1809 extending proximally from the distal end 1826, is moved distally to track over the guidewire. In FIG. 18B, the apparatus is adjusted into a clot-grabbing configuration in which the inversion support catheter 1803 is extended distally towards the distal end of the apparatus, although it is still positioned proximal to the puller distal end 1827. The intermediate catheter 1801 may also optionally be withdrawn proximally, as shown in FIG. 18C, which in some variations may allow the flexible tube to expand outwards (see, e.g., FIG. 26B).

[000143] FIG. 18C1 shows an example of a prototype device corresponding to the apparatus configured as shown in FIG. 18C. In this example the flexible tube is a woven flexible tube 1809 that is shown extending distally from the distal end face 1827 of the puller. The puller is shown over a guidewire 1807.

[000144] Once the apparatus is in position near the clot, suction may be applied through the puller catheter, as shown in FIG. 18D. This focal suction (aspiration) 1840 may be applied while advancing the apparatus distally to engage the clot, as shown in FIG. 18E. In some variations, the guidewire is left in place (not shown) or it may be optionally removed (as shown in FIGS. 18D-18E). Once the distal-facing end of the puller is engaged with the clot, as shown in FIG. 18E, connection to the clot may be detected by observing the flow and/or pressure through the puller from the suction 1840'. Thereafter, the puller may be drawn proximally and/or the inversion support catheter may be moved distally so that the flexible tube rolls over the distal end opening of the inversion support catheter (these motions are shown by the large arrows). In FIG. 18F, approximately 30% of the clot has been drawn into the inversion support catheter by rolling 1866 the flexible tube. In FIG. 18G, more, but not all (e.g., approximately 70%) of the clot has been ingested, though a substantial amount of clot remains outside of the inversion support catheter and flexible tube. The vacuum may be left on, or it may be turned off while pulling the puller proximally to engulf/grab the clot. Heavy arrows indicate movement of the components of the apparatus, such as the intermediate catheter, which may be advanced distally, the inversion support catheter, which may also be advanced distally, and the puller, which may be withdrawn proximally. These motions may

be coordinated by the handle (not shown) and/or performed manually by the user. Once the flexible tube has reached the distal end of the inversion support catheter, it may stop or be stopped, to prevent it from rolling over the distal end. Rolling of the second end of the flexible tube over the inversion support catheter distal end may cut or break the clot off, which may be highly undesirable, as it may potentially release the clot, resulting in complications, and/or may require additional removal steps.

[000145] In FIG. 18A-18J the second end of the flexible tube includes a cuff 1825 that may prevent the flexible tube from rolling over the distal end when pulling proximally on the puller, as shown in FIG. 18H. In FIG. 18I, the intermediate catheter is shown advancing distally beyond the cuff and the distal end of the intermediate support catheter. In this configuration (as also described in FIGS. 22A-22B) the motion of the intermediate catheter 1801 may invert the cuff 1825 over the distal end of the inversion support catheter 1803 and against the clot 1815 without breaking or disrupting the clot. A vacuum (suction) may be applied through the intermediate catheter is also shown in FIG. 18I (by the small arrows). In FIG. 18J, the flexible tube, puller and inversion support catheter are then drawn proximally into the intermediate catheter along with the un-engulfed portion of the clot, either by driving the intermediate catheter distally over them, and/or by pulling the inversion support catheter (which may be pulled with the puller) proximally.

[000146] Thus, in the example shown in FIGS. 18A-18J, a larger clot, both in diameter and in length, may be removed by the apparatus.

[000147] FIG. 19 illustrates another example of an apparatus that is configured or adapted to have a smaller diameter (outer diameter) than the vessel and the clot but may be capable of grabbing and removing larger clots (e.g., clots having an outer diameter that are more than 1.5x, more than 2x, more than 2.5x, etc.) the outer diameter of the flexible tube capturing the clot.

[000148] In FIG. 19, the apparatus includes a flexible tube that is configured as a knit tube. In this example the region of the knit tube 1901 on the outside of the inversion support catheter 1903 hugs the outer diameter (OD) of the inversion support catheter. In order to maximize the ingesting efficiency/power of the knit when used to capture larger clots, the stich length of the knit may be tuned to the diameter of the vessel in which the apparatus is to be used. For example, in general, the stitch length 1905 is the lateral extent of a loop formed by the knit. In general, the outer diameter 1909 of the inversion support catheter may be known, and the inner diameter of the vessel (which may be equivalent to the outer diameter of the clot) may also be known or approximated (e.g. from fluoroscopy). Thus, the user, such

as a surgeon or physician, may select the appropriate flexible tube (e.g., knit) based on the selected size. For example, in FIG. 19, twice the knit or stich length (knit/stich length) plus the outer diameter of the inversion support catheter may be approximately equal to the ~Vessel ID in order to maximize power/efficiency when grabbing and/or removing clot. The woven stitches may act as fingers or extensions that swing around the distal end opening of the inversion support catheter 1907, as shown in FIG. 19. Thus, for vessel inner diameters of between set ranges, the knit/stitch length may be determined. In general, the knitted tube may comprise a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between the difference of 25% of the ID and one half the outer diameter (OD) of the inversion support catheter and 65% of the ID and one half of the OD of the inversion support catheter. For example, twice the knit/stitch length plus the inversion support catheter OD may be equal to a range of vessel inner diameters (IDs), such as between about 90%-110% of the vessel ID, between about 80-100% of the vessel ID, between about 60-100% of the vessel ID, between about 50-100% of the Vessel ID, between about 30-100% of the vessel ID, between about 20-100% of the vessel ID, between about 10-100% of the vessel ID, and/or between about 50-130% of the vessel ID.

[000149] In practice for most neurovascular and/or peripheral vascular applications, the knit/stitch length may be between about 0.5 mm and about 10 mm (e.g., about 0.5 mm, between about 0.1 to 0.5mm, about 1. mm, between about 0.5 – 1. mm, about 1.5mm, between about 1. -1.5mm, about 2. mm, between about 1.5 – 2. mm, about 2.5 mm, between about 2. - 2.5 mm, about 3. mm, between about 3. – 3.5 mm, between about 0.5mm – 10mm (e.g., by any 0.5 mm increment), etc.

[000150] In general, the apparatuses described herein may compress a clot. For example, FIG. 20A illustrates an example of a clot 2005 shown within the bottle on the top of the figure that is 5 cm long and has an outer diameter of about 15 mm. A portion of an inverting mechanical thrombectomy apparatus is shown in the middle of FIG. 20A, showing an inverting support catheter that is an 8 French (8F) catheter 2003 over which a flexible tube, formed of a knit material 2001, has been arranged, including coupling to one end of a puller (not shown). The flexible (knitted) tube in this example is biased to expand in an uploaded state to an outer diameter than is much greater than the outer diameter of the inverting support catheter. This apparatus was used to remove the clot 2005, which resulted in compressing the clot 2007, as shown in FIG. 20A, bottom.

[000151] Another example of an apparatus for removing clot is shown in FIG. 20B, showing a 10 mm diameter clot 2005' being grabbed and engulfed by a flexible tube 2001'

having an expanded outer diameter of 5 mm extending over a 3 mm outer diameter inversion support catheter.

[000152] In general, the amount of clot that may be contained (e.g., "eaten") by the rolling and inverting devices described herein in a single pass may be a function of the diameter of the clot, the length of the flexible tube, the structure of the flexible tube (e.g., woven, knitted, etc.) and most importantly, the expanded outer diameter of the flexible tube. For example, FIG.S 21A and 21B illustrate the relationship. In FIG. 21A, the graph shows the length of the flexible tube (e.g., length of the woven tube, L, needed to fully engulf a clot of 15 mm diameter and 5 cm length. In general, the results show that for compressible clots, the length of the flexible tube necessary to fully engulf a 5 cm length of 15 mm diameter clot (depending on the type of clot, including its compressibility) may be between about 6. mm and about 60 mm. Thus, as a rough rule of thumb, as much as a 12:1 ratio of flexible tube to clot may be necessary at this exemplary dimension of a clot. FIG. 21 B illustrates example of different apparatuses 2105 used to generate the data shown in FIG. 21A.

[000153] In general, the knit expands to a larger diameter than the outer diameter of the catheter once the apparatus is delivered to a clot site when the vessel ID is much larger than the catheter OD. Furthermore, the flexible tube (e.g., knit tube) may expand to a larger diameter than the catheter once it is delivered to clot site, particularly when the vessel ID is much larger than the catheter OD. This is illustrated, e.g., in FIG. 20B. Typically, to maximize the efficiency/power of the flexible tube to ingest a clot, when the catheter is much smaller than the vessel ID/clot OD, it may be helpful to have an expanded outer diameter of the flexible tube such that it is at least 10% (e.g., at least 20%, 30%, 40%, 50%, 60%, 70%, 80%, etc. of the Vessel ID, or any range between any two of these percentages). For example, it may be preferable for the expanded flexible tube to have at least 30% of the vessel ID. Further, as mentioned above, the expanded diameter of the flexible tube may be at least about 30%, 50%, 100%, 150%, 200%, 250%, 300%, 400%, 500%, 600%, etc. of the catheter OD (or any range between any of these two percentages).

[000154] As shown in FIG. 19, and discussed above, the extension of the loop stiches in flexible tubes that are knitted (forming "fingers" on the knit, or protrusion that roll and extend beyond the expanded OD of the rest of the flexible tube) may further help grab and remove clot. These extensions for an apparatus such as shown in FIG. 19 (or 26A) may be between about 0.5mm – 10mm (e.g., between any two value in this range, typically by 0.5 mm increments, including any range between any such increments).

[000155] FIGS. 22A and 22B illustrate an example of a cuff as discussed above. In the example shown in FIGS. 22A and 22B, the cuff 2201 is made of (or includes) a radiopaque polymer filling the cuff at the second end of knit tube. This may allow it to be seen under fluoroscopy, and may also prevent unraveling of the knitted tube. In FIG. 22A, the cuff includes a plurality of lateral slits 2205 (e.g., four are shown, though 3, 4, 5, 6, 7 or more slits may be used). These slits may allow the cuff to flip over inversion support catheter, e.g., when driven by an intermediate catheter 2203, as shown in FIG. 22B. In this example, the cuff may be formed of a polymer such (e.g., as Pebax 45D + 80% tungsten filled). The cuff may have a wall thickness of less than about 0.025 inches when laminated on knit, and may have a length of between 1 and 3 loop stitches (e.g., about 1.5 knit stitches long).

[000156] FIGS. 23A-23B and 24A-24B illustrate examples of a proximal end of a mechanical thrombectomy apparatus, showing components of the apparatus (e.g., guidewire 2305, inner/inversion support catheter 2307, puller 2309, and intermediate catheter 2311. FIG. 23B shows another example, of a proximal end of the mechanical thrombectomy apparatus showing manual controls, including vacuum attachment ports (RHVs) 2317, 2319, for the different regions, as well as the puller hub 2321 at the proximal end.

[000157] FIGS. 24A-24B illustrate another example of a set of proximal end controls for a mechanical thrombectomy apparatus. In FIG. 24A the apparatus control region is shown in a first puller position (prior to pulling the clot in), and includes the inner (e.g., puller) rotating hemostat valve (RHV) 2417, outer (intermediate catheter) rotating hemostat valve (RHV) 2419, as well as the puller hub 2421. One or more stop elements 2423, 2423' may be included on the puller to prevent it from pulling and completely inverting the flexible tube over the distal end of the inversion support catheter, as described above; flush ports 2432, 2433 are also shown. In FIG. 24B the apparatus control region is shown after pulling the clot (showing the puller hub extended proximally).

[000158] FIG. 25 illustrate an example of a mechanical thrombectomy apparatus in which the flexible tube 2505 is configured to cut tissue as it rolls into the inversion support catheter. In this example, the flexible tube is a knitted tube that includes sharp cutting edges that may be used to cut through tissue. The apparatus may be used over a guidewire to prevent the cutter from dissecting the vessel wall.

[000159] FIGS. 26A-26B illustrate two exemplary side perspective views of mechanical thrombectomy apparatuses. In FIG. 26A, similar to that shown in FIGS. 18A-18J, the apparatus include a flexible (e.g., knitted) tube 2601 that is attached at the first end to a puller catheter 2603 and is configured to expand within the inversion support catheter to an outer

diameter that is greater than 40% (shown here as greater than 90%) of the inner diameter of the inversion support catheter 2605, driving the region of the flexible tube within the inversion support catheter against the walls, even when unloaded by clot. The other region (un-inverted) of the flexible tube along the outer diameter of inversion support catheter is shown as snug with the inversion support catheter in the un-constrained configuration. This results in the Y-shaped distal profile 2609, for the inverting flexible tube, which may help grab even larger diameter clots.

[000160] FIG. 26B illustrates another example of a mechanical thrombectomy apparatus in which the expanded outer profile of the flexible tube 2601' is expanded beyond the outer diameter of the inversion support catheter 2605 near the first end where it attaches to the puller 2603, but the second end 2621, that is freely sliding over the inversion support catheter, has a much smaller (nearly snug) expanded diameter. This region may also or alternatively include a cuff as described herein.

Re-sheathing the tractor

[000161] Any of the inverting tube apparatuses described herein may be configured so that the inverting tube apparatus may be retracted (e.g., re-sheathed) into an intermediate catheter. In particular, any of the inverting tube apparatuses that include a cuff at one end (e.g., at the distal end) of the inverting flexible tube may be re-sheathed into the intermediate catheter after deployment, including after capturing all or a portion of a clot. FIGS. 27A-27C illustrates operation of an inverting tube apparatus having a cuff on one end of the flexible tube. As shown in FIG. 27A, the inverting tube apparatus includes an inversion support catheter 2707, a puller 2705 within a lumen of the inversion support catheter, and a flexible tube 2709 extending over the inversion support catheter that is coupled at a first (e.g., proximal) end to the puller, and is configured to roll and invert over the open distal end of the flexible inversion support catheter. In some examples, the flexile tube 2709 may be a woven or knit material. A second end (e.g., distal) end of the flexible tube 2709 may include a cuff 2711 that is less flexible that the region of the flexible tube adjacent 2715 to the cuff. In FIG. 27A, the apparatus is shown in a deployed or partially deployed configuration, in which the flexible tube 2709 and inversion support catheter has been extended out of the distal end of an intermediate catheter 2713, also referred to as a sheath). As discussed above, the apparatus may be delivered to the clot and deployed from out of the intermediate support catheter, including using a guidewire (not shown).

[000162] As shown in FIG. 27B, the flexible tube 2709 is configure to be pulled proximally into the inversion support catheter 2707 by pulling 2715 the puller 2705 proximally so that the flexible tube rolls 2719 and inverts over a distal end of the inversion support catheter; the cuff 2711 may slide along the outside surface of the inversion support catheter. As the device is deployed, the distal end 2714 of the cuff 2711 extends further from the distal end 2715 of the intermediate catheter (sheath 2713), which may have a distal end face that faces the deployed cuff 2711, se

[000163] At any point, either before or after flexible tube has completely, or mostly completely, withdrawn and inverted into the inversion support catheter, the apparatus, and in particular the inversion support catheter, flexible tube, cuff, and any captured clot material, may be withdrawn or re-sheathed back into the intermediate catheter 2713. However, in some cases, including (but not limited to) variations having a cuff 2711 at the second (e.g., distal) end of the flexible and inverting tube 2709 may make it difficult to re-insert the cuff back into the intermediate catheter, as illustrated in FIG. 27C.

[000164] In FIG. 27C, the distal face or end 2717 of the intermediate catheter 2713 is shown catching on the distal end 2714 of the cuff 2711 when attempting to re-sheath the sub-assembly including the cuff 2711, flexible tube 2709 and inversion support catheter 2707 back into the intermediate catheter 2713. Although in some variations this may be desirable, as it may help push the cuff and end of the flexible inverting tube off of the end of the inversion support catheter (which it may further envelop and/or cut the clot, as described above in relation to FIGS. 18H-18I), in some variations it may be desired to leave the cuff 2711 on an outside of the inversion support catheter 2707. In this case, as shown in FIG. 27C, if the distal end 2717 of the intermediate catheter 2713 catches on the end face 2714 of the cuff 2711, the cuff may be driven forward, towards the end of the inversion support catheter, as shown. In FIG. 17C, this is shown also driving 2725 the flexible inverting tube 2709 towards the end of the inversion support catheter.

[000165] To avoid this, the apparatus may be configured to include one or more **cuff retainers** that hold the cuff level and/or limit its movement so that it may slide into the intermediate catheter. FIGS. 28A-28C, 29A-29C, 30A-30C, and 312A-31C all describe cuff retainers that may be used.

[000166] For example, FIGS. 28A-28C illustrate an example of an inverting tube apparatus that includes a cuff at one end of the inverting flexible tube and a cuff retainer, in which the cuff ad flexible tube over the inversion support catheter may be re-sheathed into the intermediate catheter after deployment. The cuff retainer may facilitate the re-sheathing of

the cuff and flexible tube into the distal end of the intermediate catheter by applying a force to hold the cuff in a fixed position on the outside of the inversion support catheter. In some variations, the cuff retainer may also or alternatively hold the face of the cuff level relative to the distal end of the intermediate catheter.

[000167] In FIG. 28A, the inverting tube apparatuses include a cuff 2811 on the end of an inverting flexible tube 2809 that inverts into the inversion support catheter 2807. A puller (or pusher) 2805 may slide within the inversion support catheter and is attached to the flexible tube 2809. The puller (or pusher) in any of these examples may be a catheter and may pass a guidewire. The cuff retainer in this example is one or more leashes or tether 2835 (e.g., a filament, wire, strand, cable, etc.) that is connected at one or more points on the cuff and one or more locations on the outer surface (or through the outer surface) of the inversion support catheter. The cuff retainer shown is helically arranged over the inversion support catheter so that it may be unwound or unspooled as the puller/pusher pulls and inverts the flexible tube into the inversion support catheter. The cuff retainer may be elastic. In some variations the cuff retainer may include multiple tethers that are spaced circumferentially around the cuff (e.g., spaced equal distances apart).

[000168] The inverting flexible tube sub-assembly (cuff, inverting flexible tube, and inversion support catheter) may be re-sheathed into the intermediate catheter 2813 after the puller has pulled the flexible tube into the inversing support catheter, so that the cuff has slid over the inverting support catheter to a predetermined position 2833 towards the distal end of the inversion support catheter, as shown in FIG. 28B.

[000169] Once the cuff retainer 2835 is engaged and applying force against the cuff to hold it in position relative to the inversion support catheter, the intermediate catheter 2813 maybe be slid distally 2850 over the distal end of the cuff and/or the sub-assembly including the cuff may be drawn proximally back in to the intermediate catheter. This is illustrated in FIG. 28C.

[000170] In the variation shown in FIGS. 29A-29C, the cuff retainer 2935 is configured as one or more leashes or tethers 2935 (e.g., filaments, wires, strands, cables, etc.) that is/are attached to a cuff 2911. However, in this example, the cuff retainer passes through an opening 2941 in the inversion support catheter 2907 and attaches to the puller (or pusher) 2905. Thus, as the puller 2905 is drawn proximally to pull and invert the flexible tube 2909 into the inversion support catheter 2905, the cuff retainer 2935 is also drawn with the flexible tube. This configuration may coordinate the movement of the puller with the movement of the cuff, as illustrated in FIGS. 29B and 29C. In FIG.29B. As shown in FIG. 29B the cuff retainer also limits the axial movement of the cuff along the outside of the inversion support

catheter. Thus, by pulling the puller/pusher 2905 proximally, the cuff retainer may apply a force holding the cuff in position so that, as shown in FIG. 29C, the intermediate catheter (sheath 2913) may be advanced distally 2971 and over the cuff and outer portion of the flexible tube 2909. This configuration may also be useful in reloading the flexible tube, as (not shown) force applied to pull the cuff proximally (by pulling/pushing the cuff proximally on the inversion support catheter) may be transmitted to the puller through the cuff retainer (e.g., the one or more filaments, so that force is applied to both ends of the flexible tube to reload the device and also eject any clot within the flexible tube and inversion support catheter.

[000171] FIGS. 30A-30C illustrate another example of an apparatus including a cuff and a cuff retainer 3035, 3035' in which the cuff retainer includes a pair of leashes or tethers 3035, 3035' (e.g., filaments, wires, strands, cables, etc.) that are attached to the cuff 3011 and extend proximally through the intermediate catheter 3013 all the way to a proximal end of the device where they may be used to apply force (e.g., tension) to the cuff. In FIG. 30B, the puller 3005 has been withdrawn proximally 3072 to cause the flexible tube 3009 (attached to the puller) to roll and invert over the distal end of the inversion support tube 3007. By securing and/or pulling on the cuff retainer 3035, 3035', and in some variations also securing and/or pulling on the puller 3005, the cuff may be held in a fixed location while the intermediate catheter 3013 is driven distally 3074, as shown in FIG. 30C. In this example, the cuff retainer (e.g., tethers) may be made of a metallic (e.g., stainless steel, elgiloy, Nitinol, etc.) or polymeric material. As mentioned, in use, the cuff retainer may be locked down or free to move (e.g., slide) and may be manipulated by the user near the hub of the inversion support catheter or elsewhere on the proximal end of the apparatus.

[000172] In some variations, the cuff retainer may be used to pull back the tractor to eject clot after use. For example, the apparatus (e.g., the sup-portion including the cuff, the flexible tube and the puller) may be reloaded on the inversion support catheter and/or material such as a clot captured in the apparatus may be ejected by pulling the cuff proximally (and in some variations pushing the puller/pusher 3005 distally).

[000173] Although the cuff retainer shown in FIGS. 30A-30C is shown as one or more tethers, in some examples, the cuff retainer is a tubular structure, which may be knitted, woven, solid, etc.

[000174] In some variations the cuff retainer is a cuff stop near or on a distal region of the inversion support catheter. For example, in FIG. 31A the cuff retainer is configured as a cuff stop that is formed as a collar attached to the distal end region of the inversion support

catheter. In FIG. 31A, the cuff 3111 connected to an end of the flexible tube 3109 slides freely along the inversion support catheter 3105, so that when the puller/pusher 3105 within the inversion support catheter is drawn proximally 3172 (a shown in FIG. 31B), the cuff may be pulled distally while the flexible tube rolls and inverts over the distal end of the inversion support catheter. In FIG. 31B, the cuff is stopped from moving distally by the cuff retainer 3137 (cuff stop). The intermediate catheter (sheath 3113) may then be moved distally over the cuff and any portion of the flexible tube 3109 that is external to the inversion support catheter to re-sheath the apparatus, as shown in FIG. 31C. Alternatively, or additionally, the inversion support catheter, cuff, flexible tube and puller may be drawn proximally into the intermediate catheter. In some variations, a combination of both movements may be used. The puller may be pulled or held so that the cuff is held against the cuff retainer while re-sheathing or alternatively the intermediate catheter (sheath) may drive the cuff against the cuff retainer.

[000175] In FIGS. 31C the cuff retainer is a stop that is fixed to the outside of the inversion support catheter. Any stop that may engage with the outer distal-facing edge of the cuff and the inversion support catheter may be used. For example, the cuff retainer may be a cuff stop that is a bump, ridge, button, protrusion, band, ring, lip, or the like. One or more (e.g., two, three, etc.) discrete regions arranged around the outside of the inversion support catheter may be used. The cuff retainer may made of any appropriate material, e.g., a polymer or metallic structure, and may be a solid element or a braid or knit structure.

[000176] In addition to these mechanical cuff retainers (cuff stops), electrical and/or magnetic cuff retainers may be used. For example, the cuff retainer may be a magnetic or paramagnetic material that interacts with cuff (which may include a magnetic or parametric material) to limit movement of the cuff distally.

[000177] Any of the cuffs described herein may also include one or more tapered or shaped ends that also help re-sheath the apparatus. For example, in some variations, the proximal end of the cuff may be tapered towards the inversion support catheter.

[000178] FIGS. 32A-32C illustrate examples of tapered cuffs that may be used. In FIG. 32A, the apparatus includes a cuff 3211 that has a skived or tapered proximal end 3242. The cuff is attached at the other end to the flexible tube 3209 which inverts and rolls over the inversion support catheter 3207 when pulled by the puller 3205 from within the inversion support catheter. The sub-assembly including the inversion support catheter, flexible (inverting) tube, and the cuff is shown in a deployed configuration extending from outside of the intermediate catheter 3213. The tapered cuff may aid in re-sheathing the sub-assembly,

including the cuff, back into the intermediate catheter. A tapered cuff may be used with or without a cuff retainer, including any of those described above.

[000179] FIG. 32B is another example of a tapered cuff 3211 that includes a proximal tapered region 3245'. In this example, the tapered region includes serrations that may allow some flexibility of the narrowed proximal end so that it is still free to slide on the inversion support catheter. The serrations may be configured as one or more slots, slits or cut-out regions in the tapered region. The serrations may be limited to the tapered region.

[000180] FIG. 32C is another example of a tapered cuff 3211 having a crown-like tapered region 3255 comprising a number of larger cut-out regions, similar to the serrations of the tapered region in FIG. 22B. In FIG. 32C the tapered region may include tapered fingers or projections that may be triangular, square/rectangular, curved and/or sinuous and/or irregularly shaped tapered extensions. In some variations, the tapered region is crenelated.

[000181] The tapered regions of the cuff may extend over a portion of the cuff, e.g., between 5%-50% of the length of the cuff in the long-axis of the inversion support catheter (e.g., between 10% and 50%, between 15% and 50%, between 10% and 40%, etc.). The cuff may be any appropriate length, e.g., between 0.5 mm and 30 mm, between 1 mm and 20 mm, between 2 mm and 20 mm, greater than 2 mm, greater than 3 mm, greater than 4 mm, greater than 5 mm, greater than 6 mm, etc.).

[000182] FIGS. 32D and 32E illustrate cuffs having tapered regions that are angled on the proximal-facing sides. Thus, the proximal-facing side of the cuff is angled relative to the body of the cuff and the inversion support catheter. In FIG. 32D the cuff 3211 has an angled proximal side 3265, but the distal-facing side of the cuff is flat (e.g., perpendicular to the long axis of the inversion support catheter over which it may slide. FIG. 32E shows a cuff 3211'''' that is similar to the variation shown in FIG. 32D but is also angled on the distal-facing side. The angled proximal-facing side may be tapered (and/or may include tapered cut-out regions/perforations). Cuffs having angled proximal faces may also be used with a cuff retainer. The angled proximal face may be formed by cutting the cuff at an angle. Any appropriate angle may be used, e.g., between 5 degrees and 60 degrees (e.g., between 10 degrees and 50 degrees, between 15 degrees and 45 degrees, etc.), measured as the acute angle formed between the proximal-facing side and the sidewall of the cuff.

[000183] FIG. 32F illustrates a cuff 3211 having a proximal-facing stent like structure 3275 that is low-profile and may also help with re-sheathing. Any of the tapered and/or angled cuffs may also include a proximally-extending stent-like structure. The stent-like structure may include wires, filaments, ribbons, etc. extending from the proximal edge. These sent-like

structures may be flattened toward the inversion support catheter 3207 outer surface. A stent-like structure may also be referred to as a low-profile scaffolding, and may extend completely or partially around the perimeter of the cuff.

[000184] Any of the apparatuses described herein may also be configured to be re-loadable. For example, FIGS. 33A-33D illustrate one example of a re-loading apparatus in which a single-use subassembly including a cuff 3311 (configured as a split cuff), a flexible tube 3309, and an inner puller 3305, is loaded onto the inversion support catheter 3307, and partially deployed out of the intermediate catheter (sheath 3313). The sub-assembly, which may be referred to as an inverting flexible tube sub-assembly is removable from the inversion support catheter, and may be removed from the inversion support catheter out of the intermediate catheter after removing all or part of a clot; the intermediate catheter (sheath) may then be left in place while the intermediate catheter and inverting flexible tube sub-assembly may be removed from the vessel proximally. Once withdrawn, the sub-assembly may be removed from the inversion support catheter and a new sub-assembly may be loaded onto the inversion support catheter and inserted back through the intermediate catheter to remove additional clot material. This is illustrated in FIGS. 33A-33E.

[000185] In FIG. 33A, the apparatus is shown partially deployed, with the inversion support catheter 3307 extending out of the sheath 3313, and the flexible tube 3309 connected at one end to a split cuff 3311 and at the other end to a puller (e.g., puller assembly, including a puller wire 3305 and a puller catheter segment 3306). The cuff may be slid over the inversion support catheter distally as the puller is drawn proximally (e.g., by pulling on the puller end 3356). Pulling the puller proximally causes the flexible tube to roll and invert over the distal end of the inversion support catheter. In FIG. 33A, a guidewire 3341 may be used, and passes through the catheter segment 3306 of the puller. As described in greater detail above, this may draw a clot into the inversion support catheter. Once the cuff reaches the distal end of the inversion support catheter, as shown in FIG. 33B, the cuff may split apparat and roll and invert 3372 over the distal end of the inversion support catheter as well, into the inversion support catheter. As shown in FIG. 33C, the entire sub-assembly (e.g., the puller, flexible tube 3309 and split cuff 3311 may then be housed within the inversion support catheter 3307, and withdrawn proximally out of the sheath 3313. For example, the proximal end of the inversion support catheter may include a handle or grip 3361, allowing it to be advanced and/or withdrawn from outside of the patient. The entire sub-assembly and/or inversion support catheter may be removed proximally out of the patient.

[000186] Once removed, the inverting flexible tube sub-assembly may then be removed, along with captured clot, from the inversion support catheter, and either a new inversion support-catheter pre-loaded with an inverting flexible tube sub-assembly may then be inserted into the sheath and back into the vessel to capture any additional clot material, or the same inversion support catheter may be re-loaded with a new inverting flexible tube sub-assembly, as shown in FIGS. 33D and alternative variation in FIG. 33E.

[000187] In FIG. 33D, a new inverting flexible tube sub-assembly 3360, including the puller (puller assembly including pull wire 3305 and pull catheter 3306), flexible tube 3309 and cuff 3311, is loaded 3374 into the distal end of the inversion support catheter 3307. The variation shown in FIG. 33E is similar to that shown in FIG. 33D, but the cuff 3311' is un-inverted, and therefore loads on the outer surface of the inversion support catheter. As the loaded inversion support catheter is driven back through the sheath, the flexible tube 3309 and cuff may be driven proximally, so that it prepared to be withdrawn proximally by the puller to capture clot by the time it reaches the distal end region of the sheath.

[000188] In any of these variations, a guidewire may be use to insert and guide insertion of the inverting flexible tube sub-assembly and/or inversion support catheter to the clot material.

[000189] The steps of capturing clot, withdrawing the sub-assembly proximally and reloading anew sub-assembly, as illustrated in FIGS. 33A-33E, may be repeated as necessary to remove more clot material.

[000190] Alternatively, as mentioned above, any of the apparatuses described herein may be configured to reusing inverting flexible tube sub-assembly and other portions of the apparatus. For example, the apparatus may be deployed to a clot, and used to remove at least a portion of the clot, and the clot, captured by the flexible tube, may be withdrawn out of the vessel, and ejected from the flexible tube, and the flexible tube (e.g., the inverting flexible tube sub-assembly including the flexible tube) reloaded, reinserted and used to remove additional clot. An example of this is illustrated in FIGS. 34A-34C.

[000191] In FIG. 34A, a portion of clot 3490 has been captured by an apparatus. The apparatus may include an inversion support catheter 3407, a puller 3405, a flexible tube 3409 and a cuff 3411. In this example, the puller includes a proximal handle region 3465 and the inversion support catheter includes a proximal handle region 3467. The apparatus has been withdrawn from out of the patient after grabbing the clot material in FIG. 34A. The clot material may then be ejected from the apparatus, as shown in FIG. 34B. In this example, the clot material is ejected by pulling the cuff proximally 3472 and/or by pushing the puller distally 3474. In some variations, the clot may be ejected by both pushing the puller distally

and by pulling the cuff proximally. For example, in some variations it may be beneficial to use an ejection apparatus 3522, as shown schematically in FIG. 35, to coordinate the relative motion of the puller 3505 (or puller assembly) and the inversion support catheter 3507, while drawing the cuff 3511 proximally. The ejection apparatus 3522 couples to both the puller proximal handle 3565 and the inversion support catheter proximal handle 3567 and moves the two handles 3565 and 3567 closer to each other 3572, as shown by the arrows. Force may also be provided (manually or automatically) to move the cuff 3511 proximally to eject the clot material 3590 from the flexible tube 3509. For example, the ejection apparatus may be a mechanical apparatus including one or more springs (e.g., extension springs) to assist in ejecting the clot material.

[000192] Once the clot is ejected, as shown in FIG. 34C, the apparatus is prepared for re-insertion, and may be inserted back into the patient (e.g., through an intermediate catheter with or without a guidewire) to remove additional clot material. An additional cover or sheath may be used to re-introduce the apparatus through the intermediate catheter.

CLAIMS

1. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an inversion support catheter;

a puller within a lumen of the inversion support catheter; and

a flexible tube extending over a distal end of the inversion support catheter, the flexile tube having a first end coupled at a distal end region of the puller and a second end comprising a cuff that is less flexible that a region of the flexible tube adjacent to the cuff, wherein the flexible tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the flexible tube rolls and inverts over a distal end of the inversion support catheter.

2. The apparatus of claim 1, wherein the cuff comprises one or more slits along its length extending in a proximal-to-distal direction.

3. The apparatus of claim 1 or 2, wherein the cuff comprises a polymeric material.

4. The apparatus of any of claims 1-3, further comprising a cuff retainer configured to prevent the cuff from extending over the distal end of the inversion support catheter.

5. The apparatus of claim 4, wherein the cuff retainer comprises one or more filaments coupling the cuff to the inversion support catheter.

6. The apparatus of claim 4, wherein the cuff retainer comprises a mechanical stop on the inversion support catheter.

7. The apparatus of claim 4, wherein the cuff retainer comprises one or more filament connecting the cuff to the puller through a lateral opening in the inversion support catheter.

8. The apparatus of claim 4, wherein a proximal-facing end of the cuff is tapered.

9. The apparatus of claim 4, wherein a proximal-facing end of the cuff comprises a low-profile scaffolding extending at least partially around the perimeter of the cuff.

10. The apparatus of any of claims 1-9, further comprising a first proximal port configured to couple with a vacuum source to apply vacuum through the puller.

11. The apparatus of any of claims 1-9, further comprising a second proximal port configured to couple with a vacuum source to apply vacuum between the intermediate catheter and the inversion support catheter.

12. The apparatus of any of claims 1-11, wherein the intermediate catheter is configured to push the cuff over the distal end of the inversion support catheter when the intermediate catheter is advanced distally past the cuff.

13. The apparatus of any of claims 1-12, wherein the flexible tube comprises a knit.

14. The apparatus of any of claims 1-13, wherein the cuff is radiopaque.

15. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an inversion support catheter;

a puller within a lumen of the inversion support catheter; and

a flexible tube extending over a distal end of the inversion support catheter, the flexile tube having a first end coupled at a distal end region of the puller and a second end comprising a cuff that is less flexible that a region of the flexible tube adjacent to the cuff, wherein the flexible tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the flexible tube rolls and inverts over a distal end of the inversion support catheter, and wherein the cuff is tapered at the proximal facing end.

16. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an intermediate catheter;

an inversion support catheter within a lumen of the intermediate catheter;

a puller within a lumen of the inversion support catheter; and

a knitted tube extending over the inversion support catheter, the knitted tube having a first end coupled at a distal end region of the puller and a second end that is free,

wherein the knitted tube is configured to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter,

wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, and

wherein each loop stitch has a stitch length that is between 0.5mm and 10mm.

17. The apparatus of claim 16, wherein the knitted tube extends over the inversion support catheter with an inner diameter that is within 20% of the outer diameter of the inversion support catheter.

18. The apparatus of claim 16 or 17, wherein the second end of the knitted tube comprises a cuff that is less flexible that a region of the knitted tube adjacent to the cuff.

19. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an inversion support catheter;

a puller within a lumen of the inversion support catheter; and

a knitted tube extending over the inversion support catheter in a first configuration, the knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inserting support catheter, wherein the knitted tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter into a second configuration within the inversion support catheter;

further wherein the knitted tube in the first configuration has an expanded outer diameter that is between 0.5 mm and 12 mm for a first region of the knitted tube that is adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the region of the knitted tube adjacent to the first end and within 20% of an outer diameter of the inversion support catheter.

20. The apparatus of claim 19, further comprising a cuff at the second end, wherein the cuff has a stiffness that is greater than a region of the knitted tube adjacent to the cuff.

21. The apparatus of claim 19 or 20, further comprising a stop configured to limit the travel of the knitted tube so that the second end does not roll and invert over the distal end of the inversion support catheter.

22. The apparatus of any of claims 19-21, wherein the knitted tube is shape set so that the first configuration has the outer diameter between 0.5 mm and 10 mm for the region of the kitted tube adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than 60% of the inner diameter of the inversion support catheter.

23. The apparatus of any of claims 19-22, wherein the first region of the kitted tube is at least 2 cm long.

24. The apparatus of any of claims 19-23, wherein the second region is at least 1 cm long.

25. The apparatus of any of claims 19-24, wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between 0.5 mm and 10 mm.

26. The apparatus of claim 25, wherein, at a region of the knitted tube that is inverting from the first configuration to the second configuration, a sub-set of the plurality of loop stitches forming the knitted tube extend proud from the long axis of the knitted tube by between 0.5 mm and 10 mm.

27. The apparatus of any of claims 19-26, further comprising an intermediate catheter having a lumen, wherein the inversion support catheter is within the lumen of the intermediate support catheter and may be extended distally from the intermediate catheter to deploy the knitted tube so that the knitted tube may expand into the first configuration.

28. The apparatus of any of claims 19-27, wherein the puller comprises a puller catheter.

29. A pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

an intermediate catheter having a distal end;

an inversion support catheter within a lumen of the intermediate catheter, the inversion support catheter having a distal end and a distal end opening;

a puller extending within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller so that a distal-facing face of the puller extends distally beyond the flexible tube,

wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter; and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter, and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter.

30. The apparatus of claim 29, wherein the inversion support catheter comprises a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force.

31. The apparatus of claim 29 or 30, wherein the flexible tube comprises a knitted tube.

32. The apparatus of claim 29, wherein the inversion support catheter comprises a plurality of slits or openings around the perimeter of the inversion support catheter and down the length of the inversion support catheter.

33. The apparatus of claim 29, wherein the inversion support catheter is removably secured to the intermediate catheter so that the intermediate support catheter and the intermediate catheter move relative to each other.

24. The apparatus of any of claims 19-23, further comprising a guidewire within the puller.

25. The apparatus of any of claims 19-23, wherein puller comprises a micro catheter.

26. The apparatus of any of claims 19-23, wherein the puller comprises a guidewire.

27. A pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

an intermediate catheter having a distal end;

an inversion support catheter extending distally from a lumen of the intermediate catheter, the inversion support catheter having a distal end and a distal end opening;

a puller extending distally within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller and between the intermediate catheter and the inversion support catheter,

wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter; and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter, and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter, and

wherein the puller and inversion support catheter are releasably held together so that they move together while advancing distally within a vessel lumen.

28. The apparatus of claim 27, wherein the inversion support catheter comprises a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force.

29. The apparatus of claim 27 or 28, wherein the tractor tube comprises a knitted tube.

30. The apparatus of claim 27, wherein the inversion support catheter comprises a plurality of slits or openings around the perimeter of the inversion support catheter and down the length of the inversion support catheter.

31. The apparatus of any of claims 27-30, further comprising a guidewire within the puller.

32. The apparatus of any of claims 27-30, wherein puller comprises a micro catheter.

33. The apparatus of any of claims 27-30, wherein the puller comprises a guidewire.

34. An inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

an inversion support catheter extending distally, the inversion support catheter having a distal end and a distal end opening, the inversion support catheter comprising a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force;

a puller extending distally within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller,

wherein the flexible tube comprises a knitted material that is held in compression along an outside region of the inversion support catheter and inverts over the distal end opening of the inversion support catheter and couples to the puller, and

wherein pulling the puller proximally causes the flexible tube to roll from the outside region of the inversion support catheter, over the distal end opening and invert into the inversion support catheter.

34. A pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

an intermediate catheter having a distal end;

an inversion support catheter extending distally from a lumen of the intermediate catheter, the inversion support catheter having a distal end and a distal end opening;

a puller extending distally within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller and between the intermediate catheter and the inversion support catheter,

wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter; and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter, and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter, and

wherein the puller and inversion support catheter are releasably held together so that they move together while advancing distally within a vessel lumen.

35. The apparatus of claim 34, wherein the inversion support catheter comprises a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force.

36. The apparatus of claim 33 or 34, wherein the tractor tube comprises a knitted tube.

37. The apparatus of claim 27, wherein the inversion support catheter comprises a plurality of slits or openings around the perimeter of the inversion support catheter and down the length of the inversion support catheter.

38. The apparatus of any of claims 34-37, further comprising a guidewire within the puller.

39. The apparatus of any of claims 34-37, wherein puller comprises a micro catheter.

40. The apparatus of any of claims 34-37, wherein the puller comprises a guidewire.

41. An inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

an inversion support catheter extending distally, the inversion support catheter having a distal end and a distal end opening, the inversion support catheter comprising a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force;

a puller extending distally within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller,

wherein the flexible tube comprises a knitted material that is held in compression along an outside region of the inversion support catheter and inverts over the distal end opening of the inversion support catheter and couples to the puller, and

wherein pulling the puller proximally causes the flexible tube to roll from the outside region of the inversion support catheter, over the distal end opening and invert into the inversion support catheter.

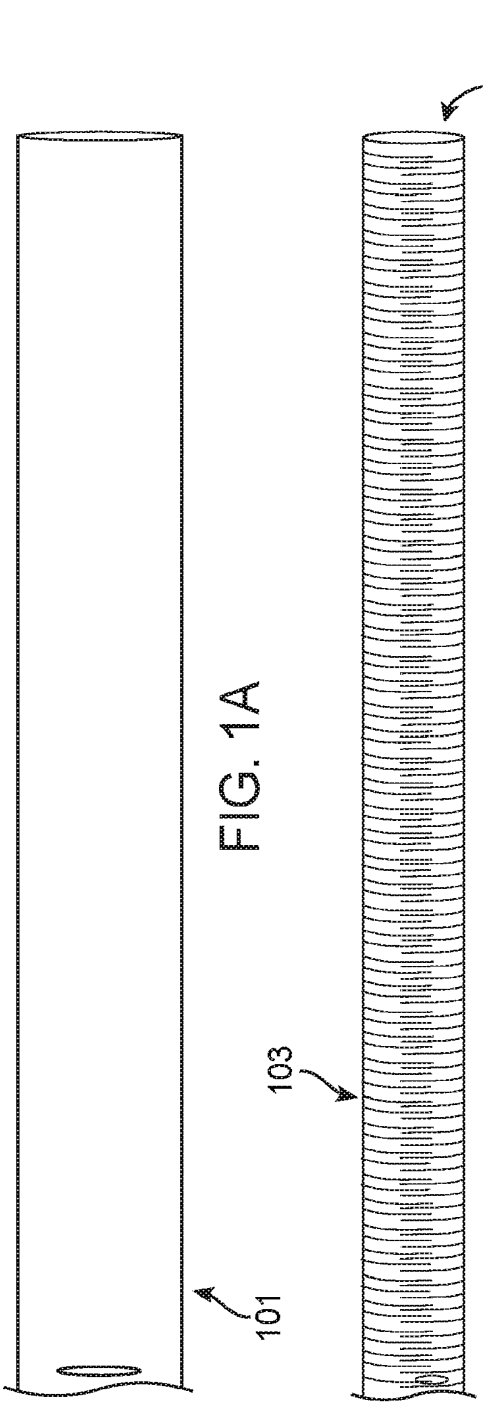


FIG. 1A

FIG. 1B

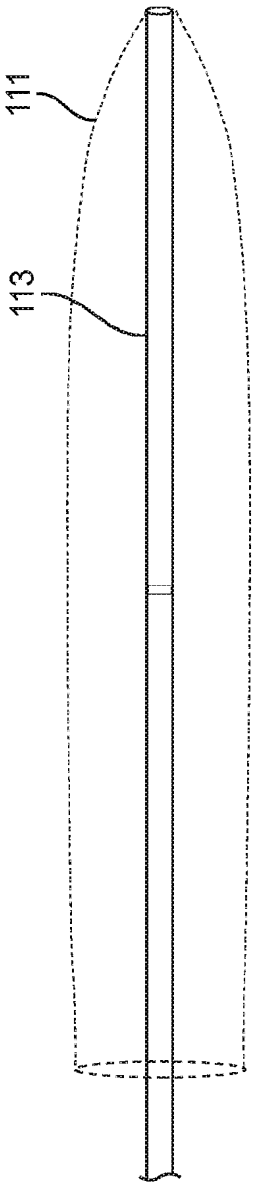


FIG. 1C1

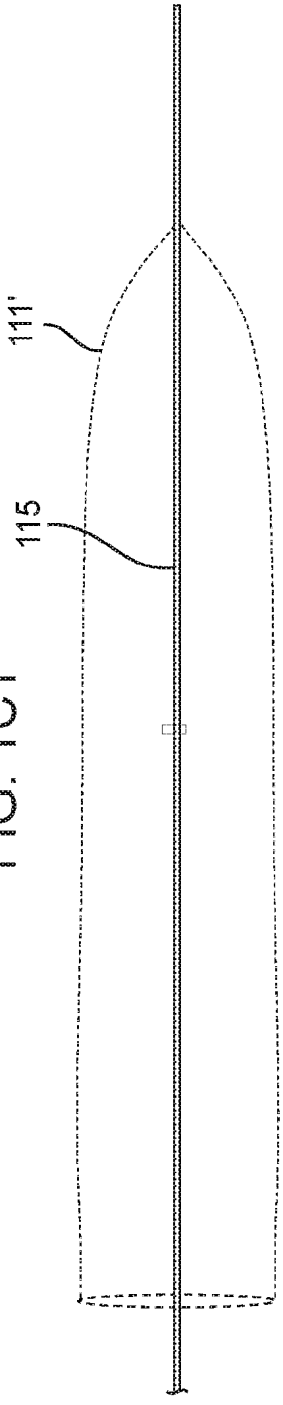


FIG. 1C2

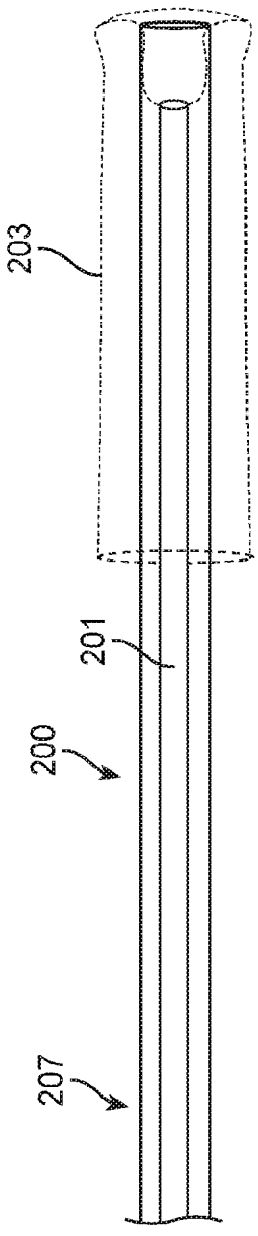


FIG. 2A

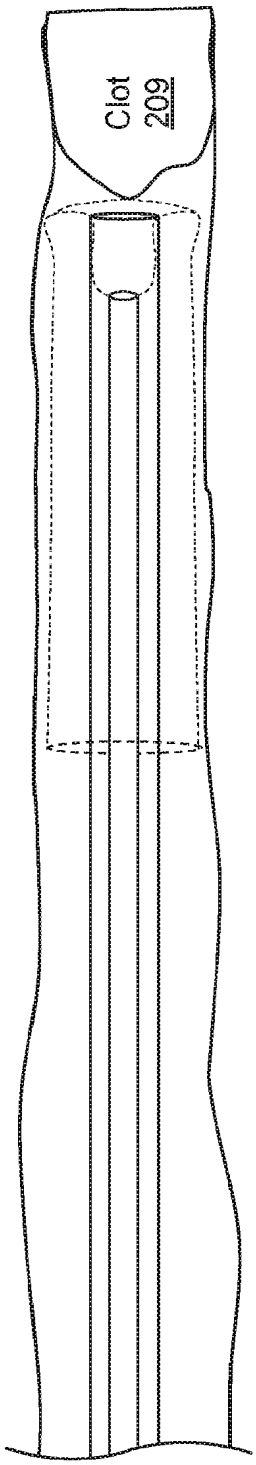


FIG. 2B

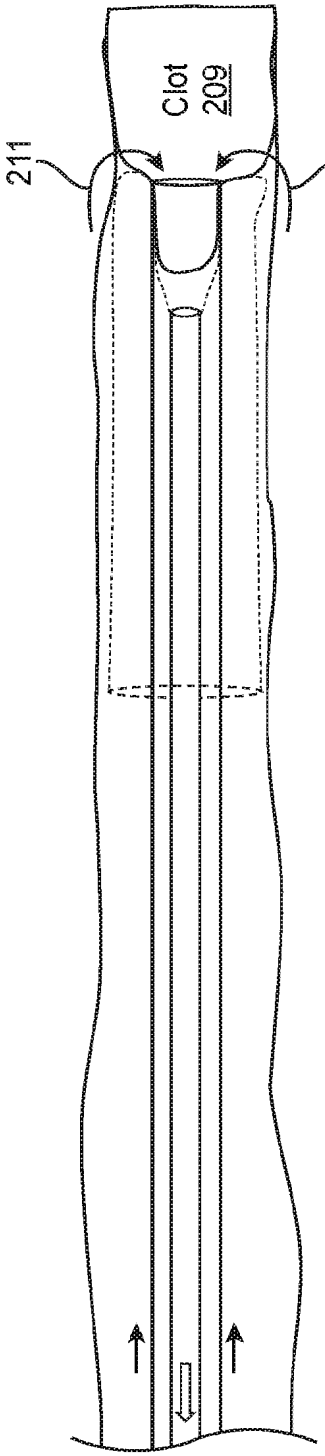


FIG. 2C

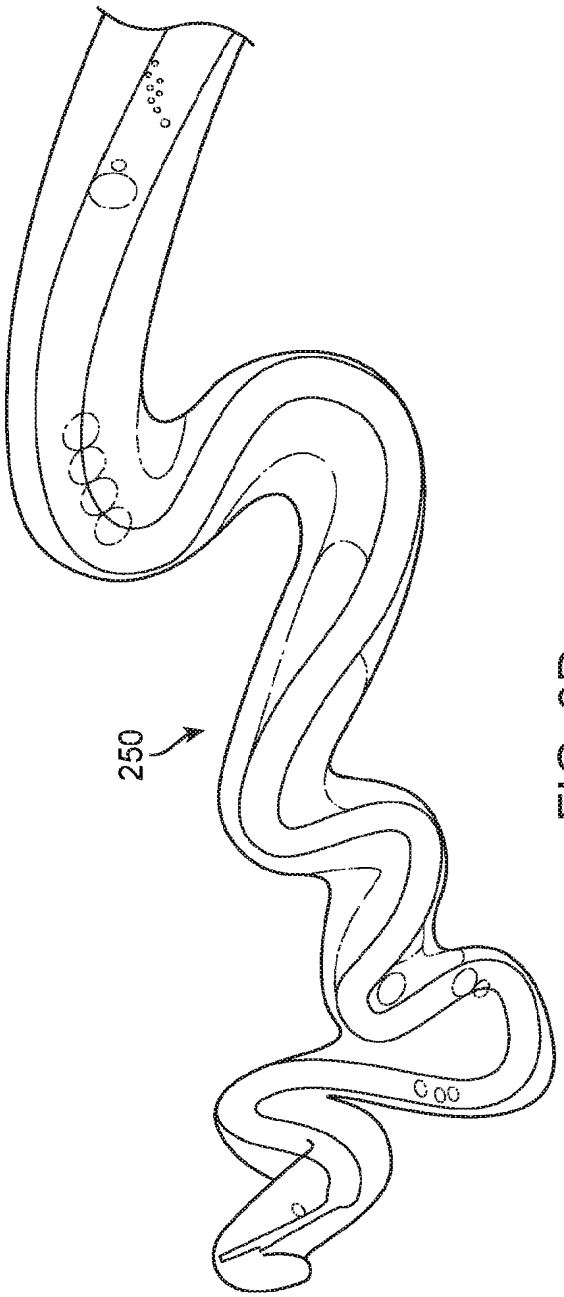


FIG. 2D

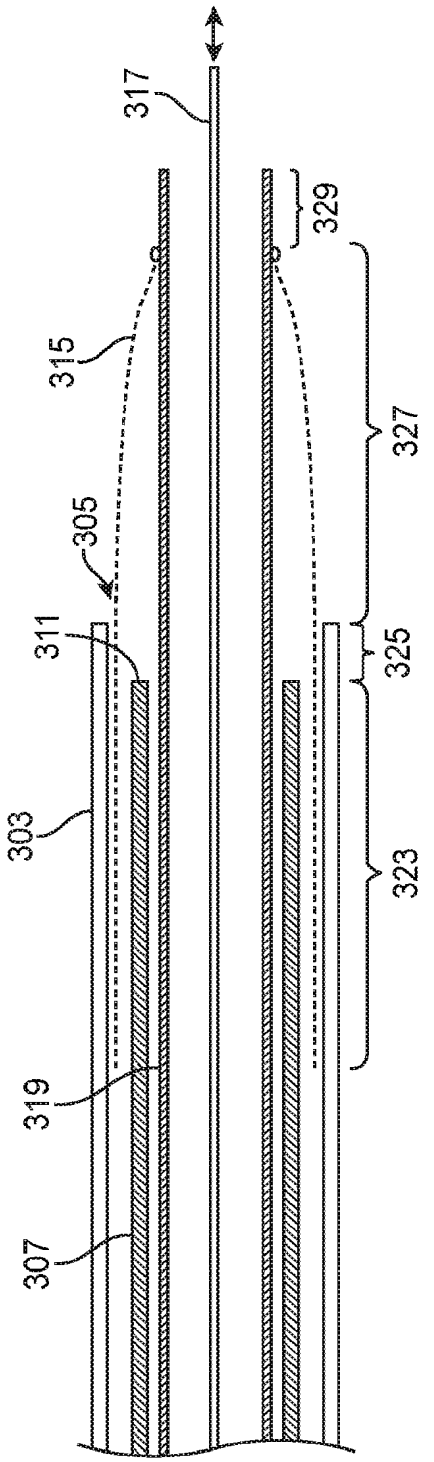

317
315
329
305
327
311
325
303
323
319
307

FIG. 3A

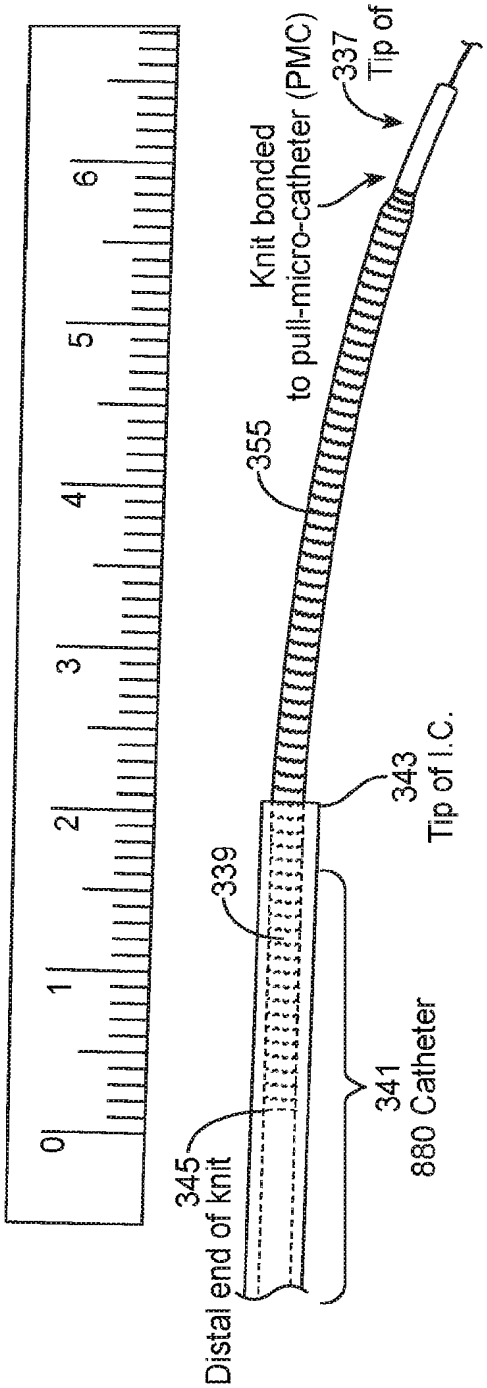

0
1
2
3
4
5
6
Knit bonded
to pull-micro-catheter (PMC)
337
Tip of PMC
355
343
Tip of I.C.
339
341
880 Catheter
345
Distal end of knit

FIG. 3B

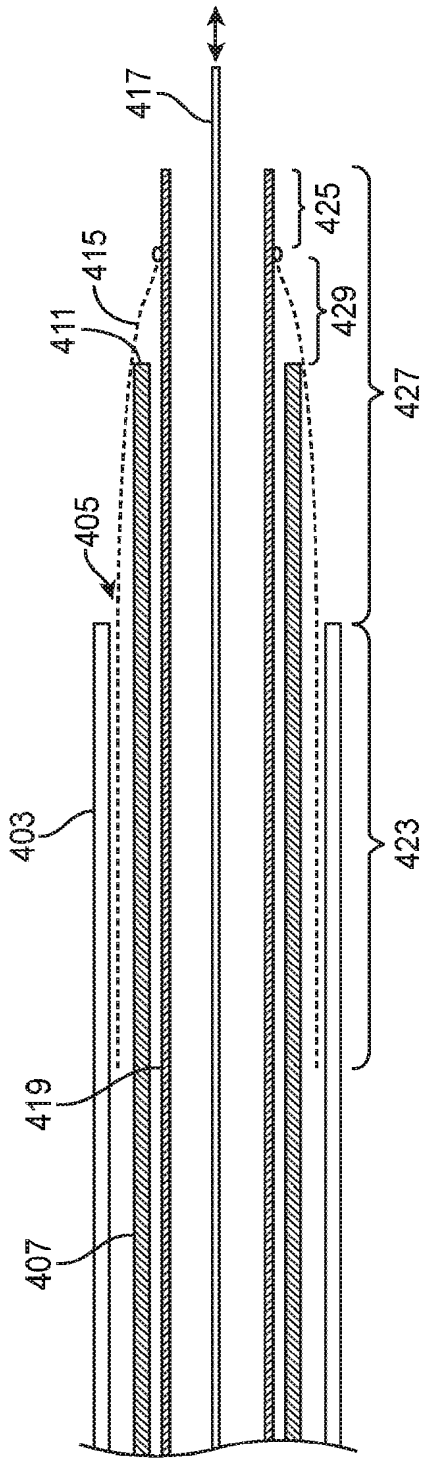


FIG. 4A

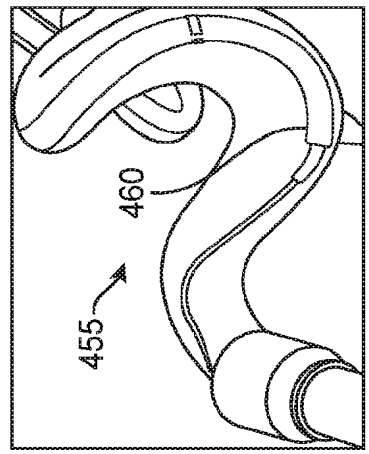


FIG. 4C

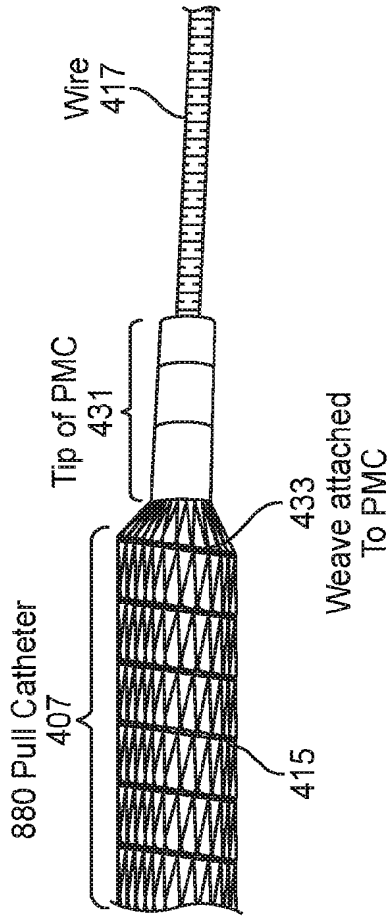


FIG. 4B

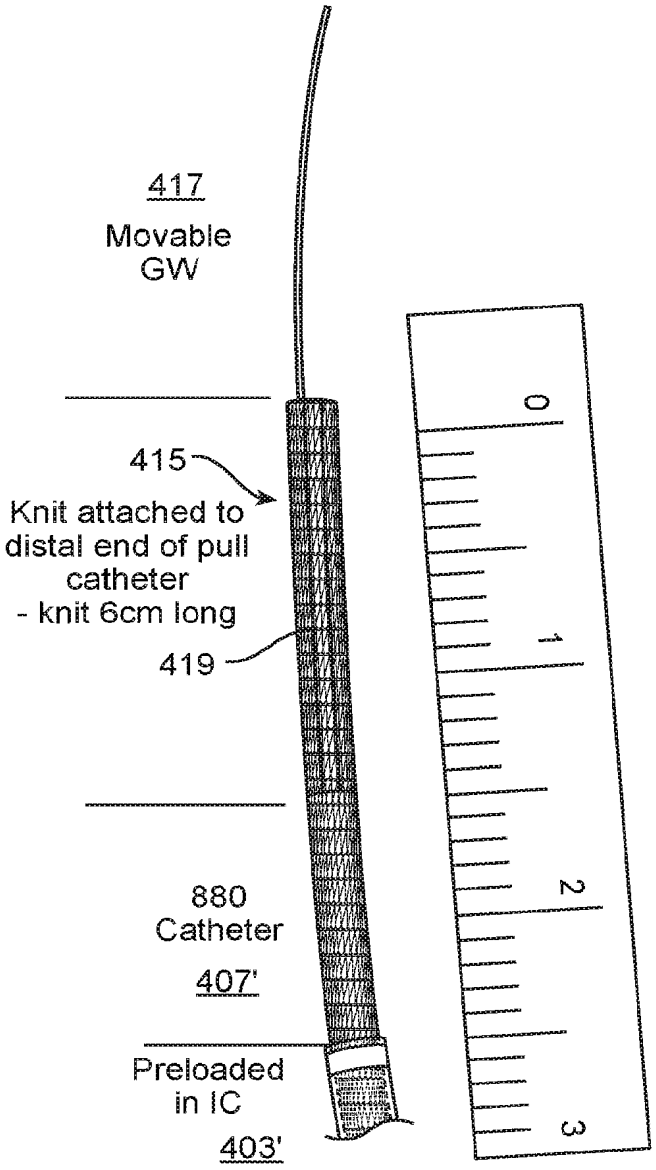

417
Movable GW
415
Knit attached to distal end of pull catheter - knit 6cm long
419
880 Catheter
407'
Preloaded in IC
403'
0
1
2
3

FIG. 4D

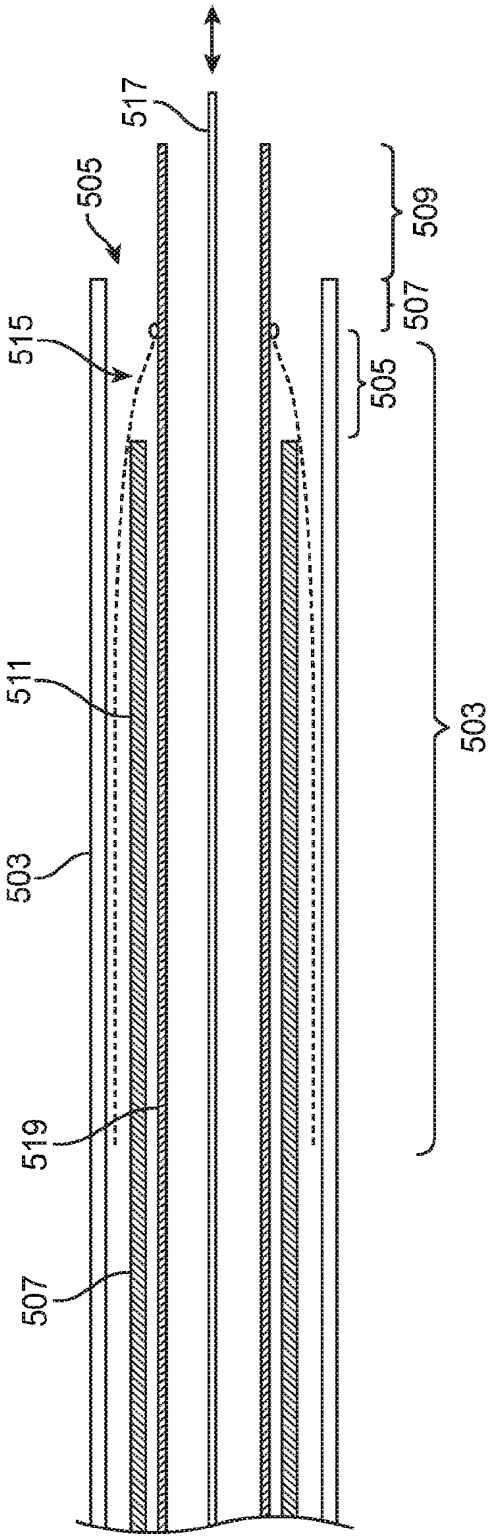

517
505
509
515
507
505
511
503
503
519
507

FIG. 5A

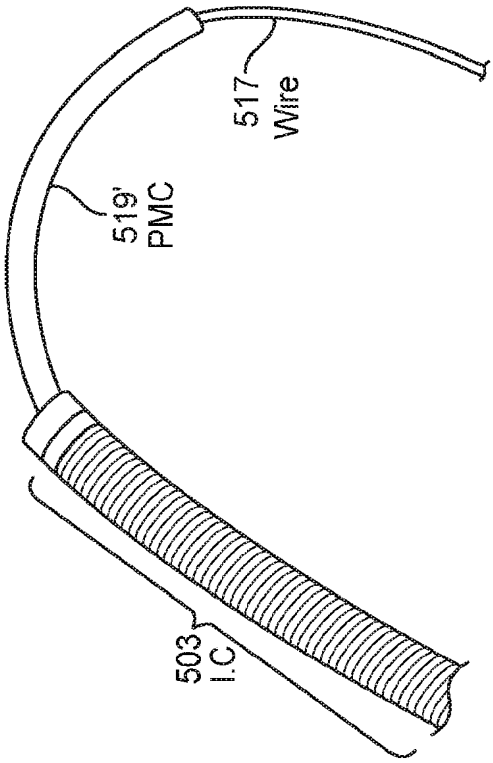

517
Wire
519'
PMC
503
I.C

FIG. 5B

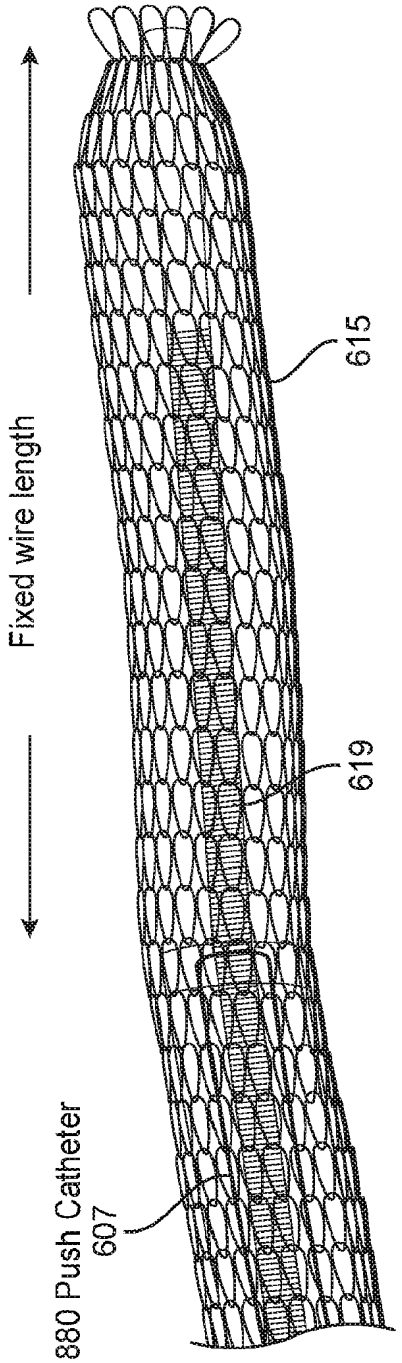


FIG. 6

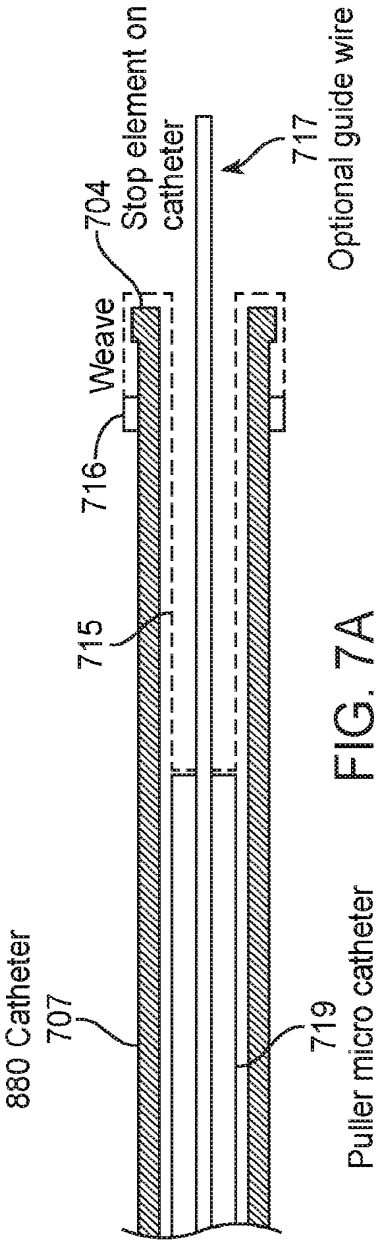


FIG. 7A

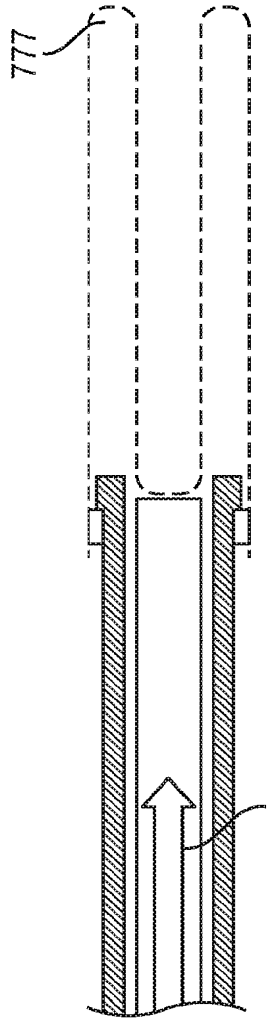


FIG. 7B

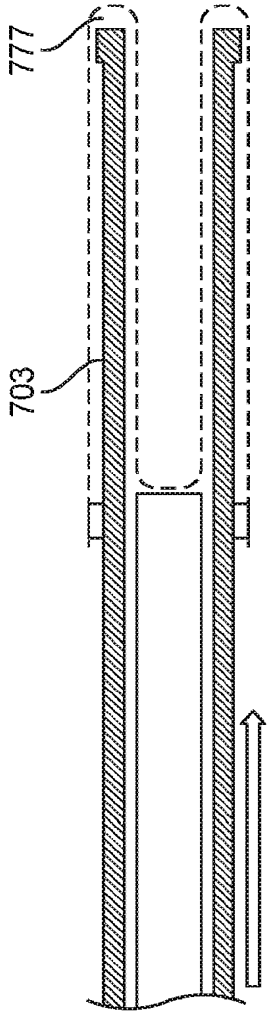
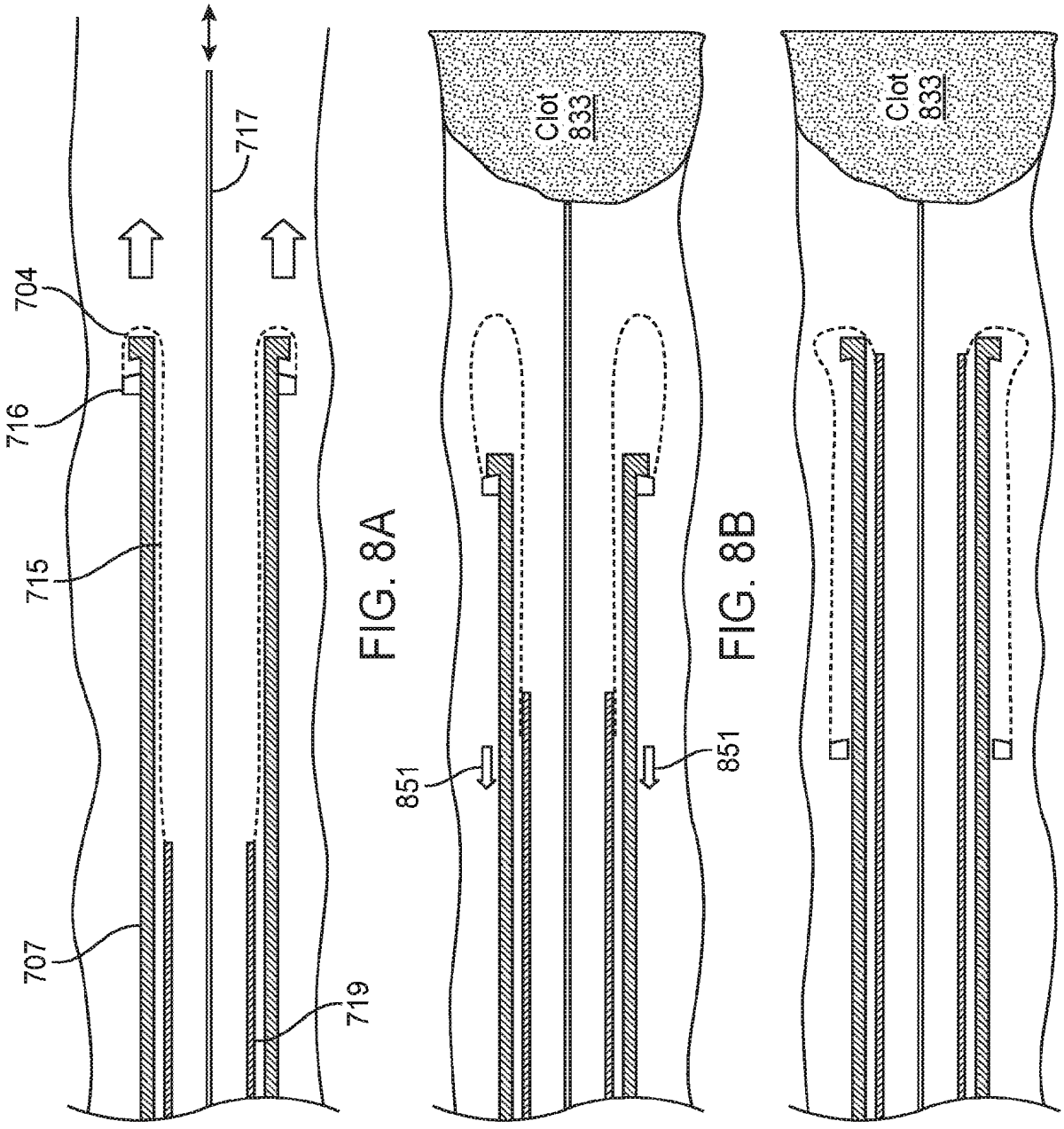


FIG. 7C


704
716
715
707
717
719
FIG. 8A
Clot
833
851
851
FIG. 8B
Clot
833
FIG. 8C

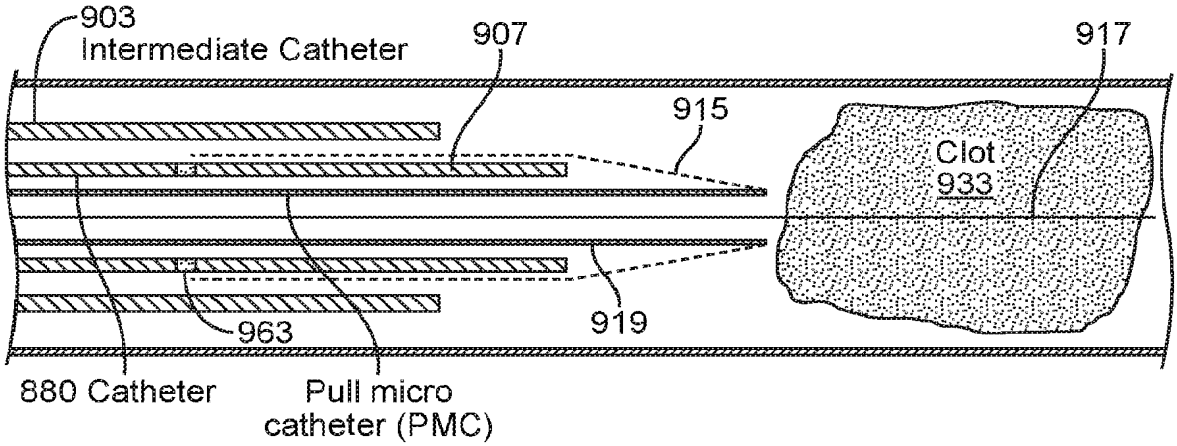


FIG. 9A

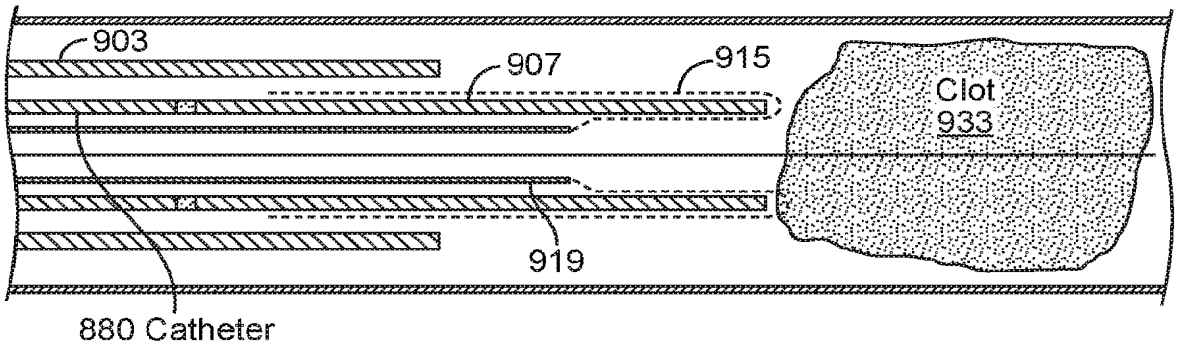


FIG. 9B

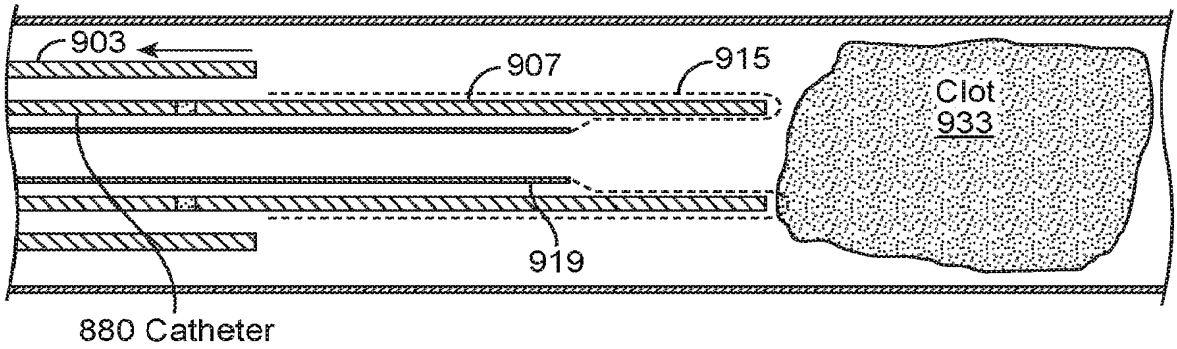


FIG. 9C

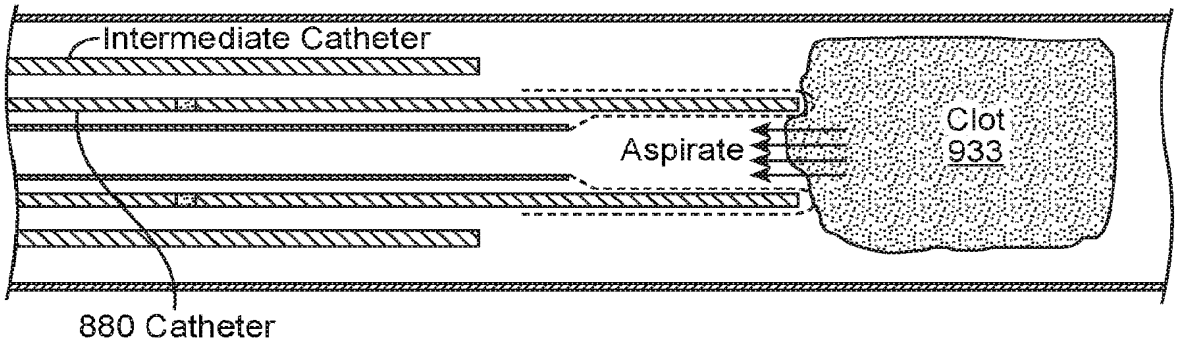


FIG. 9D

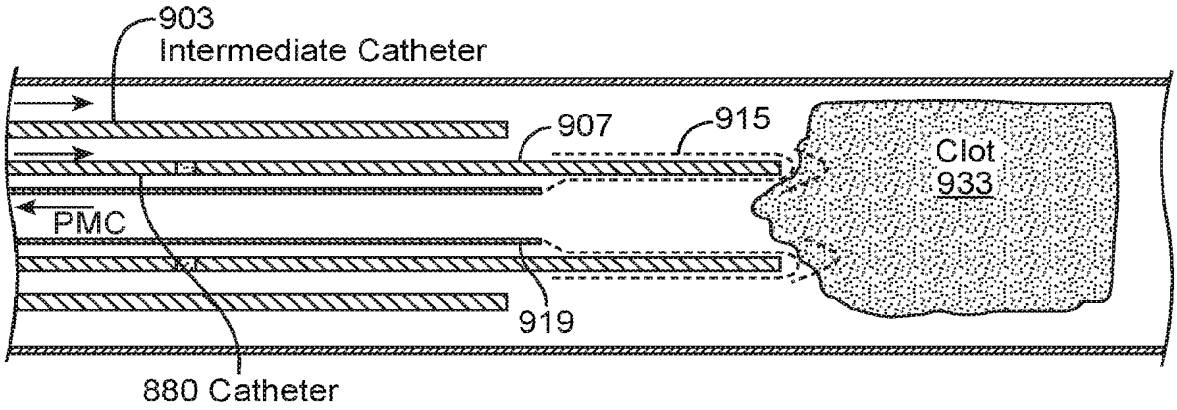


FIG. 9E

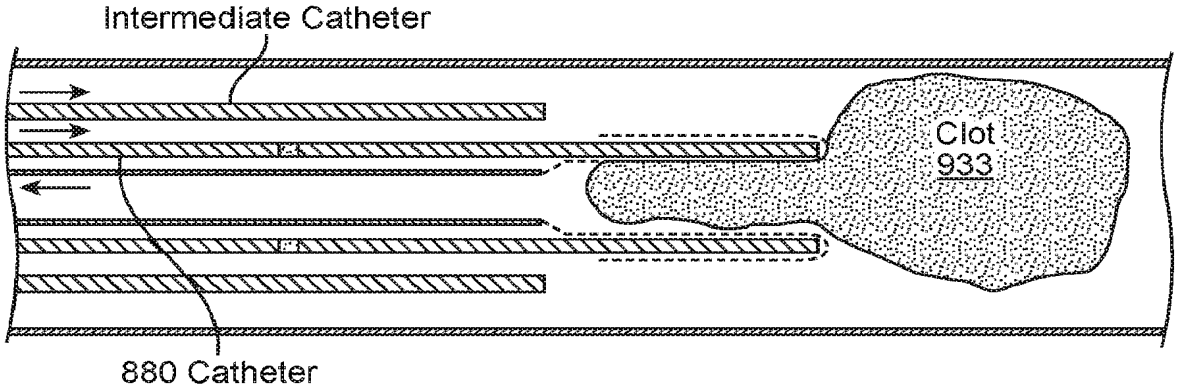


FIG. 9F

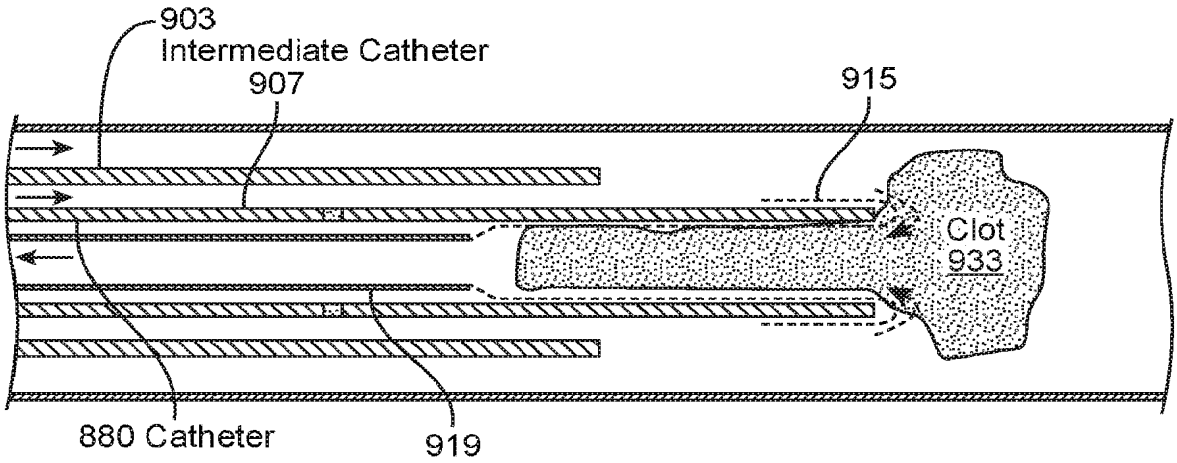


FIG. 9G

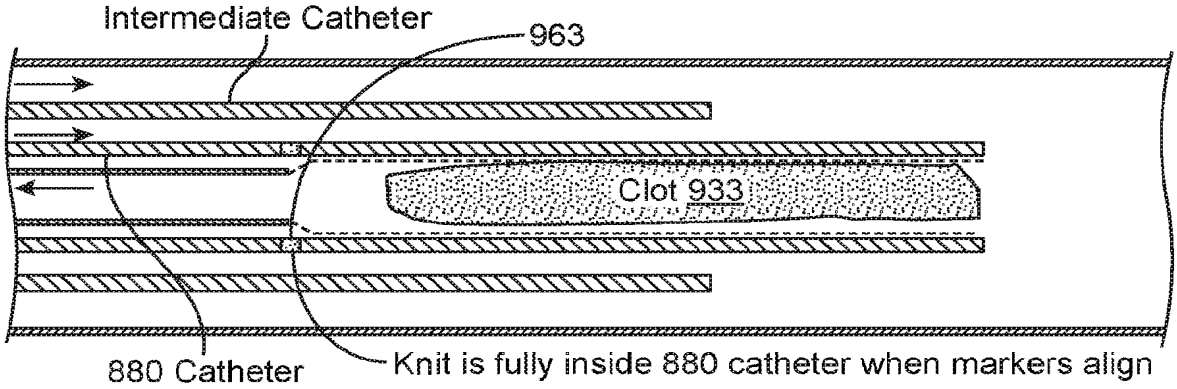


FIG. 9H

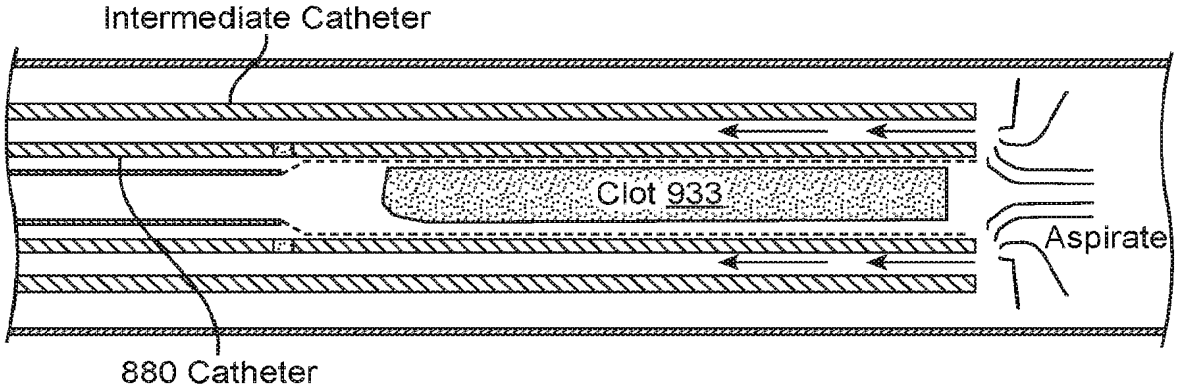


FIG. 9I

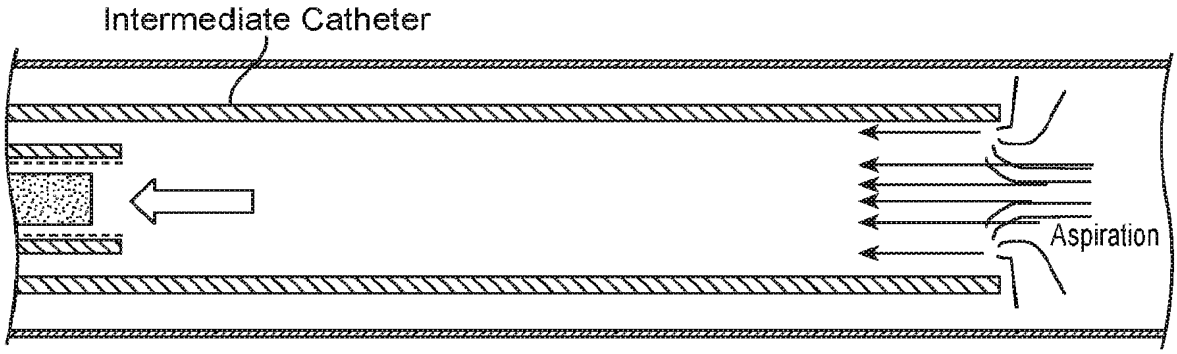

Intermediate Catheter
Aspiration

FIG. 9J

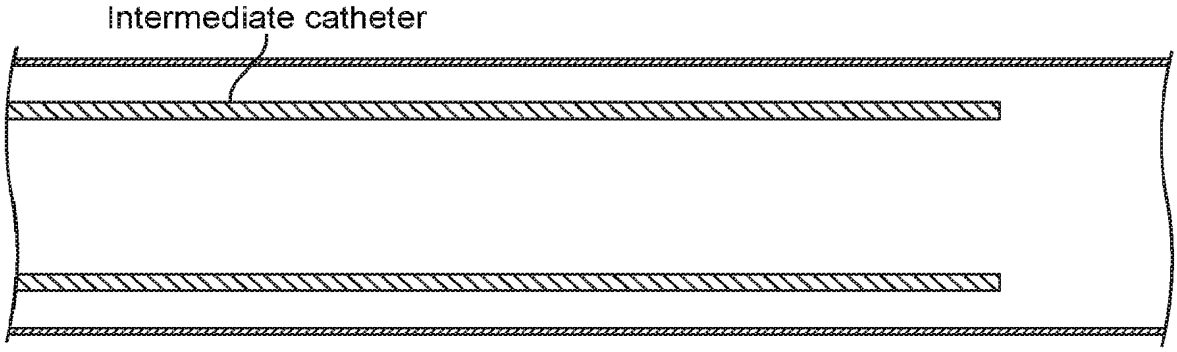

Intermediate catheter

FIG. 9K

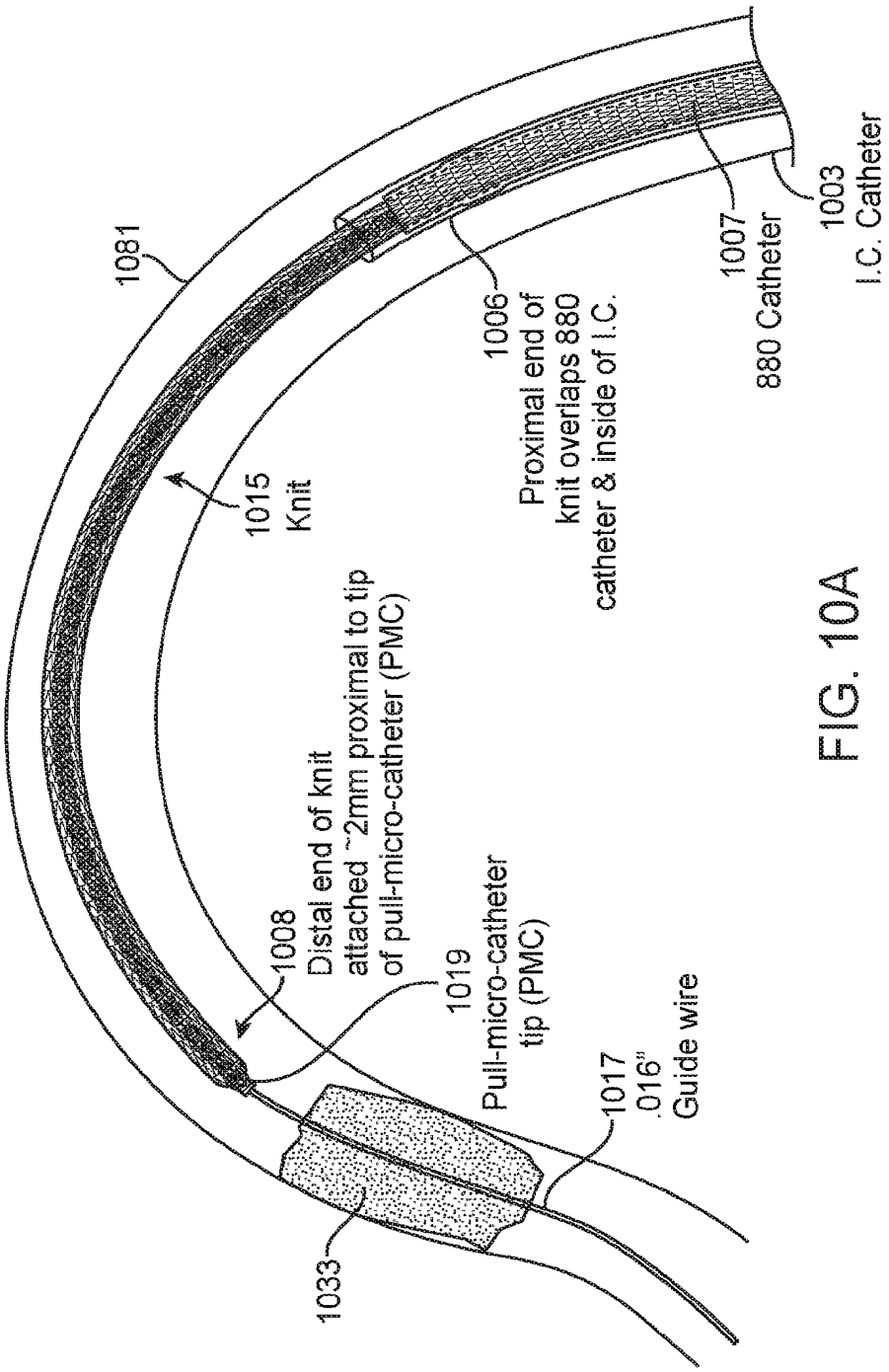

1081
1015
Knit
1008
Distal end of knit
attached ~2mm proximal to tip
of pull-micro-catheter (PMC)
1019
Pull-micro-catheter
tip (PMC)
1017
.016"
Guide wire
1033
1006
Proximal end of
knit overlaps 880
catheter & inside of I.C.
1007
880 Catheter
1003
I.C. Catheter

FIG. 10A

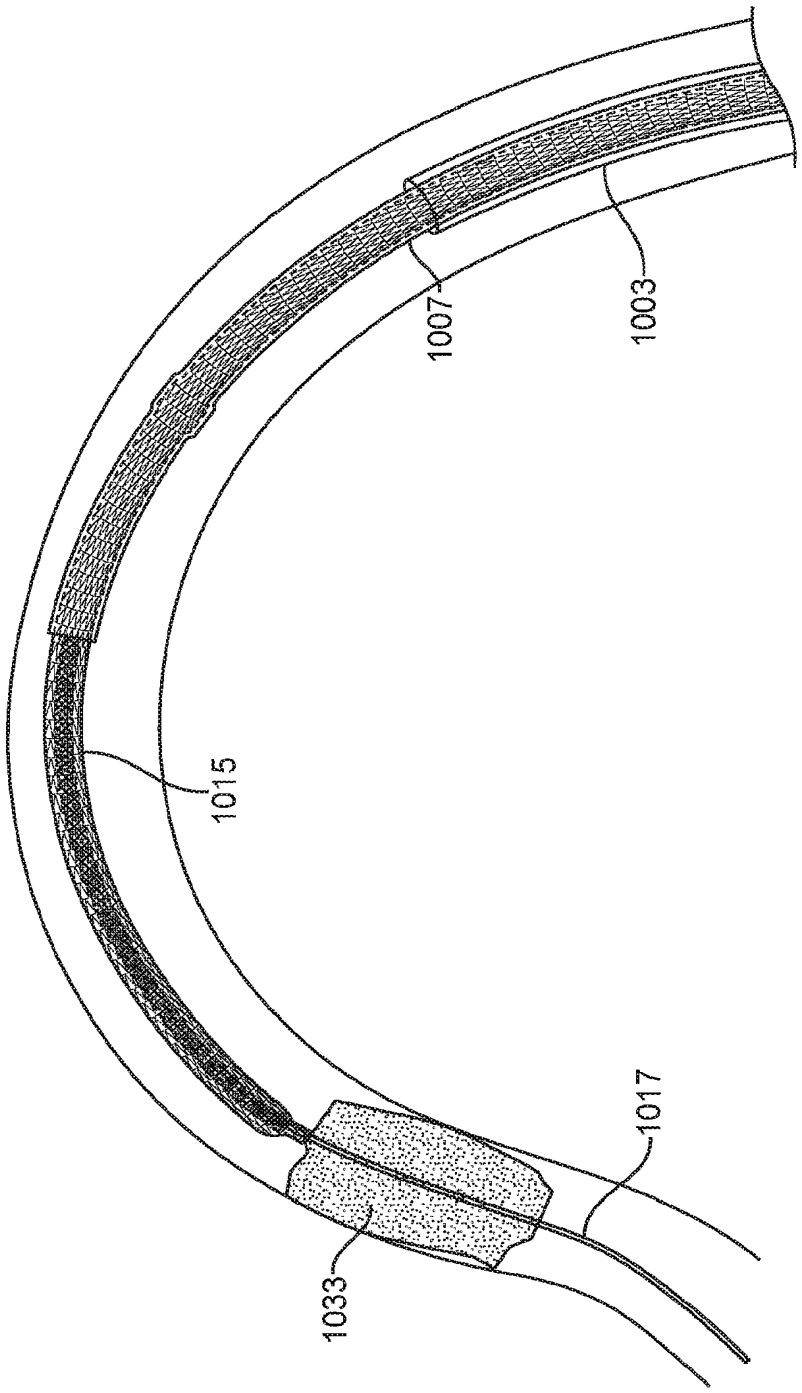


FIG. 10B

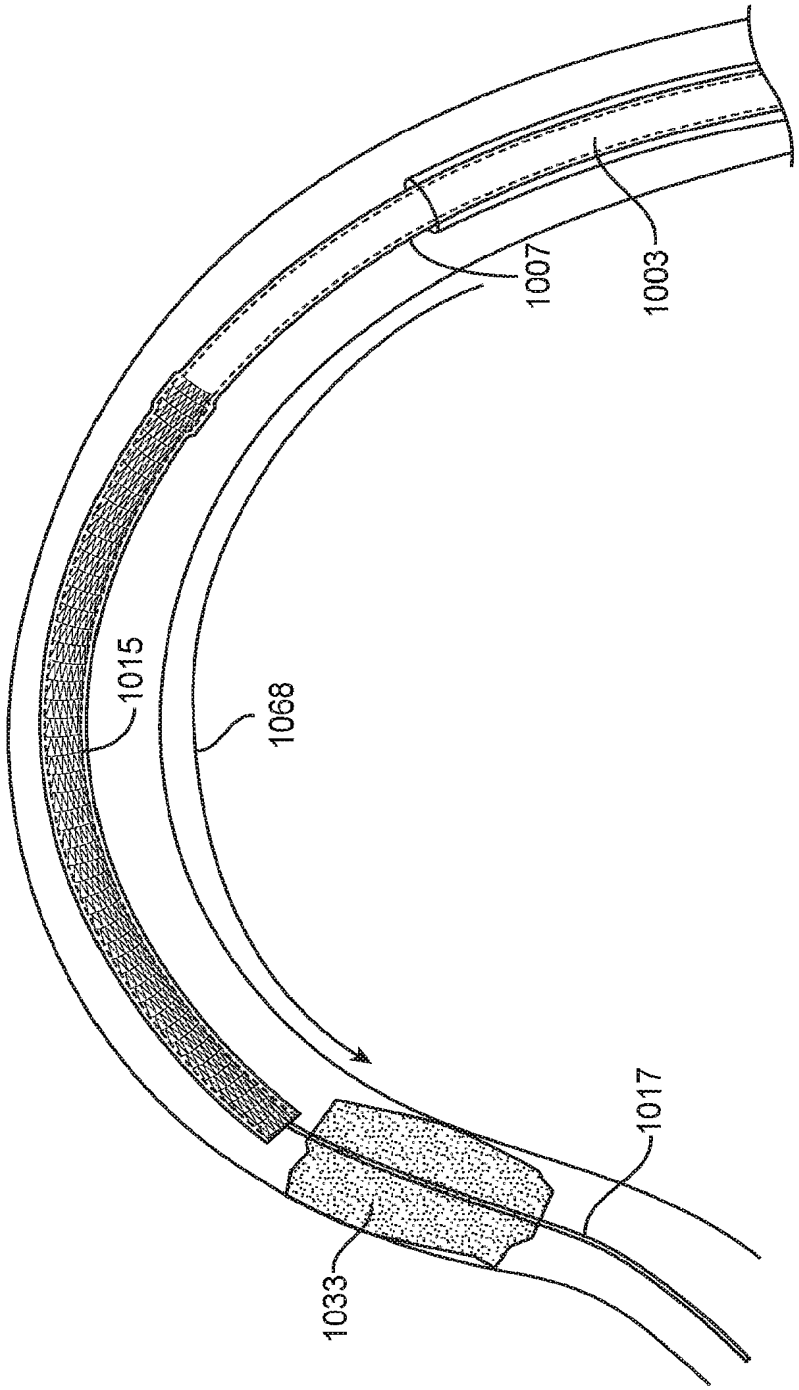


FIG. 10C

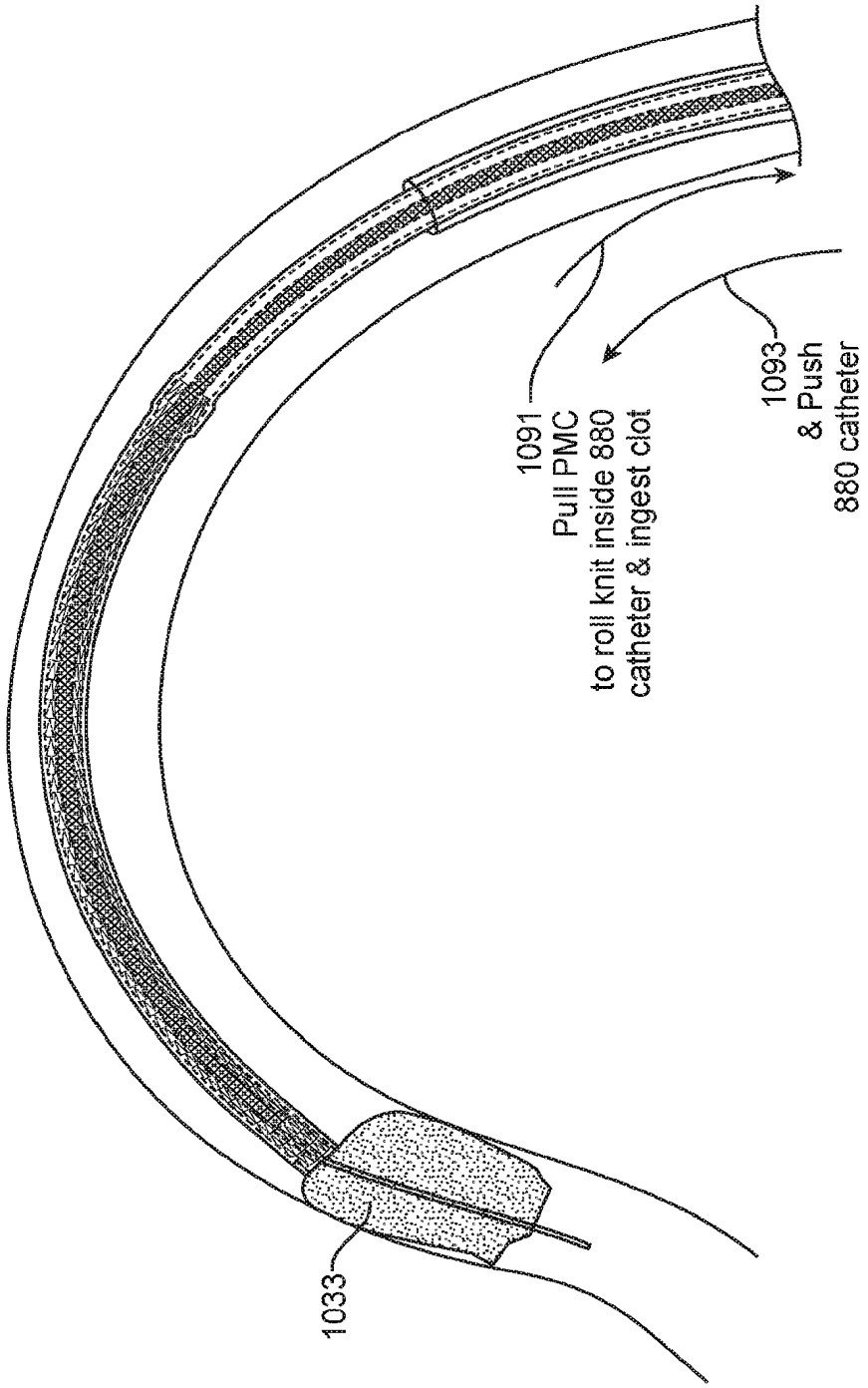

1091
Pull PMC
to roll knit inside 880
catheter & ingest clot
1093
& Push
880 catheter
1033

FIG. 10D

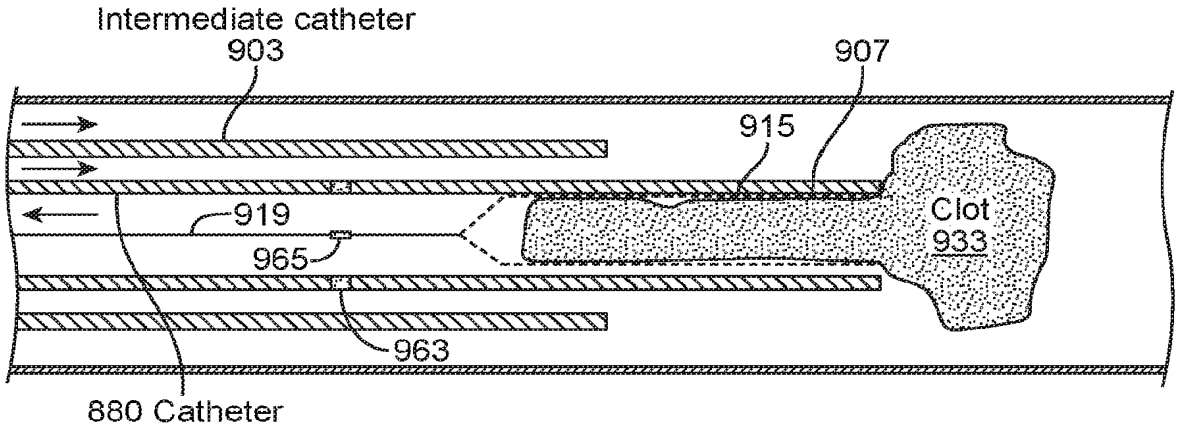


FIG. 11A

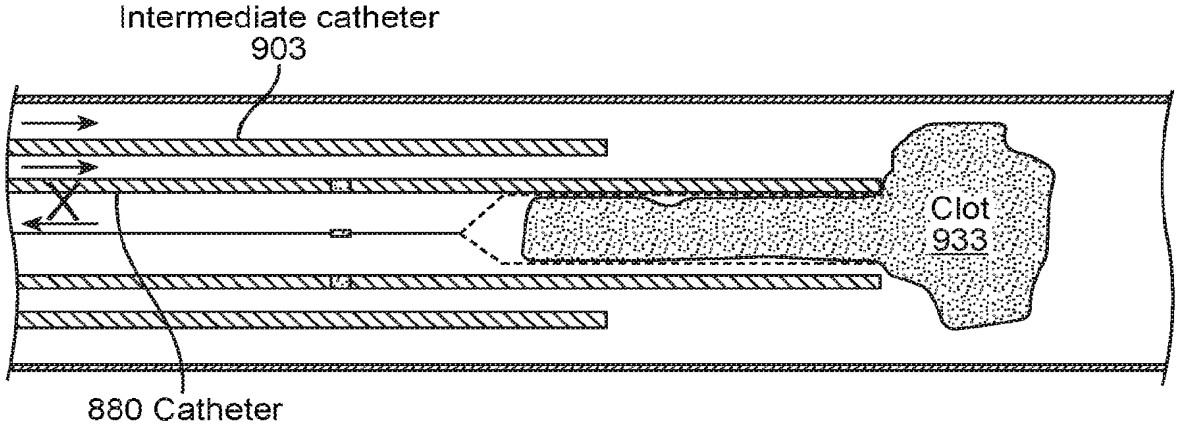


FIG. 11B

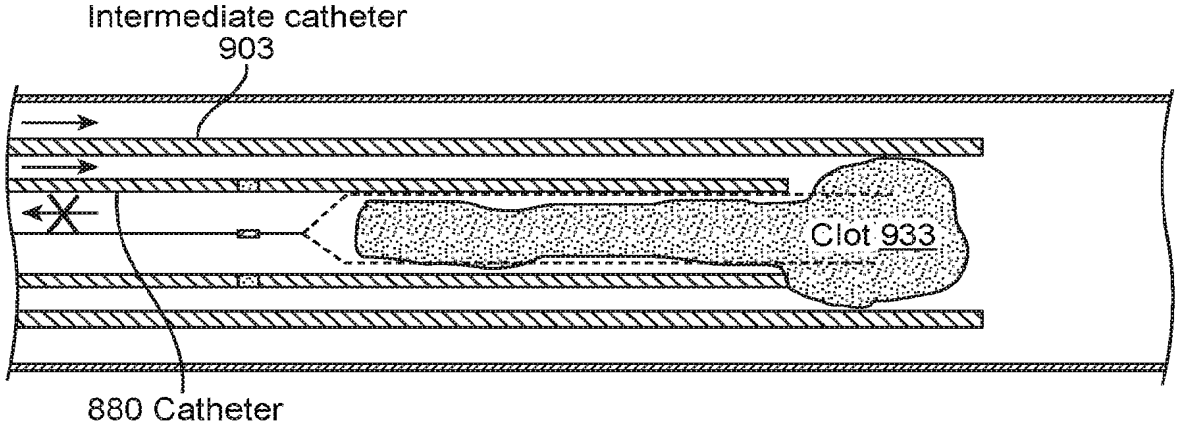


FIG. 11C

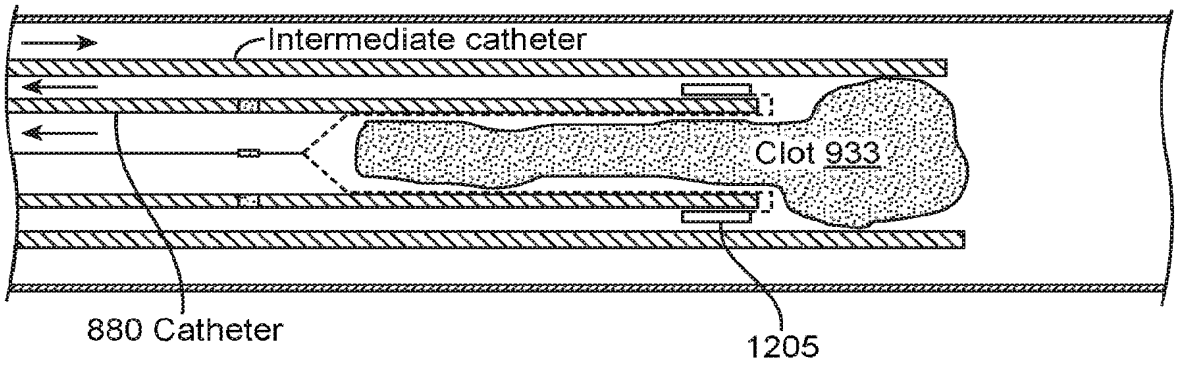


FIG. 12A

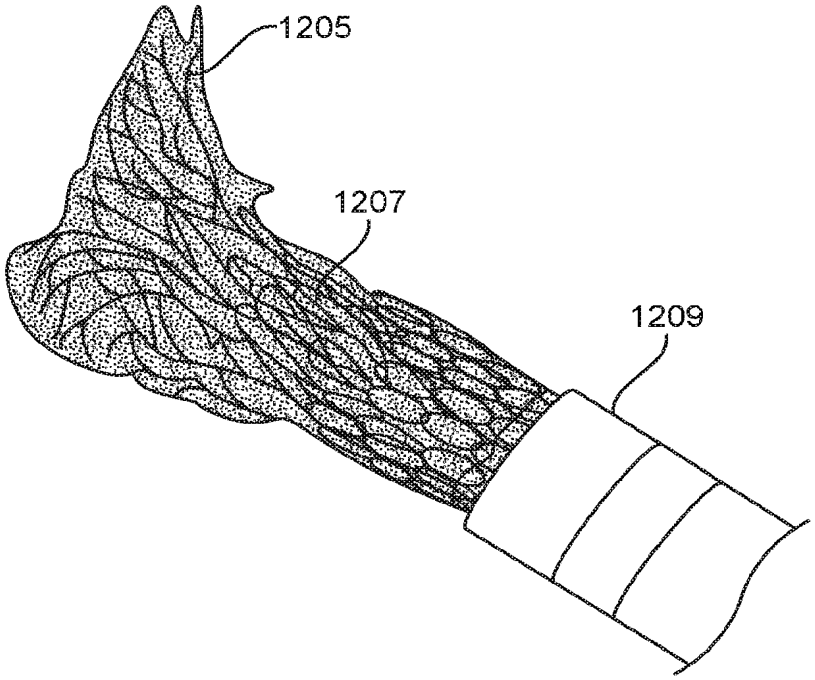


FIG. 12B

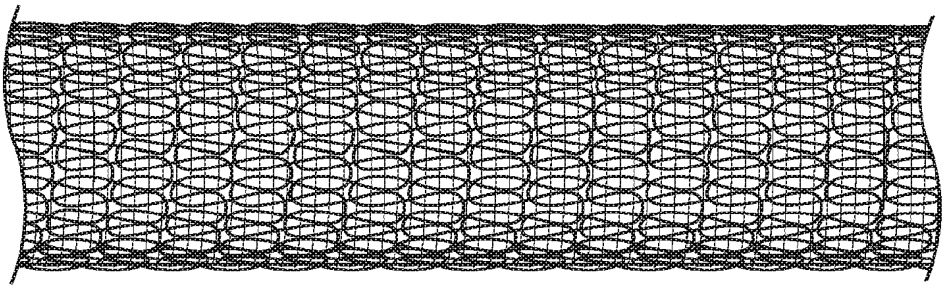


FIG. 13C

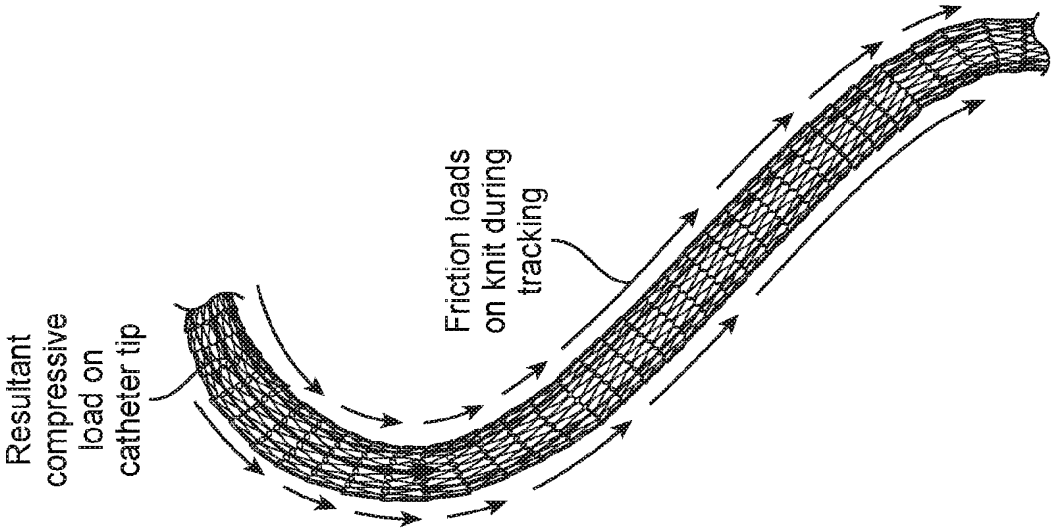


FIG. 13B

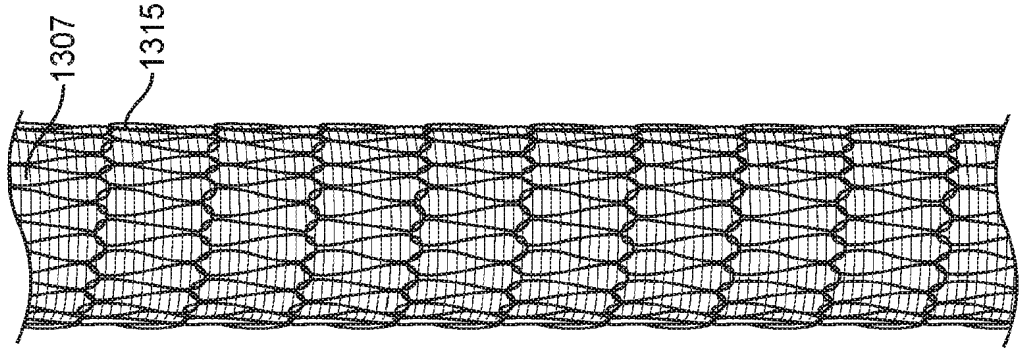
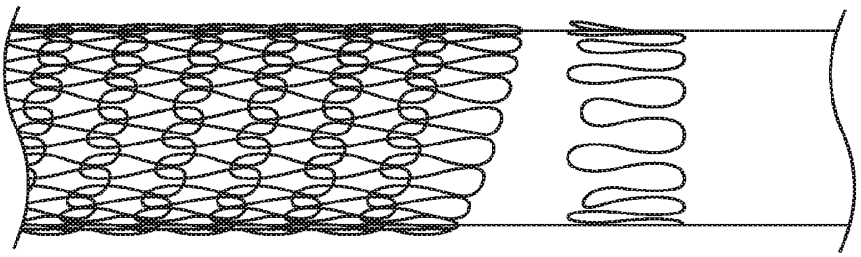
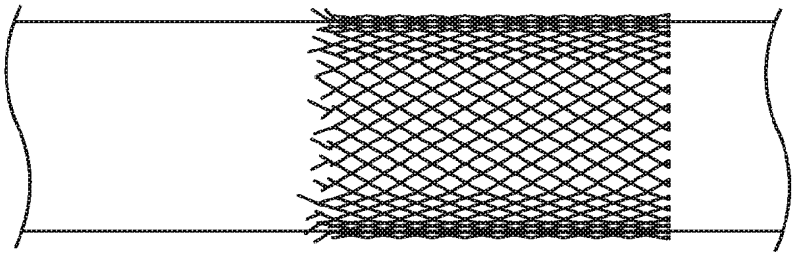


FIG. 13A



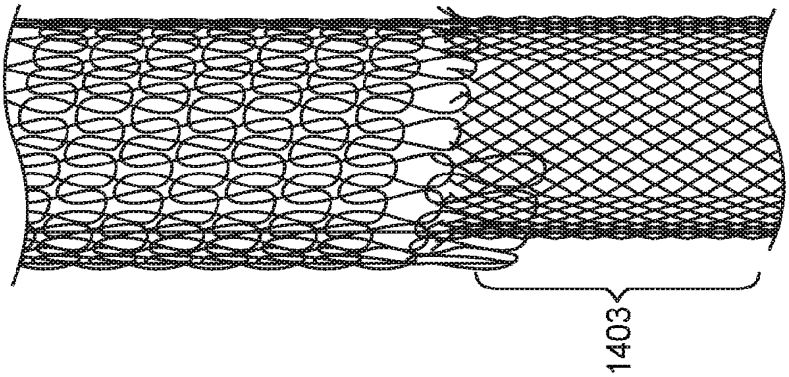
NiTi knit segment as a stop element

FIG. 14D



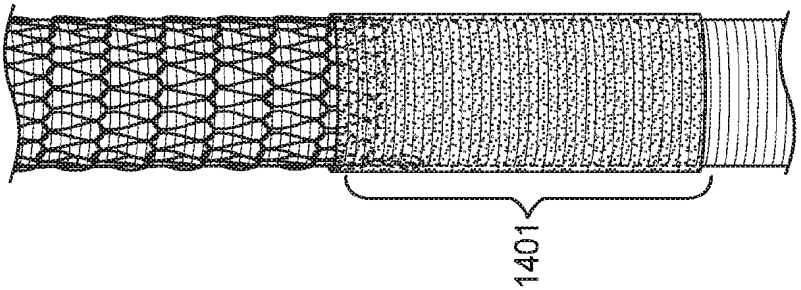
NiTi braid with exposed fingers

FIG. 14C



NiTi braid with exposed fingers

FIG. 14B



Polymer stop

FIG. 14A

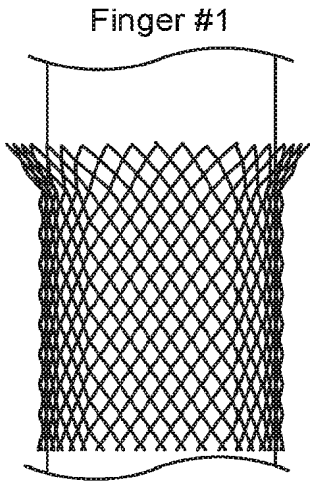


FIG. 15A

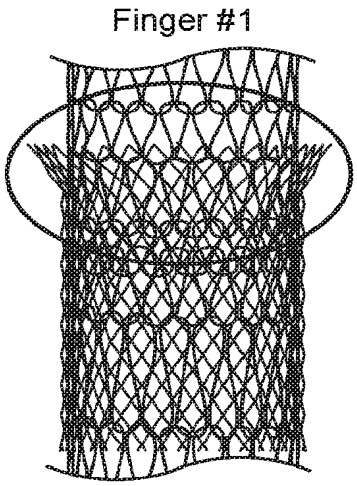


FIG. 15B

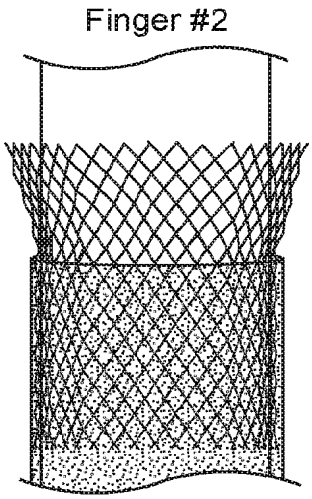


FIG. 15C

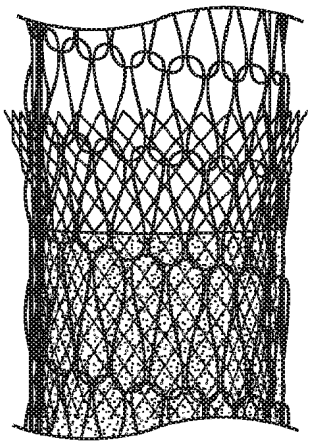


FIG. 15D

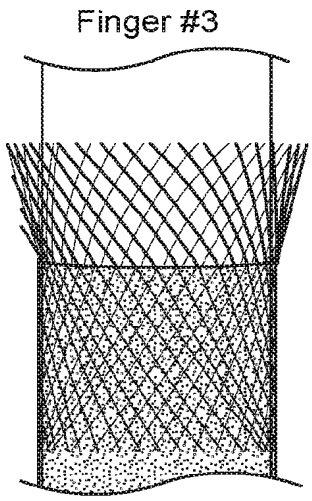


FIG. 15E

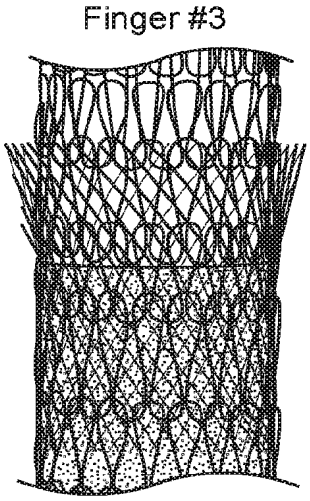


FIG. 15F

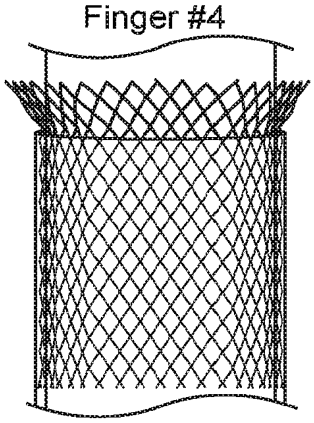


FIG. 15G

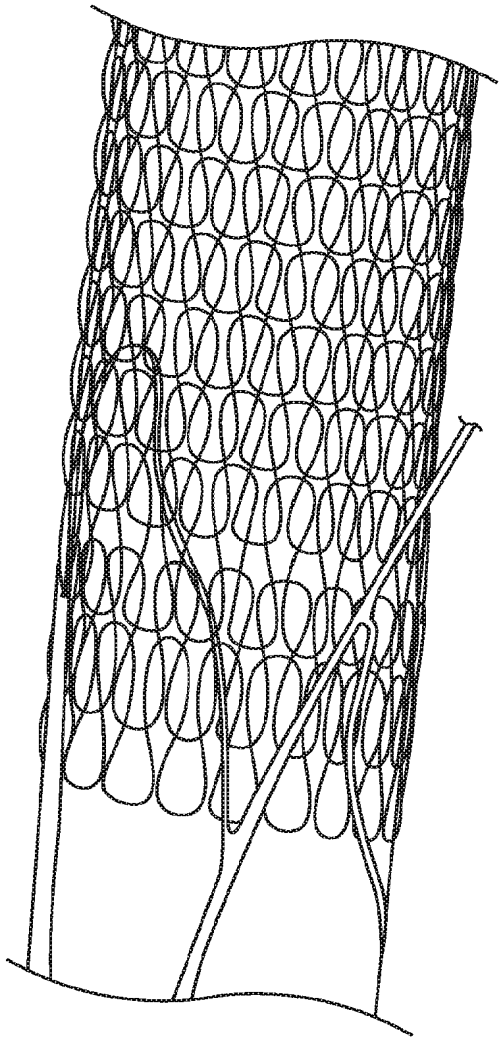


FIG. 15H

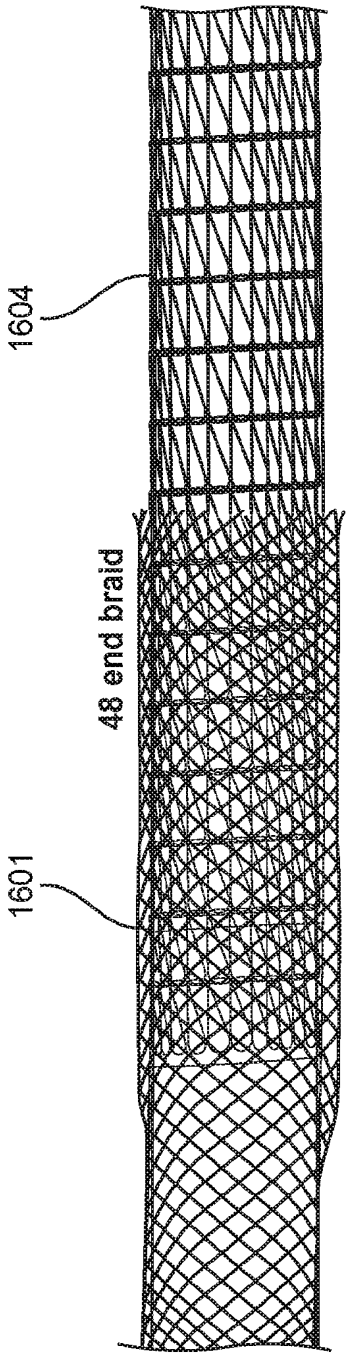


FIG. 16A

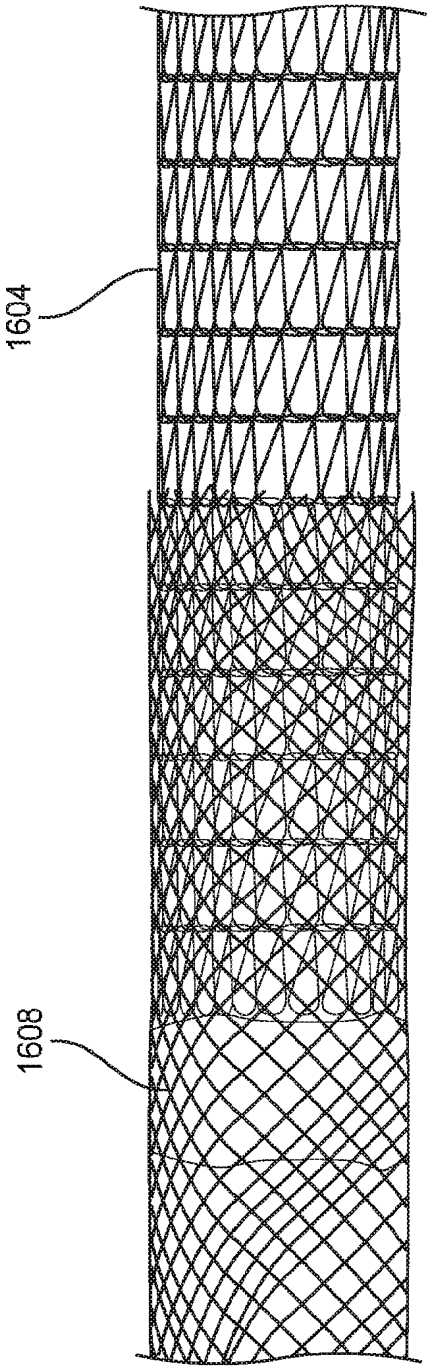


FIG. 16B

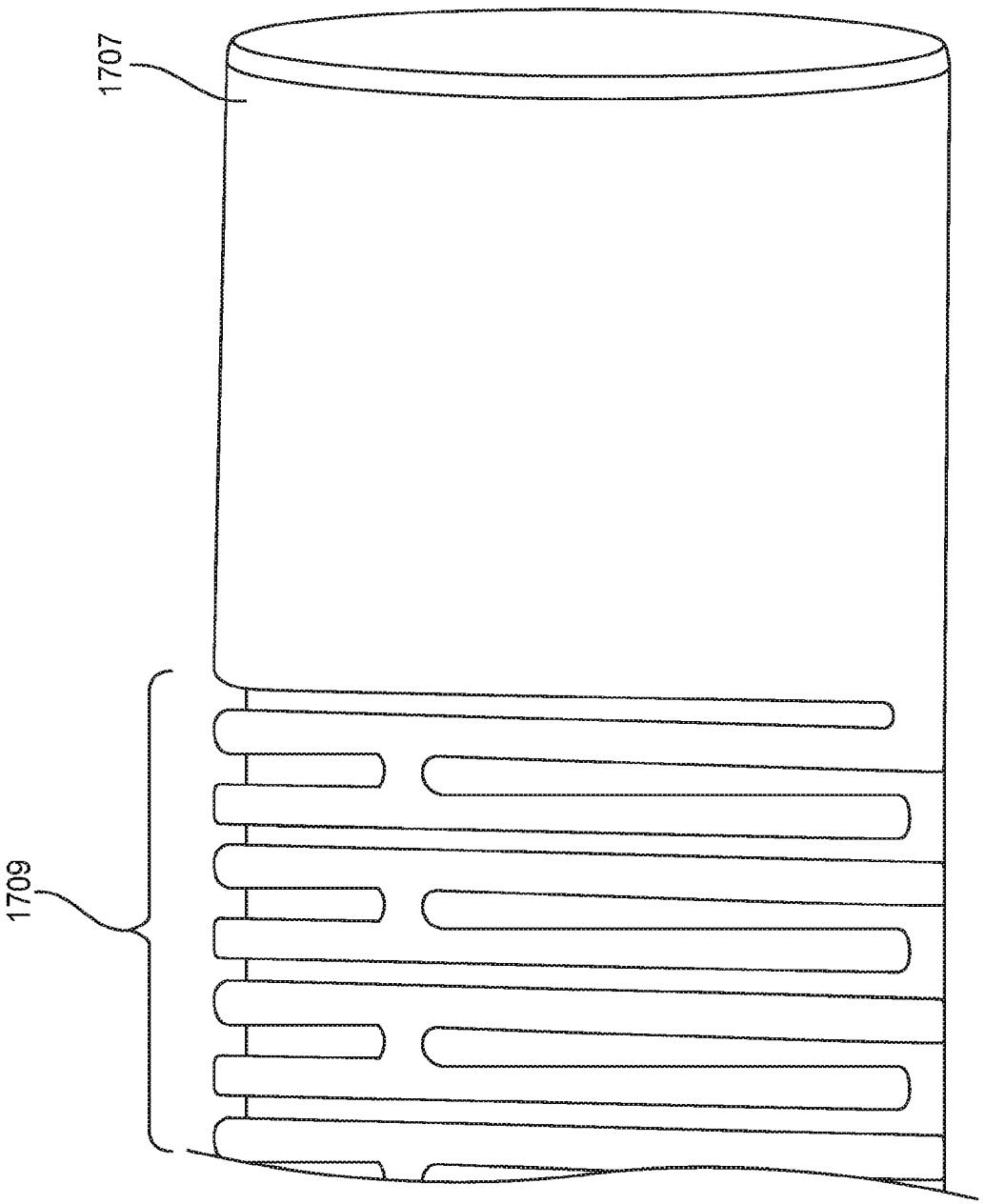


FIG. 17

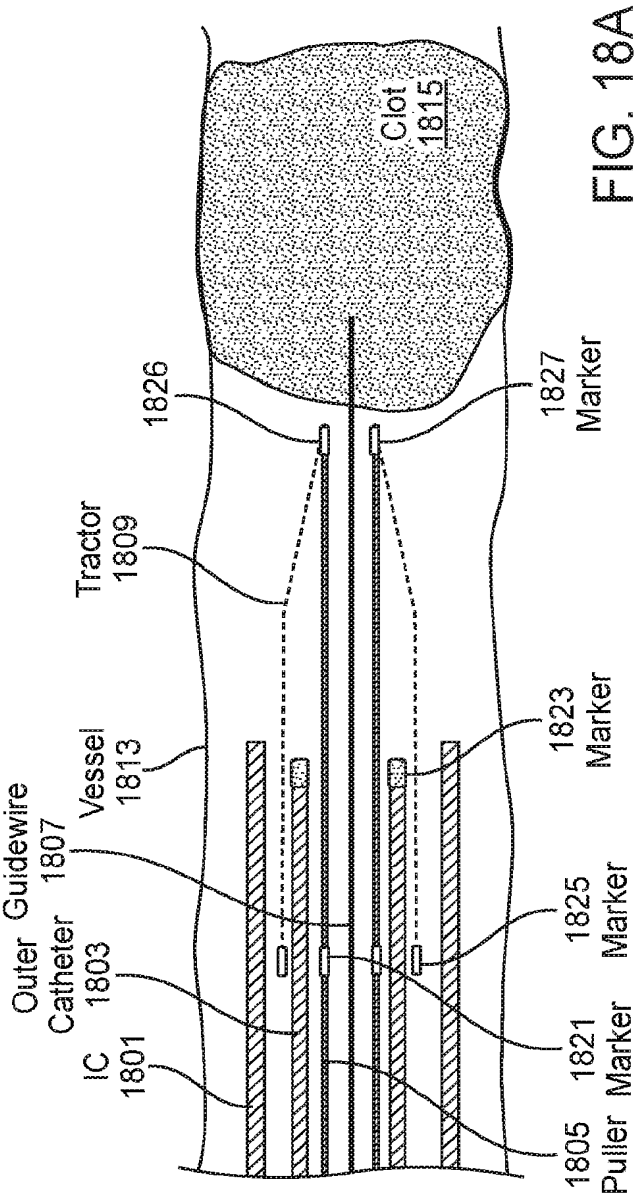


FIG. 18A

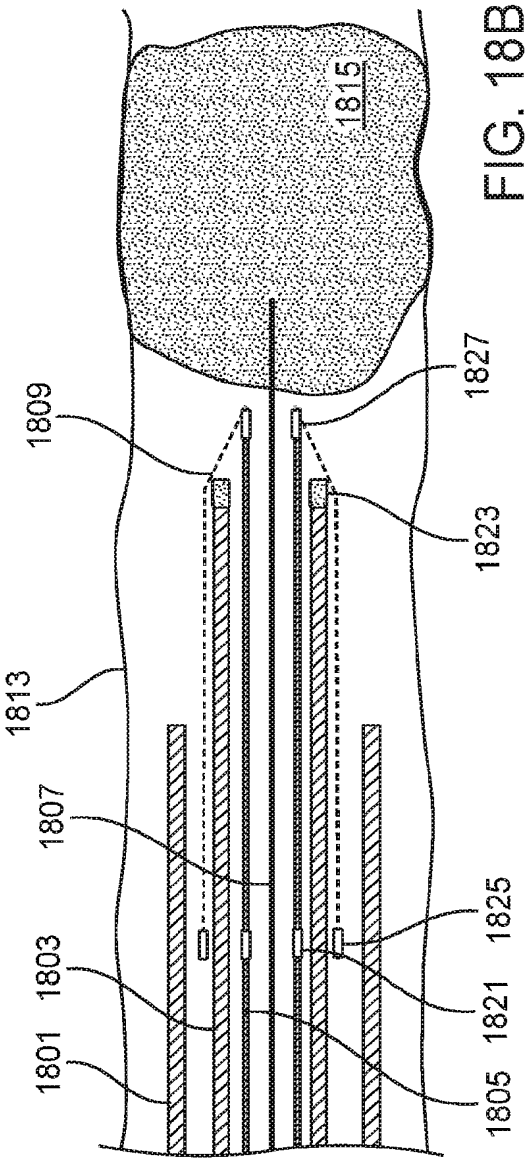


FIG. 18B

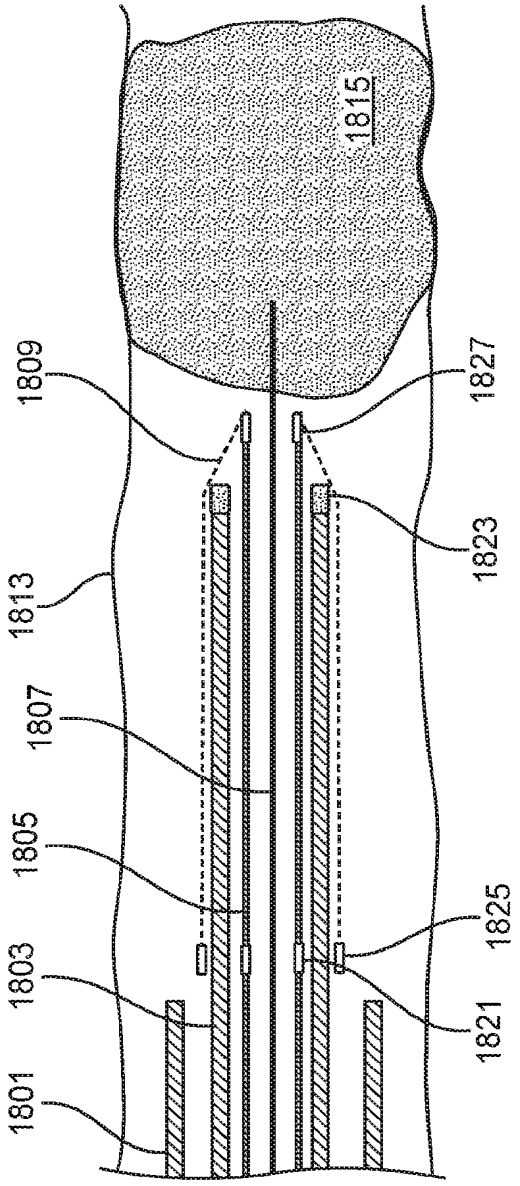


FIG. 18C

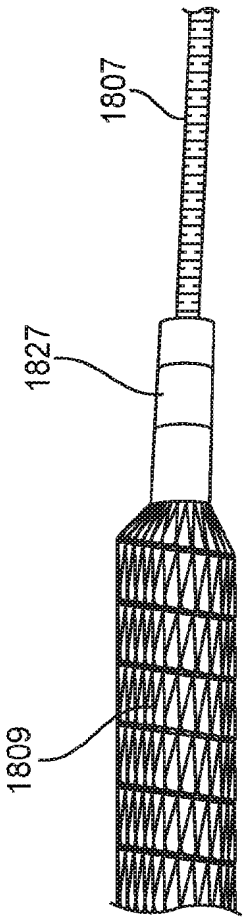


FIG. 18C1

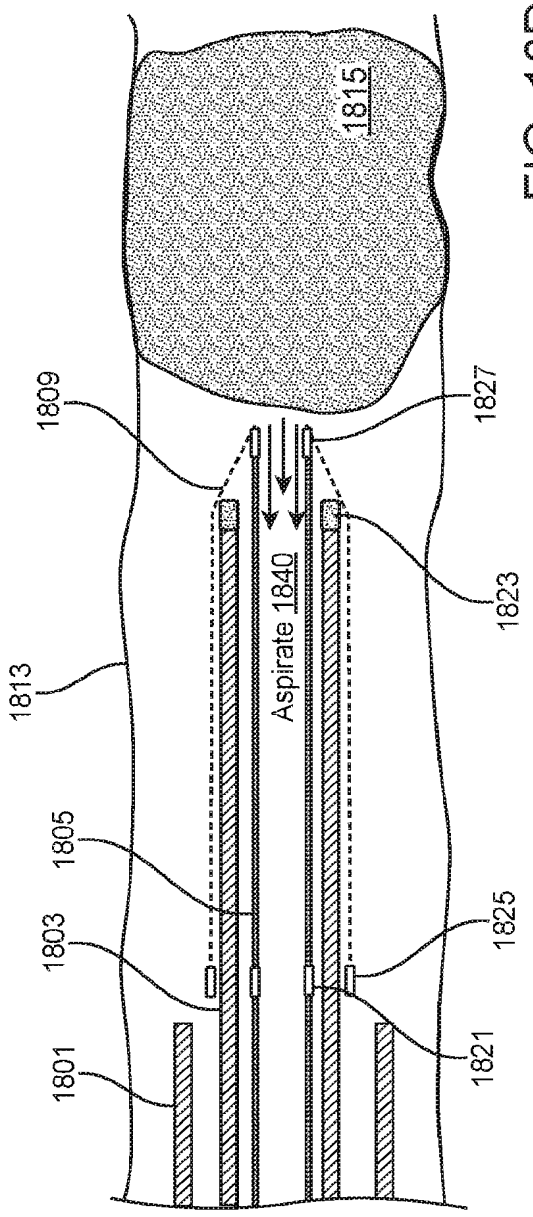


FIG. 18D

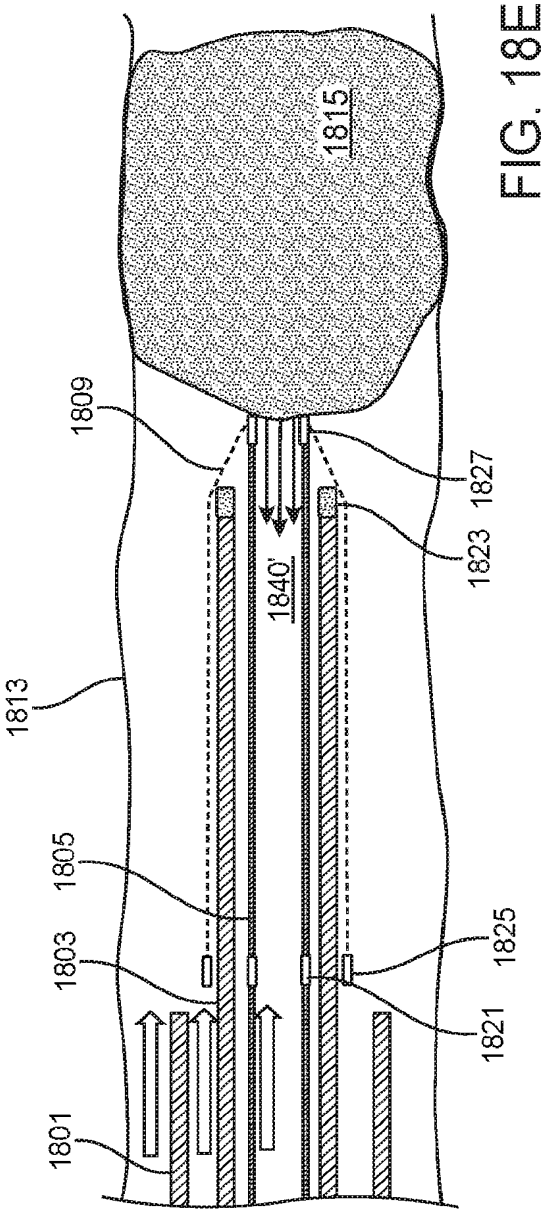


FIG. 18E

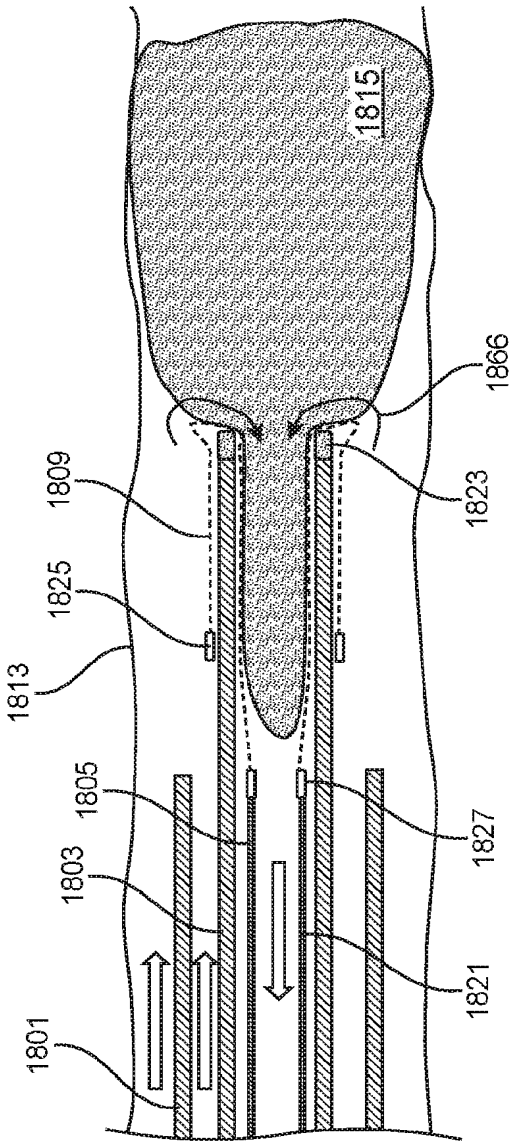


FIG. 18F

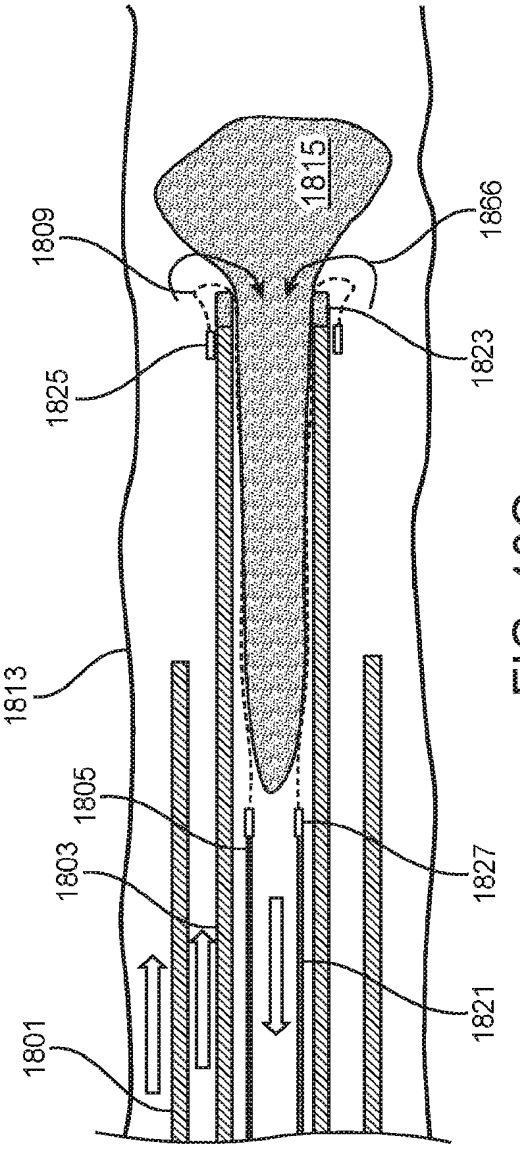


FIG. 18G

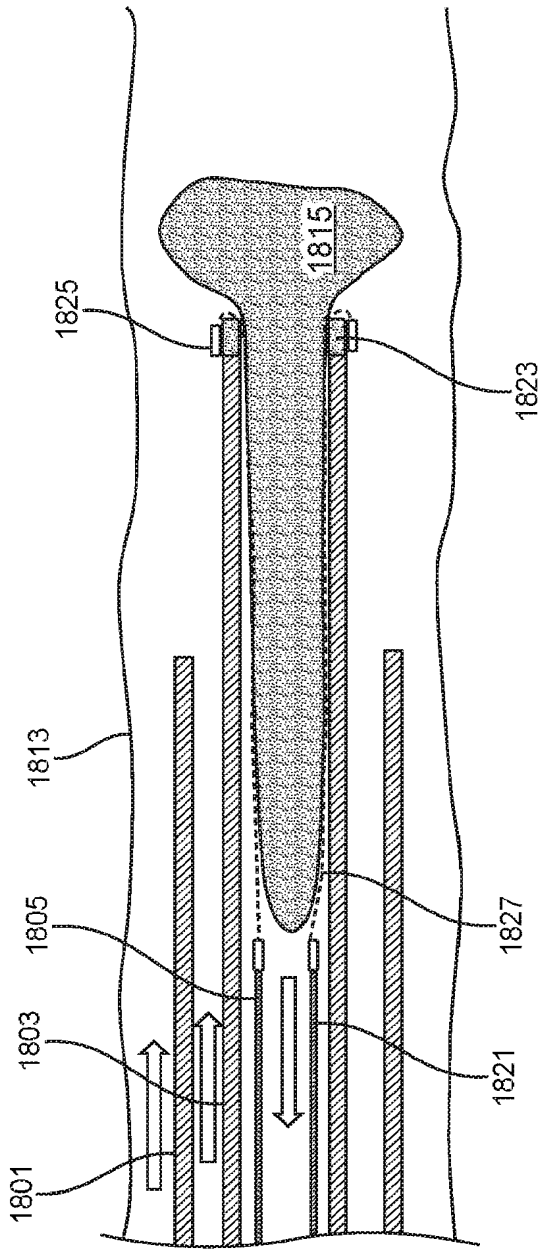


FIG. 18H

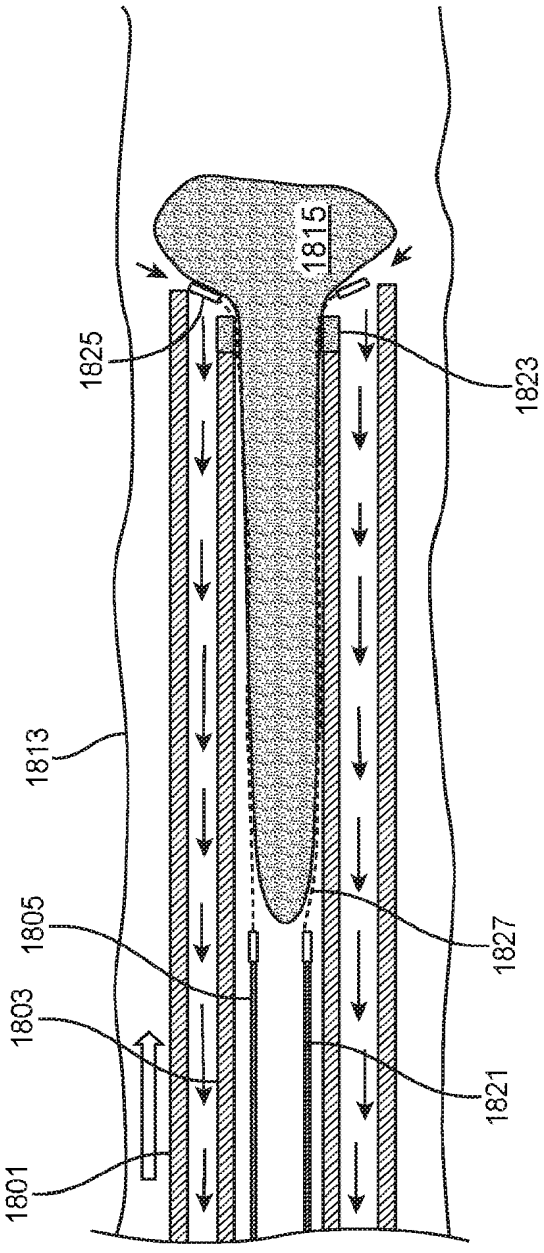


FIG. 18I

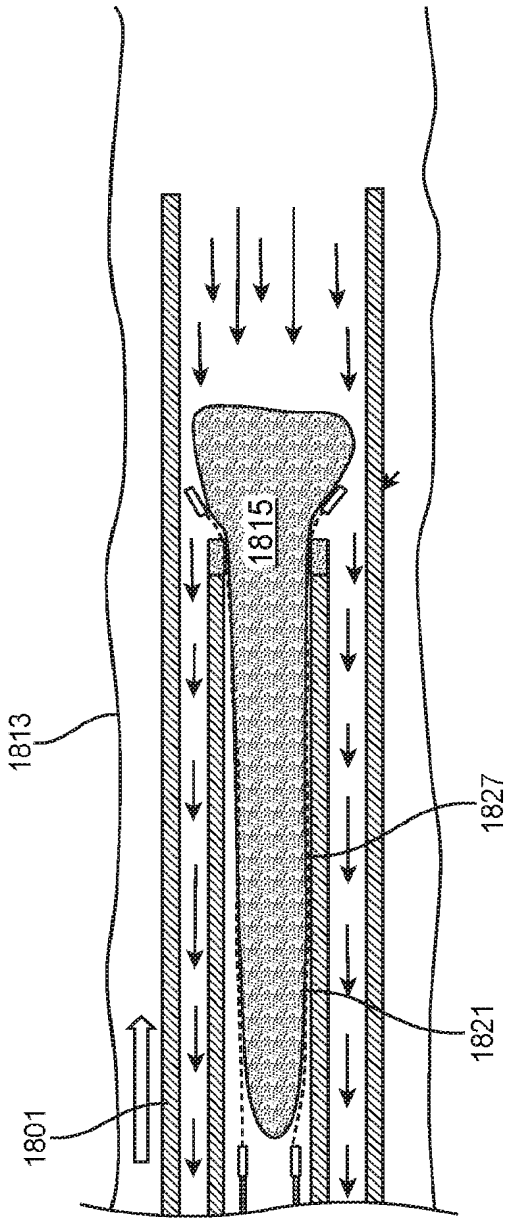


FIG. 18J

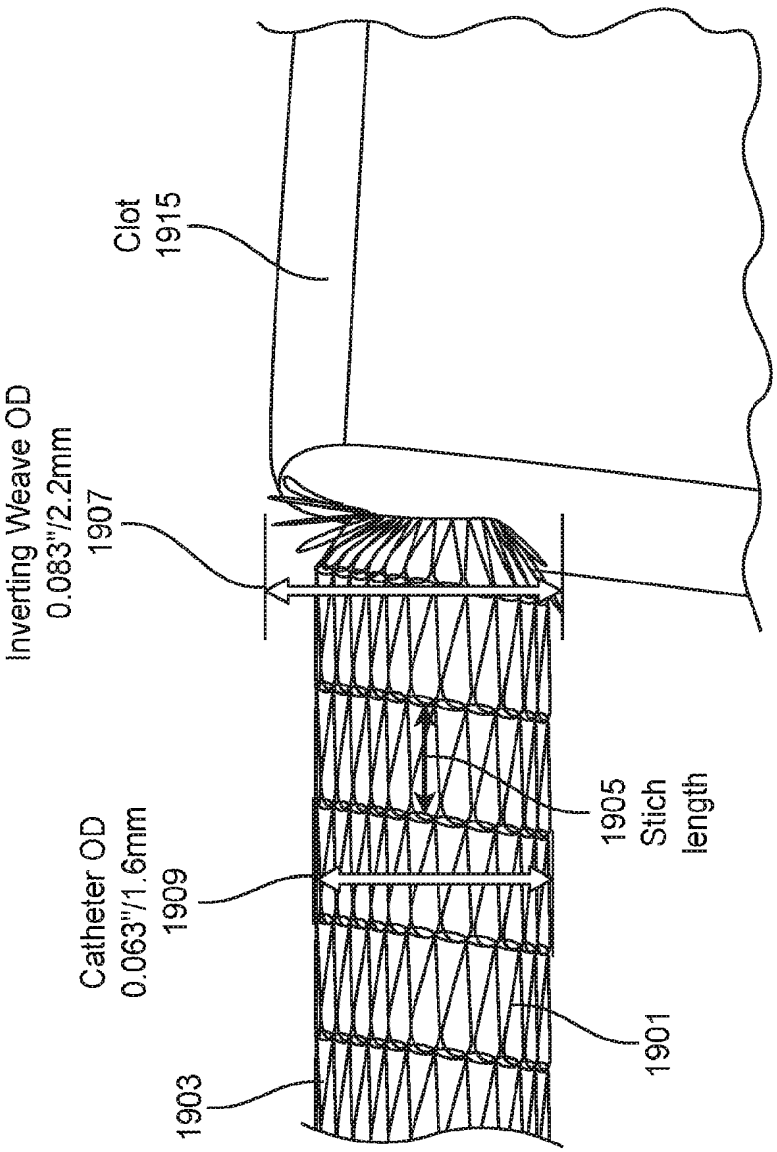

Clot
1915
Inverting Weave OD
0.083"/2.2mm
1907
Catheter OD
0.063"/1.6mm
1909
1905
Stich
length
1901
1903

FIG. 19

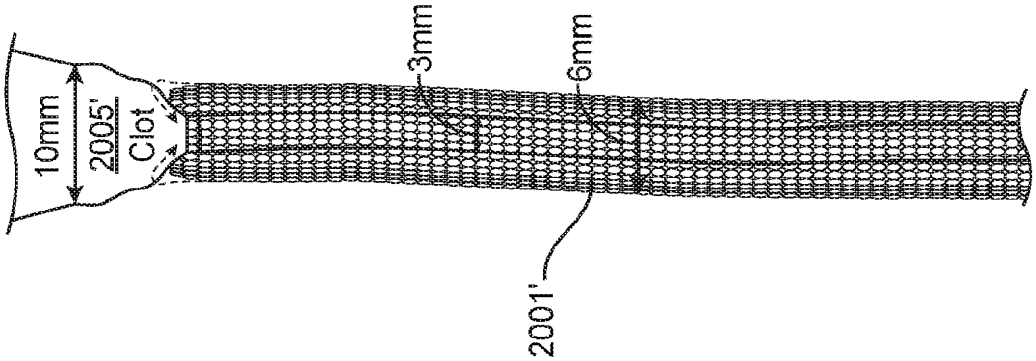


FIG. 20B

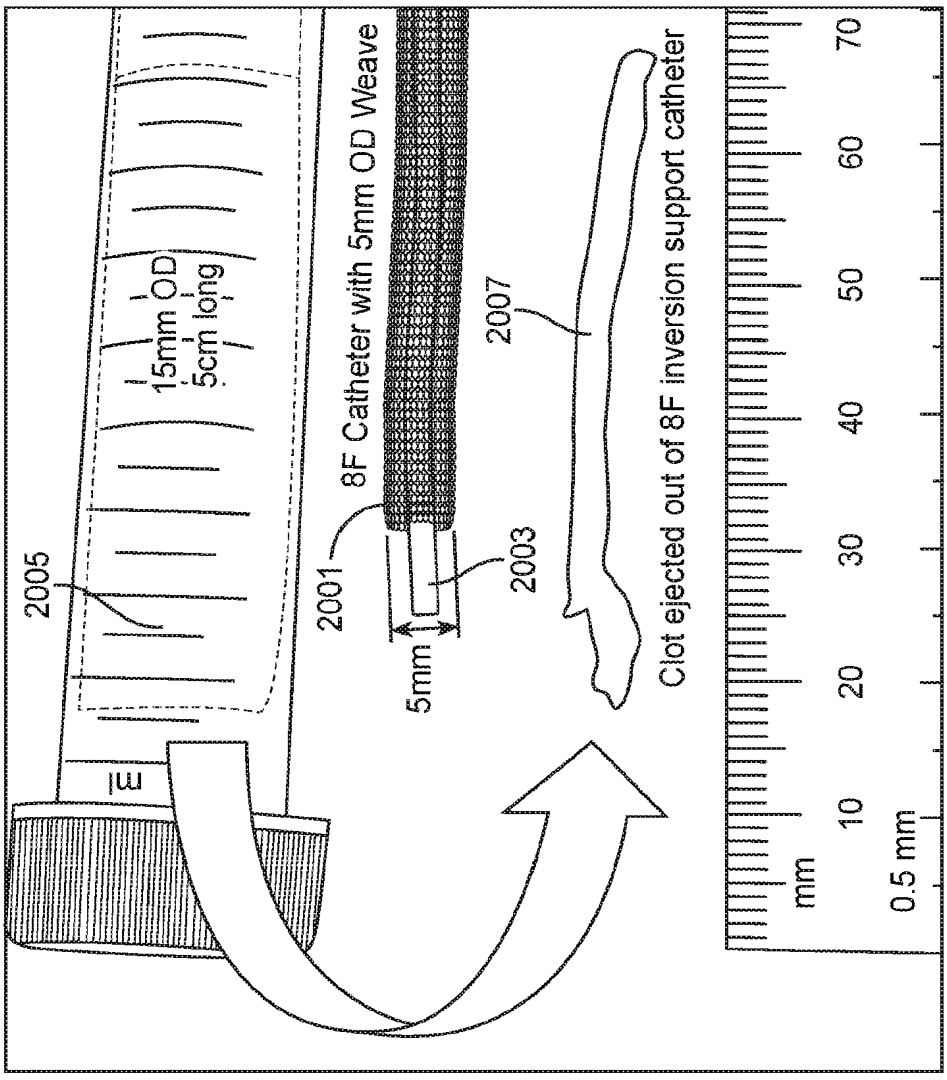


FIG. 20A

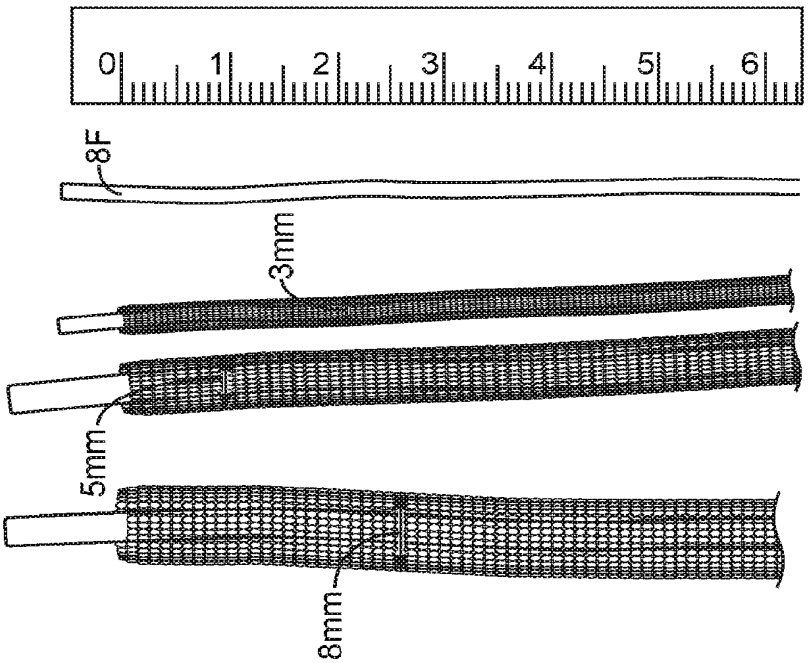


FIG. 21B

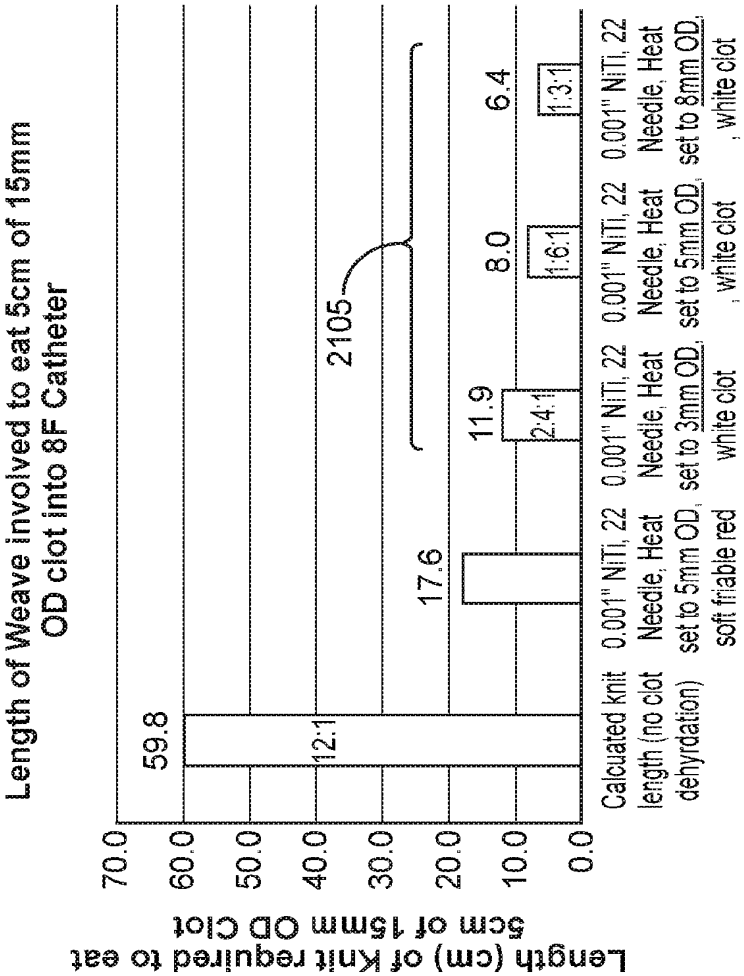


FIG. 21A

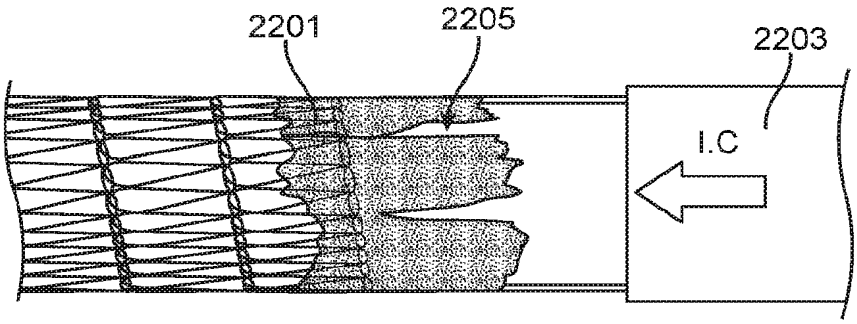


FIG. 22A

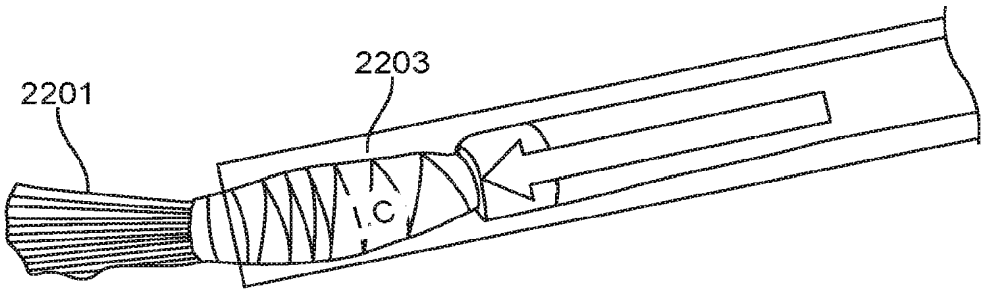


FIG. 22B

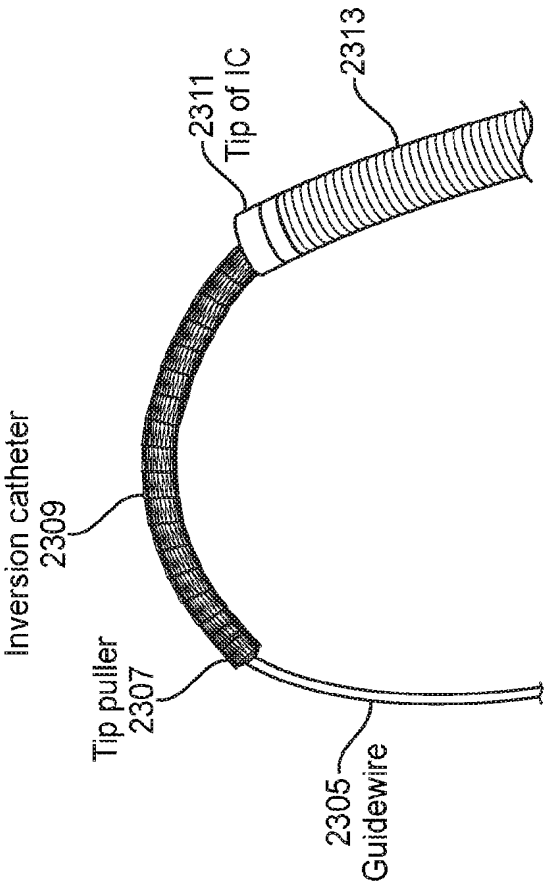


FIG. 23A

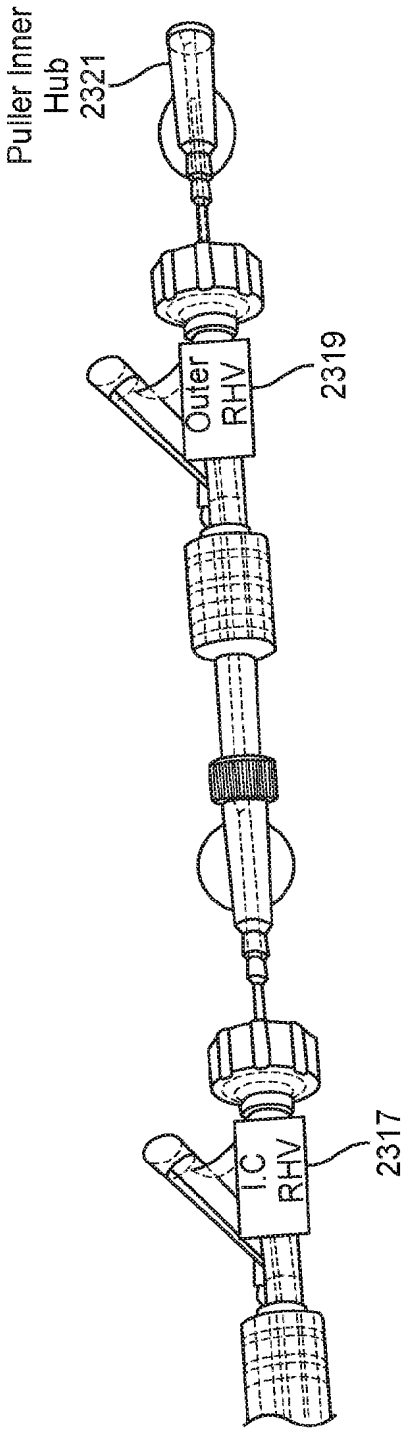


FIG. 23B

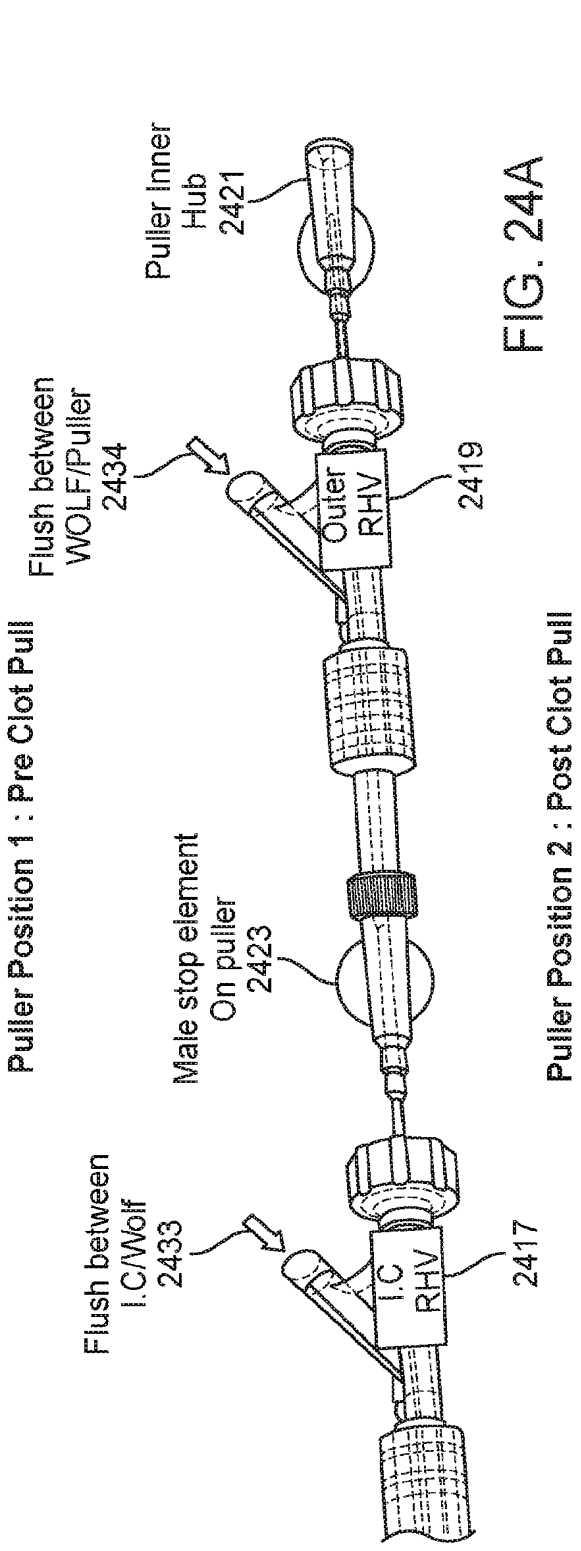


FIG. 24A

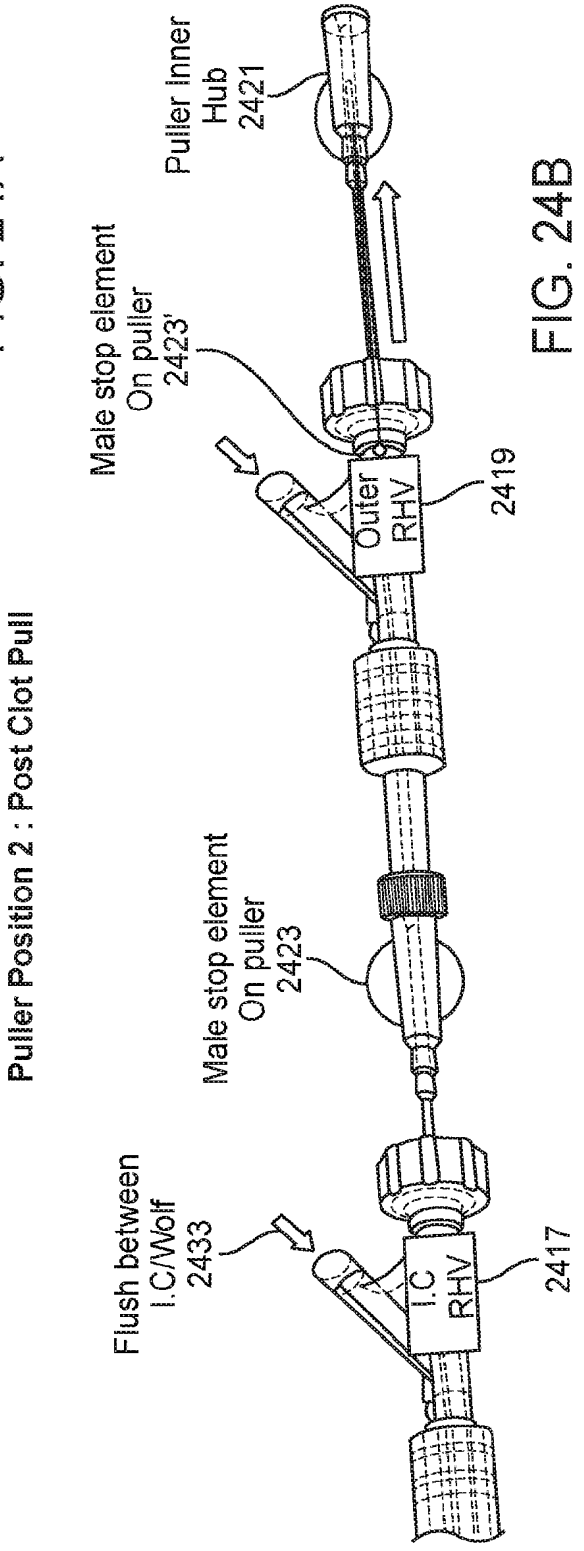


FIG. 24B

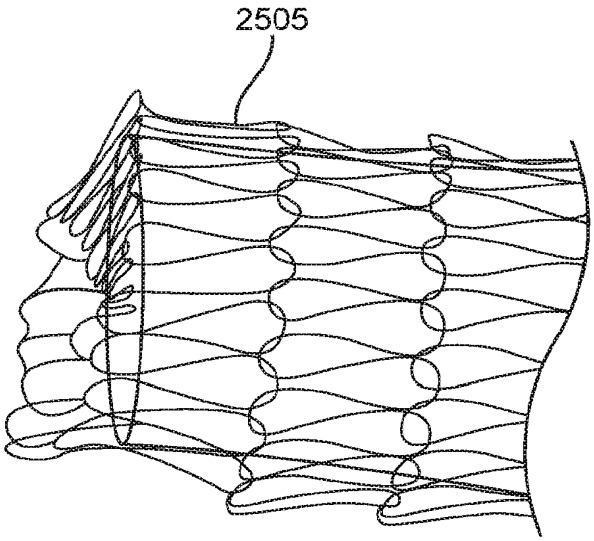


FIG. 25

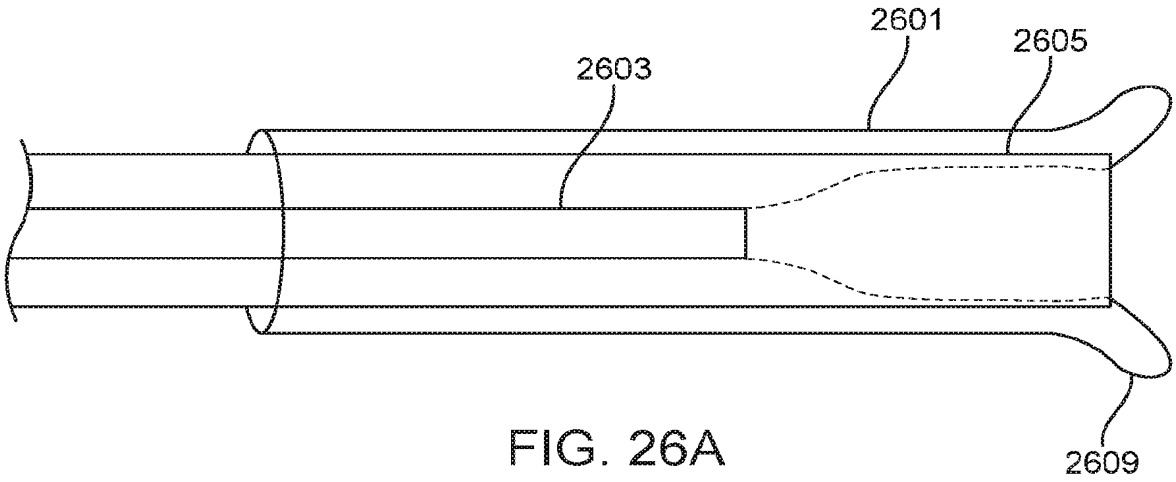


FIG. 26A

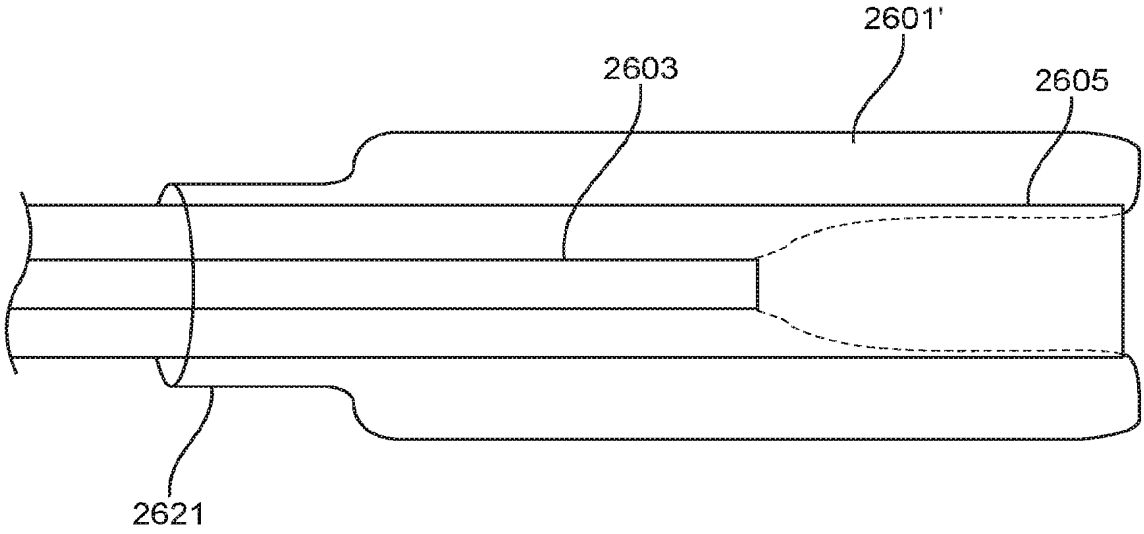


FIG. 26B

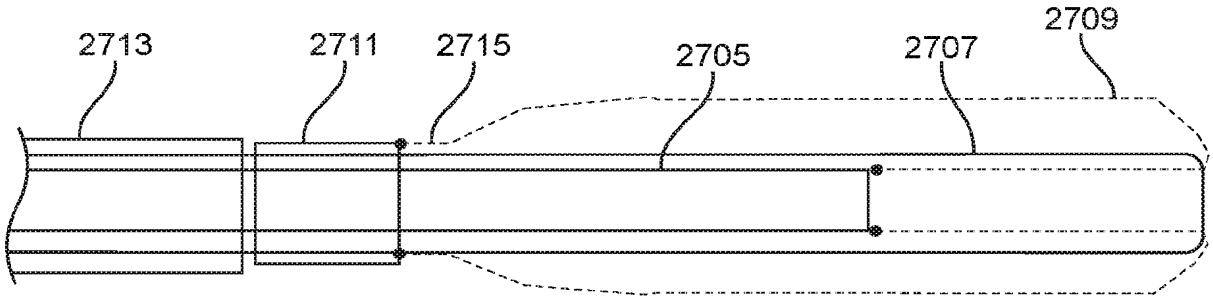


FIG. 27A

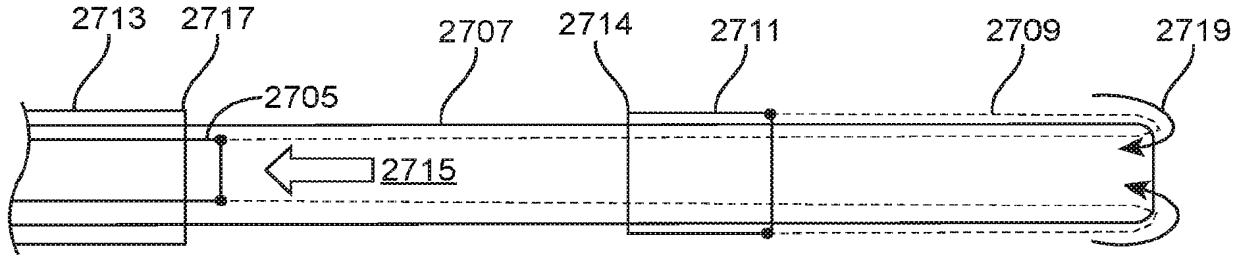


FIG. 27B

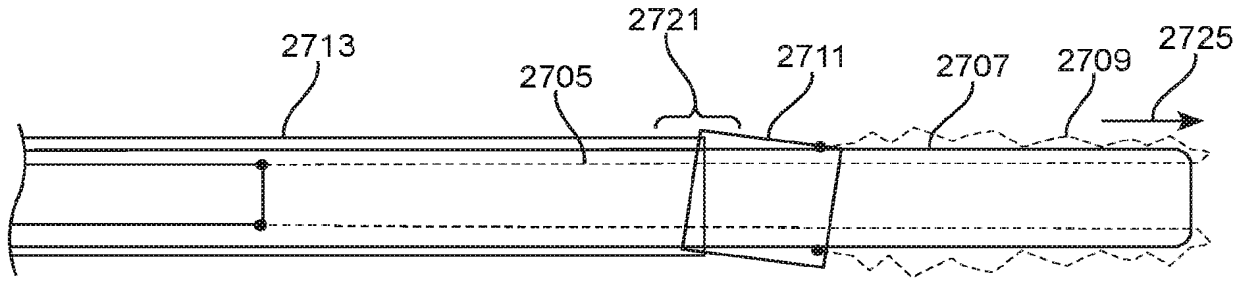


FIG. 27C

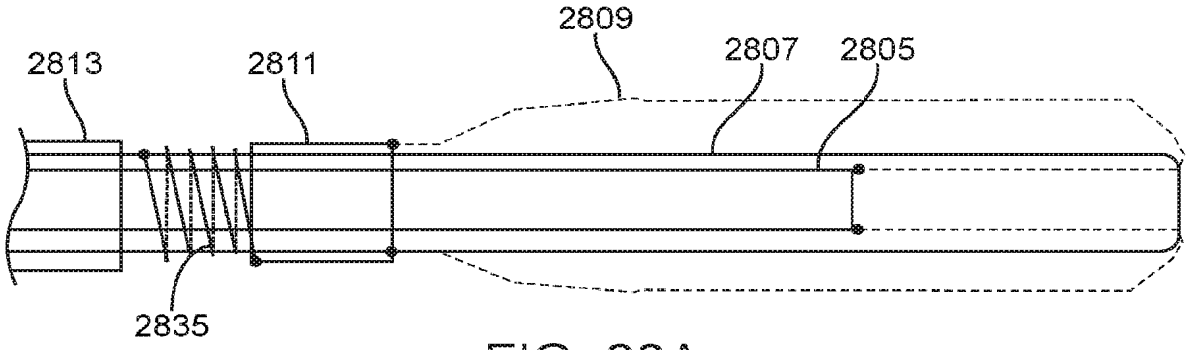


FIG. 28A

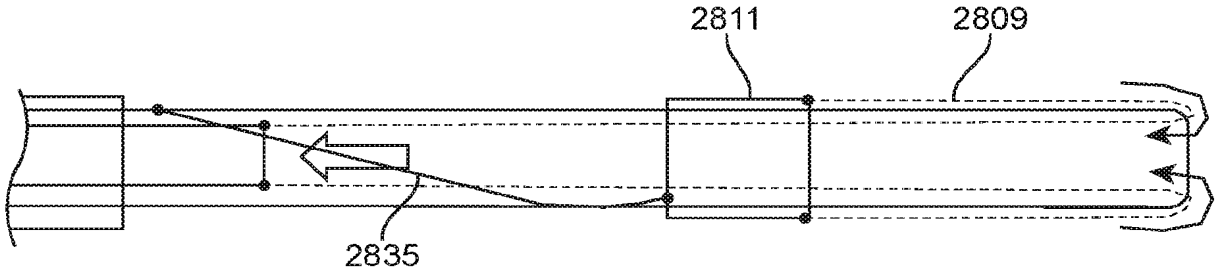


FIG. 28B

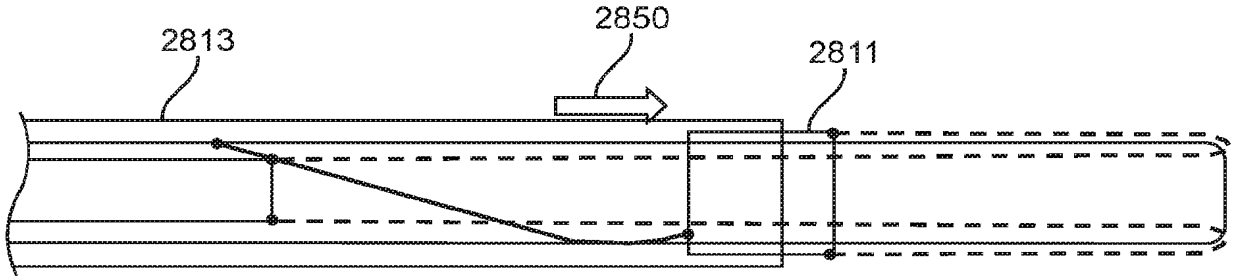


FIG. 28C

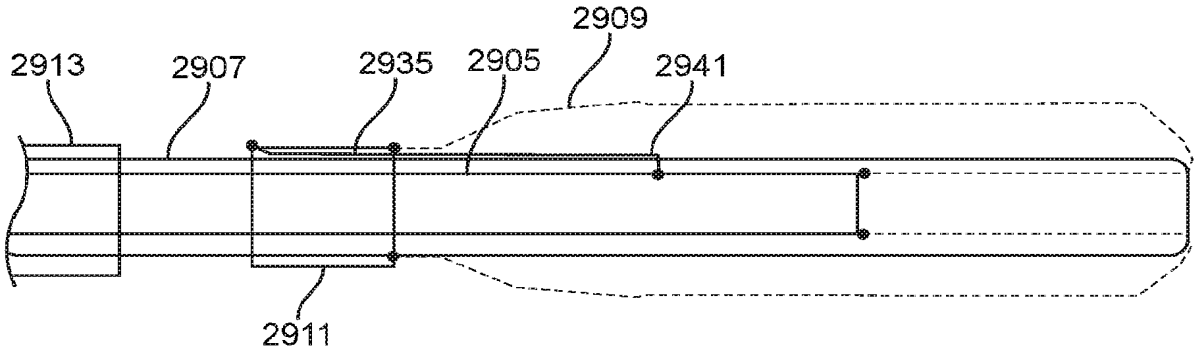


FIG. 29A

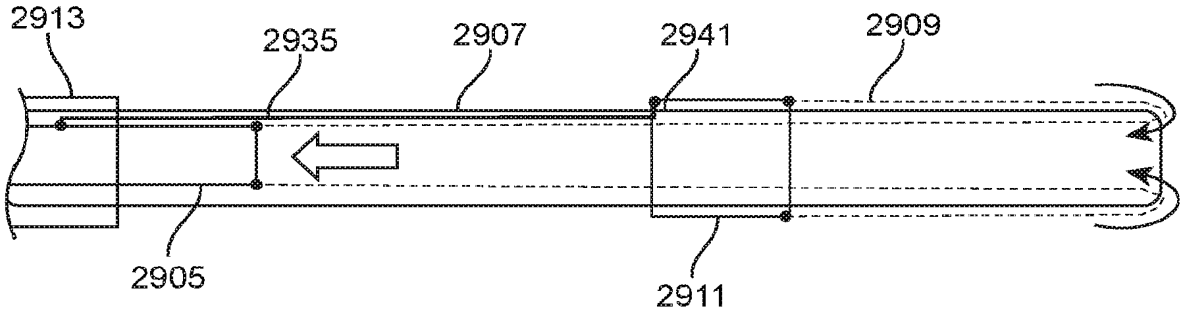


FIG. 29B

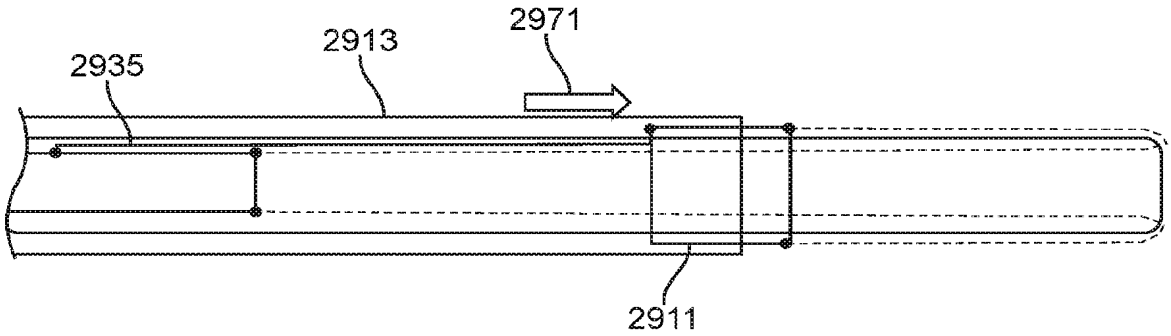


FIG. 29C

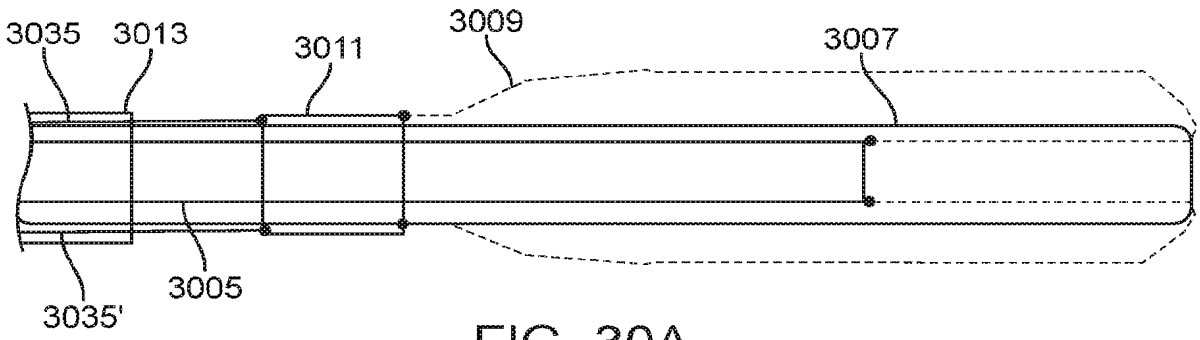


FIG. 30A

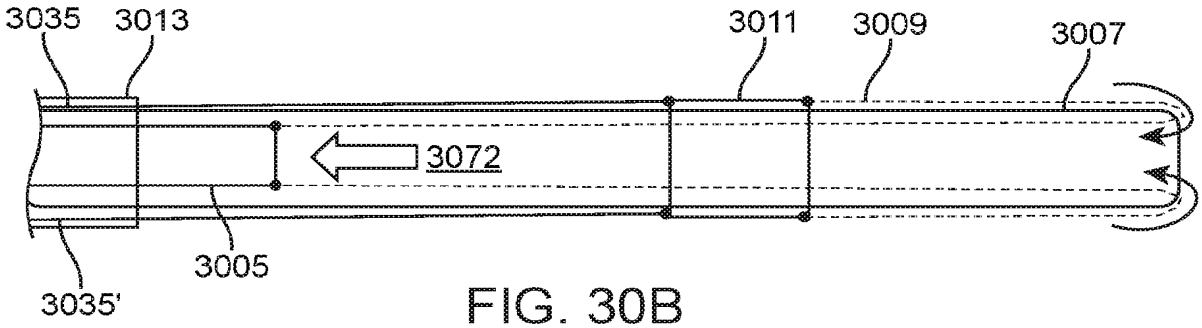


FIG. 30B

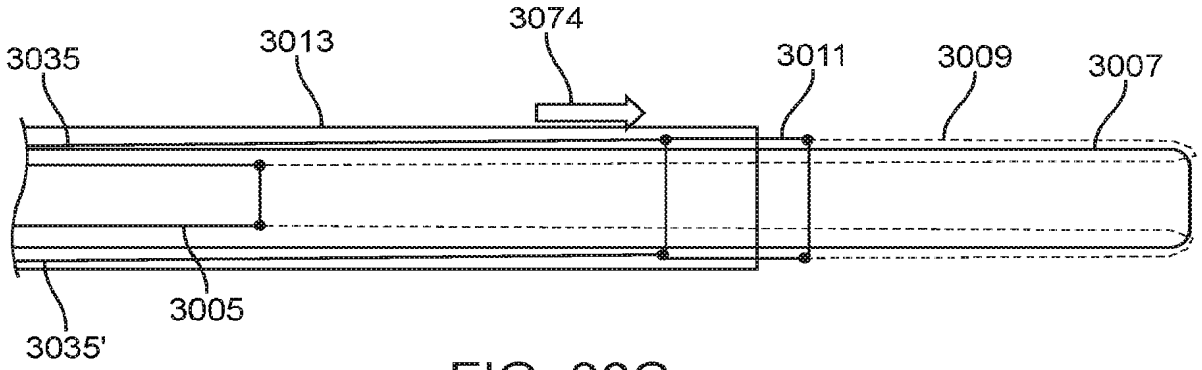


FIG. 30C

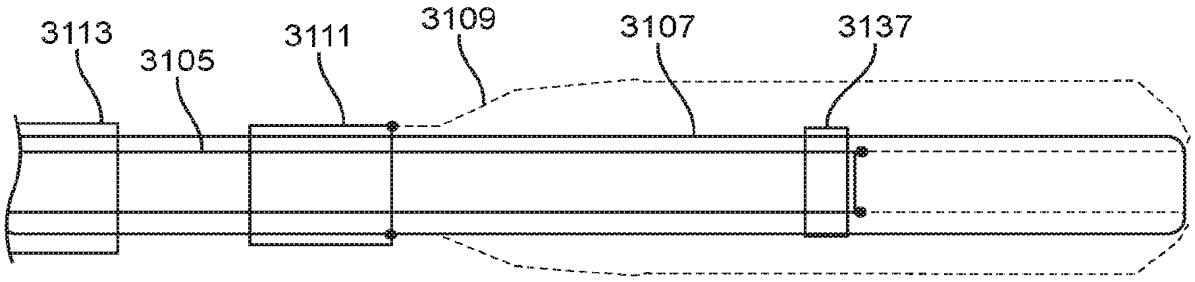


FIG. 31A

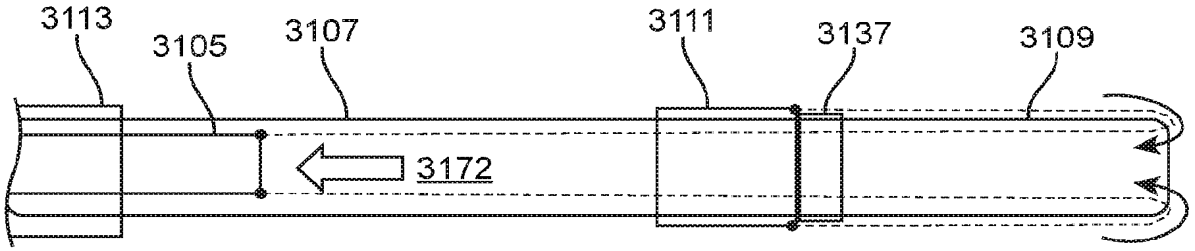


FIG. 31B

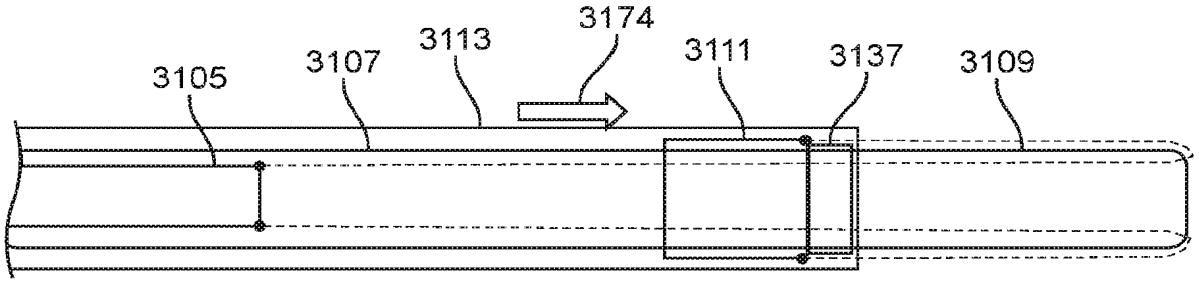


FIG. 31C

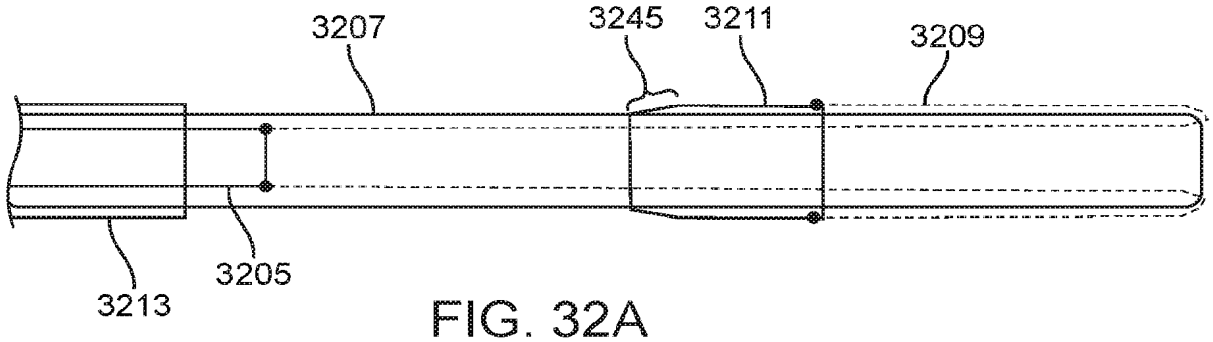


FIG. 32A

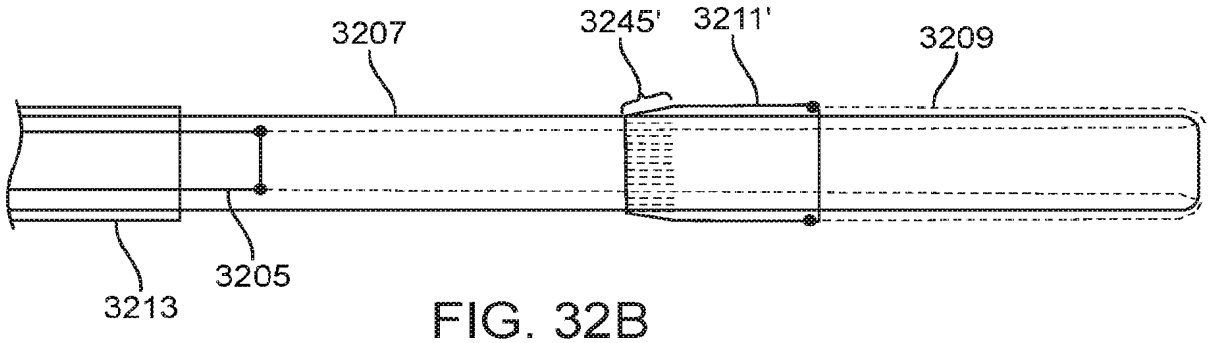


FIG. 32B

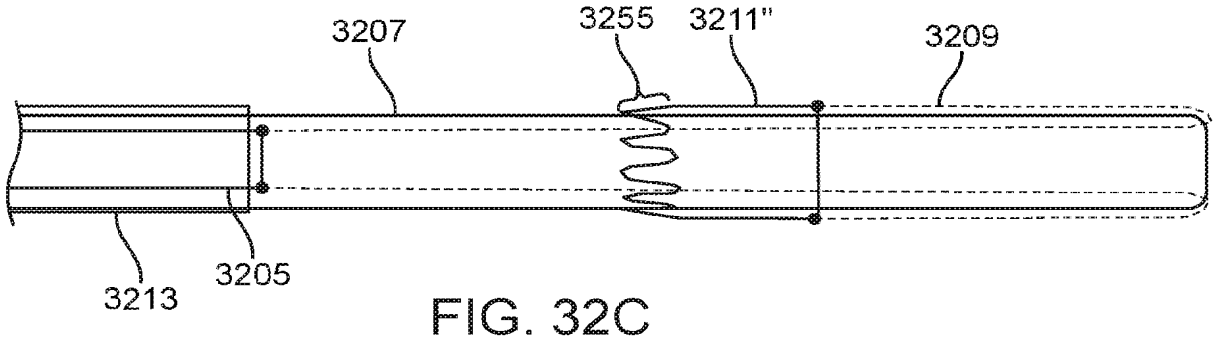


FIG. 32C

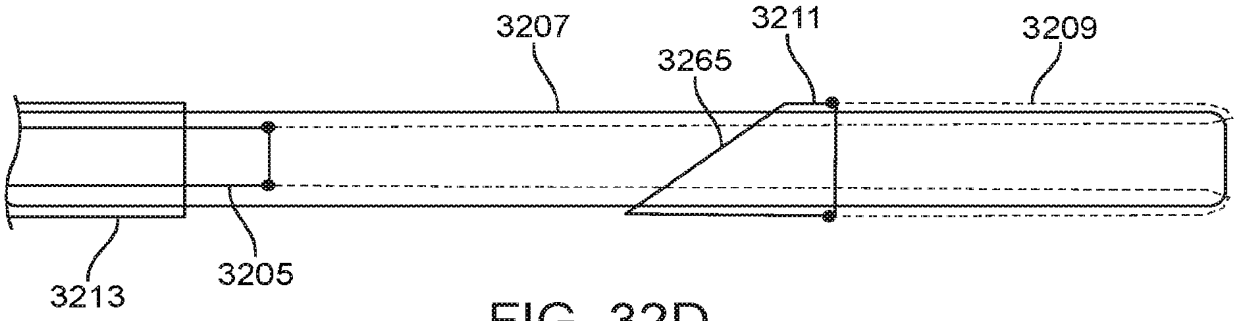


FIG. 32D

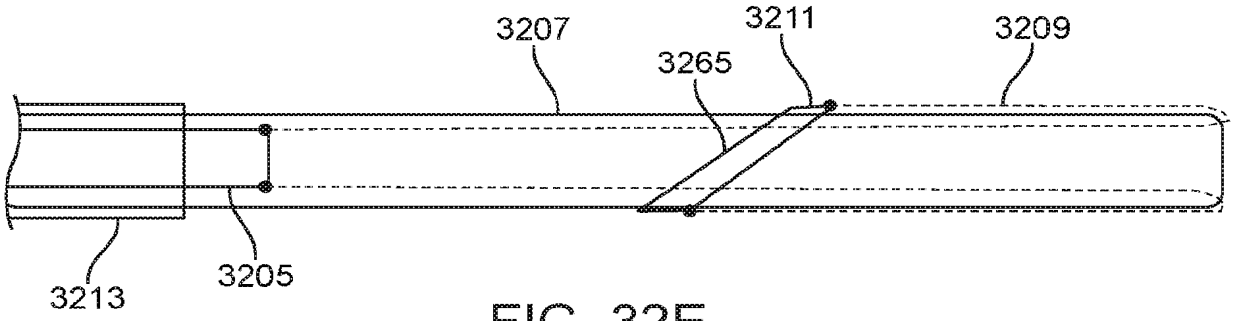


FIG. 32E

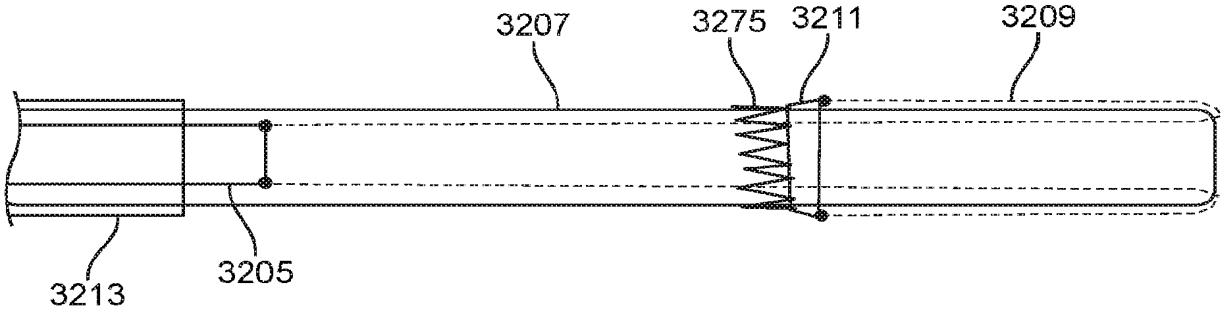


FIG. 32F

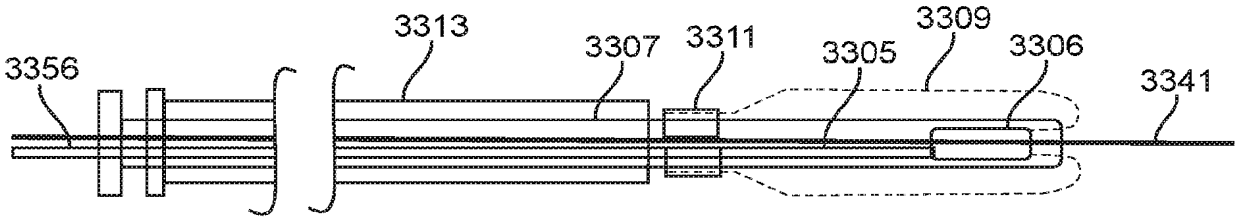


FIG. 33A

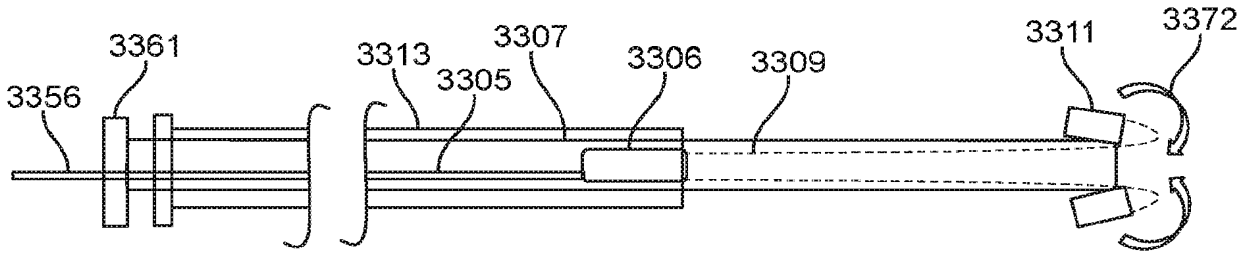


FIG. 33B

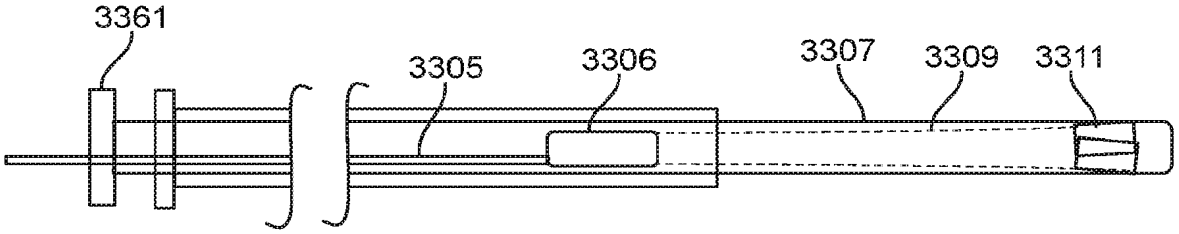


FIG. 33C

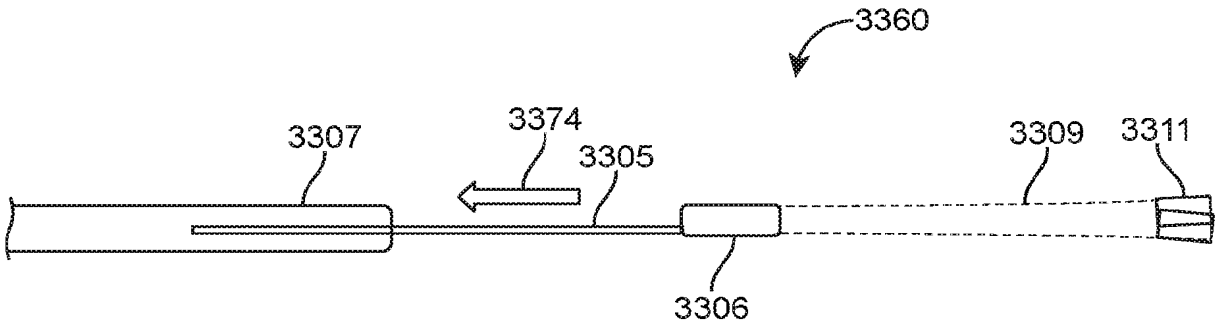


FIG. 33D

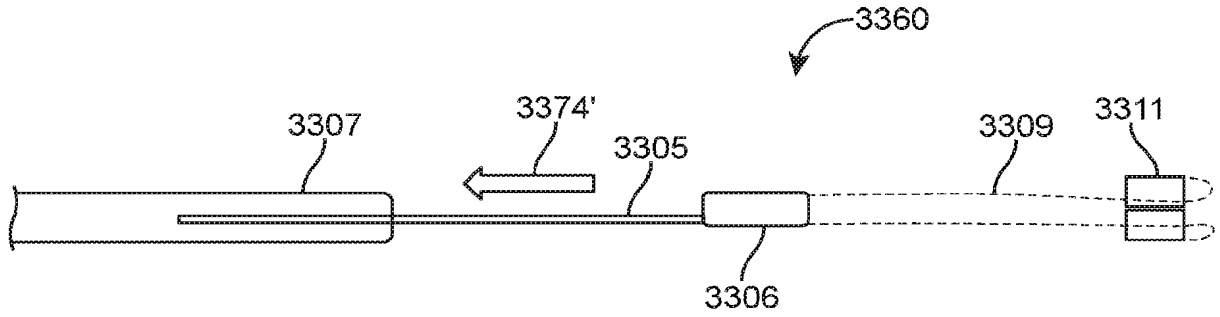


FIG. 33E

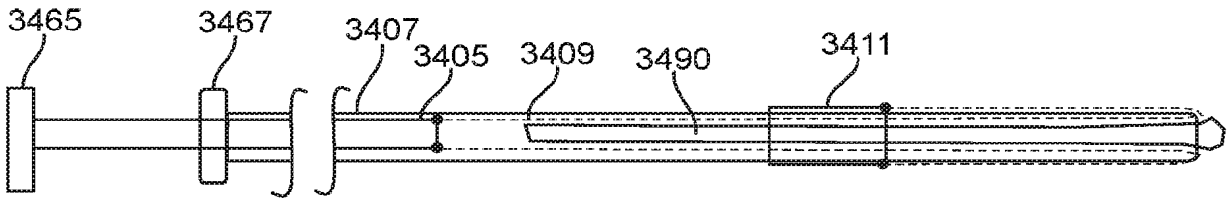


FIG. 34A

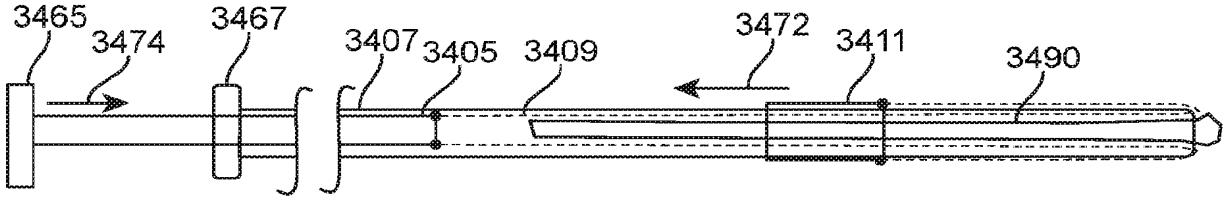


FIG. 34B

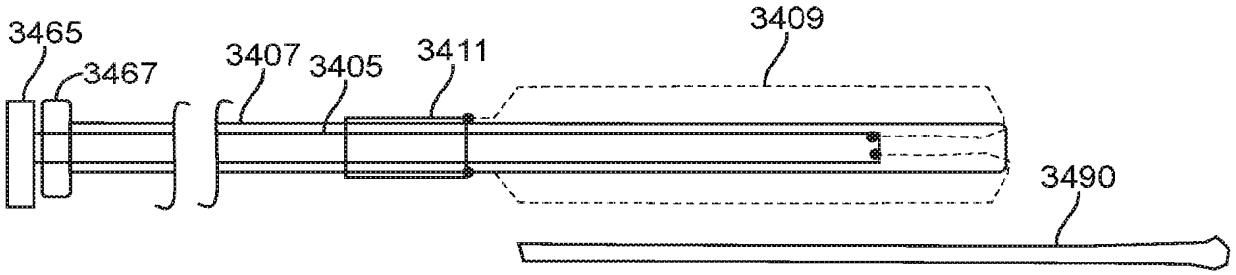


FIG. 34C

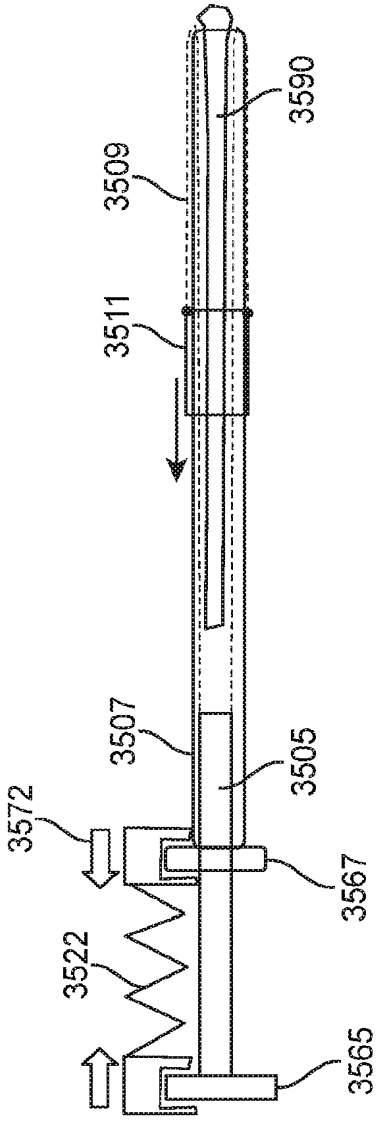


FIG. 35

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/059607

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/221 A61B17/34 A61M1/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2017/189550 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02)	1-9, 11-15, 29-41
Y	abstract	19-28
A	paragraphs [0033], [0035] - [0036], [0049] - [0109]; figures 1-12	16-18

X	WO 2017/058280 A1 (GW MEDICAL LLC [US]) 6 April 2017 (2017-04-06)	1-18, 29-40
Y	abstract	19-28
	paragraphs [0014], [0015], [0043] - [0071], [0087], [0116] - [0171], [0190]; figures 1-38	

	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 March 2019	28/03/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Ioanovici, T

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/059607

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26)	1-15,41
A	abstract paragraphs [0058] - [0064], [0116] - [0148], [0159] - [0217]; figures 1-44	16-40
A	WO 2012/009675 A2 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]) 19 January 2012 (2012-01-19) abstract paragraphs [0167] - [0171]; figures 1-22	1-41
A	US 2005/085849 A1 (SEPETKA IVAN [US] ET AL) 21 April 2005 (2005-04-21) abstract paragraph [0083]; figures 5-46	1-41
X,P	WO 2017/210487 A1 (STRYKER CORP [US]) 7 December 2017 (2017-12-07) abstract paragraphs [0011] - [0017], [0020] - [0031], [0035] - [0088]; figures 1-10	1-4, 8-10, 13-15
X,P	WO 2018/049317 A1 (STRYKER CORP [US]) 15 March 2018 (2018-03-15) abstract paragraphs [0012], [0021] - [0036], [0054] - [0055], [0087] - [0134]; figures 1-28	1,3,4,8, 10,12, 13,15, 29-40
A	US 2011/160763 A1 (FERRERA DAVID A [US] ET AL) 30 June 2011 (2011-06-30) abstract paragraphs [0134], [0244] - [0246]; figures 2-60	1-41
A	US 2012/083868 A1 (SHRIVASTAVA SANJAY [US] ET AL) 5 April 2012 (2012-04-05) abstract paragraph [0052]; figures 1-10	1-41
A	WO 2012/049652 A1 (ENDOGROWTH PROPRIETARY LTD [ZA]; SMITH JAMES [ZA]) 19 April 2012 (2012-04-19) abstract page 9 - page 17; figures 1-14	1-41
A	US 2014/155980 A1 (TURJMAN ALEXIS [US] ET AL) 5 June 2014 (2014-06-05) abstract paragraphs [0257] - [0265]; figure 41	1-41

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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/059607

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2017/189591 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02) abstract paragraph [0044]; figures 1-9	1-41

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/059607

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15, 41

Inverting tube aparatus for removing a clot from a vessel comprising an inversion support catheter, a puller and a flexible inverting tube with a cuff at the second end

1.1. claim: 41

Inverting mechanical thrombectomy aparatus for removing a clot from a vessel comprising an inversion support catheter with a plurality of slots or cut-outs for enhancing flexibility, a puller and a flexible knitted inverting tube

---

2. claims: 16, 18

Inverting tube aparatus for removing a clot from a vessel comprising an intermediate catheter, an inversion support catheter, a puller and a knitted inverting tube with filament knitted to form a plurality of interlocking loop stitched having a length between 0,5 and 10 mm

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3. claims: 17, 19-28

Inverting tube aparatus for removing a clot from a vessel comprising an inversion support catheter, a puller and a knitted inverting tube having a first and a second configuration, the knitted tube having an expanded outer diameter of 0,5-12 mm for the first region adjacent the first end in the first configuration, an inner diameter grater than 30% of an inner diameter of the inversion support catheter in the second configuration, and a second region of the knitted tube adjacent the second end has an expanded outer diameter less than the expanded outer diameter of the knitted tube region adjacent the first end and within 20% of an outer diameter of the inversion support catheter.

---

4. claims: 29-40

Pre-loaded inverting mechanical thrombectomy aparatus for removing a clot from a vessel comprising an intermediate catheter, an inversion support catheter, a puller and a flexible inverting tube extending between the inversion support catheter and the intermediate catheter, wherein the puller and the inversion support catheter are releasabl held together.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/059607

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2017189550 A1	02-11-2017	CN 109310446 A	05-02-2019
		EP 3448276 A1	06-03-2019
		EP 3448277 A1	06-03-2019
		US 2017303942 A1	26-10-2017
		US 2017303947 A1	26-10-2017
		US 2018042626 A1	15-02-2018
		WO 2017189550 A1	02-11-2017
		WO 2017189615 A1	02-11-2017
WO 2017058280 A1	06-04-2017	CN 108348319 A	31-07-2018
		EP 3355829 A1	08-08-2018
		EP 3406208 A1	28-11-2018
		JP 2018529495 A	11-10-2018
		US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
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MEDICAL TREATMENT INSTRUMENT

Inventor(s): KATO TOMIHISA ± (KATO TOMIHISA)

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Classification: **- international:** ***A61B17/00; A61B17/22; A61B17/221; A61L29/00; A61M25/01;*** (IPC1-7): A61B17/00; A61B17/22; A61L29/00; A61M25/01

- cooperative:

Application number: JP20040142997 20040513

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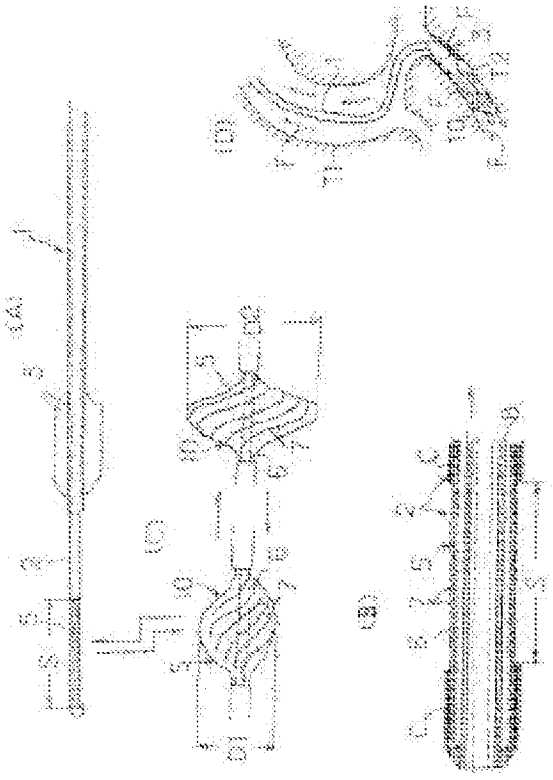
Abstract of JP2005323702 (A)

PROBLEM TO BE SOLVED: To more improve a treatment property and to improve a performance suitably to the reduction in invasion that is the direction in recent years in a medical treatment instrument used for the treatment of a blood vessel obstruction part and a vasoconstriction part. ; SOLUTION: In the medical treatment instrument 1 provided with a balloon part 3 for expanding a constriction part on the distal end part of the main wire part 2 of a flexible thin and long wire body, the main wire part 2 is composed of a hollow twisted wire coil body 6 into which a wire material 8 for an operation is inserted, and an expansion/contraction diameter part 5 composed of the coil wire 7 of the hollow twisted wire coil body 6 is provided on the front part of the balloon part 3 for expanding the constriction part. The



medical treatment instrument 1 is
structured such that a basket-like
diameter expansion variant of the expansion/contraction diameter part 5 and diameter reduction variant from the basket-like diameter expansion variant are freely carried out by the pulling operation or pushing operation of the wire material 8 for the operation. ;

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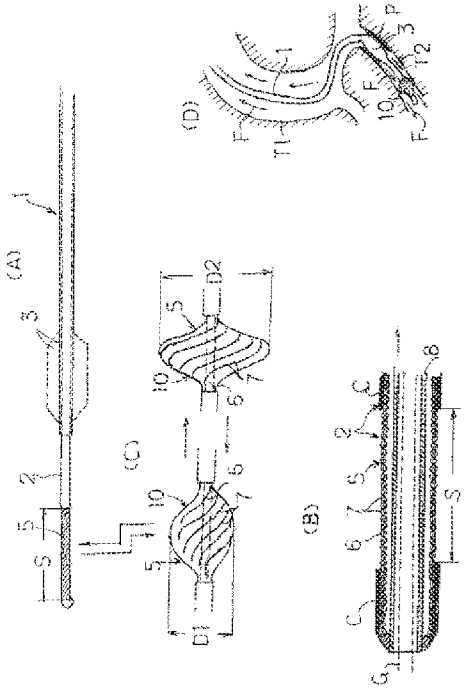
(54)【発明の名称】医療用処置具

(57)【要約】
【課題】　血管閉塞部や血管狭窄部の治療に用いる医療用処置具において、治療性の特段の向上と、低侵襲化の近年指向に適する高性能化を図る。
【解決手段】　可撓性細長線条体の主線条部２の先端部位に、狭窄部拡張用バルーン部３を備えた医療用処置具１において、主線条部２が操作用線条材８を内挿通した中空撚線コイル体６から成ると共に、狭窄部拡張用バルーン部３の前方に、中空撚線コイル体６のコイル素線７から成る膨縮径部５を備え、操作用線条材８のプル操作またはプッシュ操作による膨縮径部５のバスケット状膨径変体と、該バスケット状膨径変体からの縮径変体を自在にした構造の医療用処置具１が特徴である。
【選択図】　図１



【特許請求の範囲】
【請求項1】
可撓性細長線条体の主線条部の先端部位に、狭窄部拡張用バルーン部を備えた医療用処置具において、前記主線条部が操作用線条材を内挿通した中空撚線コイル体から成ると共に、前記狭窄部拡張用バルーン部の前方に、前記中空撚線コイル体のコイル素線から成る膨縮径部を備え、前記操作用線条材のプル操作またはプッシュ操作によって、前記膨縮径部のコイル素線によるバスケット状膨径変体と、該バスケット状膨径変体からの縮径変体を自在にした構造を特徴とする医療用処置具。
【請求項2】
主線条部の前端に、案内用ガイドワイヤ部を突設した請求項１に記載の医療用処置具。
【請求項3】
主線条部に薬液注入・吸入用チューブを外嵌装した請求項１または請求項２に記載の医療用処置具。
【請求項4】
中空撚線コイル体のコイル中空部を、薬液の注入・吸入用流路と成した構造から成る請求項１～請求項３のいずれかに記載の医療用処置具。
【請求項5】
膨縮径部の先端側の概ね２／３のゾーンに、拡縮自在の多孔質膜または薄膜を被覆した構造から成る請求項１～請求項４のいずれかに記載の医療用処置具。

【発明の詳細な説明】
【技術分野】
【0001】
本発明は、血管閉塞部や血管狭窄部の拡張治療に用いる医療用処置具に関するものである。
【背景技術】
【0002】
血管閉塞部や血管狭窄部の血管病変部の拡張治療用の医療用処置具は、血管内に挿入する細長可撓性の線条体の先端部分に「膨径変体させることによって病変部を拡張する拡張用バルーン部を設けた形態」のものが広く普及している。
【0003】
そして、その一般形態に改良を加えてより好ましい治療を施す近年公開の新技術として特許文献１～３の背景技術があり、そのうち特許文献１に示される「血管内閉塞灌注カテーテルとその使用方法」は「病変部の拡張部材・血液のフィルタ部材・吸引カテーテルの別体物の集合形態」にして、その別体物のそれぞれを交換しながら治療するカテーテルシステムを特徴としている。
【0004】
そして、特許文献２のものは病変部の治療によって弛緩した血栓等を血管内で捕捉して外体に除去するフィルタまたは閉塞装置を特徴としている。そして、特許文献３のものは、治療中の血液の連続灌流を維持しながら塞栓物質を捕捉回収する血液フィルタシステムを特徴としている。
【0005】
【特許文献1】特表２００３－５１７８７０公報
【特許文献2】特開２００３－２６５４８９公報
【特許文献3】特開２００３－２２００６２公報
【発明の開示】
【発明が解決しようとする課題】
【0006】
以上の背景技術の特許文献１のものは、別体物の前記の拡張部材・フィルタ部材・吸引部材を順次交換しながら治療する手法となるので、一連の治療システムが煩雑にして長時間化すると共に、その３部材の径大化をもたらすので、近年指向の低侵襲化の要請に反し

、患者の負担大となる難点が存在する。

【0007】

そして、特許文献２のものは、先端部にフィルタ装置を付設したガイドワイヤを案内として別体の拡張カテーテルを誘導する２体物組合せ形態にして、そのフィルタ部は多点溶接構造であることから接着剤による溶着ポイントの径大化をもたらすと共に、安全性に欠け（溶着ポイントが治療抵抗によって外れるおそれ）、前記特許文献１と同様な難点がある。

【0008】

そして、特許文献３のものは塞栓物質回収のみの単機能具にして、血管狭窄部等の病変部拡張治療用の他の用具が不可欠になるので、前記特許文献１と同様な難点が存在する。

【0009】

本発明は、以上の背景技術の難点を解消し、当該治療性の特段の向上を図り、併せて低侵襲化の近年指向に応える高品質・高性能の医療用処置具を提供するものである。

【課題を解決するための手段】

【0010】

以上の技術課題を解決する本発明の医療用処置具は、その基本形態を示す図１参照「可撓性細長線条体の主線条部２の先端部位に、狭窄部拡張用バルーン部３を備えた医療用処置具１において、主線条部２が操作用線条材８を内挿通した中空撚線コイル体６から成ると共に、狭窄部拡張用バルーン部３の前方に、中空撚線コイル体６のコイル素線７から成る膨縮径部５を備え、操作用線条材８のプル操作またはプッシュ操作による膨縮径部５のバスケット状膨径変体と、該バスケット状膨径変体からの縮径変体を自在にした構造」の医療用処置具１が特徴である。

【0011】

即ち、前記構成の本発明の医療用処置具１は、血管狭窄部の拡張治療用の狭窄部拡張用バルーン部３（以下、単にバルーン部３という）を備えた公知の医療用処置具において、バルーン部３による治療によって血液中に生ずる血管狭窄病変部の塞栓物質の捕捉回収機能を有する膨縮径部５を単一の主線条部２に連設し、バルーン部３による病変部の拡張治療と、同時に「血流利用による前記塞栓物質の捕捉回収」を可能にして当該治療性の特段の向上を図る新規思想を特徴とするものにして、その要部の膨縮径部５は下記の基本構造を有している。

【0012】

即ち（図１（Ｂ）（Ｃ）参照）主線条部２を構成する中空撚線コイル体６は「特開２００２－２７５７７４公報等に示される多数のコイル素線を同一円周上に撚合構成した可撓性線状体の中空撚線コイル体」を意味しており、この中空撚線コイル体６はスパンＳの膨縮径部５を除く外周に樹脂被覆Ｃが施されている。そして、血管治療時に、体外に出す後端の手元操作部（図示しない）によって操作用線条材８を「例えばプル操作」すると、露出状態の中空撚線コイル体６から成る膨縮径部５は、コイル素線７がそのプル外力に素直に反応して、スパイラル状の捻り形態のまま外方へ膨出弾性変形して、「コイル素線７のそれぞれがリブ群となる任意径Ｄ１・Ｄ２のボール形態のバスケット状膨径部１０」に膨径変体できる。

【0013】

そして、操作用線条材８のプル操作を弛緩させると、コイル素線７が自力弾性力によって復元して概ね原姿勢のストレート形態の膨縮径部５に復元し、その膨縮変体が自在に反復可能に設定された構造を特徴としている。

【0014】

そして、前記構成の本発明の医療用処置具１は、前記構成に基づく特有作用効果のさらなる向上を図る技術意図から「主線条部２の先端に案内用ガイドワイヤ部を突設する」「中空撚線コイル体６に薬液注入用チューブを外嵌装する」「中空撚線コイル体６の中空部を、治療用薬液の注入吸入用流路と成す構造」「膨縮径部５の先端側の概ね２／３ゾーンに、拡縮自在の多孔質膜または薄膜を被覆した構造」「操作用線条材８が、ガイドワイヤ

が貫挿可能のチューブ体、または、撚り線から成る形態」のいずれかの態様を必要に応じて採択する。

【発明の効果】

【0015】

前記構成の本発明の医療用処置具１は（図１（Ｄ）参照）例えば心臓血管の大動脈弓Ｔ１に挿入して左冠状動脈Ｔ２の血管狭窄部の病変部Ｐの拡張治療をするとき、下記の特有の作用効果を奏する。

【0016】

即ち、病変部Ｐにバルーン部３を位置させて膨大変形させて、公知のステント（図示しない）を留置させたりして血管の拡張治療を行うとき、そのバルーン部３の前方に膨縮径部５が存在し、その膨縮径部５は病変部Ｐから血流Ｆが流れ込むポジションにセットさせる位置関係となる。

【0017】

以上の位置関係から膨縮径部５を血管内で任意膨大径に膨径変体させてバスケット状膨径部１０にしてセットしておくことによって、バルーン部３による拡張治療によって病変部Ｐから離脱浮遊して血流Ｆに乗る塞栓物質を、バスケット状膨径部１０内に即時回収すると共に、必要に応じて強制縮径させて捕捉確保し、しかるのち、体外に引き出すことによって体外に取り出し除去する治療手法が可能になる。そして，以上の塞栓物質の捕捉回収に機能するバスケット状膨径部１０は、スパイラル形状のコイル素線７がリブ群を成して血管内壁に圧接するので、血流Ｆによって位置ずれするおそれがなく、セット姿勢が安定して前記捕捉回収性能が良好に安定持続できる。

【0018】

そして、その塞栓物質の捕捉回収が単一の処置具によって病変部Ｐの拡張治療と同時にできるので、背景技術の「別体物の複数の治療具によって拡張治療と塞栓物質の取り出し除去をタイムラグ存在の２手順で行う治療具」より、前記塞栓物質の取り出し除去を含む一連の治療行為が特段に能率化・時間短縮されると共に、その塞栓物質の取り出しタイミングずれによる血管内残留や血流中浮遊をもたらして「遠位毛細血管内に滞留して治療中虚血を生じたり、心筋梗塞を生ずる等の治療トラブル」が有効に防止できる。

【0019】

そして、その塞栓物質捕捉回収用の膨縮径部５は、バルーン部３を有する共通の主線条部２の一部によって構成した一体化構造であることから、下記の特有作用がある。即ち、前記背景技術のフィルタ装置は、拡張部のフィルタ材料とシャフト部が接着剤等による接続手段から成るので接続強度不安定にして径大化する傾向が避け得ない難点が存在する。しかし、本発明のものは前記の一体化構造にして、機械的強度が優れるステンレス鋼線等の主線条部２の一部が膨縮径部５として変体機能できるので、機械的強度が極めて安定すると共に、血管内挿入線条体として有害な径大化をもたらすおそれがない。

【0020】

従って、血管内挿入治療具として安定した機械的性質と細径化が確保されると共に、例えば治療中に何等かの原因によってスパスム現象（けいれん）が生じたとき簡便的確な即時引き抜きが可能にして治療トラブルの発生を有効に防止することができる。

【0021】

以上のとおり、本発明の医療用処置具１は、当該治療性が特段に向上すると共に、患者の苦痛を低減し、併せて近年指向の低侵襲化の要請に応えることができる有用な主たる作用効果が存在する。

【発明を実施するための最良の形態】

【0022】

以下、前記基本形態に基づく好ましい実施例を説明する。

【実施例】

【0023】

まず、図２を参照して本発明第１実施例を説明する。即ち、操作用線条材８を貫通内挿

した中空撚線コイル体６から成る主線条部２に、バルーン部３と膨縮径部５を並設した医療用処置具１において、バルーン部３は公知形態のものにして、主線条部２の後端は治療時に体外に出す手元操作部１２に連結固定されている。

【0024】

そして、手元操作部１２は（図２（Ｃ）参照）注入孔部１３を側方突設して後端外周を雄ねじ部１６に成して、主線条部２の後端を連結した中空管体のバルーン操作部１５と、このバルーン操作部１５の雄ねじ部１６に螺合する雌ねじ部１７を前端内周に有して操作用線条材８を中空部に挿入する中空管体の進退操作部１４との２部材の組合せから成り、この進退操作部１４の回転操作によるバルーン操作部１５との相対進退によって操作用線条材８の進退操作ができる。

【0025】

即ち、主線条部２に内挿した操作用線条材８は、中空部を貫通した可撓性のチューブ体にして主線条部２の前端に固着されると共に、後端が（図２（Ｃ）参照）手元操作部１２の進退操作部１４に連結されて中空部が貫通しており、この進退操作部１４の押し引き操作によって主線条部２に内挿した操作用線条材８を進退させ、膨縮径部５のスパンＳの拡縮変化による前記バスケット状膨径部１０の膨径変体と縮径変体ができる。

【0026】

そして、主線条部２には「手元操作部１２の注入孔部１３に後端を開口して前端をバルーン部３に連通させた可撓性の注入チューブ１１」が外嵌装されており、この注入チューブ１１を通して注入孔部１３からバルーン部３へ拡張用の薬液Ｌ（主に生理食塩水）を注入して拡張させる。

【0027】

なお、この図２実施例のものは、膨縮径部５のストレート形態時の「スパンＳ＝５粍」主線条部２の中空撚線コイル体６は「０．０４粍直径の素線８本を撚合した「１×７」形態の０．１２粍直径のコイル素線７を８本撚合した外直径＝０．４４粍」「樹脂被覆Ｃの外直径＝０．５５粍」のサイズ諸元である。そして、進退操作部１４とバルーン操作部１５の相対位置をロックして、膨縮径部５の膨径度を好ましい形態にロックするロックナット１８が雄ねじ部１６に螺合セットされ、進退操作部１４の後端開口部には注入孔部１３から注入した薬液の流出防止用の逆止弁１９が設けてある。そして、チューブ体の操作用線条材８は前端・後端とも開口されており、その中空部が公知のガイドワイヤＧの貫挿孔として活用できる。

【0028】

以上の図２実施例のものは前記の主たる作用効果の他、下記の特有の従たる作用効果がある。即ち、膨縮径部５の膨径度のロック手段が存在するので、バスケット状膨径部１０が患者個有の血管状態にマッチングした膨径度にセット維持可能になることから、過大膨径・過小膨径が原因となる血管内膜解離・塞栓物質体内浮遊・治療難渋性等の治療トラブルが防止できると共に、長時間の治療時間中の好ましい膨径状態の安定維持が可能にして当該治療性が一段と向上する。そして、膨縮径部５は、中空撚線コイル体６の樹脂被覆Ｃを剥離するのみで成形できるので、任意位置に任意長の膨縮径部５が簡便かつ正確に成形できるメリットがある。

【0029】

次に、図３を参照して本発明の医療用処置具１の第２実施例を説明する。即ち、同じく中空撚線コイル体６から成る主線条部２に、バルーン部３と膨縮径部５を連設したものにおいて、この実施例のものは前記図２実施例の操作用線条材８が、前端を主線条部２の内側に固定して後端を手元操作部１２の進退操作部１４に固定した「撚り線ワイヤ」によって構成されている。

【0030】

そして、その主線条部２の前端には、主線条部２の中空撚線コイル体６に固定して、自由状態で若干長ストレート状に伸長する金属線材単条コイルばね体から成る可撓性細長体のガイドワイヤ部２０が突設され、このガイドワイヤ部２０を血管内挿入の先導案内部と

して機能させて、図２実施例に示す従来のガイドワイヤＧを不必要に成す形態に構成されている。

【0031】

以上の図３実施例のものは、予め血管内に挿入セットする別体物の従来ガイドワイヤが無用にして単一物となるので物品構成が簡素化して取扱い性が向上する。そして、ガイドワイヤ部２０は応分の剛性と柔軟性を有する金属線材から成るので、血管内への良好な挿入先導性と手元操作部１２による先端部分の「押し・引き・回転」の良好なステアリング性が確保できる。以上の従たる特有作用が存在する。なお、このガイドワイヤ部２０は前記のコイルばね体に代えて、撚り線ワイヤ等にすることがる。

【0032】

なお、このガイドワイヤ部２０突設形態のものは、ガイドワイヤ部２０を帯状板にして、その帯状板の板厚方向の高曲げ特性を活用して、複雑多岐に屈曲する血管への先導挿入性の特段の向上を図る形態にしたり、ガイドワイヤ部２０を金・タングステン等の放射線不透過性材によって形成して、血管内挿入状態の放射線投影による視認性向上を図る態様を必要に応じて採択する。

【0033】

続いて、図４を参照して本発明の第３実施例を説明する。即ち、前記実施例と同様な手元操作部１２を備えたものにおいて、手元操作部１２の前方近傍に「注入孔部１３を側方突設し、かつ前記の注入チューブ１１、または被覆つき主線条部２を内嵌遊挿入する可撓性チューブ体の薬液注入パイプ２３を前方開口で前方突設した薬液注入部２２が設定されている。

【0034】

そして、その薬液注入孔部２２に薬液注入器２５を接続して、その注入器２５からウロキナーゼ・ＴＰＡ等の薬液Ｌを血管Ｔ内に注入することによって、ステントを拡張セットした病変部Ｐから生ずる塞栓物質の剥離・浮遊を促進させ、膨縮径部５による該塞栓物質の捕捉回収性を促進向上したり、または、造影剤を注入することによって治療中の血管状態の視認把握性の一段の向上を図る構造に設定されている。

【0035】

なお、この実施例の薬液注入部２２は薬液Ｌの注入のみではなく、必要に応じて注入薬液の吸引部として機能させる。以上の図４実施例のものは、前記の塞栓物質の浮遊促進による捕捉回収性の向上・造影剤投入による治療性の一段の向上を図る特有の作用効果がある。

【0036】

次に、図５を参照して本発明の第４実施例を説明する。即ち、この第４実施例のものは前記第３実施例と同一の薬液注入部２２・手元操作部１２を備えたものにおいて、手元操作部１２に「主線条部２の中空撚線コイル体６の中空部に所要の薬液Ｌを注入・吸出する中空部用薬液注入部３０が、注入孔部１３を側方突設させた形態に付設されている。

【0037】

そして、この中空部用薬液注入部３０から中空撚線コイル体６のコイル中空部の遊隙（操作用線条材８の外周と中空撚線コイル体６内周に存在するクリアランスＣ１を薬液Ｌの流路として活用し、中空撚線コイル体６のコイル素線７が膨隆したバスケット状膨径部１０に薬液Ｌを強制注入したり、強制吸引することによって、バスケット状膨径部１０における塞栓物質の捕捉回収作用を迅速化・効率化させる構造に設定されている。

【0038】

この第４実施例のものは下記の・Ａ・Ｂのいずれかの手順によって操作される。即ち、・Ａ：病変部Ｐを通過させた膨縮径部５をバスケット状膨径部１０に膨大変体させ、その状態でバルーン部３によって（必要に応じてステントと共に）病変部Ｐを拡張治療する。しかるのち、バルーン部３を収縮させ（必要に応じてステントを留置）、続いて中空部用薬液注入部３０から生理食塩水・リンゲル乳酸塩溶液の薬液Ｌを注入して中空撚線コイル体６の中空部を経由して（図５（Ｃ）参照）膨径状態のバスケット状膨縮部１０を通過さ

せて、主線条部２の外周のクリアランスＣ２の流路に送出し、主線条部２の外側を薬液Ｌの吸入路にする薬液注入部２２から吸引して排出させて当該治療を行う。・Ｂ：同じくバルーン部３による治療において、前記Ａの逆コースに薬液Ｌを注入・吸引して当該治療を行う。

【0039】

以上の第４実施例のものは、下記の従たる特有作用がある。即ち、薬液Ｌの流路となる中空撚線コイル体６の内周がコイル素線７によるスパイラル溝の連続形態であることから、薬液Ｌはスパイラル流を生じて病変部Ｐ・バスケット状膨径部１０を通過するので、病変部Ｐ・ステントに付着している塞栓物質の剥離性と、膨径部１０における捕捉回収性能が向上する。

【0040】

そして、薬液Ｌによる塞栓物質の即時体外取り出しができるので、回収捕捉した塞栓物質の血管内落下トラブルがなく極めて効率的な体外取り出しができる。そして、その取り出し確認が的確に視認確認できる（取り出し液の色調によって塞栓物質の含有度が推定判別できる）。以上のメリット作用がある。

【0041】

続いて、図６を参照して本発明の他の実施例を説明する。即ち、膨縮径部５を備えた本発明の医療用処置具１において、図６（Ａ）のものは、膨縮径部５の前方側の概ね２／３のゾーン（スパンＳの２／３の部分）に「伸縮自在の多孔質膜または薄膜」から成る血流透過・遮断膜３１が被覆セットされている。

【0042】

なお、この血流透過・遮断膜３１は、ポリウレタン・シリコン・ポリエステルまたは、これ等のエラストマーの材料（好ましくは、ポリウレタン）で、膜厚＝８０～１６０ミクロン、多孔質のものの細孔＝２０～２００ミクロン（好ましくは８０～１２０ミクロン）の諸元のものを用いる。

【0043】

以上の図６（Ａ）実施例のものは、バスケット状膨径部１０が開傘状となり、その開傘内側に血流Ｆを受け入れる血流透過・遮断膜３１が存在するので、バスケット状膨径部１０による塞栓物質の捕捉回収性能が一段と向上する。

【0044】

一方、図６（Ｂ）は膨縮径部５の他の形態が示してあり、この実施例の膨縮径部５Ａは、自由状態において所定の膨径状態を維持する形状に塑性変形して設定されており、操作用線条材８を主線条部２に対してプッシュ操作することによって、塑性変形されたコイル素線７が弾性伸長してストレート状の縮径変体を呈し、そのプッシュ操作力をルーズにすると自力弾性復元して元の膨径状態になる構造に設定されている。

【0045】

そして，血管内挿入するときは前記縮径変体に強制変形させて挿入し、しかるのち、血管内において膨径変体させて機能させる構造に成っている。この図６（Ｂ）のものも本発明の前記作用効果が存在する。

【0046】

次に、以上の本発明の各実施例の構成部材の材質・形状等について、以下のとおり補足する。即ち、操作用線条材８を構成するチューブ体・注入チューブ１１・薬液注入チューブ２３は「ステンレス鋼管・Ｎｉ－Ｔｉ（ニッケル―チタン）管材・ポリアミド等の樹脂チューブ、または樹脂被覆不存在の中空撚線コイル体、または、これ等の組合せ等を用いる。そして、バルーン部３は「ポリアミド・ポリエチレン・ポリエステル、または、これ等のエラストマー材」を用い、手元操作部１２・進退操作部１４・バルーン操作部１５・薬液注入部２２等はポリカーボネット等の樹脂材を用いる。

【0047】

そして、主要部を構成する中空撚線コイル体６の樹脂被覆は、ポリアミド・ポリウレタン・ポリエステル・または、これ等のエラストマー材・ＰＴＦＥ（テフロン）等の樹脂材

を用いる。

【0048】

なお、本発明の医療用処置具１は、前記の実施例に限定されず、主線条部２は、膨縮径部５以外の部分を樹脂製・金属製の可撓性管体にしても良く、また、膨縮径部５は長さ方向の両端部位に、コイル素線７の膨縮反復による形状崩れの防止手段（固定リングの巻着等）を施すことがある。

【産業上の利用可能性】

【0049】

なお、前記実施例は冠状動脈Ｔ２の狭窄病変部の治療について説明したが、前記各実施例のもののサイズアップを図ることによって、大腿動脈・静脈や内頚動脈・静脈の治療用処置具として広く適用できる。

【図面の簡単な説明】

【0050】

【図1】本発明の医療用処置具の基本形態を示し、（Ａ）は要部正面図、（Ｂ）は（Ａ）の部分拡大正面図、（Ｃ）（Ｄ）はその作用説明図

【図2】本発明の第１実施例を示し、（Ａ）はその全体正面図、（Ｂ）（Ｃ）は（Ａ）の部分拡大図

【図3】本発明の第２実施例を示し、（Ａ）はその全体正面図、（Ｂ）（Ｃ）は（Ａ）の部分拡大図

【図4】本発明の第３実施例を示し、（Ａ）はその部分正面図、（Ｂ）は（Ａ）の部分拡大図

【図5】本発明の第４実施例を示し、（Ａ）はその全体正面図、（Ｂ）（Ｃ）は（Ａ）の部分拡大図

【図6】本発明の他の実施例を示し、（Ａ）はそのバスケット状膨径部の正面図、（Ｂ）は膨縮径部の構造と作用説明図

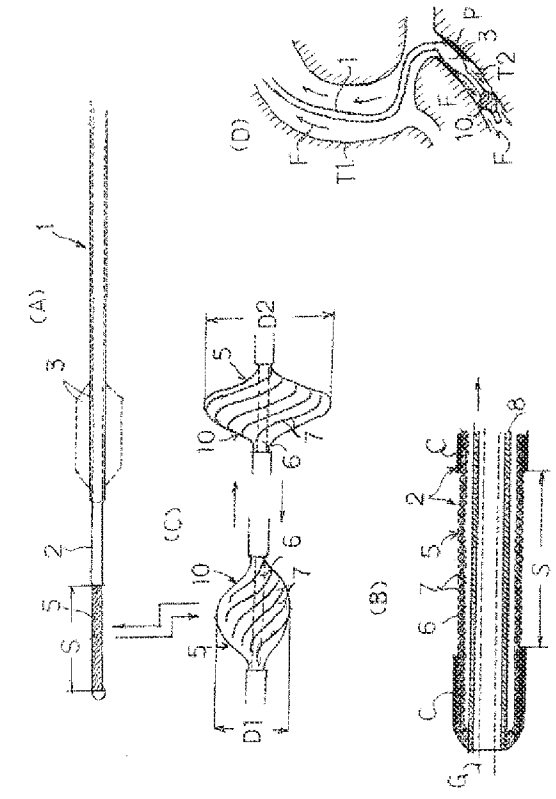
【符号の説明】

【0051】

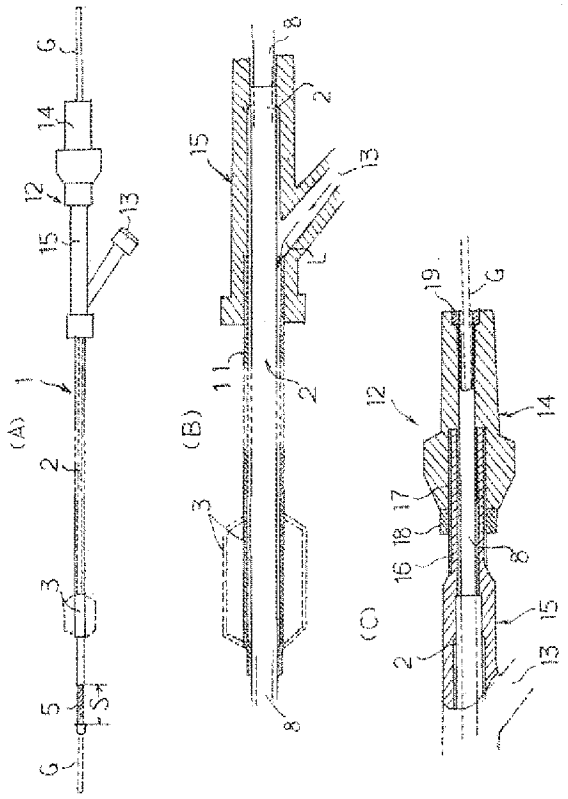
１　本発明の医療用処置具
２　主線条部
３　狭窄部拡張用バルーン部
５　膨縮径部
６　中空撚線コイル体
７　コイル素線
８　操作用線条材
１０　バスケット状膨径部
１１　注入チューブ
１２　手元操作部
１３　注入孔部
１４　進退操作部
１５　バルーン操作部
２０　ガイドワイヤ部
２２　薬液注入部
２３　薬液注入パイプ
３０　中空部用薬液注入部
３１　血流透過・遮断膜
Ｃ　樹脂被覆
Ｆ　血流
Ｌ　薬液
Ｐ　病変部
Ｔ　血管

Ｔ１　大動脈弓
Ｔ２　冠状動脈

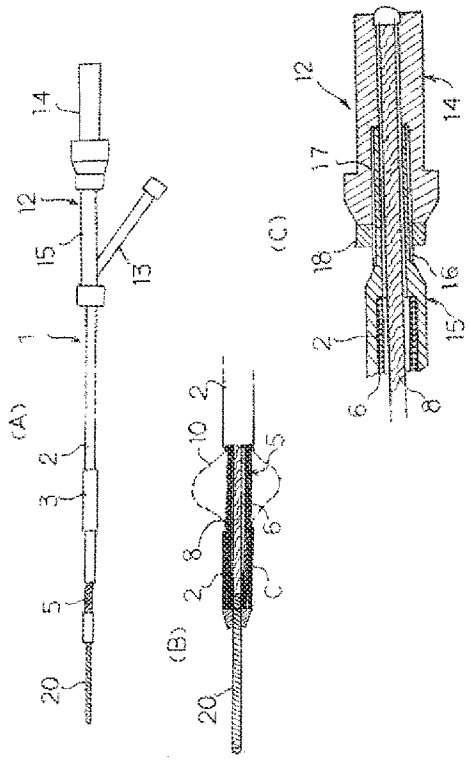
【図1】



【図2】



【図3】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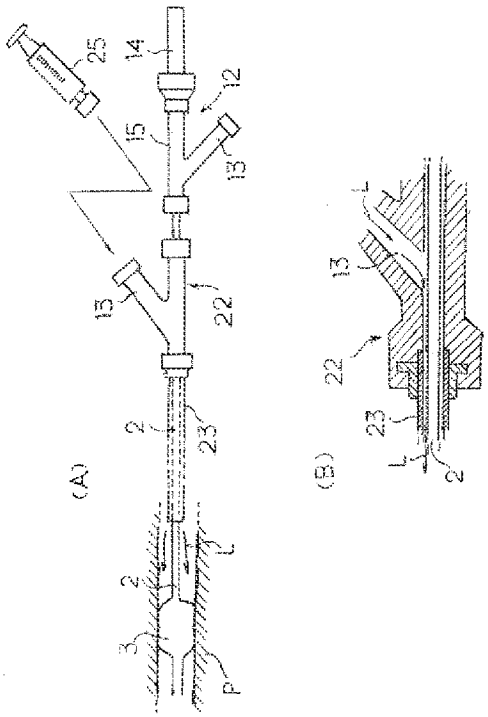
【図4】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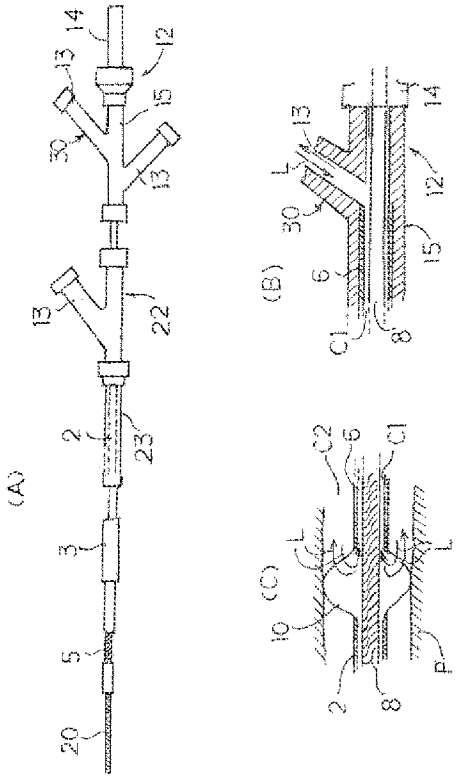
【図5】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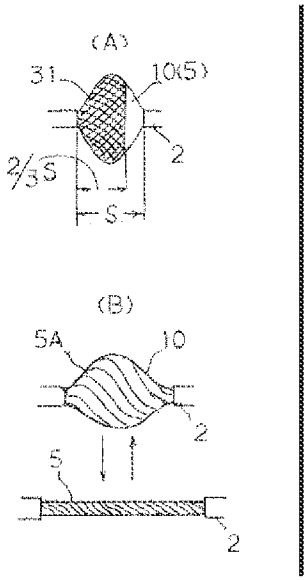
【図6】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(54) **Title**: MEDICAL DEVICE FOR RECANALIZATION OF THROMBI

(54) **Bezeichnung** : MEDIZINISCHE VORRICHTUNG ZUR REKANALISATION VON THROMBEN

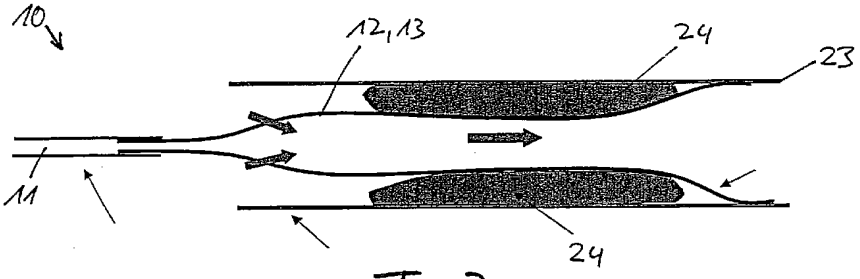

Fig. 2

(57) **Abstract**: The invention relates to a medical device for recanalization of thrombi, comprising a catheter (10) having a proximal hollow guide (11) and a distal recanalization element (12) arranged in an axially relocatable manner in the hollow guide (11) and movable to an expanded recanalization position from a compressed catheter position in the hollow guide (11), in said recanalization position the recanalization element (12) is located outside of the hollow guide (11) at least in sections, wherein the recanalization element (12) comprises a hollow-body-shaped lattice structure (13), at least in sections, that is designed to expand a thrombus in such a way that a flow passage is created in the thrombus in the recanalization position.

(57) **Zusammenfassung**: Die Erfindung betrifft eine medizinische Vorrichtung zur Rekanalisation von Thromben umfassend einen Katheter (10) mit einer proximalen Hohlführung (11) und einem distalen Rekanalisationselement (12), das in der Hohlführung (11) axial verschieblich angeordnet und aus einer komprimierten Katheterstellung in der Hohlführung (11) in eine expandierte Rekanalisationsstellung bewegbar ist, in der das Rekanalisationselement (12) zumindest abschnittsweise außerhalb der Hohlführung (11) angeordnet ist, wobei das Rekanalisationselement (12) zumindest abschnittsweise eine hohlkörperförmige Gitterstruktur (13) aufweist, die zur Aufweitung eines Thrombus angepasst ist derart, dass in der Rekanalisationsstellung eine Durchflusspassage im Thrombus entsteht.

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Medizinische Vorrichtung zur Rekanalisation von Thromben

Beschreibung

Die Erfindung betrifft eine medizinische Vorrichtung zur Rekanalisation von Thromben.

Bei der Thrombose bzw. Thromboemobolie wird ein Blutgefäß von einem Blutgerinnsel verschlossen, so dass es zu einer Unterversorgung des distal liegenden Gewebes kommt (Ischämie). Es ist bekannt, die Behandlung einer Thrombose bzw. die Entfernung eines Thrombus sowohl medikamentös als auch mechanisch vorzunehmen.

Bei der medikamentösen Behandlung wird ein Thrombus-lösendes Mittel in den Blutkreislauf verabreicht. Bei der venösen Thrombolyse wird das Medikament in eine Vene zugeführt, so dass sich dieses im gesamten Blutkreislauf verteilt. Dabei kommt es zu einer Dilution des Medikamentes im gesamten Blutvolumen. Die Medikamentkonzentration vor bzw. im Bereich des Thrombus ist durch die Dilution im gesamten Blutkreislauf beschränkt, wodurch eine schnelle und effektive Auflösung des Thrombus verhindert wird. Bei der arteriellen Thrombolyse wird das Medikament durch einen Katheter vor dem Thrombus zugeführt. Bei dieser Behandlungsart ist die Konzentration des Medikamentes im Vergleich zur venösen Thrombolyse höher. Ein Beispiel für die medikamentöse Behandlung bei der arteriellen Thrombolyse mittels eines Katheters ist in Fig. 16 (Stand der Technik) dargestellt. Wenn der Thrombus, wie in Fig. 16 dargestellt, das gesamte Gefäß-Lumen verschließt, kann die Verabreichung von Medikamenten nur auf der proximalen Seite des Thrombus erfolgen. Die Fläche des Thrombus,

auf die das Medikament wirkt, ist daher relativ klein und entspricht im Wesentlichen dem Querschnitt des Gefäßlumens. Darüber hinaus ist die Wirkung des Medikaments auf den Thrombus auch deshalb nicht optimal, da aufgrund des Gefäßverschlusses kein Blutfluss stattfindet und sich das Medikament im Bereich vor dem Thrombus staut. Die Bewegung der Medikamentmoleküle zum Thrombus hin erfolgt nur durch Diffusionsmechanismen. Es bildet sich dabei an der Thrombusfläche eine Diffusionsgrenzschicht, die zu einer niedrigen Konzentration des Medikaments führt. Die Auflösung des Thrombus ist daher zum einen aufgrund der kleinen Angriffsfläche und zum anderen aufgrund des Blutstaus vor dem Thrombus beschränkt. Die medikamentöse Behandlung ist nur dann effektiv, wenn sie spätestens vier bis fünf Stunden nach Auftreten der Symptome durchgeführt wird. Die Auflösung der Thromben ist aber ein langsamer Prozess, der je nach der Größe des aufzulösenden Thrombus mehrere Stunden in Anspruch nehmen kann, bis der Blutfluss wieder hergestellt ist. Außerdem besteht die Gefahr, insbesondere wenn der letzte Teil des Thrombus aufgelöst wird, dass Partikel des Thrombus abgelöst werden und in die Blutbahn gelangen. Es kommt zu einer unkontrollierten Auflösung.

Ein weiteres Problem bei der medikamentösen Behandlung arterieller Thrombolysen ist in Fig. 17 (Stand der Technik) dargestellt. Wenn nämlich der Thrombus in der Nähe eines Abzweigungsgefäßes einen Gefäßverschluss verursacht, besteht die Gefahr, dass das Medikament vom Blut in das abzweigende Gefäß gespült wird und somit praktisch kaum Wirkung zeigt.

Insgesamt besteht bei der medikamentösen Behandlung von Thrombolysen die Gefahr der Hirnblutung.

Ferner ist es bekannt, Thromben mechanisch zu entfernen. Ein Beispiel dafür ist die Absaugung eines Thrombus mit einem Aspirationskatheter. Ferner ist es bekannt, den Thrombus durch Laser-, Ultraschall-, oder Kavitationseffekte zu zertrümmern. Eine weitere Möglichkeit der mechanischen Thrombusentfernung besteht darin, den Thrombus durch eine mechanische Vorrichtung zu fangen (Retriever) und in proximaler Richtung in einen Katheter einzuziehen. Die mechanische Entfernung von Thromben birgt die Gefahr der Partikelablösung, wobei Partikel in distale Hirnbereiche gelangen können. Um die Gefahr der Partikelablösung zu minimieren, müssen mechanische Vorrichtungen äußerst vorsichtig und mit langsamen Bewegungen benützt werden. Dies steht im Widerspruch zu dem Ziel, den Blutdurchfluss so schnell wie möglich wieder herzustellen.

Der Erfindung liegt die Aufgabe zu Grunde, eine medizinische Vorrichtung anzugeben, die eine effektive und schnelle Behandlung von Thromben ermöglicht und das Risiko der Ablösung von Partikeln bei der Behandlung verringert.

Erfindungsgemäß wird diese Aufgabe durch die medizinische Vorrichtung mit den Merkmalen des Anspruchs 1 gelöst.

Die Erfindung beruht auf dem Gedanken, eine medizinische Vorrichtung zur Rekanalisation von Thromben anzugeben. Das bedeutet, dass die Erfindung einen prinzipiell anderen Weg einschlägt, als dies im Stand der Technik bisher bekannt war. Im Stand der Technik beruht die Behandlung von Thrombose darauf, den Thrombus möglichst schnell und komplett aus dem Blutgefäß bzw. insgesamt aus dem Blutkreislauf zu entfernen. Bei der Erfindung geht es nicht darum, den Thrombus möglichst schnell zu entfernen, sondern in erster Linie darum, den Blutfluss im Gefäß wieder herzustellen. Der Fokus der Erfindung liegt daher auf der Wiederherstellung der Durchblutung und nicht auf der möglichst schnellen vollständigen Entfernung des Thrombus. Dies wird erfindungsgemäß durch eine Rekanalisation von Thromben erreicht. Dazu umfasst die medizinische Vorrichtung zur Rekanalisation von Thromben einen Katheter mit einer proximalen Hohlführung und einem distalen Rekanalisationselement. Das Rekanalisationselement ist in der Hohlführung axialverschieblich angeordnet und aus einer komprimierten Katheterstellung in der Hohlführung in eine expandierte Rekanalisationsstellung bewegbar. In der Rekanalisationsstellung ist das Rekanalisationselement zumindest abschnittsweise außerhalb der Hohlführung angeordnet. Das Rekanalisationselement weist zumindest abschnittsweise eine hohlkörperförmige fluiddurchlässige Gitterstruktur mit veränderbarem Durchmesser auf, die zur Ausweitung eines Thrombus angepasst ist derart, dass in der Rekanalisationsstellung eine Durchflusspassage im Thrombus entsteht.

Die medizinische Vorrichtung zur Rekanalisation von Thromben umfasst daher zwei relativ zueinander bewegbare Elemente, nämlich die Hohlführung und das Rekanalisationselement. Das Rekanalisationselement ist aufgrund der relativen Axialbeweglichkeit im Bereich eines Thrombus platzierbar. Aufgrund des veränderbaren Querschnitts der hohlkörperförmigen Gitterstruktur des Rekanalisationselements kann der zu behandelnde Thrombus aufgeweitet werden, so dass eine Durchflusspassage für das Blut im Thrombus entsteht. Damit ist es möglich, mittels der erfindungsgemäßen Vorrichtung den Blutdurchfluss durch den Thrombus herzustellen.

Das vorrangige Behandlungsziel wird somit erreicht, ohne dass eine komplette Ablösung des Thrombus von der Gefäßwand bzw. eine komplette Entfernung auf dem Blutgefäß erforderlich ist. Vielmehr ist es möglich, mit der erfindungsgemäßen Vorrichtung das Zeitfenster für die Behandlung zu vergrößern, da der Blutfluss schnell hergestellt ist und die Behandlung mit Medikamenten ohne Zeitdruck eingeleitet werden kann.

Bei einer bevorzugten Ausführungsform ist das Rekanalisationselement selbst expandierbar. Die Durchmesseränderung, konkret die Aufweitung des Durchmessers des Rekanalisationselements wird damit beim Entlassen des Rekanalisationselements aus der Hohlführung des Katheters durch die inhärenten Rückstellkräfte erreicht. Die dadurch erzielbare Radialkraft drückt den Thrombus radial nach außen und öffnet somit die Durchflusspassage.

Dabei ist die Gitterstruktur des Rekanalisationselements angepasst derart, dass der Radialdruck, der von der Rekanalisation in der Rekanalisationsstellung auf den Thrombus ausübbar ist, wenigstens 300 mmHg, insbesondere wenigstens 400 mmHg, insbesondere wenigstens 500 mmHg bei einer Expansion von bis zu 33 % des Durchmessers des Rekanalisationselements 12, insbesondere wenigstens 250 mmHg, weiter insbesondere wenigstens 300mmHg bei einer Expansion von bis zu 40 % des Durchmessers des Rekanalisationselements 12, insbesondere wenigstens 100mmHg bei einer Expansion von bis zu 66 % des Durchmessers des Rekanalisationselements 12 jeweils in der Ruhestellung beträgt. Dies hat den Vorteil, dass bei der Herstellung der Durchflusspassage, bei der das Rekanalisationselement einen relativ kleinen Durchmesser aufweist, ein hoher Radialdruck auf den Thrombus wirkt.

Die Gitterstruktur des Rekanalisationselements kann angepasst sein derart, dass der Radialdruck, der vom Rekanalisationselement in der Rekanalisationsstellung auf den Thrombus ausübbar ist, höchstens 50 mmHg, insbesondere höchstens 25 mmHg, bei einer Expansion mehr als 80 % des Durchmessers des Rekanalisationselements in der Ruhestellung beträgt. Durch die Begrenzung des Radialdrucks auf 50 mmHg, insbesondere höchstens 25 mmHg, bei einer Expansion von mehr als 80 % des Durchmessers wird erreicht, dass der Radialdruck mit zunehmendem Durchmesser sinkt, wodurch vermieden wird, dass die Gefäßwand aufgrund der radialen Ausdehnung des Thrombus übermäßig nach außen gedehnt und möglicherweise verletzt wird.

Das bedeutet, dass bei kleinem Durchmesser des Rekanalisationselements zum Öffnen der Durchflusspassage ein hoher Radialdruck einstellbar ist, der, wenn die Durchflusspassage geöffnet ist und das Rekanalisationselement einen größeren Durchmesser aufweist, stark fällt, so dass eine Belastung der Gefäßwand vermieden wird.

Bei einer weiteren bevorzugten Ausführungsform ist ein Betätigungselement vorgesehen, das mit dem Rekanalisationselement zusammenwirkt derart, dass der Durchmesser des Rekanalisationselements veränderbar ist. Das Rekanalisationselement kann beispielsweise durch einen Ballon oder mittels eines Führungsdrahtes betätigt werden, um die Durchmessererhöhung zur Bildung der Durchflusspassage zu erreichen.

Das Rekanalisationselement kann in der expandierten Rekanalisationsstellung einen mittleren Thrombenbereich und zwei äußere Gefäßbereiche aufweisen, wobei der Durchmesser des Thrombenbereichs kleiner als der Durchmesser der Gefäßbereiche ist, insbesondere in der Ruhestellung des Rekanalisationselement, in der keine äußeren Kräfte einwirken.. Mit dieser Anordnung wird erreicht, dass sich das Rekanalisationselement der Form des Thrombus anpasst, wobei sich der mittlere Thrombenbereich an den Thrombus und die beiden äußeren Gefäßbereiche an die an den Thrombus angrenzenden thrombusfreien Gefäßwände anlegt. Auf diese Weise wird die Sicherheit bei der Behandlung erhöht, da die beiden äußeren Gefäßbereiche eine Filterfunktion übernehmen können, falls es trotz der schonenden Behandlungsweise zu einer Partikelablösung kommt. Bevorzugte Durchmesserverhältnisse zwischen Thrombenbereich und Gefäßbereich betragen 1:6, insbesondere 1:5, insbesondere 1:4, insbesondere 1:3, insbesondere 1:2.

Die in den Unteransprüchen angegebenen Porengrößen bezogen auf die jeweiligen Durchmesser des Rekanalisationselements führen zu einer Feinmaschigkeit, die eine effektive Filterfunktion bewirkt. Damit wird erreicht, dass Thrombenpartikel, die sich bei einer beispielsweise medikamentösen Behandlung eventuell ablösen, vom Rekanalisationselement gefangen werden. Außerdem bewirkt die erhöhte Feinmaschigkeit, dass die Auflösung des Thrombus in den kleinen Maschen bzw. Poren des Rekanalisationselements kontrolliert erfolgt. Die in den Unteransprüchen angegebenen längenspezifischen Dimensionen haben den Vorteil, dass das expandierbare Rekanalisationselement so ausgelegt werden kann, dass auch die radiale Ausweitung längerer Thromben möglich ist. Insbesondere kann die Rekanalisationseinheit bzw. das Rekanalisationselement aus der proximalen Hohlführung so weit herausgeschoben werden,

bis die gesamte Thrombuslänge abgedeckt ist. Durch die feine Gitterstruktur wird außerdem eine Thrombenablösung bzw. die Ablösung von Partikeln verhindert.

Bei einer weiteren bevorzugten Ausführungsform weist das Rekanalisationselement zumindest bereichsweise eine fluiddichte Abdeckung zur Konzentration von Medikamenten im thrombennahen Bereich auf. Die fluiddichte Abdeckung erhöht die Wirksamkeit einer medikamentösen Behandlung, indem ein gezielter Blutstau mittels der fluiddichten Abdeckung eingestellt wird. Im Unterschied zum Stand der Technik wird der Blutstau nicht auf der proximalen Thrombenseite, sondern auf der distalen Thrombenseite erzeugt, so dass das Medikament im Bereich der Durchlasspassage auf eine größere Thrombenfläche einwirken kann, als dies im Stand der Technik der Fall ist, bei der die Angriffsfläche auf das proximale Gefäßlumen beschränkt ist. Dabei kann der Durchmesser des distalen Endes des Rekanalisationselements veränderbar sein derart, dass das distale Ende aus einer Dichtstellung in eine Durchlassstellung bewegbar ist. Dies hat den Vorteil, dass nach Abschluss der medikamentösen Behandlung oder auch temporär während der Behandlung der Blutdurchfluss durch den Thrombus wiederhergestellt wird.

Die fluiddichte Abdeckung kann zumindest am proximalen Ende des Rekanalisationselements angeordnet sein, wobei die Abdeckung eine erste Öffnung für den Blutdurchfluss aufweist, die seitlich neben der Hohlführung ausgebildet ist. Bei dieser Ausführungsform wird die Medikamentenkonzentration auf der proximalen Thrombenseite erhöht, da es aufgrund der fluiddichten Abdeckung zu einem lokalen Blutstau und einer entsprechenden Erhöhung der Medikamentenkonzentration im Bereich der Stirnflächen des Thrombus, bzw. im Bereich zwischen Abdeckung, Gefäßwand und Thrombus kommt. Die in der Abdeckung vorgesehene erste Öffnung seitlich neben der Hohlführung des Katheters erlaubt – im Gegensatz zum Stand der Technik – eine Aufrechterhaltung des Blutflusses durch den Thrombus. Der Blutstau und somit die Konzentration des Medikaments ist lokal auf die zugänglichen Wirkflächen des Thrombus beschränkt.

Eine weitere Verbesserung der Einwirkung des Medikaments auf den Thrombus wird bei einer weiteren Ausführungsform dadurch erreicht, dass aus dem Außenumfang des Rekanalisationselements, insbesondere in der Abdeckung ein oder mehrere in Längsrichtung des Rekanalisationselements erstreckte Kanäle angeordnet sind, die radial nach außen geöffnet sind. Durch die auf dem Außenumfang, insbesondere in der Abdeckung ausgebildeten Kanäle wird die Fläche des Rekanalisationselements vergrö-

ßert, über die das Medikament bereitgestellt wird und auf den Thrombus einwirken kann. Dazu erstrecken sich die Kanäle in Längsrichtung des Rekanalisationselements und sind radial nach außen geöffnet, so dass nicht nur die proximale Stirnfläche des Thrombus mit dem auflösenden Medikament in Berührung kommt, sondern auch die im Bereich der Durchflussöffnung angeordneten sich in Längsrichtung erstreckenden Thrombenflächen. Das Rekanalisationselement kann einen sternförmigen Querschnitt aufweisen, so dass die Medikamente-führenden Kanäle auf dem gesamten Umfang des Rekanalisationselements angeordnet sind und somit die behandelbare Wirkfläche des Thrombus weiter vergrößert wird. Wenn die sternförmig angeordneten Kanäle helixförmig über den Umfang des Rekanalisationselements verlaufen, wird deren Länge weiter vergrößert und somit auch die behandelbare Thrombenfläche.

Die Blutströmung durch den Thrombus wird bei den vorstehend genannten Ausführungsformen durch die in der proximalen Abdeckung vorgesehene Öffnung erreicht, so dass ein größerer Zeitraum zur Verfügung steht, den Thrombus medikamentös zu behandeln.

Vorzugsweise weist der Katheter wenigstens eine neben der Hohlführung angeordnete Medikamentenleitung auf. Damit ist die Medikamentenzufuhr in den Katheter integriert, wodurch die Handhabung des Katheters bei der medikamentösen Behandlung erleichtert wird. Die Medikamentenleitung kann auf der von der ersten Öffnung der Abdeckung abgewandten Seite des Rekanalisationselementes münden. Dies hat den Vorteil, dass das Medikament gezielt in den durch die Abdeckung gebildeten Totraum zwischen der Abdeckung und der Gefäßwand bzw. dem Thrombus eingebracht werden kann.

Die Medikamentenleitung kann einen schlauchförmigen Fortsatz umfassen, der sich über das axiale Ende der Hohlführung in axialer Richtung hinaus erstreckt und seitlich vom Rekanalisationselement platzierbar ist. Bei dieser Ausführungsform kann auf die fluiddichte Abdeckung verzichtet werden, da durch den schlauchförmigen Fortsatz die Möglichkeit besteht, das Medikament nahe der Stirnseite des Thrombus oder, bei geeigneter Länge des Fortsatzes, direkt in den Thrombus einzubringen. Dazu ist der schlauchförmige Fortsatz seitlich vom Rekanalisationselement platzierbar. Die die Abdeckung betreffenden Ausführungsformen können mit dieser Ausführungsform kombiniert werden.

Unter Stirnfläche des Thrombus ist jeweils das distale und proximale Axialende des Thrombus zu verstehen, das nach dem Aufweiten durch das Rekanalisationselement ringförmig den Thrombus begrenzt.

Der Katheter kann wenigstens eine neben der Hohlführung angeordnete Aspirationsleitung umfassen. Damit können bei der medikamentösen Behandlung eventuelle sich lösende Thrombenpartikel abgesaugt werden. Die Aspirationsleitung kann einen schlauchförmigen Fortsatz umfassen, der sich über das axiale Ende der Hohlführung in axialer Richtung hinaus erstreckt und seitlich vom Rekanalisationselement platzierbar ist. Diese Ausführungsform ist besonders zur Kombination mit dem schlauchförmigen Fortsatz der Medikamentenleitung geeignet und ermöglicht eine Absaugung von Thrombenpartikeln in unmittelbarer Nähe des Thrombus.

Die Erfindung wird nachfolgend anhand von Ausführungsbeispielen mit weiteren Einzelheiten unter Bezug auf die beigefügten schematischen Zeichnungen näher erläutert. In diesen zeigen:

Fig. 1 einen schematischen Querschnitt durch eine Vorrichtung zur Rekanalisation von Thromben nach einem erfindungsgemäßen Ausführungsbeispiel in der expandierten Rekanalisationsstellung;

Fig. 2 die Vorrichtung gemäß Fig. 1, die mittig in einem Thrombus angeordnet ist;

Fig. 3 ein weiteres Ausführungsbeispiel einer Vorrichtung zur Rekanalisation von Thromben, bei der das distale Rekanalisationselement von der Hohlführung abgekoppelt ist;

Fig. 4 die Vorrichtung gemäß Fig. 3 bei der medikamentösen Behandlung;

Fig. 5 eine Detailansicht der Gitterstruktur einer Rekanalisationseinheit mit relativ großer Porengröße;

Fig. 6 eine Detailansicht der Gitterstruktur einer Rekanalisationseinheit mit relativ kleiner Porengröße;

Fig. 7 eine Detailansicht der Gitterstruktur der Rekanalisationseinheit mit gewölbter Thrombenfläche;

Fig. 8a – d eine Vorrichtung zur Rekanalisation von Thromben nach einem weiteren Ausführungsbeispiel in verschiedenen Stadien der Abkopplung von der Hohlführung und einem Betätigungselement;

Fig. 9 eine Vorrichtung zur Rekanalisation von Thromben nach einem weiteren erfindungsgemäßen Ausführungsbeispiel mit einem Betätigungselement;

Fig. 10a die Vorrichtung gemäß Fig. 9 mit einer distalen Abdeckung in Durchlassstellung;

Fig. 10b die Vorrichtung gemäß Fig. 10a in Dichtstellung;

Fig. 11 eine Vorrichtung zur Rekanalisation von Thromben nach einem weiteren erfindungsgemäßen Ausführungsbeispiel mit proximaler Abdeckung und Medikamentenzufuhr;

Fig. 12a eine Vorrichtung zur Rekanalisation von Thromben nach einem weiteren erfindungsgemäßen Ausführungsbeispiel mit proximaler Abdeckung und Längskanälen in der Abdeckung;

Fig. 12b einen Querschnitt durch die Vorrichtung gemäß Fig. 12a;

Fig. 13a, 13b eine Vorrichtung zur Rekanalisation von Thromben nach einem weiteren erfindungsgemäßen Ausführungsbeispiel mit verlängerter Medikamentenleitung;

Fig. 14a, 14b die Vorrichtung gemäß Fig. 13 mit verlängerter Aspirationsleitung;

Fig. 15 einen vergrößerten Ausschnitt aus Fig. 14b;

Fig. 16 die Darstellung eines Gefäßverschlusses durch einen Thrombus und die herkömmliche Behandlung und

Fig. 17 die Darstellung eines Gefäßverschlusses durch einen Thrombus im Bereich einer Abzweigung mit herkömmlicher Behandlung.

Figuren 1 und 2 zeigen eine medizinische Vorrichtung zur Rekanalisation von Thromben, mit deren Hilfe eine Durchflusspassage durch den Thrombus gebildet werden kann. Mittels dieser Vorrichtung kann die Durchblutung innerhalb kürzester Zeit hergestellt werden, so dass das Zeitfenster für die medikamentöse Auflösung des Thrombus erhöht wird. Dazu umfasst die Vorrichtung einen Katheter 10, der zwei relativ zueinander verschiebliche Bauteile aufweist, nämlich eine proximale Hohlführung 11 und ein distales Rekanalisationselement 12. Das Rekanalisationselement 12 ist in der Hohlführung axial verschieblich angeordnet und kann aus einer komprimierten Katheterstellung in eine expandierte Rekanalisationsstellung (Fig. 1, 2) bewegt werden. In der komprimierten Katheterstellung ist das Rekanalisationselement 12 vollständig in der Hohlführung 11 aufgenommen. In der in den Fig. 1 und 2 dargestellten expandierten Rekanalisationsstellung ist das Rekanalisationselement 12 zumindest abschnittsweise außerhalb der Hohlführung 11 angeordnet. Konkret ist in der Rekanalisationsstellung nur ein axialer Endbereich des Rekanalisationselements 12 in der Hohlführung 11 angeordnet, um ein Zurückziehen des Rekanalisationselements 12 in die Hohlführung 11 zu ermöglichen, nachdem die medikamentöse Behandlung des Thrombus 24 abgeschlossen ist.

Das Rekanalisationselement 12 weist zumindest abschnittsweise eine hohlkörperförmige Gitterstruktur auf. Bei dem Ausführungsbeispiel gemäß den Fig. 1, 2 ist die Gitterstruktur 13 zylinderförmig. Andere geometrische Formen der Gitterstruktur 13 sind möglich. Die Gitterstruktur 13 kann durch ein Gittergeflecht oder durch eine geschnittene, insbesondere lasergeschnittene Struktur ausgebildet sein. Die Gitterstruktur 13 ist fluiddurchlässig, so dass der Blutstrom durch den Thrombus in der Rekanalisationsstellung, d.h. bei geöffneter Durchflusspassage durch den Thrombus, nicht behindert wird. Die offene Maschenstruktur bzw. Öffnungen der Rekanalisationseinheit 12 sorgen dafür, dass der Blutfluss wieder hergestellt ist, selbst wenn die Rekanalisationseinheit mit dem restlichen Katheter weiterhin verbunden bleibt, wie durch die Pfeile in Fig. 1, 2 verdeutlicht.

Zur Aufweitung des Thrombus und zur Bildung der Durchflusspassage weist die Gitterstruktur 13 einen veränderbaren Durchmesser auf. Die Gitterstruktur 13 ist dabei so angepasst, dass der Durchmesser des Rekanalisationselements 12 aus dem gecrimpten Zustand in den expandierten Zustand überführbar ist. Hierfür bestehen ver-

schiedene Möglichkeiten. Das Rekanalisationselement kann als selbstexpandierbares Element ausgebildet sein. Geeignete Materialien hierfür sind bekannt und umfassen beispielsweise Nitinol, CrCo-Legierungen, Elgiloymetall oder Kunststoffe. Allgemein sind Formgedächtniswerkstoffe möglich. Die Gitterstruktur 13 kann geschnitten, insbesondere lasergeschnitten oder geflochten sein. Bei der Verwendung eines Geflechtes kann die Gitterstruktur aus Drähten oder Bändern bestehen.

Wie in den Fig. 1, 2 zu erkennen, ist die axiale Länge des Rekanalisationselements 12 so bemessen, dass sich das Rekanalisationselement 12 in distaler Richtung über den Thrombus 24 hinaus erstreckt und im expandierten Zustand an die Gefäßwand 23 anlegt. Damit übergreift das Rekanalisationselement 12 den Thrombus 24 und verhindert wirksam, dass sich eventuell aus dem Thrombus 24 lösende Partikel in die Blutbahn gelangen. Die an den Enden aufgeweitete Struktur kann vorkonditioniert sein, um den Effekt zu verstärken. Die Konditionierung von Formgedächtniswerkstoffen ist dem Fachmann geläufig.

Ein weiteres Ausführungsbeispiel ist in Fig. 3 dargestellt, bei dem das Rekanalisationselement 12 im expandierten Rekanalisationszustand abkoppelbar ist. Dies hat den Vorteil, dass ein Verbleib des Katheters 12 im Gefäß nicht während der gesamten Behandlungsdauer erforderlich ist. Vielmehr kann der Katheter 10 vor der maximalen Verweildauer von 6 Stunden aus dem Gefäß entfernt werden und das Rekanalisationselement 12 verbleibt im Gefäß. Das Rekanalisationselement erfüllt daher für längere Zeit die Funktion der Rekanalisation und dient darüber hinaus als Filter für nach der Auflösung eventuell verbleibende Thrombuspartikel.

Das Rekanalisationselement 12 und die Hohlführung 11 bilden die proximalen und distalen Teile eines Katheters 10 und somit eine zum Katheter gehörende Einheit. Dies ändert nichts daran, dass das Rekanalisationselement 12 von der Hohlführung 11 bei dem Ausführungsbeispiel gemäß Fig. 3 abkoppelbar ist. Das Rekanalisationselement 12 und die Hohlführung 11 können alternativ auch fest verbunden sein derart, dass eine axiale Relativbeweglichkeit möglich ist und das Rekanalisationselement 12 in der Rekanalisationsstellung, also im ausgefahrenen Zustand, mit der Hohlführung 11 fest verbunden ist.

Die Funktion des Katheters gemäß Fig. 1 bis 3, insbesondere des Rekanalisationselements 12 des Katheters 10 besteht darin, eine radiale Kraft auf den Thrombus auszuüben, und zwar über die gesamte Länge des Thrombus. Dadurch wird die Beschaffen-

heit des Thrombus beeinflusst. Zum einen werden durch die auf den Thrombus wirkende Radialkraft dessen Dichte erhöht und seine Dimensionen reduziert. Dieser Vorgang erhöht das freie Lumen durch den Thrombus und somit die Rekanalisationsrate. Außerdem wird die im Thrombus befindliche Flüssigkeit vom Rekanalisationselement 12 aus der Thrombusmasse herausgedrückt. Durch die fluiddurchlässige Gitterstruktur 13 des Rekanalisationselements 12 wird das Wasser bzw. der flüssige Thrombusanteil durch die Gittermaschen herausgedrückt. Feste Bestandteile des Thrombus werden vom Gitter filtriert. Die verbliebene Thrombusmasse wird dadurch verringert, so dass die medikamentöse Behandlung beschleunigt wird.

Diese Wirkungsweise gilt für alle in der Anmeldung offenbarten Ausführungsbeispiele.

Wie in den Fig. 1 bis 3 zu erkennen, besteht die Wirkung des Katheters 10 darin, eine Passage durch den Thrombus zu öffnen. Dafür ist es nicht erforderlich, das gesamte Lumen des Gefäßes zügig und mit hoher Kraft wieder herzustellen. Die Gefäßwand ist in den meisten Fällen bei Thrombose gesund, so dass eine übermäßige Ausweitung zur Beschädigung des gesunden Gewebes führen kann. Vielmehr ist es ausreichend, im Thrombus bzw. am Thrombus vorbei (Fig. 1) eine vergleichsweise kleine Öffnung zu erzeugen, durch die Blut in die distal gelegenen Bereiche strömt und diese durchblutet. Eine Passage mit einem Durchmesser von 1 – 2 mm vermag 50 bis 90 % des physiologischen Blutflusses in einem Gefäß mit einem Durchmesser zwischen 4 und 6 mm wieder herzustellen.

Im Unterschied dazu weisen herkömmliche Gefäßstützen, wie beispielsweise Stents für die Behandlung von Stenosen oder zur Behandlung von Aneurhysmen eine weitaus höhere Radialkraft auf, um die Ausweitung des Gefäßes bis zum ursprünglichen Durchmesser zu ermöglichen. Dies ist bei dem Katheter 10 gemäß den Fig. 1 bis 3 insbesondere beim Rekanalisationselement 12 nicht erforderlich. Konkret ist bei dem Rekanalisationselement 12 gemäß den Fig. 1 bis 3, das eine selbstexpandierende Gitterstruktur 13 aufweist, die Radialkraft so eingestellt, dass die Öffnungspassage mit verhältnismäßig kleinem Durchmesser mit relativ großer Radialkraft erfolgt. Bei progressiver Auflösung des Thrombus sinkt die Radialkraft, damit nach vollständiger Auflösung des Thrombus die gesunde Gefäßwand nicht unnötigerweise beansprucht wird. Am Rand des Thrombus ist somit die auf die gesunden Gefäße wirkende Radialkraft ebenfalls beschränkt.

Es hat sich als zweckmäßig erwiesen, wenn der Radialdruck (Kraft/Oberfläche) zur Ausweitung bis zu 33 % des ursprünglichen Gefäßvolumens mehr als 300 mmHg, insbesondere mehr als 400 mmHg, insbesondere mehr als 500 mmHg und/oder zur Ausweitung bis zu 50 % des ursprünglichen Gefäßvolumens mehr als 250 mmHg, insbesondere mehr als 300 mmHg und/oder der Radialdruck bei vollständiger Ausweitung weniger als 50 mmHg, insbesondere weniger als 25 mmHg beträgt. Bezogen auf den Durchmesser des Rekanalisationselements 12 beträgt der Radialdruck (Kraft/Oberfläche) zur Ausweitung bis zu 33 % des Rekanalisationsdurchmessers mehr als 300 mmHg, insbesondere mehr als 400 mmHg, insbesondere mehr als 500 mmHg zur Ausweitung bis zu 40 % des Rekanalisationsdurchmessers mehr als 250 mmHg, insbesondere mehr als 300 mmHg, zur Ausweitung bis zu 66 % des Rekanalisationsdurchmessers mehr als 100 mmHg und zur Ausweitung von mehr als 80 % des Rekanalisationsdurchmessers weniger als 50 mmHg, insbesondere weniger als 25 mmHg.

Die Wirkung des Katheters im Zusammenhang mit einer medikamentösen Behandlung der Thrombolyse ist in den Fig. 4 bis 7 dargestellt. Diese Wirkung tritt generell bei Kathetern ein, die eine Rekanalisationseinheit 12 mit einer Gitterstruktur 13 aufweisen. Aufgrund der Bildung der Durchflusspassage erfolgt die Medikamentwirkung auf einer größeren Fläche, insbesondere bei langen Thromben. Durch das Rekanalisationselement 12 wird eine zusätzliche Wirkfläche in der Durchflusspassage gebildet, die wesentlich größer als die im Stand der Technik mögliche rein proximale Wirkfläche ist. Wie in den Fig. 4 bis 7 zu erkennen, wird das Medikament durch Konvektion zum Thrombus gebracht, da in der Durchflusspassage ein Blutfluss stattfindet. Der Prozess der Auflösung wird dadurch beschleunigt. Außerdem strömt das gesamte Medikament gezielt in das zu behandelnde Gefäß und nicht in Abzweigungsgefäße. Da das Gefäß durch das Rekanalisationselement 12 bereits rekanalisiert ist und somit ein Blutfluss stattfindet, kann die medikamentöse Behandlung langsamer und somit schonender stattfinden. Die Dosis kann feiner eingestellt werden als dies bisher möglich ist, wodurch das Risiko von Hirnblutungen sinkt.

Die Wirkung der Feinmaschigkeit ist in den Fig. 5 und 6 dargestellt. Durch die Feinmaschigkeit bzw. die kleine Porengröße bzw. Gittergröße wird eine effektive Filterfunktion gewährleistet. Dies gilt sowohl für die Durchflusspassage durch den Thrombus als auch für die proximalen Enden des Thrombus, die wie in Fig. 4 dargestellt, durch die aufgeweitete Rekanalisationseinheit 12 abgedeckt sind. Die erhöhte Feinmaschigkeit hat ferner die Wirkung, dass die Auflösung des Thrombus in den kleinen

Maschen kontrolliert erfolgt. Bei einer relativ großen Porengröße ist die Thrombusfläche in den Poren relativ groß, so dass der Thrombus sich in mehrere kleine Partikel auflösen kann. Der Thrombus zerfällt somit in mehrere kleine Partikel, die in die Blutbahn gelangen können, so dass sich der Thrombus nicht homogen auflöst (Fig. 5). Demgegenüber hat die Feinmaschigkeit der Gitterstruktur 13 den Vorteil, dass einzelne, kleine Thrombusbereiche innerhalb der Maschen bzw. Poren sich homogen auflösen (Fig. 6). Wie in Fig. 7 dargestellt, hat die relativ kleine Porengröße den Vorteil, dass die angreifbare Thrombusfläche erhöht wird, da sich die Fläche des Thrombus in die Maschen wölbt. Die Wölbung der Thrombusfläche wird bei der Ausweitung des Thrombus durch das Rekanalisationselement 12 erreicht, das eine radial nach außen wirkende Kraft auf die Thrombusfläche ausübt. Auch hierbei kommt es, wie in Fig. 7 durch die Pfeile angedeutet, zu einer turbulenten Blutverwirbelung, was eine verbesserte Wirkung des Medikaments nach sich zieht. Bei der lokalen Wölbung der Thrombusfläche in die Maschen der Gitterstruktur 13 hinein kann es überdies zu einem Eindringen der Gitterstruktur 13 in den Thrombus kommen, wodurch das Thrombengebilde mechanisch vorbehandelt wird, so dass das Medikament in die durch die Einwirkung der Gitterstruktur 13 entstehenden Risse eindringt.

Die in den Unteransprüchen angegebenen Porengrößen beziehen sich auf einen in eine Zelle bzw. Masche bzw. Pore eingeschriebenen Kreis. Die offenbarten Werte entsprechen dem Durchmesser dieses eingeschriebenen Kreises.

In den Fig. 8a, 8b, 8c, 8d ist eine konstruktive Anordnung beschrieben, mit der die Gitterstruktur 13 des Rekanalisationselements 12 gestreckt und von der Hohlführung 11 abgekoppelt werden kann. Die in den Figuren 8a bis d schematisch dargestellte medizinische Vorrichtung wird sowohl im Zusammenhang mit der Thrombolysebehandlung als auch unabhängig davon offenbart und beansprucht. Dazu umfasst die Vorrichtung wenigstens zwei relativ zueinander bewegliche Elemente, insbesondere die Hohlführung 11, sowie ein im Gefäß zu implantierendes bzw. zu platzierendes Element, das beispielsweise das Rekanalisationselement 12 sein kann. Das im Gefäß zu platzierende Element ist auf seiner distalen und proximalen Seite bzw. an den distalen und proximalen Enden mit Arretierungselementen 25a, 25b lösbar verbunden. Der Abstand zwischen den Arretierungselementen 25a, 25b ist veränderbar. Es ist auch möglich, dass der Abstand starr bzw. fest ist.

Das distale Arretierungsmittel 25a, das mit dem distalen Ende des Elements, insbesondere des Rekanalisationselements 12 verbunden ist, ist mit einer in axialer Rich-

tung des Elements wirkenden Kraft beaufschlagbar. Die Kraft wirkt insbesondere in proximaler und/oder in distaler Richtung, also zum Katheter 10 hin und/oder vom Katheter 10 fort gerichtet. Das distale Arretierungselement 25a kann mit einem Betätigungselement 14 verbunden sein, insbesondere mit einem Führungsdraht, so dass die Lage des distalen Arretierungsmittels 25 bezüglich des Katheters bzw. der Hohlführung 11 in proximaler und distaler Richtung veränderbar ist. Das distale Arretierungsmittel 25a ist mit dem distalen Ende des Rekanalisationselements 12 lösbar verbunden, insbesondere verrastet. Das distale Arretierungselement 25a weist Arme 29a, 29b bzw. allgemein Arretierungsmittel mit radial nach innen gerichteten Enden bzw. Haken auf, die klammerartig im Arretierungszustand in die Gitterstruktur 13 eingreifen (Fig. 8a). Die Arme 26a, 26b sind mit einer radial nach innen wirkenden Federkraft beaufschlagt, die bspw. durch eine elastische Verformung der Arme 26a, 26b im Arretierungszustand erreicht wird.

Es wird also generell eine medizinische Vorrichtung offenbart und beansprucht, die ein distales Arretierungselement 25a aufweist, das mit einem distalen Ende eines im Gefäß zu platzierenden Elements, insbesondere des Rekanalisationselements 12 lösbar verbunden ist. Das distale Arretierungselement 25a ist mit einer zumindest in distaler Richtung wirkenden Axialkraft beaufschlagbar derart, dass das distale Arretierungselement 25a aus einer Haltestellung, in der das distale Arretierungselement 25a mit dem distalen Ende des zu platzierenden Elementes verbunden ist, in eine Lösestellung bewegbar ist, in der das distale Arretierungselement 25a das zu platzierende Element, insbesondere das Rekanalisationselement 12 freigibt. Dazu kann das distale Arretierungselement 25a mit einem Betätigungselement 14, insbesondere einem Führungsdraht verbunden sein, der durch den Katheter 10 von einem Anwender in axialer Richtung bewegt werden kann.

Dem distalen Arretierungselement 25a kann ein proximales Arretierungselement 25b zugeordnet sein. Das distale Arretierungselement 25a kann auch ohne proximales Arretierungselement 25b vorgesehen sein. Das proximale Arretierungselement 25b ist mit dem proximalen Ende des zu platzierenden Elements bzw. des Rekanalisationselements 12 verbunden und zwar in der Haltestellung, in der das proximale Ende des Elements in der Hohlführung 11 angeordnet ist.

Dazu weist das proximale Arretierungselement 25b Arme 30a, 30b mit radial nach außen gerichteten Enden bzw. Haken auf, die im arretierten Zustand in die Gitterstruktur 13 des Katheters bzw. des Rekanalisationselement 12 eingreifen (Fig. 8a bis 8c).

Die Arme 30a, 30b sind mit einem proximal angeordneten Hülsenabschnitt 28 verbunden, der axial verschieblich in der Hohlführung 11 angeordnet ist.

Es wird also in allgemeiner Form ein proximales Arretierungselement 25b offenbart und beansprucht und zwar im Zusammenhang mit der medizinischen Vorrichtung, das längsaxial verschieblich im Katheter 10, insbesondere in der Hohlführung 11 angeordnet ist und zwischen einer Haltestellung und einer Lösestellung bewegbar ist. In der Haltestellung sind die Arretiermittel, insbesondere die Arme 30a, 30b mit den radial nach außen gerichteten Enden im Katheter 10 bzw. in der Hohlführung 11 angeordnet und wirken mit einer Innenwandung der Hohlführung 11 zusammen. Die Innenwandung der Hohlführung 11 wirkt dabei als eine Art Verschluss, der das proximale Ende des zu platzierenden Elementes mit dem Arretierungsmittel des Arretierungselements 25b, insbesondere den Armen 30a, 30b verbindet. In der Lösestellung des proximalen Arretierungselements 25b ist der durch die Hohlführung 11 gebildete Verschluss geöffnet derart, dass die Arretierungsmittel, insbesondere die Arme 30a, 30b das proximale Ende des zu platzierenden Elementes freigeben. Insbesondere sind in der Lösestellung die Arretierungsmittel, insbesondere die Arme 30a, 30b außerhalb der Hohlführung 11 angeordnet.

Die axiale Verschieblichkeit des proximalen Arretierungselements 25b in der Hohlführung 11 kann, wie in den Figuren 8a bis 8d dargestellt, durch den proximal angeordneten Hülsenabschnitt 28 erreicht werden, der mit den Arretierungsmitteln, insbesondere den Armen 30a, 30b verbunden ist. Eine andere Lagerung des proximalen Arretierungselements 25b im Katheter 10 ist möglich.

Das proximale Arretierungsmittel 25b ist, ebenso wie das distale Arretierungsmittel 25a, koaxial zum Betätigungselement 14, insbesondere dem Führungsdraht, angeordnet.

Wie in Fig. 8a gezeigt, kann durch die doppelseitige Arretierung das Rekanalisationselement 12 gestreckt werden. Das proximale Ende wird dabei festgehalten. Durch das Strecken gegen eine weiter erhöhte Axialkraft wird die das distale Arretierungselement 25a verschließende Federkraft überwunden und das distale Ende des Rekanalisationselements 12 abgekoppelt, wie in den Fig. 8b, 8c dargestellt. Zum Abkoppeln des proximalen Endes des Rekanalisationselements 12 wird die Hohlführung 11, d.h. die begrenzende Außenhülle des Katheters in proximale Richtung zurückgezogen, so

dass das proximale Ende des Rekanalisationselements 12 freigegeben wird und expandiert.

In den Fig. 9 bis Fig. 15 sind Ausführungsbeispiele für Katheter zur Rekanalisation von Thromben offenbart, die eine axiale Streckung bzw. Stauchung der Rekanalisationseinheit bzw. des Rekanalisationselements 12 ermöglichen. Dazu weist der Katheter 10 jeweils ein Betätigungselement 14, beispielsweise einen Führungsdraht auf, der mit dem distalen Ende 12a des Rekanalisationselements 12 verbunden ist. Das Betätigungselement 14 ist koaxial zum Rekanalisationselement 12 und zur Hohlführung 11 angeordnet.

Im gestreckten Zustand (nicht dargestellt) ist der Führungsdraht bzw. das Betätigungselement 14 ausgefahren und die Länge des Rekanalisationselementes 12 maximal. Dadurch wird der veränderbare Durchmesser des Rekanalisationselementes 12 verringert, so dass das Element 12 mit dem Führungsdraht 14 durch den Thrombus gestochen werden kann. Um das Durchstechen zu vereinfachen, kann eine Spitze am distalen Ende des Führungsdrahtes 14 oder auch an der Hohlführung 11 vorgesehen sein. Zum Vergrößern des Durchmessers des Rekanalisationselements 12 und somit zum Aufweiten des Thrombus wird der Führungsdraht 14 in proximaler Richtung in die Hohlführung 11 eingezogen, wodurch entgegengesetzte Axialkräfte auf die Gitterstruktur 13 wirken und diese stauchen, wie durch die entgegengesetzt zeigenden Pfeile in Fig. 9 dargestellt. Durch die Längenverkürzung wird der Durchmesser des Rekanalisationselementes 12 erhöht. Dabei wird ein Thrombenbereich 15a und zwei äußere Gefäßbereiche 15b, 15c gebildet. Der Thrombenbereich 15a bewirkt die Öffnung der Durchflusspassage durch den Thrombus. Die beiden äußeren Gefäßbereiche 15b, 15c legen sich an die Gefäßwand 23 an und bilden somit zwei Filter, die die Ablösung von Thrombenpartikeln verhindern. Durch die Komprimierung des Rekanalisationselementes 12 ist es möglich, die Ausweitung des Thrombus zu steuern. Der Anwender kann, je nach Art des Thrombus und des Verschlusses, die Kraft und den Grad der Rekanalisation erhöhen oder verringern. Ein weiterer Vorteil bei diesem Ausführungsbeispiel ist die doppelte Filtrierung von Partikeln, die sich eventuell ablösen durch die beiden äußeren Gefäßbereiche 15b, 15c. Die Partikel werden zunächst vom thrombusnahen Gitterbereich der beiden äußeren Gefäßbereiche 15b, 15c abgefangen. Eventuell nicht zurückgehaltene Partikel, die in die Blutbahn gelangen, werden durch die feine Gitterstruktur im Bereich des distalen Endes 12a gefiltert. Das distale Ende 12a kann daher eine erhöhte Feinmaschigkeit aufweisen.

Es ist auch möglich, nur einen, insbesondere nur einen distalen Gefäßbereich 15c mit dem Thrombenbereich 15a zu verbinden, wie in Fig. 8c dargestellt. Der Thrombenbereich 15a weist proximal einen annähernd konstanten oder einen verjüngten Durchmesser auf.

Die Ausführungsbeispiele mit Betätigungselement 14, bzw. Führungsdraht können mit einem proximal mit dem Rekanalisationselement 12 verbundenen Stabilizer kombiniert sein.

Bei den Ausführungsbeispielen gemäß Fig. 10a, 10b ist zusätzlich zu den Merkmalen des Ausführungsbeispiels gemäß Fig. 9 der distale Bereich 12a mit einer Abdeckung 16 versehen, die nach Art einer Kappe das distale Ende 12a umspannt. Damit ist es möglich, die Rekanalisation für kürzere Zeit einzustellen. Beispielsweise kann das Ende des Geflechtes so abgedichtet werden, dass ein Lumen bzw. eine Durchflusspassage durch den Thrombus besteht und das distale Ende 12a zumindest temporär verschlossen ist (Dichtstellung Fig. 10b). Dadurch kann das Medikament auf der Innenfläche des Thrombus wirken, ohne dass dieses weggespült wird. Durch die Streckung des Rekanalisationselementes 12 wird die Rekanalisation wieder hergestellt (Durchlassstellung Fig. 10a).

Die Verbindung des distalen Endes 12a des Rekanalisationselementes 12 mit dem Betätigungselement 14 ist bei dem Ausführungsbeispiel gemäß Fig. 10a, 10b fest bzw. dauerhaft. Alternativ kann die Verbindung durch eine lösbare Arretierung erfolgen, so dass das Element 12 von der Hohlführung 11 abkoppelbar ist. Die Arretierung kann durch die in den Fig. 11a – d offenbarten Arretierungselemente 25a, 25b ausgebildet sein.

Ein weiteres Beispiel für einen Katheter 10 mit einer fluiddichten Abdeckung 16 ist in den Fig. 11, 12a, 12b beschrieben. Die Abdeckung 16 erstreckt sich im Wesentlichen über die gesamte Länge des Rekanalisationselementes 12, zumindest aber im Bereich des proximalen Endes 12b. Wie in den Fig. 11, 12a zu erkennen, weist die Abdeckung 16 im Bereich des proximalen Endes 12b eine erste Öffnung 17a auf, die seitlich neben der Hohlführung 11 ausgebildet ist. Die erste Öffnung 17a bildet eine Eintrittsöffnung, durch die das Blut in das Rekanalisationselement 12 strömt. Am distalen Ende 12a ist eine zweite Öffnung 17b vorgesehen, die einen Blutauslass bildet, durch den das Blut aus dem Rekanalisationselement 12 strömt. Die beiden Öffnungen 17a, 17b ermöglichen den Blutfluss durch den Thrombus. Die Abdeckung 16 erstreckt sich bis

in den distalen Bereich des Rekanalisationselementes 12. Es ist auch möglich, dass die Abdeckung 16 kürzer ist und beispielsweise im mittleren Bereich des Rekanalisationselementes, insbesondere im Thrombenbereich 15a endet.

Für die Medikamentenzufuhr ist der Katheter 10 mehrlumig ausgebildet. Konkret umfasst der Katheter 10 die Hohlführung 11 und eine Medikamentenleitung 19, die in den Katheter 10 integriert ist. Die Medikamentenleitung 19 mündet auf der von der ersten Öffnung 17a der Abdeckung 16 abgewandten Seite. Damit schirmt die Abdeckung 16 die erste Öffnung 17a ab, so dass der Medikamentenzustrom nicht durch die erste Öffnung 17a abfließt. Die Abdeckung 16 bildet zusammen mit der Gefäßwand 23 und dem Thrombus 24 einen Totraum, in dem sich das Blut staut. In diesem Totraum sammelt sich das Medikament, wodurch die Konzentration steigt und die lösende Wirkung auf den Thrombus verbessert wird.

Bei dem Ausführungsbeispiel gemäß Fig. 12a, 12b ist zusätzlich zu der Anordnung gemäß Fig. 11 eine Kanalstruktur auf dem Außenumfang des Rekanalisationselements 12, insbesondere in der Abdeckung vorgesehen, die ein Eindringen des Medikamentes zwischen die Abdeckung 16 und den Thrombus 24 im Bereich der Durchlassöffnung ermöglicht. Konkret weist das Rekanalisationselement 12 einen sternförmigen Querschnitt auf, wie in Fig. 12b zu erkennen. Dadurch wird eine Vielzahl von Kanälen 18 auf dem Außenumfang des Rekanalisationselementes gebildet, durch die das Medikament an die Thrombenoberfläche im Bereich der Durchflusspassage gelangt. Dazu sind die Kanäle 18 radial nach außen geöffnet. Es ist möglich, dass die Kanäle 18 helixförmig auf dem Umfang verlaufen, wodurch eine längere Wirkstrecke erreicht wird.

Es ist auch möglich, die Kanäle 18 auf andere Weise zu bilden. Beispielsweise kann die Abdeckung 16, die beim Ausführungsbeispiel gemäß Figuren 12a, 12b auf der Außenseite der Gitterstruktur 13 angeordnet ist, alternativ auf der Innenseite der Gitterstruktur 13 angeordnet sein. Die Gitterstruktur 13 begrenzt die Außenkontur des Rekanalisationselementes 12 und bildet durch ihre Geometrie die Kanäle 18 zur Verteilung des Medikaments.

Ein weiteres Beispiel für einen mehrlumigen Katheter ist in den Fig. 13a, 13b dargestellt. Bei dieser Ausführungsform ist eine fluiddichte Abdeckung nicht zwingend erforderlich, kann aber vorgesehen sein. Bei diesem Ausführungsbeispiel ist die Medikamentenleitung 19 über das axiale Ende der Hohlführung 11 hinaus verlängert und bildet einen schlauchförmigen Fortsatz 20. Der schlauchförmige Fortsatz 20 ist seitlich

zum Rekanalisationselement 12 positionierbar derart, dass eine Spitze des Fortsatzes 20 bis in den Bereich des Thrombus 24 ragt. Der Fortsatz erstreckt sich dabei wenigstens über 10% der Länge des expandierten Rekanalisationselementes 12, insbesondere wenigstens über 20% der Länge, insbesondere wenigstens über 30% der Länge, insbesondere wenigstens über 40% der Länge, insbesondere wenigstens über 50% der Länge, insbesondere wenigstens über 60% der Länge, insbesondere wenigstens über 70% der Länge, insbesondere wenigstens über 80% der Länge, insbesondere wenigstens über 90% der Länge, insbesondere wenigstens über 100% der Länge, insbesondere wenigstens über 110% der Länge. Dabei kann die Spitze des Fortsatzes 20 in den Thrombus einstechen, so dass das Medikament direkt in den Thrombus eingebracht werden kann. Der Fortsatz 20 weist am distalen Ende eine Auslassöffnung 26 auf, durch die das thrombenlösende Medikament zugeführt werden kann. Vorteilhafterweise ist die in den Thrombus einstechende Spitze des Fortsatzes 20 mit einer Vielzahl von Öffnungen, insbesondere von radial angeordneten Öffnungen versehen, so dass das Medikament auf einer möglichst großen Thrombenfläche verabreicht wird. Eine Positionierung des Fortsatzes 20 an anderer Stelle ist möglich. Beispielsweise kann der Fortsatz 20 so positioniert sein, dass dieser zwischen Thrombus und der Gitterstruktur 13 angeordnet ist. Der Fortsatz kann ferner so lang dimensioniert sein, dass dieser den Thrombus durchsticht und distal aus dem Thrombus hinausragt. Die Medikamentenleitung 19 kann fest mit dem Katheter verbunden sein oder zusammen mit dem Fortsatz 20 relativ zur Hohlführung 11 bewegbar angeordnet sein. Damit kann der Fortsatz 20 bzw. die Zufuhrspitze durch den Thrombus bewegt werden, um die Verteilung des Medikamentes zu begünstigen. Für die axiale Beweglichkeit der Medikamentenleitung 19 ist diese als separater Schlauch ausgebildet, der in einer weiteren Hohlführung angeordnet ist, die neben der Hohlführung 11 für das Rekanalisationselement 12 angeordnet und integral mit dem Katheter 10 ausgebildet ist, wie in Fig. 14a dargestellt. Die Medikamentenleitung 19 ist in der weiteren Hohlführung axial verschieblich angeordnet.

Zusätzlich zu der Medikamentenleitung 19 kann, wie in Fig. 14a, 14b dargestellt, eine Aspirationsleitung 21 vorgesehen sein. Die Aspirationsleitung 21 kann mit dem Katheter 10 fest verbunden sein bzw. integral mit diesem ausgebildet sein. Alternativ, wie auch in Fig. 14a, 14b dargestellt, kann die Aspirationsleitung 21 als gesonderter Schlauch ausgebildet sein, der in einer weiteren Hohlführung neben der Hohlführung 11 für das Rekanalisationselement 12 axial verschieblich angeordnet ist. Die weitere Hohlführung kann sowohl die Aspirationsleitung 21 als auch die Medikamentenleitung 19 aufnehmen, wie in Fig. 14a verdeutlicht. Die Aspirationsleitung 21 umfasst einen

schlauchförmigen Fortsatz 22, der sich über das distale Ende der Hohlführung 11 bzw. der weiteren Hohlführung erstreckt und somit die Aspirationsleitung 21 verlängert. In dem dargestellten Ausführungsbeispiel ist der schlauchförmige Fortsatz 22 etwas kürzer als der schlauchförmige Fortsatz 20 der Medikamentenleitung, so dass die Aspirationsleitung 21 proximal vor dem Ende der Medikamentenleitung 19 bzw. des Fortsatzes 20 endet. Es ist auch möglich, dass der schlauchförmige Fortsatz 22 der Aspirationsleitung 21 genauso lang ist, wie die Medikamentenleitung 19 bzw. deren Fortsatz 20. Es ist auch möglich, dass die Aspirationsleitung 21 länger ist, als die Medikamentenleitung 19. Bei der Aspirationsleitung 19 ist eine axial angeordnete Öffnung zum Absaugen eventuell entstehender Thrombuspartikel vorgesehen, die durch die Medikamenteneinwirkung abgelöst werden. Es ist auch möglich, dass, wie bei der Medikamentenleitung 19 radial, angeordnete Öffnungen vorgesehen sind (zusätzlich oder alternativ zur axialen Öffnung), so dass mittels der Aspirationsleitung 21 auch seitlich aspiriert werden kann. Es versteht sich, dass auch bei der Medikamentenleitung 19 eine axiale Öffnung (alternativ oder zusätzlich zu den radialen Öffnungen) vorgesehen sein kann.

Zusätzlich kann die Oberfläche des Rekanalisationselementes so gestaltet sein, dass präferenzielle Kanäle an der Schnittstelle zur Thrombusfläche gebildet sind, an denen das Medikament gut verteilt wird. Alternativ können diese Kanäle für die Aspiration verwendet werden. Zu diesem Zweck kann das Rekanalisationselement 12 eine nichtzylindrische Form aufweisen. Trotz der Aufweitung und der Radialdrücke, die auf die Thrombusfläche wirken, bleiben diese Kanäle für die Medikamentenzufuhr offen.

Bei dem Katheter handelt es sich um einen kleinlumigen Katheter für die Behandlung von Thromben in sehr kleinen Gefäßen, beispielsweise in zerebralen Gefäßen. Der Katheter hat einen Außendurchmesser von weniger als zwei, weniger als 1,5, weniger als 1, weniger als 0,9, weniger als 0,8, weniger als 0,7, weniger als 0,6 mm. Der Katheter kann zwei oder drei oder mehr Lumen aufweisen. In diesem Fall ist der Außendurchmesser des Katheters kleiner als 3, kleiner als 2, kleiner als 1,4, kleiner als 1,2, kleiner als 1,0 mm. Die Wandstärke des Katheters ist kleiner als 0,2, kleiner als 0,15, kleiner als 0,1 mm. Die Bespannung des Rekanalisationselementes 12 kann mit Kunststoff, insbesondere lösbar in Form von Folien für eine vollständige Filterfunktion erfolgen. Die Medikamentabgabe kann durch die Außenbeschichtung des Rekanalisationselementes bzw. durch die Bespannung erfolgen.

Im Rahmen der Erfindung wird ferner ein Verfahren zur Behandlung von Thrombolysen offenbart, bei dem ein Katheter umfassend zwei relativ zueinander verschiebbare proximale und distale Elemente, insbesondere eine Hohlführung 11 und ein Rekanalisationselement 12 durch den zu behandelnden Thrombus gestochen wird. Durch eine Relativbewegung zwischen den beiden Elementen wird eines der beiden Elemente, die Hohlführung 11 aus dem Thrombenbereich entfernt. Das andere im Thrombenbereich verbleibende Element, das Rekanalisationselement 12 wird ausgedehnt derart, dass eine Aufweitung des Thrombus und die Bildung einer Durchflusspassage erfolgen. Dabei ist das im Thrombus verbleibende und für die Aufweitung sorgende Element so gestaltet, dass eine Blutströmung durch die Passage möglich ist. Zusätzlich und gleichzeitig zur Bildung der Durchflusspassage kann eine medikamentöse Behandlung durchgeführt werden. Bei dem Verfahren kann das Rekanalisationselement 12 von der Hohlführung in der Rekanalisationsstellung abgekoppelt werden, wobei der Katheter 10 bzw. die Hohlführung 11 aus dem Blutgefäß entfernt werden.

Die zur Durchführung des Verfahrens verwendeten Bauteile bzw. die medizinische Vorrichtung umfasst die vorstehend offenbarten Ausführungsbeispiele.

Bezugszeichenliste

10	Katheter
11	Hohlführung
12	Rekanalisationselement
12a	distales Ende
12b	proximales Ende
13	Gitterstruktur
14	Betätigungselement
15a	Thrombenbereich
15b, c	Gefäßbereich
16	Abdeckung
17a	erste Öffnung
17b	zweite Öffnung
18	Kanäle
19	Medikamentenleitung
20	Fortsatz
21	Aspirationsleitung
22	Fortsatz

23	Blutgefäß
24	Thrombus
25a	distales Arretierungsmittel
25b	proximales Arretierungsmittel
26	Auslassöffnung
27	Ansaugöffnung
28	Hülsenabschnitt
29a, b	Arme
30a, b	Arme

Ansprüche

1. Medizinische Vorrichtung zur Rekanalisation von Thromben umfassend einen Katheter (10) mit einer proximalen Hohlführung (11) und einem distalen Rekanalisationselement (12), das in der Hohlführung (11) axial verschieblich angeordnet und aus einer komprimierten Katheterstellung in der Hohlführung (11) in eine expandierte Rekanalisationsstellung bewegbar ist, in der das Rekanalisationselement (12) zumindest abschnittsweise außerhalb der Hohlführung (11) angeordnet ist, wobei das Rekanalisationselement (12) zumindest abschnittsweise eine hohlkörperförmige fluiddurchlässige Gitterstruktur (13) mit veränderbarem Durchmesser aufweist, die zur Aufweitung eines Thrombus angepasst ist derart, dass in der Rekanalisationsstellung eine Durchflusspassage im Thrombus entsteht.

2. Thrombus nach Anspruch 1,
d a d u r c h g e k e n n z e i c h n e t, dass
das Rekanalisationselement (12) selbstexpandierbar ist.

3. Vorrichtung nach Anspruch 2,
d a d u r c h g e k e n n z e i c h n e t, dass
die Gitterstruktur (13) des Rekanalisationselements (12) angepasst ist derart, dass der Radialdruck, der vom Rekanalisationselement (12) in der Rekanalisationsstellung auf den Thrombus ausübbar ist, wenigstens 300 mmHg, insbesondere wenigstens 400 mmHg, insbesondere wenigstens 500 mmHg bei einer Expansion von bis zu 33 % des Durchmessers des Rekanalisationselements 12, insbesondere mindestens 250 mmHg, weiter insbesondere mindestens 300 mmHg bei einer Expansion von bis zu 40 % des Durchmessers des Rekanalisationselements 12, insbesondere mindestens 100 mmHg bei einer Expansion von bis zu 66 % des Durchmessers des Rekanalisationselements (12) jeweils in der Ruhestellung beträgt.

4. Vorrichtung nach Anspruch 2 oder 3,
d a d u r c h g e k e n n z e i c h n e t, dass
die Gitterstruktur (13) der Rekanalisationselements (12) angepasst ist derart, dass der Radialdruck, der vom Rekanalisationselement (12) in der Rekanalisationsstellung auf den Thrombus ausübbar ist, höchstens 50 mmHg, insbesondere höchstens 25 mmHg bei einer Expansion von mehr als 80 % des Durchmessers

des Rekanalisationselements (12) in der Ruhestellung beträgt.

5. Vorrichtung nach Anspruch 1,
d a d u r c h g e k e n n z e i c h n e t, dass
ein Betätigungselement (14) vorgesehen ist, das mit dem Rekanalisationselement (12) zusammenwirkt derart, dass der Durchmesser des Rekanalisationselements (12) veränderbar ist.

6. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 5,
d a d u r c h g e k e n n z e i c h n e t, dass
das Rekanalisationselement (12) in der expandierten Rekanalisationsstellung einen mittleren Thrombenbereich (15a) und zwei äußere Gefäßbereiche (15b, 15c) aufweist, wobei der Durchmesser des Thrombenbereichs (15a) kleiner als der Durchmesser der Gefäßbereiche (15b, 15c) ist.

7. Vorrichtung nach Anspruch 6,
d a d u r c h g e k e n n z e i c h n e t, dass
das Durchmesserverhältnis zwischen dem Thrombenbereich (15a) und den Gefäßbereichen (15b, 15c) 1:6, insbesondere 1:5, insbesondere 1:4, insbesondere 1:3, insbesondere 1:2 beträgt.

8. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 7,
d a d u r c h g e k e n n z e i c h n e t, dass
die Poren der Gitterstruktur (13)

- bei einem Durchmesser des Rekanalisationselements (12) zwischen 2,0 und 3,0 mm eine maximale Größe von 0,2 mm, insbesondere 0,15 mm, insbesondere 0,1 mm, insbesondere 0,05 mm;

- bei einem Durchmesser des Rekanalisationselements (12) zwischen 3,0 und 5,0 mm eine maximale Größe von 0,4 mm, insbesondere 0,3 mm, insbesondere 0,2 mm, insbesondere 0,1mm;

- bei einem Durchmesser des Rekanalisationselements zwischen 5,0 und 8,0 mm eine maximale Größe von 0,8 mm, insbesondere 0,6 mm, insbesondere 0,4 mm, insbesondere 0,2 mm

aufweisen.

9. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 8,
d a d u r c h g e k e n n z e i c h n e t, dass
die axiale Länge des Rekanalisationselements im Ruhezustand mindestens 30 mm, insbesondere mindestens 40 mm, insbesondere mindestens 50 mm, insbesondere mindestens 80 mm, insbesondere mindestens 100 mm, insbesondere mindestens 120 mm, insbesondere mindestens 150 mm beträgt.

10. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 9,
d a d u r c h g e k e n n z e i c h n e t, dass
das Verhältnis der Länge des Rekanalisationselements (12) in mm zur Breite der Stege der Gitterstruktur (13) in µm mindestens 1, insbesondere mindestens 2, insbesondere mindestens 3, insbesondere mindestens 4, insbesondere mindestens 5 beträgt.

11. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 10,
d a d u r c h g e k e n n z e i c h n e t, dass
das Verhältnis der Länge des Rekanalisationselements (12) in mm zur Porengröße in µm mindestens 1, insbesondere mindestens 2, insbesondere mindestens 3 beträgt.

12. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 11,
d a d u r c h g e k e n n z e i c h n e t, dass
das Verhältnis der Länge in mm des Rekanalisationselements (12) zum expandierten Durchmesser in mm des Rekanalisationselements (12) mindestens 20, insbesondere mindestens 25, insbesondere mindestens 30, insbesondere mindestens 35, insbesondere mindestens 40, insbesondere mindestens 45, insbesondere mindestens 50, insbesondere mindestens 55, insbesondere mindestens 60, insbesondere mindestens 65, insbesondere mindestens 70, insbesondere mindestens 75 beträgt.

13. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 12,
d a d u r c h g e k e n n z e i c h n e t, dass
das Verhältnis der Länge in mm des Rekanalisationselements (12) zum gecrimpten

Durchmesser in mm des Rekanalisationselements (12) mindestens 50, insbesondere mindestens 100, insbesondere mindestens 150, insbesondere mindestens 200, insbesondere mindestens 250 beträgt.

14. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 13,
d a d u r c h g e k e n n z e i c h n e t, dass
das Verhältnis der Länge in mm des Rekanalisationselements (12) zur Wandstärke in mm der Stege der Gitterstruktur (13) mindestens 1, insbesondere mindestens 2, insbesondere mindestens 3, insbesondere mindestens 4, insbesondere mindestens 5 beträgt.

15. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 14,
d a d u r c h g e k e n n z e i c h n e t, dass
das Rekanalisationselement (12) zumindest bereichsweise eine fluiddichte Abdeckung (16) zur Konzentration von Medikamenten im thrombennahen Bereich aufweist.

16. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 15,
d a d u r c h g e k e n n z e i c h n e t, dass
die fluiddichte Abdeckung (16) zumindest am distalen Ende des Rekanalisationselements (12) angeordnet ist.

17. Vorrichtung nach Anspruch 16,
d a d u r c h g e k e n n z e i c h n e t, dass
der Durchmesser des distalen Endes (12a) des Rekanalisationselements (12) veränderbar ist derart, dass das distale Ende (12a) aus einer Dichtstellung in eine Durchlassstellung bewegbar ist.

18. Vorrichtung nach wenigstens einem der Ansprüche 15 bis 17,
d a d u r c h g e k e n n z e i c h n e t, dass
die fluiddichte Abdeckung (16) zumindest am proximalen Ende (12b) des Rekanalisationselements (12) angeordnet ist, wobei die Abdeckung (16) eine ersten Öffnung (17a) für den Blutdurchlass aufweist, die seitlich neben der Hohlführung (11) des Katheters (10) ausgebildet ist.

19. Vorrichtung nach wenigstens einem der Ansprüche 15 bis 18,
d a d u r c h g e k e n n z e i c h n e t, dass

auf dem Außenumfang des Rekanalisationselementes (12), insbesondere in der Abdeckung (16) ein oder mehrere in Längsrichtung des Rekanalisationselements (12) erstreckte Kanäle (18) angeordnet sind, die radial nach außen geöffnet sind.

20. Vorrichtung nach wenigstens einem der Ansprüche 15 bis 19,
d a d u r c h g e k e n n z e i c h n e t, dass
das Rekanalisationselement (12) einen sternförmigen Querschnitt aufweist.

21. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 20,
d a d u r c h g e k e n n z e i c h n e t, dass
der Katheter (10) wenigstens eine neben der Hohlführung (11) angeordnete Medikamentenleitung (19) umfasst.

22. Vorrichtung nach Anspruch 21,
d a d u r c h g e k e n n z e i c h n e t, dass
die Medikamentenleitung (19) auf der von der ersten Öffnung (17a) der Abdeckung (16) abgewandten Seite des Rekanalisationselements (12) mündet.

23. Vorrichtung nach Anspruch 21 oder 22,
d a d u r c h g e k e n n z e i c h n e t, dass
die Medikamtenleitung (19) einen schlauchförmigen Fortsatz (20) umfasst, der sich über das axiale Ende der Hohlführung (11) in axialer Richtung hinaus erstreckt und seitlich von Rekanalisationselement (12) platzierbar ist.

24. Vorrichtung nach wenigstens einem der Ansprüche 1 bis 23,
d a d u r c h g e k e n n z e i c h n e t, dass
der Katheter (10) wenigstens eine neben der Hohlführung (11) angeordnete Aspirationsleitung (21) umfasst.

25. Vorrichtung nach Anspruch 24,
d a d u r c h g e k e n n z e i c h n e t, dass
die Aspirationsleitung (21) einen schlauchförmigen Fortsatz (22) umfasst, der sich über das axiale Ende der Hohlführung (11) in axialer Richtung hinaus erstreckt und seitlich vom Rekanalisationselement (12) platzierbar ist.

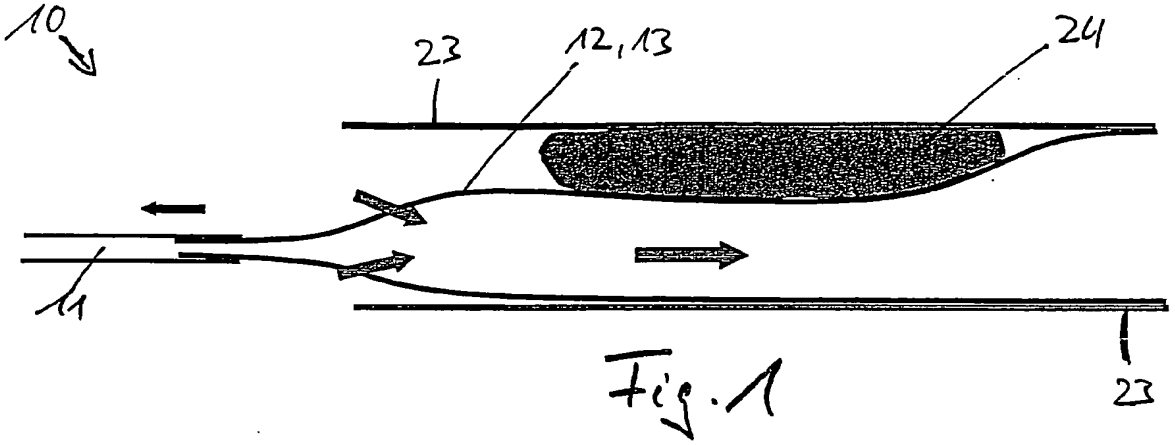

Fig. 1

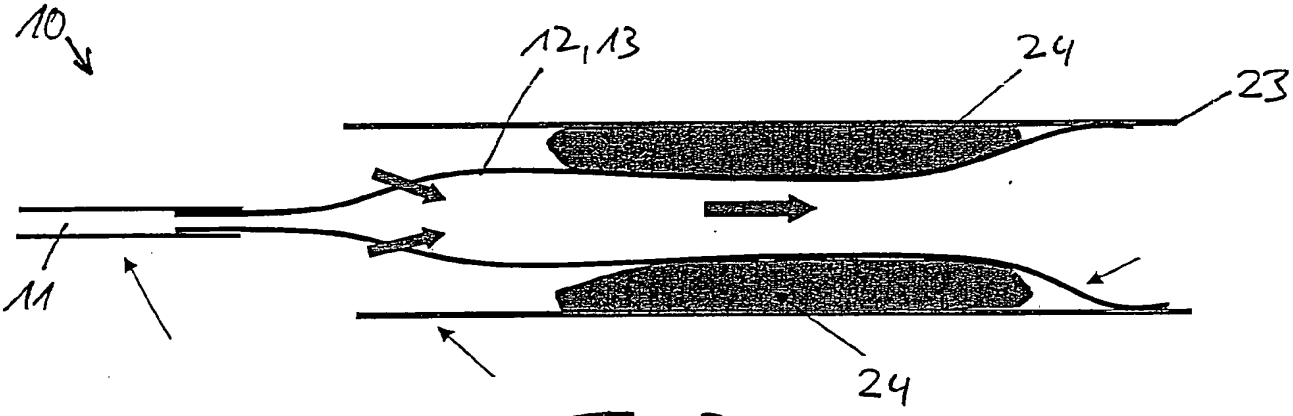

Fig. 2

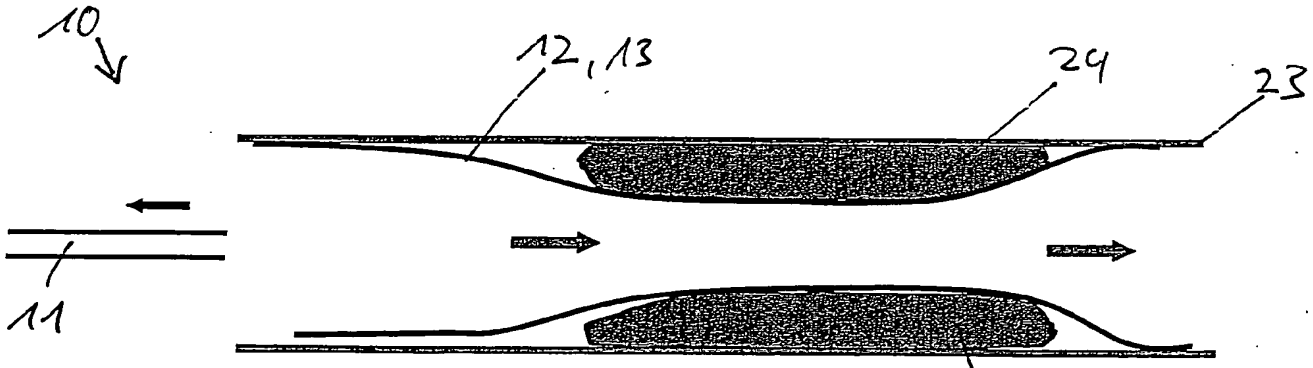

Fig. 3

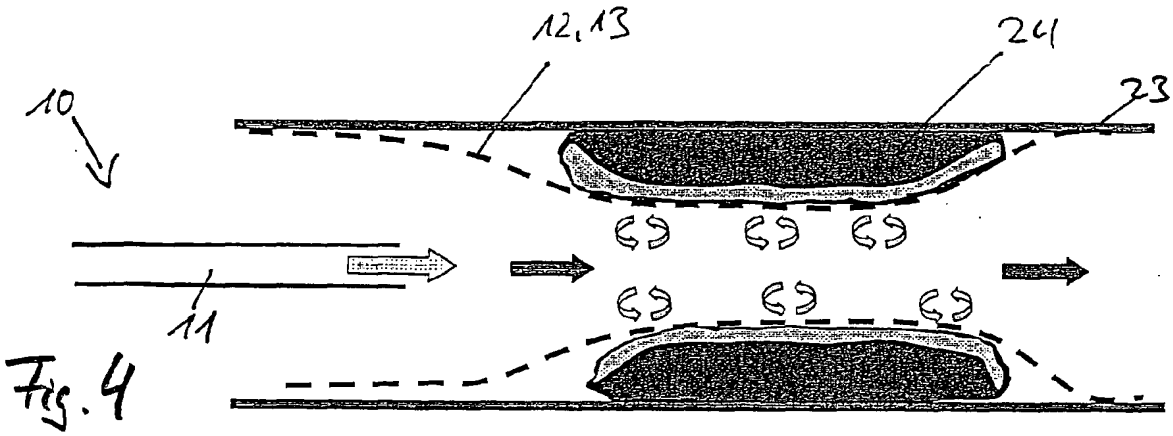

Fig. 4

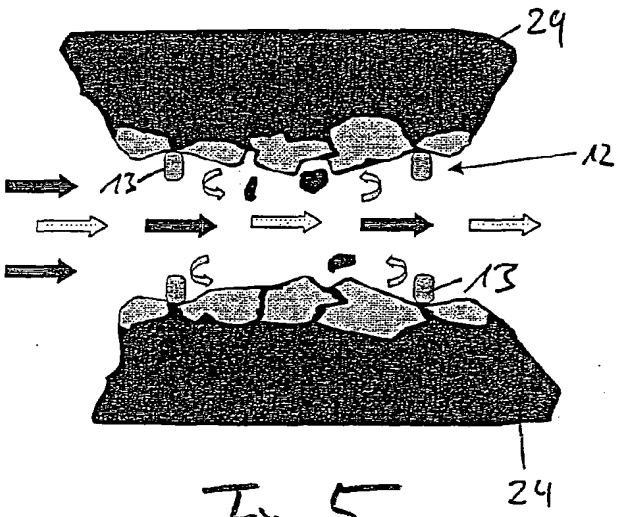

Fig. 5

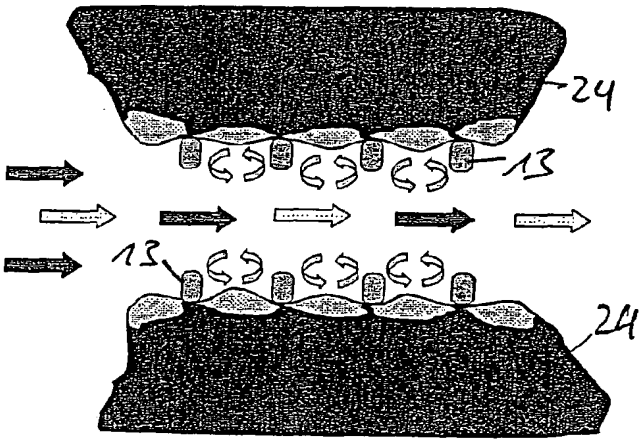

Fig. 6

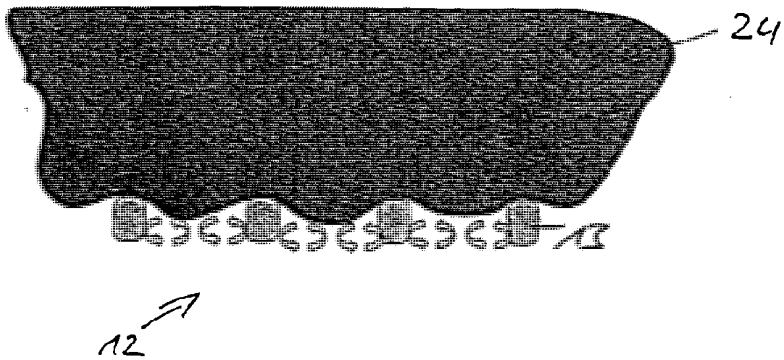

Fig. 7

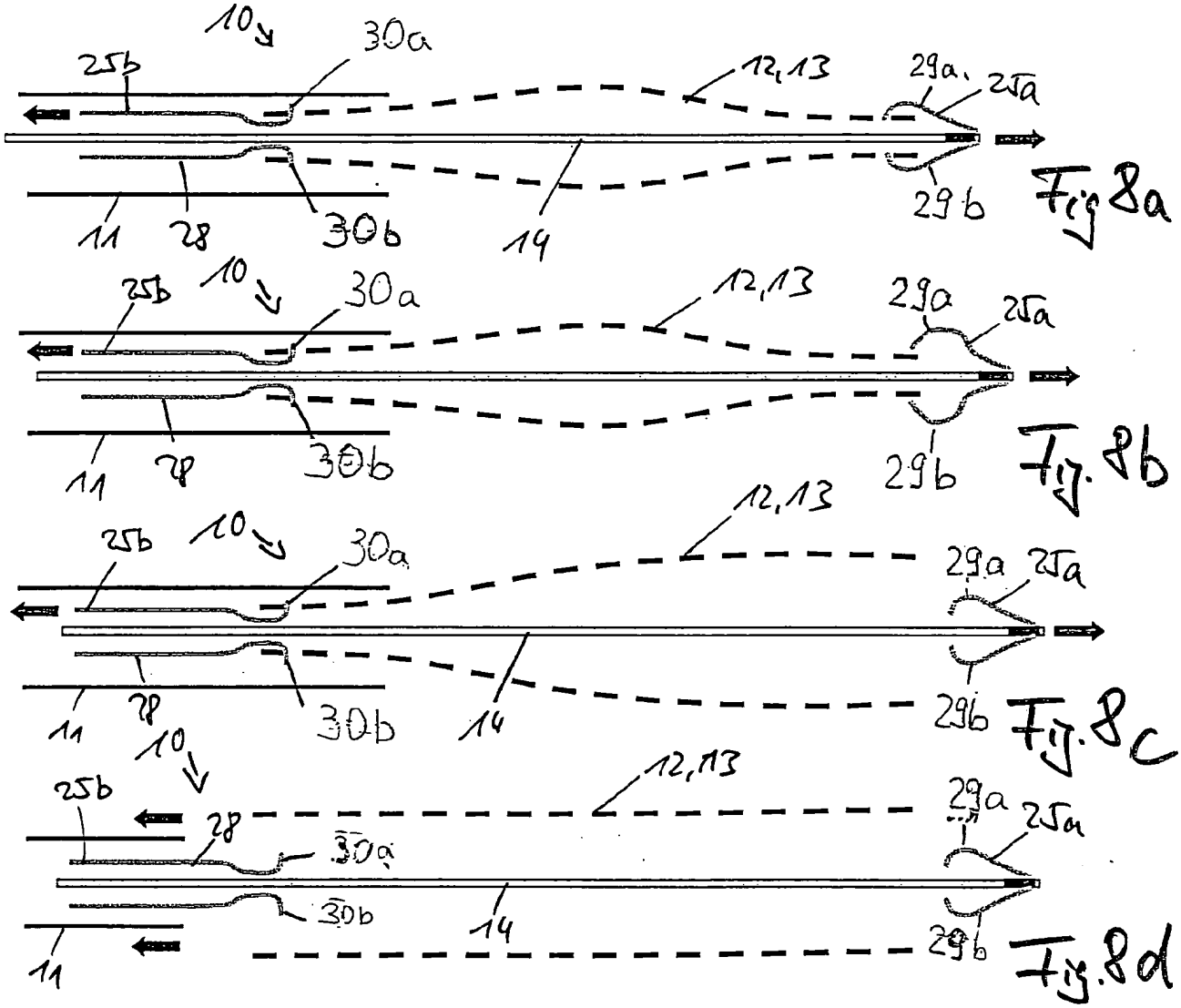

Fig 8a

Fig. 8b

Fig. 8c

Fig. 8d

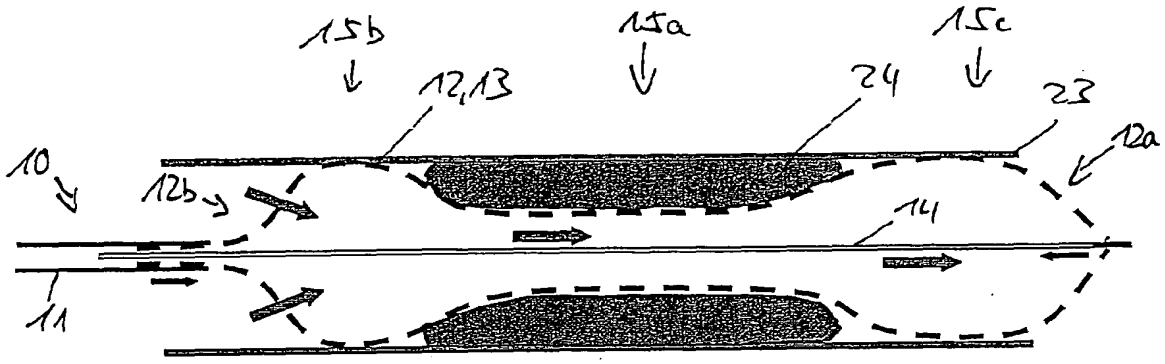

Fig. 9

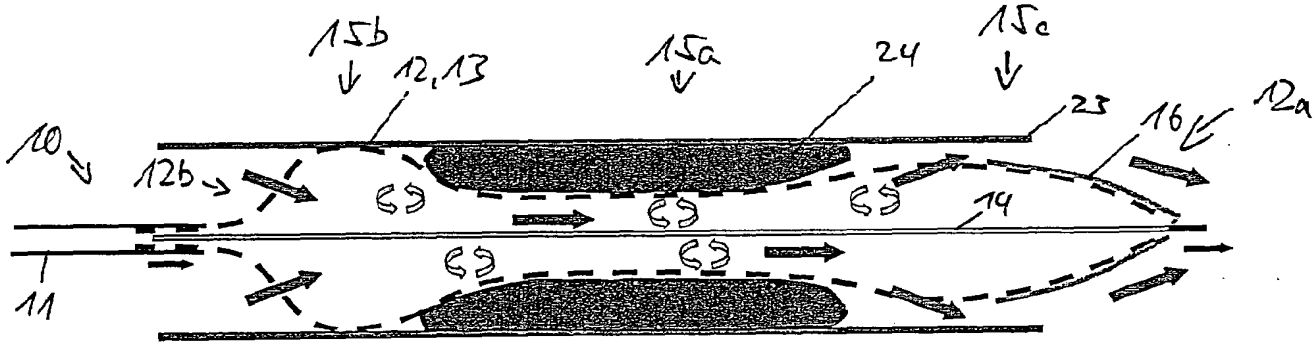

Fig. 10a

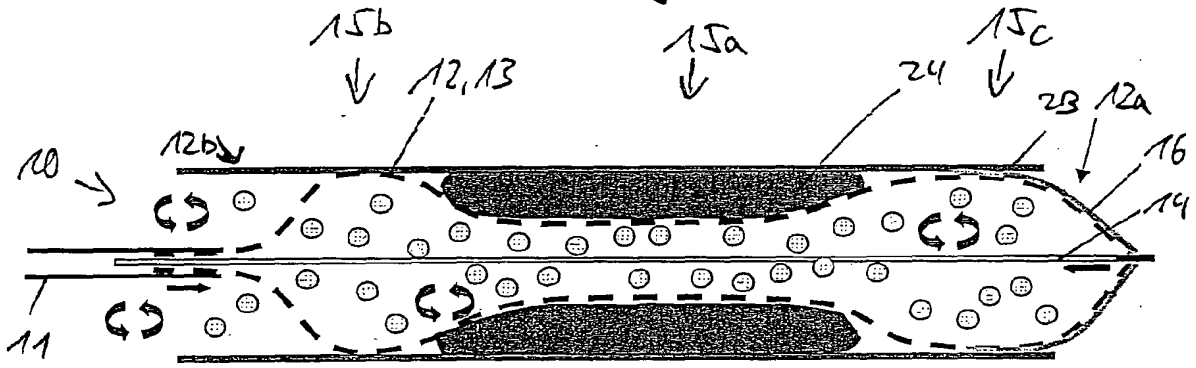

Fig. 10b

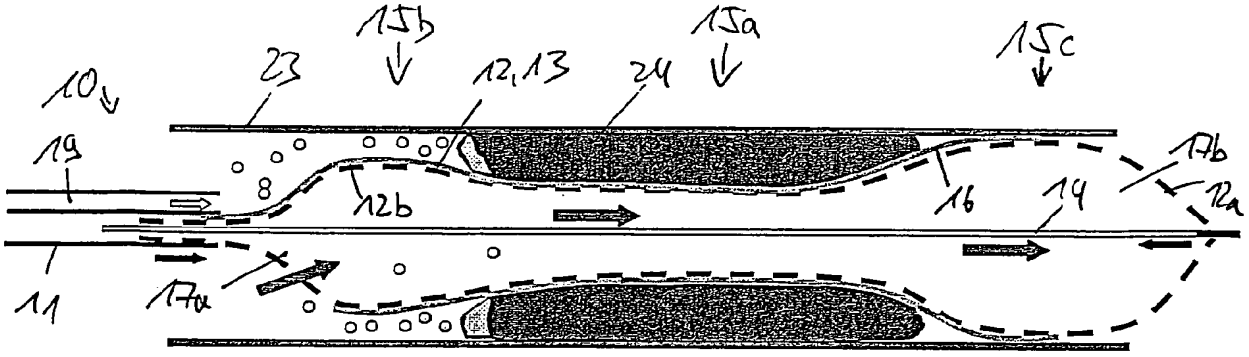

Fig. 11

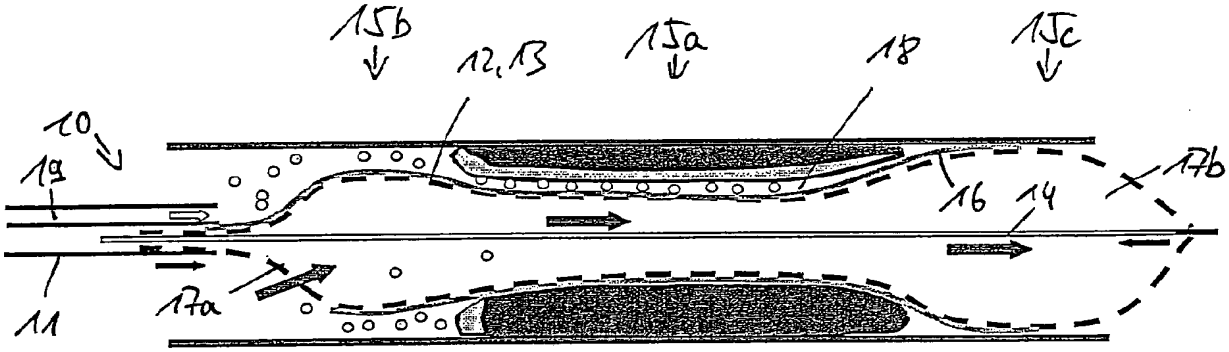

Fig. 12a

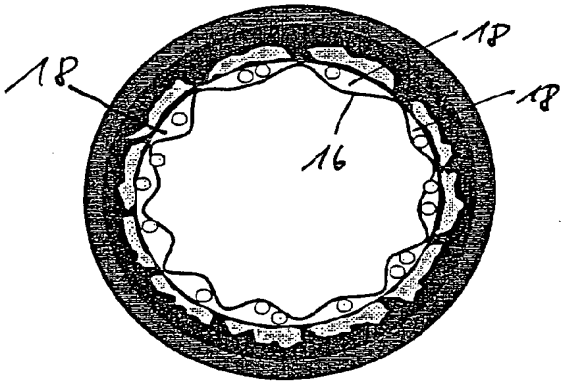

Fig. 12b

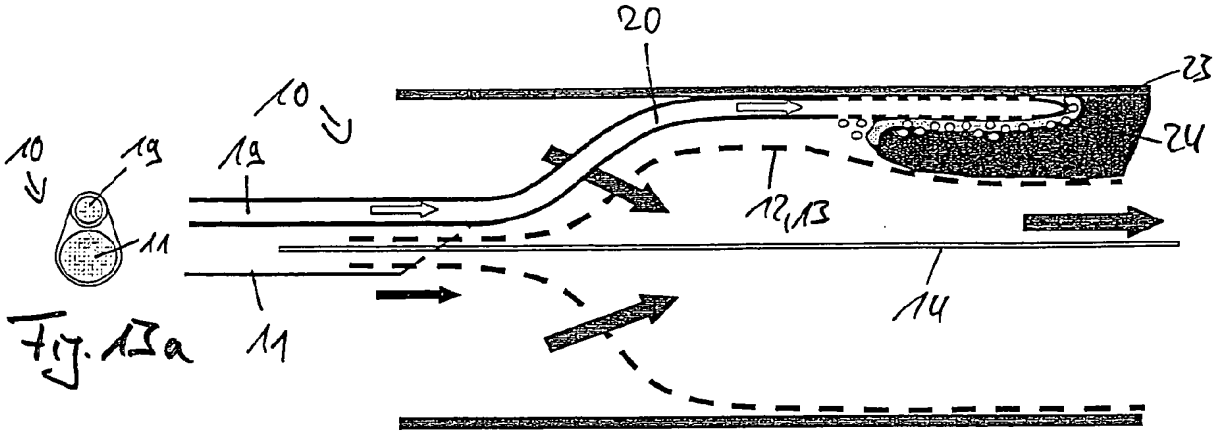

Fig. 13a

Fig. 13b

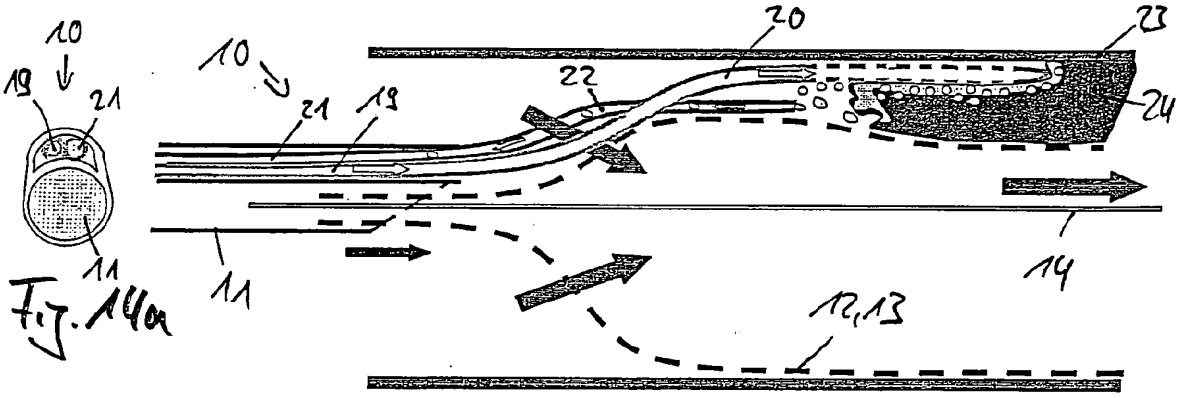

Fig. 14a

Fig. 14b

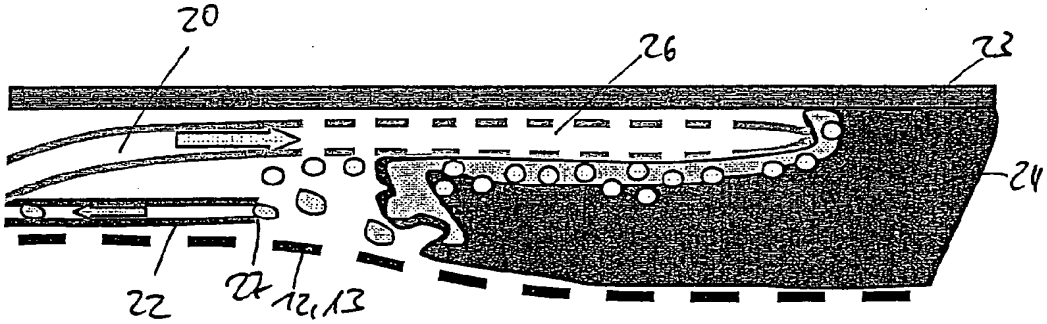

Fig. 15

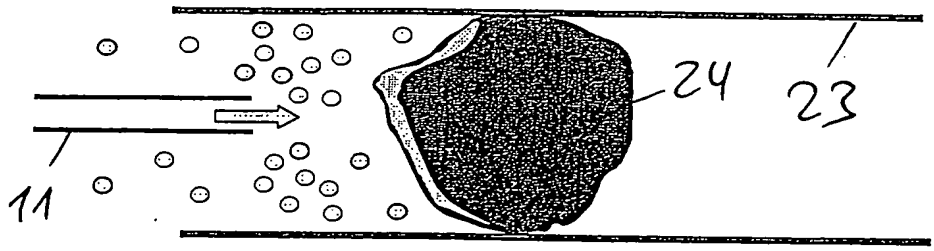

Fig. 16 (Stand der Technik)

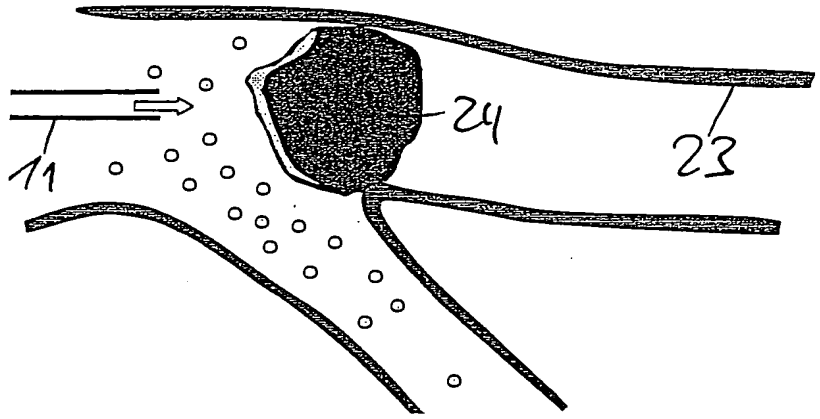

Fig. 17 (Stand der Technik)

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(54) **Title:** RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

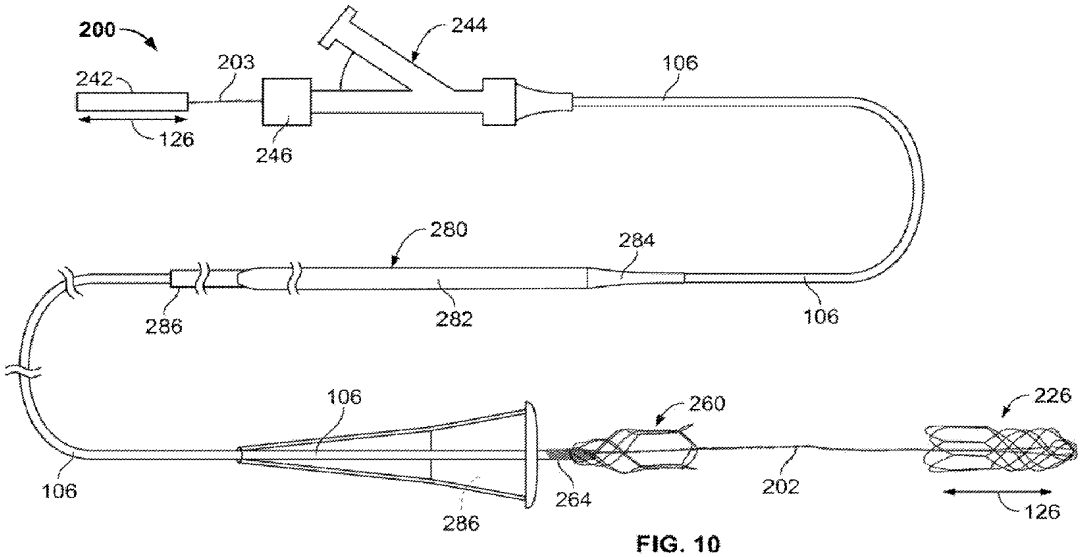

FIG. 10

(57) **Abstract:** The devices and methods described herein relate to improved structures for removing obstructions from body lumens. Such devices have applicability in through-out the body, including clearing of blockages within the vasculature, by addressing the factional resistance on the obstruction prior to attempting to translate and/or mobilize the obstruction within the body lumen.

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RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

RELATED APPLICATIONS

[0001] This application is a non-provisional application of U.S. Provisional Application No. 61/016,651 filed on December 26, 2007, the entirety of which is incorporated by reference herein.

FIELD OF THE INVENTION

[0002] The devices described herein are intended to retrieve obstructions from the body. In a first variation, the devices are constructed in wire form where the wires diverge from a main bundle to form a variety of shapes that form a composite device. The benefit of such a diverging wire construction is that the composite complex device can be of a "joint-less" construction. Such devices have applicability through out the body, including clearing of blockages within body lumens, such as the vasculature, by providing a capturing portion that can envelop the obstruction to address the frictional resistance between the obstruction and body lumen prior to attempting to translate and/or mobilize the obstruction within the body lumen. In addition, the devices described below include features that prevent unwanted and premature mobilization of the obstruction when removing the obstruction through tortuous anatomy.

BACKGROUND OF THE INVENTION

[0003] Many medical device applications require advancement of device in a reduced profile to a remote site within the body, where on reaching a target site the device assumes or is deployed into a relatively larger profile. Applications in the cerebral vasculature are one such example of medical procedures where a catheter advances from a remote part of the body (typically a leg) through the vasculature and into the cerebral region of the vasculature to deploy a device. Accordingly, the deployed devices must be capable of achieving a larger profile while being able to fit within a small catheter or microcatheter. In addition, the degree to which a physician is limited in accessing remote regions of the cerebral vasculature is directly related to the limited ability of the device to constrain into a reduced profile for delivery.

[0004] Treatment of ischemic stroke is one such area where a need remains to deliver a device in a reduced profile and deploy the device to ultimately remove a blockage in an artery leading to the brain. Left untreated, the blockage causes a lack of supply of oxygen and nutrients to the brain tissue. The brain relies on its arteries to supply oxygenated blood from the heart and lungs. The blood returning from the brain carries carbon dioxide and cellular waste. Blockages that interfere with this supply eventually cause the brain tissue to stop functioning. If the disruption in supply occurs for a sufficient amount of time, the continued lack of nutrients and oxygen causes irreversible cell death (infarction). Accordingly, immediate medical treatment of an ischemic stroke is critical for the recovery of a patient.

[0005] Naturally, areas outside of ischemic stroke applications can also benefit from improved devices. Such improved devices can assume a profile for ultimate delivery to remote regions of the body and can remove obstructions. There also remains a need for devices and systems that can safely remove the obstruction from the body once they are secured within the device at the target site. Furthermore, there remains a need for such devices that are able to safely removed once deployed distally to the obstructions in the even that the obstructions is unable to be retrieved.

[0006] Accordingly, a need remains for devices that can assume deployed configurations and are fabricated to eliminate or reduce the number of joints and/or connection points in the device.

SUMMARY OF THE INVENTION

[0007] The examples discussed herein show the inventive device in a form that is suitable to retrieve obstructions or clots within the vasculature. The term obstructions may include blood clot, plaque, cholesterol, thrombus, naturally occurring foreign bodies (i.e., a part of the body that is lodged within the lumen), a non-naturally occurring foreign body (i.e., a portion of a medical device or other non-naturally occurring substance lodged within the lumen.) However, the devices are not limited to such applications and can apply to any number of medical applications where elimination or reduction of the number of connection points is desired.

[0008] One variation of the device includes a medical device for removing an obstruction from a blood vessel, the medical device comprises a main bundle comprising a group of wires having a first end and a second end, a capturing portion formed by the group of wires and having a translating surface adjacent to a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, where the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface, the translating surface, and open proximal end about the main bundle; and where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than a capturing surface axial strength, wherein application of a tensile force on the main bundle causes axial compression of the capturing surface without causing axial compression and deformation of the translating surface sufficient to deform the translating surface as the capturing portion engages the obstruction.

[0009] The medical device can include a capturing surface that is configured to generate a spring force against the translating surface when a proximal force applied by the main bundle of wires compresses the capturing surface against the translating surface when encountering resistance from the obstruction, where the capturing surface is configured to have a sufficient axial stiffness to direct the spring force and proximal force to the open proximal end as the open proximal end engages the obstruction where the capturing surface is also sufficiently flexible to conform to a shape of the vessel.

[0010] In another variation, the capturing section is configured so that when the open proximal end of the translating section engages resistance equal to or greater than a threshold force, proximal movement of the leading wire inverts the capturing section within the translating section and reduces a size of the capturing section to enable the capturing section to re-enter a catheter.

[0011] In those variation of the device that are navigated in tortuous anatomy (such as the cerebral vasculature), the device can include a main bundle joined to a proximal bundle, where the proximal bundle comprises a stiffness greater than the main bundle and where the main bundle extends for at least a predetermined range

from the permeable distal end to allow navigation of a distal portion of the medical device within the cerebral vasculature.

[0012] Another variation of the device includes a retrieval device for removing an obstruction from a body lumen, the system comprising at least one leading wire; a retrieval body comprising a translating section adjacent to a capturing section, the translating section having an open proximal end and the capturing section having a permeable distal end, where the leading wire is extends to a portion of the capturing section to permit articulation of the open proximal end relative to the leading wire; and where the translating section and capturing section are configured so that a translating section axial strength is greater than a capturing section axial strength, wherein application of a tensile force on the leading wire causes axial compression of the capturing surface without causing axial deformation of the translating surface when the retrieval body engages the obstruction.

[0013] Variations of the retrieval system can also include a sheath having a hub located at a proximal end, a proximal capture portion affixed to a distal end of the sheath, at least one leading wire extending through the sheath, where a distal section of the leading wire comprises a distal stiffness and where a proximal section of the leading wire comprises a proximal stiffness, where the proximal stiffness is greater than the distal stiffness, a distal capturing portion at the distal end of the leading wire, the distal capturing portion being axially moveable relative to the proximal capture portion, and an insertion tool slidably located over the sheath, the insertion tool comprising a gripping region affixed to a rigid section, where compression of the gripping portion creates a frictional fit between the insertion tool such that when the insertion tool is coupled to the catheter, compression of the gripping portion and axial movement of the insertion tool advances the sheath within the catheter.

[0014] In one variation of the devices described herein, the device comprises a main bundle or group of wires that diverge to form a device having various shapes but few or no connections points or joints (where fabrication of such a construction is referred to as "jointless"). Clearly, the inventive devices described herein are not limited to such a jointless construction. Additional variation includes one or more leading wires that are attached to a capturing portion as described below.

[0015] In another variation, the device includes a main bundle comprising one or a group of wires. The device also includes a capturing portion formed by the wires or wire of the main bundle. The capturing portion includes a cavity or space that is able to surround the obstruction. Accordingly, the capturing portion includes an open proximal end, a permeable distal end, and a capturing surface extending therebetween. The permeable distal end should be sufficiently permeable to allow blood to flow but have sufficient surface area to prevent escape of the obstruction or to prevent particles such as pieces of clot or emboli that would otherwise cause a complication if such pieces migrate through the body. In some variations of the device, the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface and open proximal end about the main bundle. Although some closing of the open proximal end can occur, it will not be sufficient to interfere with the obstruction as the capturing portion moves over the obstruction. In some variations, the permeable end may be the distal end or be towards the distal end (meaning anywhere past a proximal end). The terms distal and proximal are relative to the physician (e.g., the distal end is the farthest end from the catheter/physician).

[0016] The devices of the present invention typically include a main bundle from which the wires extend. In most case, the main bundle extends for a length sufficient to withdraw the device from a body of a patient. Accordingly, in such cases, the main bundle shall extend through the length of a catheter. In alternate constructions, the main bundle may be affixed to a single wire or member. In such cases, a main bundle does not extend from the capturing portion to the exterior of the patient. Instead, a single wire extends to the operator interface of the device where the wire is affixed to a main bundle.

[0017] Devices of the present invention can incorporate any number of wires of different characteristics including, but not limited to, materials, shapes, sizes and/or diameters. Clearly, the number of permutations of device configurations is significant. Providing devices with such a composite construction allows for the manipulation of the device's properties to suite the intended application.

[0018] In an additional variation, the surface of the capturing portion can include a wire frame structure, a mesh, a single wound wire, a film, a membrane, a polymer

covering, and a plurality of crossing wires or a heterogeneous mixing of these. In additional variations, a section of the capturing portion can include wires, while another section of the capturing portion can include a film. Clearly, any number of permutations is within the scope of this disclosure. In any case, the capturing surface should prevent the obstruction from escaping as the device is removed from the body. Clearly, the capturing surface can comprise any number of shapes or configurations.

[0019] As noted herein, the joint-less construction improves the flexibility and strength of the device by eliminating joints, connection points, or other attachment points. In addition, the joint-less construction improves the ability of the device to be delivered through a small microcatheter. As a result, the device and microcatheter are able to access remote regions of the vasculature.

[0020] The devices may be fabricated to be self-expanding upon deployment from a catheter. Alternatively, the devices can be constructed from shape-memory alloys such that they automatically deploy upon reaching a pre-determined transition temperature.

[0021] The devices of the present invention may also include features to prevent migration of the obstruction as the capturing portion encapsulates the obstruction. For example, a proximal foot (such as region of increased surface area) can be located on or in the catheter. In another variation, an additional capture portion is located on the catheter where the proximal end of this capture is a mesh, a single wound wire, a film, a membrane, a polymer covering, or a plurality of crossing wires affixed to or in the catheter. Accordingly, the capturing portions both envelope or surround the obstruction as they are moved together. As noted below, additional variations may allow for temporarily locking of the two capturing portions together for increase effectiveness in removing the obstruction from the body.

[0022] The capturing portions disclosed herein can include mechanical features that assist in removal of the obstruction. These features can be hooks, fibers, barb, or any such structure. Any portion of the capturing portion or even the device can have such hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. It will be important that such features prevent the obstruction from sliding proximally but do not hinder the ability of the practitioner to remove the device from the body.

[0023] The operation of the devices and method described herein secure the obstruction, overcome the friction forces acting on the obstruction, and then remove the obstruction from the anatomy without losing or fractionating the obstruction. In a first variation, the inventive method includes advancing a catheter distal to the obstruction, deploying a first capturing portion distal of the obstruction, where the first capturing portion comprises a translating surface and a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, and at least one leading wire affixed to the capturing surface and extending through the capturing portion and through the catheter, where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than that of a capturing surface axial strength, proximally moving the leading wire to compress the capturing surface without compressing the translating surface such that the translating surface gradually advances over the obstruction, and removing the obstruction and first capturing portion from the blood vessel

[0024] Additional variations of the method include (1) passing a catheter distally to the obstruction by passing either through the obstruction and/or between the obstruction and the vascular wall; (2) deploying a first capturing portion distally to the obstruction and the catheter is withdrawn proximal to the obstruction; (3) the capturing portion is then translated over the obstruction by withdrawing the main bundle. Since the main bundle is affixed to a distal end of the capturing portion, misalignment between the bundle and the capturing portion does not cause distortion of the open proximal end. Since the open proximal end remains expanded against the lumen wall, the capturing portion can then be advanced over the obstruction.

[0025] The method and systems may also include the use of an additional capturing portion having an open distal end. This configuration allows the first capturing portion and second capturing portion to envelop or ensnare the obstruction from both the proximal and distal sides. Additional variations even allow for temporarily locking the two capturing portions together. Such a feature increases the ability to remove the obstruction from the body

[0026] It should be noted that reference to surrounding, capturing or securing the obstruction includes partially and/or fully surrounding, engulfing, encapsulating,

and/or securing the obstruction. In any case, a portion of the device engages the obstruction prior to translation of the obstruction within the lumen.

[0027] It should be noted that in some variations of the invention, all or some of the device can be designed to increase their ability to adhere to the obstruction. For example, the wires may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to "weld" to the obstruction. Application of energy to the device can allow the surrounding portion to deform into the obstruction and "embed" within the obstruction. Alternatively, the device can impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. In another variation, a negative charge could be applied to further build thrombus and nest the device for better pulling force. The wires can be made stickier by use of a hydrophilic substance(s), or by chemicals that would generate a chemical bond to the surface of the obstruction. Alternatively, the filaments may reduce the temperature of the obstruction to congeal or adhere to the obstruction.

[0028] Additional variations of the invention include a reentry device for withdrawing an object into a distal end of a sheath, the reentry device comprising a elongate member having a distal portion and a lumen extending therethrough, a plurality of first tines arranged circumferentially at the distal portion, the plurality of first tines each having a distal end forming a first discontinuous funnel where the distal end of each first tine is spaced from the distal end of an adjacent first tine, wherein the first discontinuous funnel is collapsible upon withdrawal into the distal end of the sheath, a second funnel spaced proximal to the first funnel, where the second funnel is collapsible upon withdrawal into the distal end of the sheath, and wherein a distal perimeter of the first discontinuous funnel shape is distal to a distal perimeter of the second funnel.

[0029] In an additional variation, the second funnel comprises a plurality of second tines arranged circumferentially at the distal portion, the plurality of second tines each having a distal end forming a second discontinuous funnel shape where the distal end of each second tine is spaced from the distal end of an adjacent second tine.

[0030] Another example of a reentry device includes an elongate member having a distal portion and a lumen extending therethrough, the elongate member sized to slidably fit within the sheath, a first slotted funnel comprising a plurality of first tines each having free ends discontinuous with free ends of adjacent first tines, where the first

slotted funnel is collapsible upon withdrawal into the distal end of the sheath; and a second funnel located proximal to the free ends of the first tines.

[0031] The reentry device can also comprises a retrieval system for withdrawing an object into a distal end of a sheath. The term sheath, when used with a reentry device, is intended to include any tube, introducer, sheath, or access device. Typically, when the retrieval device is used with neurovascular retrieval devices, the sheath will be a femoral access sheath or device. Regardless, the reentry device includes a first elongate member having a distal portion and a lumen extending therethrough, a second elongate shaft extending through the first elongate member, a flexible layer having a first end inverted on a distal end of the second elongate shaft and a second end affixed to an exterior of the first elongated shaft, where decreasing a distance between the distal end of the second elongate shaft and the exterior of the first elongated member causes the flexible material to form a funnel when the flexible layer further inverts about the second elongate shaft.

[0032] Additional devices and methods for treating ischemic stroke are discussed in commonly assigned U.S. Patent application nos.: 11/671,450 filed February 5, 2007; 11/684,521 filed March 9, 2007; 11/684,535 filed March 9, 2007; 11/684,541 filed March 9, 2007; 11/684,546 filed March 9, 2007; 11/684,982 filed March 12, 2007, 11/736,526 filed April 17, 2007, 11/736,537 filed April 17, 2007, and 11/825,975 filed September 10, 2007; the entirety of each of which is incorporated by reference. The principles of the invention as discussed herein may be applied to the above referenced cases to produce devices useful in treating ischemic stroke. In other words, the wire-shaped construction of devices according to present invention may assume the shapes disclosed in the above-referenced cases when such a combination is not inconsistent with the features described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.

[0034] Fig. 1A illustrates an example of a device according to the present invention when used in a system for removing obstructions from body lumens.

[0035] Fig. 1B illustrates a first example of an obstruction removal medical device.

[0036] Fig. 1C illustrates the obstruction removal device articulating relative to leading wires (or a main bundle) without deforming an open end of the capturing portion.

[0037] Figs. 2A to 2E show a capturing portion for use with systems described herein where the capturing portion has sections of varying axial strengths. Such features can optionally be designed to provide a spring force when a section of the capturing portion is compressed and/or staged inversion of the capturing portion so that it can be removed through an immovable obstruction.

[0038] Fig. 3A illustrates a first variation of the device having a joint-less construction of a capturing portion that articulates about a main bundle of wires.

[0039] Figs. 3B to 3H illustrate various constructions of capturing portions for use in the present invention.

[0040] Fig. 4A illustrates a variation of a capturing portion having a main bundle that extends beyond a certain distance to provide a device having an extremely flexible distal region and a relatively stiff proximal region with a strong joint region that will be sufficiently spaced from tortuous anatomy during use of the device.

[0041] Fig. 4B illustrates a main bundle having a curved or shaped portion.

[0042] Figs. 4C to 4E illustrate wires of different constructions within a main bundle.

[0043] Fig. 5A illustrates am example of a proximal foot located on a catheter of the present system.

[0044] Fig. 5B illustrates a distal and a proximal capturing portion located on a system under the present invention.

[0045] Figs. 5C to 5E illustrate an overview of a variation of a delivery system employing a proximal and distal capturing portion.

[0046] Figs. 5F illustrates compression or collapsing of a proximal capturing portion about an obstruction prior to translation of the obstruction in the vessel.

[0047] Figs. 6A to 6B illustrate an example of traversing an obstruction with a sheath to deploy a distal capturing portion.

[0048] Figs. 7A to 7C illustrates a condition where a section of the capturing portion deflects to provide a spring force that gradually drives a traversing section along the obstruction.

[0049] Figs. 7D to 7G illustrate staged inversion of the distal capturing portion to allow removal of the device from an immovable clot.

[0050] Fig. 8A illustrates closure of the proximal opening of a capturing portion without the benefit of articulation of the capturing portion about a leading wire.

[0051] Fig. 8B illustrates, conceptually, one benefit of articulation of a capturing portion about a leading wire or main bundle of wires.

[0052] Figs. 8C to 8D illustrate a proximal capturing portion and a distal capturing portion approaching an obstruction.

[0053] 8F illustrates a device after securing an obstruction between proximal and distal capturing sections.

[0054] Fig. 9 illustrates a main bundle as including an increased surface area or medial foot that is used to dislodge or loosen the obstruction from a wall of the body passage.

[0055] Fig. 10 illustrates a variation of a proximal and distal end of a retrieval device.

[0056] Figs. 11A to 11C illustrate a variation of a funnel catheter useful for retrieving objects from vessels or body lumens.

[0057] Fig. 12A shows an example of a retrieval device getting caught on a guide sheath.

[0058] Figs. 12B to 12C provide illustrative examples of funnel catheter used for removal of an obstruction.

[0059] Fig. 13A to 13G illustrates another variation of a funnel catheter using a mesh or layer of material to form a funnel.

[0060] Figs. 14A to 14D illustrate additional concepts to prevent or minimize flaring of the distal capture portion so that it may be withdrawn into a guide sheath.

DETAILED DESCRIPTION

[0061] It is understood that the examples below discuss uses in the cerebral vasculature (namely the arteries). However, unless specifically noted, variations of the device and method are not limited to use in the cerebral vasculature. Instead, the invention may have applicability in various parts of the body. Moreover, the invention may be used in various procedures where the benefits of the method and/or device are desired.

[0062] Fig. 1A illustrates a system **10** for removing obstructions from body lumens as described herein. In the illustrated example, this variation of the system **10** is suited for removal of an obstruction in the cerebral vasculature. Typically, the system **10** includes a catheter **12** microcatheter, sheath, guide-catheter, or simple tube/sheath configuration for delivery of the obstruction removal device to the target anatomy. The catheter should be sufficient to deliver the device as discussed below. The catheter **12** may optionally include an inflatable balloon **18** for temporarily blocking blood flow or for expanding the vessel to release the obstruction.

[0063] It is noted that any number of catheters or microcatheters maybe used to locate the catheter/microcatheter **12** carrying the obstruction removal device **200** at the desired target site. Such techniques are well understood standard interventional catheterization techniques. Furthermore, the catheter **12** may be coupled to auxiliary or support components **14**, **16** (e.g., energy controllers, power supplies, actuators for movement of the device(s), vacuum sources, inflation sources, sources for therapeutic substances, pressure monitoring, flow monitoring, various bio-chemical sensors, bio-chemical substance, etc.) Again, such components are within the scope of the system **10** described herein.

[0064] In addition, devices of the present invention may be packaged in kits including the components discussed above along with guiding catheters, various devices that assist in the stabilization or removal of the obstruction (e.g., proximal-assist devices that holds the proximal end of the obstruction in place preventing it from straying during removal or assisting in the removal of the obstruction), balloon-tipped guide catheters, dilators, etc.

[0065] Fig. 1B illustrates a first example of an obstruction removal medical device according to the features described herein. As shown, the device **200** generally includes capturing portion **226** comprising a translating section/surface **222** and a capturing section/surface **224**. In the illustrated variation, the translating section **222** shown comprises a wire framework. However, any number of configurations is within the scope of this disclosure. In many variations of the device, the translating section **222** provides a low friction surface so that it translates over the obstruction without significantly moving the obstruction. This permits the capturing portion **226** to envelop or surround the obstruction prior to attempting to move the obstruction within the body lumen. As noted herein, the translating

section **222** attempts to reduce the outward radial force applied by the obstruction against the wall of the lumen during movement of the obstruction within the lumen.

[0066] Fig. 1B illustrates a distal section of the capturing portion **226** that serves as a capturing section/surface **232**. The capturing section **232** has an increased frictional surface (in this variation illustrated by the crossing **204** wires) so that it can capture and ultimately remove the obstruction. The frictional surface of the capturing section **232** can also be described as an increased coverage density. In essence, as the frictional surface of capturing section **232** coverage density increases, there is a greater "device" surface area to interact with the obstruction. In some variations the capturing section **232** increases in frictional surface between the translating section **234** and the end of the device **200**.

[0067] As shown, the device **200** includes a main bundle **202** comprising a group of individual leading wires **204**. In this variation, the bundle of leading wires **204** is surrounded by a coil or coiled wire **205**. The coiled wire **205** can comprise a single leading wire that joins the device **202**. Alternatively, the coiled wire **205** can extend terminate or wrap back prior to forming the capture portion **226**. Moreover, the coiled wire **205** can extend throughout a length the main bundle **202**, or along one or more segments of the main bundle **202**.

[0068] While the example shows the group consisting of four individual leading wires **204**, the bundle **202** can have any number of leading wires. In various examples 2, 4, or 8 wires were used to construct the device. In certain variations, the number of wires in the main bundle loop around from the capturing portion. For example, if 2 leading wires are used to construct the device, then when constructing the main bundle **202** 2 wires are set to extend distally towards the capturing portion, where the 2 wires are then shaped to form the capturing portion. Eventually, the wires then loop back to extend proximally away from the capturing portion. Therefore, the 2 wires are doubled in the main bundle to create 4 separate wires in the main bundle.

[0069] The individual wires **204** themselves may be comprised of a number of different "micro" filaments, wires, or a single type of wire. Variations of the wires **204** are discussed in detail below; however, the wires **204** can be strands, filaments, or any similar structure that is able to be joined to form the device. The bundle **202** may be braided, wrapped, twisted, or joined in any manner such that

they do not separate or become unbundled except where desired. For example, wires in any section of the device **200** can be bonded together (e.g., with epoxy, a polymeric coating, weld, solder, and/or adhesive, etc.) to prevent the wires from separating during deformation of the device as it deploys or removes the obstruction. In addition, the main bundle **202** can incorporate any number of features to assist in orienting the device **200** within the body passage. For example, the main bundle **202** can include a pre-set bend that would bias the capturing portion **226** in a desired orientation upon deployment as discussed below.

[0070] As also discussed below, variations of the present device **200** include capturing portions **226** where the translating section **234** provides a greater axial strength than an axial strength of the capturing section **232**. The axial strength (e.g., column strength) determines whether the respective section of the capturing portion **226** compresses when the device **200** encounters resistance from an object and as a proximal or pulling force is applied through the main bundle or leading wire **202**. In use, the translating section **234** resists axial compression and deformation so that it can locate about the obstruction. While the nature of moving the translating section will place the structure in a state of compression, there will be no visible deformation or deflection that prevents the translating section from advancing across an obstruction.

[0071] There are a number of approaches to adjust the axial strength of a capturing section **232** as well as the entire structure. In a first example, the manner in which the leading wire is wound to form the respective surface **232**, **234** impact the respective axial strength. As shown, the traversing section **234** comprises a series of wrapped wires extending in an axial direction. This axial alignment causes the wires to oppose axial forces and thus increases the axial strength of the traversing section **234** relative to the capturing section **232**. In the latter section, the wires **232** extend in a helical direction about the section **232**. Thus there is less resistance to an axial load when compared to the traversing section **234**.

[0072] Alternatively, or in combination, additional techniques can produce a device **200** with a capturing portion **226** that has sections of varying axial strength. In one example, the wire diameter can be adjusted to produce the desired column strength. Generally, for a given construction, a larger diameter wire increases the column strength of the section. In addition, larger diameter leading wires can

terminate at the translating section **234** to permit smaller diameter wires to form the capturing section **232**. In another example, the leading wire **204** composition can be selected to produce the desired axial strength. For example, drawn filled tube (DFT) wire has 30% platinum 70% nitenol. Decreasing the amount of platinum and increasing the nitenol increases the wire strength and results in higher column strength. In yet another example, the respective section, or the entire capturing portion **226**, can be processed to produce the desired axial strength. For example, changing the annealing profile (e.g., temp, time) affects the wire strength, and therefore the axial strength.

[0073] Variations of devices **200** described herein can have capturing portions with alternate configurations than those shown in above. The capturing portion **226** can include constructional designs such as a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a film, a membrane, a polymer covering, , or a plurality of crossing wires. In variations of the device, the capturing portion **226** is sufficiently permeable to allow blood or other fluid flow therethrough. As noted above, capturing portion **226** may be any structure that covers, encapsulates, engulfs, and/or ensnares the obstruction either fully or partially. Accordingly, although the capturing portion **226** is illustrated as a filter/bag, the wires may diverge to form a coil, helical shape, other mesh structure, or any other structure that defines a space that can be translated over the obstruction to ultimately remove the obstruction **2**.

[0074] The capturing portion **226** can include an open proximal end **228**, a permeable distal end **230** and a capturing surface **232** located therebetween. The capturing surface **232** of the capturing portion **226** defines a volume, cavity, or space that is able to cover, encapsulate, envelop, engulf, ensnare and/or surround the obstruction. Generally, the term traversing wire or filament refers to the section of leading wire **204** that forms the traversing surface **238**. Generally, the traversing wires form the capturing surface **238** and then form the open proximal end **228**. As discussed herein and illustrated below, the open proximal end **228** expands within the lumen, typically to the lumen walls, so that the obstruction enters the open proximal end **228** as the bundle **202** (or leading wire) translates the device **200** proximally.

[0075] The permeable distal end **230** is typically sufficiently porous so that fluid or blood may flow through. However, the end **230** is sufficiently closed (or has an

increased surface area) so that the obstruction should not escape through the distal end **230** of the device **200**. This construction typically causes the the obstruction to become ensnared within the capturing portion **226** and prevented from passing through by the permeable distal end **230**.

[0076] As shown in Fig. 1C, an important feature of the present devices **200** is that the main bundle **202** and capturing portion **226** can articulate relative to one another without interfering with the size or profile of the open proximal end **228**. This feature is described more fully below. As shown, the main bundle **202** extends through the open proximal end **228** and through at least a the traversing section **234**capturing portion **226**.

[0077] Fig. 1C illustrates a condition where the main bundle **202** and capturing portion **226** articulate relative to one-another. Because the main bundle **202** joins the capturing section **232** at a distance from the open proximal end **228** movement of the main bundle **202** relative to an axis **236** of the capturing portion **226** does not reduce a profile of the open proximal end **228**. If the main bundle **202** were affixed or connected to the open proximal end **228**, then any movement of the bundle **202** away from the capturing portion's axis **236** would exert a force on the open end. This force, in turn, would cause the open end to narrow or deform. By doing so, the open end would not be able to uniformly expand against the lumen wall to capture the obstruction.

[0078] Turning now to the construction of the device **200**, as shown above, the main bundle or a leading wire **202** extends beyond the open proximal end **228** and forms the capturing portion. In one variation, the construction of the device relies on converging/diverging wires to form continuous shapes so that the device is completely joint or connection free. However, as noted herein, the leading wire or main bundle **202** can be affixed to a structure that forms the capturing portion via an attachment point, joint, or junction. In addition, the structures forming the capturing portion can be fabricated from such processes as laser cutting of tubes, etching, metal injection molding, or any other such process.

[0079] The devices of the present invention can also include additional features to aid in removal of obstructions. For example, as shown in Figs. 1B to 1C, the open proximal end **228** can include one or more petals or flanges **238** extending radially outward. The flanges **238** allow device **200** to have a flared structure at the open proximal end **228**. In one example, the capturing portion **226** can be slightly

oversized relative to the body passage containing the obstruction or slightly larger than the capturing portion. The flanges **238** provide an additional force against the wall of the passage to ensure that the device **200** is able to surround or encapsulate the obstruction. In yet another feature, in variations of a system having a proximal and distal capturing portion, the flanges can serve to lock the proximal and distal capturing portions together once they encapsulate or surround an obstruction. This feature minimizes the chance that the obstruction escapes from the capturing portions as the device and obstruction are removed from the body lumen.

[0080] In additional variations, the main bundle can diverge to form the capturing portion in multiple locations so long as the capturing portion's ability to articulate is not sacrificed. For example, the main bundle can diverge in several locations along the capturing surface (not shown).

[0081] Figs. 1B to 1C also shows an integrally formed reinforcement ring **240** located along the length of the capturing surface **232** (i.e., on the traversing wires). The reinforcement ring **240** can be a separate or discrete ring located on or in the capturing surface **232**. Alternatively, or in combination, the reinforcement ring **240** can be a ring shape that is integrally formed through arrangement of the wires **204** (as show in Figs. 1B to 1C). The reinforcement ring **240** assists in expanding the device when deployed in the body lumen and/or prevents the device (e.g., the open proximal end) from collapsing as the device moves within the lumen to secure the obstruction. The reinforcement ring **240** can comprise a single wire, or a twisted pair of wires. Alternatively, the rings do not need to extend entirely circumferentially around the capturing surface. Instead, a reinforcement portion may extend between adjacent traversing wires but does not necessarily extend around the circumference of the capturing section. As noted herein, reinforcement portions may extend between adjacent traversing wires in multiple locations.

[0082] Figs. 2A to 2E show several benefits of varying axial strengths of the different sections of a capture portion **226**. As shown in Fig. 2A, when the physician retrieves the capturing portion **226** by pulling on the leading wire or main bundle **202** (as shown by arrow **120**), the entire capturing portion **226** translates as shown by arrow **122**. However, when the device **200** encounters resistance (as schematically shown by force arrows **124**) the lesser axial strength of the capturing section **232** causes axial deformation or compression of the capturing section **232** (as shown by Fig. 2B). In certain variations, the capturing section **232**

can be constructed to function as spring such that deformation of the capturing section **232** stores energy. Accordingly, the physician can pull the main bundle **202** to build energy in the capturing section **232**, then relax the force on the main bundle **202**. The stored energy in the capturing section **232** gradually drives the open proximal end of the translating section **234** over or along the obstruction. The physician can apply this "pull and relax" technique repeatedly until the obstruction is sufficiently captured by the capturing portion **226**.

[0083] Fig. 2C shows an additional safety benefit given the varying axial strengths of the different sections of a capture portion **226**. In the event the capturing portion **226** encounters an excessive degree or threshold of force (as denoted by arrows **124**), the reduced axial strength of the capturing section **232** can invert within the translating section **234**. As shown, the permeable distal end **230** of the capturing section **232** inverts and is pulled by the main bundle **202** within the translating section **234** and reduces in size. As shown in Fig. 2D, continued pulling on the main bundle **202** causes eventual inversion of the translating section **234** so that the capturing section **232** extends through the translating section **234** and the permeable distal end **230** is now proximal to the translating section **234**. Continuing to apply move the main bundle **202** in a proximal direction **120** inverts the capturing portion **226** as shown in Fig. 2E. As shown, the translating section **234** is now distal to the capturing section **232**. This causes a reduction in the size of the capturing portion through inversion of the capturing portion **226**. This feature permits withdrawal of the capturing portion **226** within a delivery sheath **106** or through an immobile obstruction (as discussed below). As shown below, the ability to sequentially invert the capturing portion **226** and reduce its diameter enables retrieval of the device if deployed distal to atherosclerotic plaque or an immobile object where continued pulling against the object could cause damage or tearing of the body passage or vessel wall. It was found that retrieval devices that are not constructed with regions of varying axial strength, spring function, or staged inversion can often flatten or expand in diameter when attempting to retrieve the device though an immobile or stubborn obstruction.

[0084] Fig. 3A illustrates an additional variation of a capturing portions **226** according to the present disclosure. In Fig. 3A, the main bundle **202** and the group of wires **204** branch or diverge at the permeable distal end **230** to form the capturing portion **226**. In additional variations, the main bundle **202** can branch or

diverge within a mid-portion of the capturing surface **232** rather than at the permeable distal end **230**. In such a case, the wires **204** form the capturing surface **232** first and ultimately branch to form the remainder of the capturing portion. In any case, by extending through the open proximal end **228**, the main bundle **202** is able to articulate relative to the capturing portion **226** without significantly reducing a profile of the open distal end **228**. As discussed above, the capturing surface **232** of these variations is fabricated (either through processing or wire construction) to have an axial strength that is lower than that of the traversing section **234**.

[0085] Fig. 3B illustrates a variation having an integrated reinforcement ring **240**. Typically, the reinforcement ring **240** provides radial strength to the capturing portion **226** to prevent collapse or deformation that would otherwise interfere with enveloping the obstruction. A reinforcement ring **240** may allow for use of wires that would otherwise provide unacceptable radial strength. For example, the reinforcement ring **240** may permit use of smaller diameter wires thereby allowing the device **200** to compress to a smaller diameter during delivery via a catheter.

[0086] In addition to the reinforcement ring **240**, Fig. 3B includes an open proximal end **228** having a number of petals/flanges **238**. In this variation, although the flanges **238** intersect one another, they are independently moveable.

[0087] Fig. 3C shows a variation of a device **200** where the capturing portion **226** includes flanges **238** that are interwoven or connected with adjacent flanges **238**. (Variations include bonding or otherwise joining the adjacent flanges together.) This feature provides the flanges **238** with a higher radial strength that reduces the likelihood that the flanges **238** bend or distort when moving in the body lumen or removing the obstruction.

[0088] Figs. 3D to 3E illustrate additional variations of devices having capturing portions **226** that have a basket type configuration. As shown, the capturing portions **226** and surface **232** comprise a denser mesh of traversing wires that ultimately lead to the traversing section **234** that terminates in flanges **238** at the open proximal end **228**. In such variations, a first portion of the traversing surface **232**that is adjacent to the open proximal end has a low coverage density relative to the remaining portion of the capturing surface having a higher coverage density that eventually forms the permeable distal end **230**. This construction lowers the lowering frictional resistance of the first portion of the capturing surface when

moving over or against the obstruction but allows the remaining portion of the capturing surface to encapsulate and secure the obstruction.

[0089] As shown in Fig. 3E, the wires diverge from the main bundle towards the distal end of the capturing portion **226** to form the permeable distal end **230**. The permeable distal end **230** can actually have the same configuration as the capturing surface **232**. In other words, the permeable distal end can simply be an extension of the capturing surface that extends over the distal end of the capturing portion.

[0090] Naturally, the divergence of the wires can occur over a length of the capturing portion **226** rather than immediately at the distal end. For example, as show in Fig. 3D, the wires diverge towards a mid-section of the capturing portion and ultimately form the permeable distal end **230**.

[0091] Fig. 3F illustrates a variation of a device **200** having multiple reinforcement rings **240**. As noted above, the reinforcement rings provide additional radial strength to the capturing portion **226** as the device **200** moves within the body lumen and prevents distortion of the capturing portion **226**. However, as noted above, the device will be fabricated to provide varying regions of axial strength to allow for either the spring effect or the staged inversion discussed above. In any case, the rings **240** do not need to extend around an entire circumference of a device, variations include any number of supports that extend between adjacent traversing wires.

[0092] Fig. 3G illustrates another variation of a device **200** having a leading wire **202** extending to a distal end **230** of a capturing portion **226**. In this variation the capturing portion **226** is fabricated from a stent-type structure. As noted above, it is within the scope of this disclosure to use any type of similar structure such as a laser cut tube, a chemically etched or photo etched tube, a polymer or metal injection molded structure, a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a film, a membrane, a polymer covering, or a plurality of crossing wires as the capturing portion **226** so long as the device can be compressed to a small size for delivery and expand after traversing the obstruction. The illustrated variation also shows a covering **270** located on the distal end **230** of the capturing portion **226**. The length of the polymeric covering **270** can vary across the capturing portion **226** to prevent the obstruction from escaping as the device is translated over the obstruction. Furthermore, the covering **270** can be polymeric or a wire mesh. However, typically the covering has sufficient porosity

to allow blood to flow through the device **200**. In this variation, the flanges **238** form the translating surface.

[0093] Fig. 3H illustrates another feature for use with system described herein. In this variation, the system includes a proximal capturing portion **260** located on an exterior of a delivery sheath **106**. The main bundle **202** extends through the sheath **106** to a distal capturing portion (not shown). As discussed below, the proximal capturing portion **260** can be similar to the distal capturing portions **226** described herein with the exception that the distal end **262** of the proximal capturing portion is open while the proximal end **264** of the proximal capturing portion is closed. Furthermore, the proximal capturing portion **260** articulates with respect to the sheath **106** much in the same manner as the distal capturing portion **226** articulates relative to the main bundle **202**. In this variation, the proximal end **264** of the proximal capturing portion **260** is tapered or has a smaller profile than the remaining proximal capturing portion **260**. Such a feature may be useful to improve the deliverability of the device to the intended site as well as to maneuver around any obstructions within the body passage. In addition, as noted below, the proximal capturing portion **260** can be compressed about the obstruction to improve the ability of the system to remove the obstruction. The construction of the proximal capturing portion **260** can optionally include variations having regions of differing axial strength, or sections capable of generating spring force. Typically, since the proximal capturing portion **260** is not advanced distal to the obstruction, the need for staged inversion is not necessary. Accordingly, any number of capturing designs can be incorporated for the proximal capturing portion.

[0094] In some variations, the leading wire can extend to the proximal end of the system for manipulation by the physician. However, it is often the case that the characteristics of the device must vary along its length. For example, when the device is intended for use in remote tortuous anatomy, the proximal section of the device is desirably stiffer (to advance the distal portion of the device to the target anatomy). However, the distal section of the device must have properties that make it suitable for the tortuous anatomy. In the case where devices are used in the cerebral vasculature, the distal section must be extremely flexible, while the proximal section should be stiff. In many cases, different material properties are

required. A problem then arises in attempting to join different materials especially in the joining region.

[0095] Conventional joining methods include soldering, welding, gluing, thermal junctions, etc. These joining methods produce an area having an increase in the stiffness of the device. For example, if two wires are to be laser welded together, then the section where they are joined has an overlap which yields greater stiffness than the rest of the wire. This increased area of stiffness is often balanced against the strength of the joined segment. If the joined region is too long, the strength will be sufficient but the increase in stiffness often prevents navigation through the tortuous anatomy. IF the joined region is too short, then the device can navigate through the anatomy but the bond is weaker and a risk of failure increases.

[0096] Fig. 4A illustrates another variation of an improvement for use with the devices described herein especially for use in tortuous anatomy such as the cerebral vasculature. In this example, the capturing portion **226** is show with a number of leading wires **204** extending proximally. To provide the desired characteristics, the leading wires **204** are joined in region **196** to wires **198** having a structure that is suitable for the proximal anatomy (e.g., the wires are larger in diameter or stiffer). To enable use of the device **200** in the cerebral anatomy without compromising bond strength characteristics or flexibility of the device **200**, the leading wires extend a pre-determined region so that the bond region **196** is placed out of the tortuous anatomy. Since the cerebral vasculature is approximately 30 centimeters in length, the leading wires **204** can extend for a length **195** of at least a predetermined length so that it remains very flexible when navigating the cerebral vasculature or other tortuous anatomy. In one example the length was 20 centimeters (but can be 30 or more centimeters). By deliberately extending the leading wires **204** by length **194**, the length of the bond region **196** can be chosen to accommodate the proximal anatomy (where a greater stiffness of the bond region **196** can be accommodated). The length of the bond region **196** can vary depending on the application (e.g., from 2 to20 cm for a device intended for cerebral the cerebral vasculature). However, the bond can extend along the entire proximal section of leading wire.

[0097] Fig. 4B illustrates an addition aspect of for use with devices described herein where the main bundle **202** has a curved or bend portion **252**. This pre-set

shape assists in orienting the capturing portion **226** within the body passage since the bend will cause the device to bias against a wall of the body passage.

[0098] Fig. 4C and 4D show cross sectional views taken along the line A-A in Fig. 4B. As shown, the wire form construction described herein allows for a number of configurations depending on the particular application. For example, the individual wires **204** (as discussed herein) may themselves comprise a bundle of smaller wires or filaments. In addition, the wires can be selected from materials such as stainless steel, titanium, platinum, gold, iridium, tantalum, Nitinol, alloys, and/or polymeric strands. In addition, the wires used in a device may comprise a heterogeneous structure by using combinations of wires of different materials to produce a device having the particular desired properties. For example, one or more wires in the device may comprise a shape memory or superelastic alloy to impart predetermined shapes or resiliency to the device. In some variations, the mechanical properties of select wires can be altered. In such a case, the select wires can be treated to alter properties including: brittleness, ductility, elasticity, hardness, malleability, plasticity, strength, and toughness.

[0099] The device may include a number of radiopaque wires, such as gold and platinum for improved visibility under fluoroscopic imaging. In other words, any combination of materials may be incorporated into the device. In addition to the materials, the size of the wires may vary as needed. For example, the diameters of the wires may be the same or may vary as needed.

[0100] In addition, the individual wires may have cross-sectional shapes ranging from circular, oval, d-shaped, rectangular shape, etc. Fig. 4C illustrates one possible variation in which a number of circular wires **204** are included with a d-shaped wire 205. Moreover, the device is not limited to having wires having the same cross-sectional shape or size. Instead, the device can have wires having different cross-sectional shapes. For example, as shown in Fig. 4D, one or more wires **205** can have a different cross-sectional shape or size than a reminder of the wires **204**. Clearly, any number of variations is within the scope of this disclosure.

[0101] To illustrate one such example, a device can have 8-12 wires made of .003" round superelastic material (e.g., nitinol). The device may additionally have 2-4 wires made from .002" platinum for fluoroscopy. Of the 8-12 nitinol wires, 1-4 of these wires can be made of a larger diameter or different cross-section to increase the overall strength of the device. Finally, a couple of polymer fibers can

be added where the fibers have a desired surface property for clot adherence, etc. Such a combination of wires provides a composite device with properties not conventionally possible in view of other formation means (such as laser cutting or etching the shape from a tube or joining materials with welds, etc.). Clearly, any number of permutations is possible given the principles of the invention.

[0102] In another example, the device may be fabricated from wires formed from a polymeric material or composite blend of polymeric materials. The polymeric composite can be selected such that it is very floppy until it is exposed to either the body fluids and or some other delivered activator that causes the polymer to further polymerize or stiffen for strength. Various coatings could protect the polymer from further polymerizing before the device is properly placed. The coatings could provide a specific duration for placement (e.g., 5 minutes) after which the covering degrades or is activated with an agent (that doesn't affect the surrounding tissues) allowing the device to increase in stiffness so that it doesn't stretch as the thrombus is pulled out. For example, shape memory polymers would allow the device to increase in stiffness.

[0103] In another variation, one or more of the wires used in the device may comprise a Drawn Filled Tube (DFT) such as those provided by Fort Wayne Metals, Fort Wayne, Indiana. As shown in Fig. 4E, such a DFT wire 252 comprises a first material or shell 208 over a second material 210 having properties different from the outer shell. While a variety of materials can be used, one variation under the present devices includes a DFT wire having a superelastic (e.g., Nitinol) outer tube with a radiopaque material within the super-elastic outer shell. For example, the radiopaque material can include any commercially used radiopaque material, including but not limited to platinum, iridium, gold, tantalum, or similar alloy. One benefit of making a capturing portion from the DFT wire noted above, is that rather than having one or more markers over the capturing portion, the entire capturing portion can be fabricated from a super-elastic material while, at the same time, the super-elastic capturing portion is made radiopaque given the core of radiopaque material within the super-elastic shell. Clearly, any composite DFT wire 252 can be incorporated into the system and capturing portions described herein.

[0104] Fig. 5A shows a working end of a variation of a system **10** for removing an obstruction from a body lumen. In this variation, the system **10** includes a main

bundle **202** and capturing portion **226** extending out of a micro-catheter or catheter **102**. The micro-catheter **102** can optionally include a proximal foot **256** that can slide axially over main bundle **202** and can be variably positioned in relation to the capturing portion **226**. The proximal foot **256** can include any number of configurations apart from the petal/flange **258** configuration (i.e., the foot can be a balloon, coil, shoulder, etc. where such structures simply replace the petals in Fig. 5A). In any case, the proximal foot **256** provides an increased surface area that provides an opposing force to the capturing portion **226**, where the opposing force aids the movement of the obstruction within the capturing portion **226**. Alternatively, the proximal foot stabilizes the obstruction and keeps the obstruction from moving with the capturing portion until the capturing portion envelops the obstruction.

[0105] The size of the proximal foot **256** can be adjusted depending on the target site anatomy. For example, a larger surface area can be employed if the target site is within a bifurcation of the body passage. The size of the proximal foot **256** can also be adjustable during the procedure. For example, in the case of a petal/flange **258** configuration, the petals **258** can assume a larger size to initially stabilize the obstruction and then reduce in size to allow the obstruction to be completely engulfed by capturing section **226**.

[0106] The proximal foot **256** can extend from an interior of the catheter **102**, such as from within the internal lumen of the catheter, or from an additional lumen within a wall of the catheter. Alternatively, the proximal foot **256** can be permanently affixed to the catheter **102**. In such a case, a separate catheter (without a proximal foot) can be employed to traverse the obstruction for deployment of the device distally to the obstruction. Once the device is deployed, the catheters can be exchanged to provide the proximal foot. In an additional variation, the proximal foot **256** can be affixed to a delivery sheath (as described below) and be collapsed within the catheter, where advancement out of the catheter expands the proximal foot **256** so that it may function as described above.

[0107] In an additional variation, a proximal capturing portion (as shown in Fig. 3H) can be used with a foot **256** that is located about the main bundle **202**. Such a variation may or may not include a distal capturing portion. Accordingly, the construction of the proximal capturing portion (as described herein to include

sections of varying axial strength) can be used to perform a push and relax technique (similar to that of the pull and relax technique described herein).

[0108] Fig. 5B illustrates another variation of the system **10** where the system includes a proximal capturing portion **260** located on an exterior of a delivery sheath **106**. Naturally, the proximal capturing portion **260** could also be affixed to an exterior of a micro-catheter. The proximal capturing portion **260** is similar to the capturing portions **226** described herein with the exception that the distal end **262** of the proximal capturing portion is open while the proximal end **264** of the proximal capturing portion is closed. The proximal capturing portion can also optionally be configured to have regions of varying axial strength, spring rate, and various other features associated with the distal capturing portion **226**. In the illustrated variation, the capturing portion **226** and main bundle **202** move relative to the proximal capturing portion **260** to capture an obstruction. Furthermore, the proximal capturing portion **260** articulates with respect to the sheath **106** much in the same manner as the distal capturing portion **226** articulates relative to the main bundle **202**. As shown, the petals **238** on the open ends **228** and **262** can interact to nest once the capturing portions **226** and **260** are moved sufficiently close to one another. The outward force caused by the retained obstruction provides a frictional interaction between adjacent petals/flanges **238** to maintain the nesting.

[0109] Variations of the device include additional structures, such as springs, hooks, barbs, etc, to cause the open ends 228 and 262 to interlock. As noted above, a separate catheter can be used to initially deploy the capturing portion **226** beyond the obstruction. Although the capturing portions shown have the same configuration, the capturing portions **226** and **260** used in any given system do not have to match in size, shape, and configuration. For example, the proximal capturing portion can be impermeable to flow while the distal capturing portion allows flow. In another example, one basket may be undersized relative to the other to improve nesting.

[0110] In any case, the construction of the system **10** shown in Fig. 5B includes open ends **228** and **262** of capturing portions **226** and **260** that are unconnected. Accordingly, as the capturing portions **226** and **260** move towards one another as a result of the main bundle **202** translating relative to the delivery sheath **106** the open ends are free to articulate around the main bundle **202** and delivery sheath **106** respectively to remain expanded against the lumen wall.

[0111] Figs. 5C to 5E illustrate a variation of a system for delivery of the capturing portions **226** and **260**. Fig. 5C shows the proximal **260** capturing portion affixed to a delivery sheath **106**. In alternate variations, the proximal capturing portion **260** can be replaced with a proximal foot (not shown). As noted above, the main bundle or leading wires **202** extends through the delivery sheath **106** and connects to the distal capturing portion **226** beyond the opening **228** of the distal capturing portion **200**. The main bundle or leading wire **202** extends through the proximal capturing portion **260**. This allows the free ends of the capturing portions **228** and **262** to remain relatively unattached so that they can articulate and conform to the curvature of the vessels (as discussed below). The capturing portions **226** and **260**, main bundle **202** and delivery sheath **106** extend through a microcatheter **102**.

[0112] Fig. 5D illustrates a state of deployment after the microcatheter **102** traverses the obstruction (not shown). Once the microcatheter **102** is distal to the obstruction, the distal capturing portion **226** deploys from the end of the microcatheter **102**. As noted herein, the capturing portions can self-expand or can expand upon actuation by the physician. In any case, the distal capturing portion **226** should be sufficiently collapsible to remain within the microcatheter **102** for deployment distal to an obstruction. To deploy the distal capturing portion **200** from the catheter **102**, the main bundle **202** can translate to push the distal capturing portion **226** to eject it from the catheter **102**. Alternatively, the microcatheter **102** can be withdrawn from the distal capturing portion **226**.

[0113] Fig. 5E illustrates the deployment state after the catheter **102** is withdrawn proximal to the obstruction (not shown) and after the proximal capture portion **260** is delivered from the microcatheter **102**. As noted above, the proximal capture portion **260** can be affixed to an exterior of the catheter, in which case the catheter may be either de-sheathed or exchanged. Alternatively, and as shown, the proximal capturing portion **260** is affixed to a delivery sheath **106** and is fabricated to collapse within the microcatheter for ultimate deployment, whereby translating the sheath **106** delivers the proximal portion **260** from the microcatheter.

[0114] Fig. 5F shows another aspect of the system **10** where the proximal end **264** of the proximal capturing portion **260** is collapsed or compressed about an obstruction **2** prior to translation of the obstruction **2** within the vessel. In this illustration, the proximal capturing portion **260** is compressible by advancing the catheter **102** over the closed proximal end **264** of the capturing portion **260**. In

such a case, the proximal capturing portion **260** is slidable within and relative to the catheter **102.** Naturally, variations may include compressing the proximal end **264** during translation of the obstruction **2**. In either case, the proximal capturing portion **260** can be compressed in a number of different ways. For instance, the proximal basket can be compressed using a catheter **102**(as shown), or the delivery sheath **106**, or any other number of mechanisms (not illustrated).

[0115] As shown, the proximal end **264** can be compressed using a sheath **106** and/or catheter **102** However, other means of compressing may be employed (e.g., a loop structure, a tube over the sheath, a draw-string configuration, etc.) In use, once the distal capturing portion **226** is deployed distally to the obstruction **2** and the catheter **102** is withdrawn proximal to the obstruction **2**, the proximal capturing portion **260** is deployed. As the proximal capturing portion **260** partially (or totally) engulfs the obstruction **2**, the physician can collapse or compress the proximal capturing portion **260** to better secure the obstruction within the system **10**.

[0116] It is noted that any number of shapes, configurations, as well as any number of joined wires may be contemplated to form devices under the present disclosure. However, variations of the invention include selecting a number of wires to produce specific structural properties to the device. For example, the devices can have any number of wires where the limit is determined by the ability to produce a device of a sufficiently small size to access the area containing the obstruction. However, in some cases, it may be desired that wires are chosen to impart specified characteristics. For example, in the illustrated variation, the main bundle may comprise any number of wires that do not diverge to form subsequent shapes in the device. In other words, not all of the wires forming a section are required to diverge to form an adjacent section. Instead, these non-diverging wires may simply "loop" back away from the device. In an additional variation, one or more wires may diverge to form a particular portion of the capturing portion (e.g., the closed end, traversing wires, etc.). Then the wires can loop back to converge again with the main bundle.

[0117] Figs. 6A to 6E show one example of the deployment of a variation of a device according to the present invention about an obstruction in a vessel. The figures are intended to demonstrate the initial placement of the device immediately prior to removal of the obstruction.

[0118] Fig. 6A illustrates an obstruction **2** lodged within a body lumen or vessel **6**. In the case where the vessel is a cerebral artery, the obstruction may result in an ischemic stroke. Using standard interventional catheterization techniques, a microcatheter **102** and guidewire **104** traverse the obstruction. The microcatheter **102** may be advanced through the obstruction **2**. Alternatively, the microcatheter **102** may "push" aside the obstruction and is advanced around the obstruction. In any case, the microcatheter **102** travels from the near end **3** (or proximal side) of the obstruction **2** to the far end **4** (or distal side) of the obstruction **2**. It is noted that the catheter **102** may be centered or off-center with respect to the obstruction **2**. Furthermore, the device may or may not be used with a guidewire to navigate to the site and traverse the obstruction.

[0119] Some variations of the device may be placed without an accompanying guidewire. Moreover, the structures discussed herein may be directly incorporated into a guidewire assembly where deployment may require a sheath or other covering to release the components from constraint.

[0120] Fig. 6B illustrates deployment of a capturing portion **226** and main bundle **202** of the device **200** from within the microcatheter **102** distal to the obstruction **2**. Accordingly, in most variations, the capturing portion **226** is designed to fit within the catheter **102** for delivery and expand upon deployment. Alternatively, the device may be actuated to assume the desired shape (e.g., upon reaching a transition temperature where one or more wires comprise a shape memory alloy). As shown, the capturing portion **226** includes a traversing section **234** and a capturing section **232**. In some procedures the traversing section **234** engulfs the obstruction **2** with little or no complication as the main bundle **202**, catheter **102**, or sheath **106** pulls the capturing portion **226** in a proximal direction.

[0121] However, as discussed above, there may be some procedures where the distal capturing portion **226** is deployed distal to an obstruction **2** that is deposited within the vessel or lumen such that a steady translation of the capturing portion **226** will not engulf the obstruction **2**. Figs. 7A to 7G illustrate some examples of such a situation. As shown in Fig. 7A, a sheath **106** might be able to traverse the obstruction **2** to deploy the distal capturing portion **226** in preparation for engulfing the obstruction **2**. Fig. 7B illustrates a condition where the traversing section **234** engages the obstruction **2** but is unable to easily or fully engulf the obstruction **2**. However, in those variations where the capturing portion **226** includes regions

having different axial strength (as discussed above), continued pulling of the main bundle **202** in a proximal direction **120** causes the capturing section **234** to compress. When the capturing section **234** is constructed to function as spring, the deformation of the capturing section **232** stores energy from the proximal movement of the main bundle **202**. This storing of energy allows the physician to relax the pulling force **120** on the main bundle **202**. Fig. 7C shows a compressed capturing section **234**. The energy stored in the capturing section **232** gradually drives the open proximal end **228** of the translating section **234** over or along the obstruction **2**. The physician can apply this "pull and relax" technique repeatedly until the obstruction is sufficiently captured by the capturing portion **226**. In some variations, the capturing section **234** remains compressed as the obstruction **2** finally breaks loose and removed.

[0122] Fig. 7D represents the situation where a distal capturing portion distal to an object **2** that is significantly embedded within a vessel or body lumen. In such cases, the force required to remove the obstruction **2** may damage the vessel or lumen. Such obstructions include atherosclerotic plaque or other immobile objects. As shown, when the distal capturing portion **226** is pulled once the proximal force **120** reaches a threshold value (as determined by the construction of the capturing portion **226**) the capturing portion **226** undergoes a staged inversion as the permeable end **230** enters the traversing section **232**. In this variation, the permeable end **230** actually enters the obstruction **2**. The construction of the capturing portion **226** prevents flattening or expanding in diameter, where such movements would prevent removal of the capturing portion. Again, if the force applied by the capturing portion **226** breaks the obstruction **2** free. The obstruction **2** can be removed even though a part of the capturing portion **226** is within the obstruction **2** as shown in Fig. 2D.

[0123] Fig. 7E shows advanced inversion of the capturing portion **226** as the capturing section **234** is now proximal to the traversing section **232**. The traversing section **232** may be deformed upon inversion but will taper towards the capturing section **234** as the capturing section **234** passes through the obstruction **2** (typically via an opening that was previously created by advancement of a sheath **106** through or around the obstruction **2**).

[0124] Fig. 7F shows the capturing portion **226** nearly passing through the obstruction **2** so that it may be removed from the body. As shown in Fig. 7G, the

capturing portion **226** is now fully inverted and is in a state where it can re-enter a catheter for removal from the patient.

[0125] The construction described herein that allows for staged inversion of the capturing portion **2** provides a significant safety feature. A physician must undertake additional surgical intervention to remove any retrieval device that has become lodged distally to an immobile obstruction. The ability of staged inversion allows the physician to invert and remove the capturing portion **226** if application of a predetermined or threshold force is exceeded by proximal displacement of the device. This feature reduces the need for additional surgical intervention to remove a retrieval device that would otherwise become lodged or separated as a result of excessive forces being applied.

[0126] Figs. 8A to 8B illustrate an additional benefit of affixing a leading wire or bundle of wires **202** beyond a proximal opening **228** of a capturing portion **226**. Fig. 5A illustrates a basket type structure **90** where a wire **202** is affixed to a proximal end **92**. As shown, as the leading wire **202** pulls the basket **90** through tortuous anatomy **6**, the force component pulling away from an axis of the device **90** causes the proximal open end **92** to constrict or reduce in size. As shown, as the proximal end **92** approaches the obstruction **2** the perimeter of the end is not placed against the walls of the body passage **6**. As a result, the constricted opening **92** places an increased axial force on the obstruction **2** as the basket **90** translates over the obstruction **2** (because the proximal end **92** pushes against the obstruction rather than sliding around it), making encapsulation of the obstruction more difficult and possible leading to vascular damage.

[0127] Fig. 8B shows a device **200** according to the principles disclosed herein. The leading wire **202** is affixed to the distal end **230** of the capturing portion **226**. As the main bundle 202 is pulled through the curved vascular path, the capturing portion **226** pivots or articulates about the bundle 202 and remains aligned with the axis of the vessel. As a result any misalignment between the leading wire **202** and an axis of the capturing portion **226** does not affect the open proximal end **228**. As noted above, some closing of the open proximal end may occur, though it will not be sufficient to interfere with the obstruction as the capturing portion moves over the obstruction. Such a configuration allows the perimeter of the open proximal end **228** to remain against the wall of the passage **6**. As shown, because the open

proximal end **228** is not constricted, the open proximal end **228** is better suited to slide around the obstruction for eventual removal.

[0128] Fig. 8C shows withdrawal of the microcatheter **102** to the proximal side **3** of the obstruction **2** and deployment of a proximal capturing portion **260** (in alternate variations, a proximal foot can be used or the capturing portion **226** alone can be used). Again, the catheter **102** can be exchanged for a catheter **102** having a proximal capturing portion **260**. Alternatively, and as shown in the accompanying figures, the proximal capturing portion **260** can be affixed to a delivery sheath **106** that is fed through the microcatheter **102**.

[0129] As also shown in the figure, the main bundle **202** and capturing portions become misaligned due to the tortuousity of the anatomy. However, because the capturing portions **226** and **260** are able to pivot or articulate relative to the main bundle **202** and catheter **102** or sheath **106**, the open ends are able to remain against the lumen wall. In conventional devices where the open end is attached to either a wire or catheter, when the wire or catheter bends in the anatomy, the forces exerted on the open ends deform or distort the end to assume a reduced profile. Accordingly, the physician may have difficulty in removing an obstruction if the profile of the open end becomes reduced in size. Closing of the open end can also result in vascular damage if the physician applies too much force in translating the device.

[0130] Fig. 8D shows movement of the capturing portions **226** and **260** adjacent to the obstruction **2**. The proximal capturing portion **260** can remain stationary or may be advanced relative to the distal capturing portion **226**. Regardless, the physician is able to ensnare the obstruction **2** within the cavities defined by the capturing portions **226** and **260**. Fig. 8E illustrates the system as the two capturing portions are drawn together. For purposes of clarity, the obstruction is not shown. Upon sufficient advancement of the capturing portion **226** and proximal capturing portion **260** relative to one-another, flanges **238** on the respective open ends can interlock. This feature provides added safety in removing the device as the obstruction is encapsulated between the two nested portions.

[0131] Fig. 8F illustrates a device **200** after securing an obstruction between a proximal **260** and distal **226** capturing sections. As shown, the captured obstruction **2** is held between capturing portions **226** and **260** where the flanges **238** nest within one-another to "lock" the capturing portions together. In some

variations of the device, one of the capturing portions can be undersized relative to the other. This configuration allows for the undersized capturing portion to become further compressed as the devices are pulled together. The compression of the capturing surface then serves to further compress the obstruction **2** captured within the device.

[0132] The capturing portions described herein can include coverings or wrappings so long as the other features of the device are not impaired. Such coverings can be located on both capturing portions **226** and **260**, only one or more capturing portions. The covering can include a strand or fiber wrapped or woven about the section, a polymer film, or a dipped polymer coating such as silicone, urethane, etc. The coating on either capturing portion can be solid or porous. In the latter case, blood can continue to flow through the coating. In one variation, the proximal capturing portion **260** could employ a solid covering while the distal capturing portion **200** could include a porous covering. In such a case, blood or other fluid flow could be temporarily halted by the presence of the solid covering to assist in removal of the obstruction.

[0133] Fig. 9 illustrates a variation of the system where the main bundle **202** includes a medial foot **274**. The construction of the medial foot **274** can be similar to that of the proximal foot discussed above (e.g., wires looped into a petal configuration.) However, the medial foot includes a surface area or diameter larger than a diameter of the main bundle. In any case, the increased surface area of the medial foot **274** provides an increased resistance to the obstruction **2** as the distal capturing portion **200** and main bundle **202** are pulled in a proximal direction towards an obstruction **2**. The medial foot **274** engages the obstruction **2** to partially displace or loosen the obstruction from the walls of the body passage. The medial foot **274** can be slidably located on the main bundle such that after a threshold force, the medial foot moves within the distal capturing portion **200**. The main bundle **202** can include any number of medial feet **274**.

[0134] Although the illustrated variation shown above comprise open-ended, circular, looped or partial loop shape cross sectional areas, variations of the capturing portions can include any number of shapes. For example, such a shape can include a circle, an arcuate shape, a partial circular shape, a loop, an oval, a square, a rectangle, a polygon, an overlapping loop, a pair of semi-circles, etc.) The various shapes may be heat set to be either self-expanding (i.e., superelastic)

or the use of shape memory alloys can allow for the device to assume the particular shape upon reaching a desired transition temperature.

[0135] The exemplary shapes discussed above permit the shaped section to adjust in diameter in response to placement in varying diameters of body lumens. It is noted that a device may have different shaped sections on different ends of the device.

[0136] While many different shapes are contemplated to be within the scope of this disclosure, the shapes will depend upon the ultimate application of the device. As noted herein, the illustrated examples have particular applicability in retrieving obstructions from the vasculature. Accordingly, for these applications the shaped sections should form a shape so that they can expand against a vessel wall without causing trauma to the vessel. For example, upon release from the catheter, the shaped section can assume their resting shape and expand within the vessel. The resting shape can be constructed to have a size slightly greater than that of the vessel. Sizing the device relative to the target vessel may assist in placing the parts of the device against a vessel.

[0137] In an additional aspect, the shaped sections may be designed to have an unconstrained shape that is larger than the intended target vessel or simply different than a cross sectional profile of the intended vessel (i.e., not circular or tubular, but e.g., linear or other different shape). In such an example, as the shaped section is released from the delivery catheter, the shape section attempts to return to the unconstrained shape. In those variations where the unconstrained shape is different from the circular profile of the vessel, the leading wire assumes a shape that accommodates the vessel but is more rigid and stable since its unconstrained shape is entirely different from that of the vessel. In other words, the shaped section continually exerts an outward force on the vessel.

[0138] In yet another aspect, the shaped sections shown herein may not necessarily lie in the same plane. Instead, they can be axially spaced by an offset. One benefit of constructing the device to have non-planar shaped section is that the configuration might allow for delivery of the device through a smaller microcatheter because the shaped sections do not interfere with one another when collapsed to fit within the microcatheter.

[0139] Another aspect applicable to all variations of the devices is to configure the devices (whether the traversing filament or the surrounding portion) for better

adherence to the obstruction. One such mode includes the use of coatings that bond to certain clots (or other materials causing the obstruction.) For example, the wires may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the device secures about a clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction. Coatings may also be combined with the capturing portions or catheter to improve the ability of the device to encapsulate and remove the obstruction (e.g., a hydrophilic coating).

[0140] Such improvements may also be mechanical or structural. Any portion of the capturing portion can have hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. The hooks, fibers, or barbs **154** can be incorporated into any portion of the device. However, it will be important that such features do not hinder the ability of the practitioner to remove the device from the body.

[0141] In addition to additives, the device can be coupled to an RF or other power source (such as **14** or **16** in Fig. 1A), to allow current, ultrasound or RF energy to transmit through the device and induce clotting or cause additional coagulation of a clot or other the obstruction.

[0142] The methods described herein may also include treating the obstruction prior to attempting to remove the obstruction. Such a treatment can include applying a chemical or pharmaceutical agent with the goal of making the occlusion shrink or to make it more rigid for easier removal. Such agents include, but are not limited to chemotherapy drugs, or solutions, a mild formalin, or aldehyde solution.

[0143] As for other details of the present invention, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts that are commonly or logically employed. In addition, though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention.

[0144] Fig. 10 illustrates one variation of a retrieval device **200** including a distal capture portion **226** coupled to one or more leading wires in the form of a main bundle **202**. The main bundle extends through a sheath **106** that includes a

proximal capture portion **260**. The configuration of the retrieval device **200** can incorporate the proximal and distal capture portions discussed herein as well as various other configurations discussed in the commonly assigned patent applications noted above. In addition, the relative sizes of the various components shown in Fig. 10 and discussed below are for illustrative purposes only.

[0145] An end **264** of the proximal capture portion **260** is affixed to a distal end of the sheath **106**. However, as noted above, other variations are within the scope of the disclosure. The main bundle **202** can optionally terminate at a handle **242**. As noted above, in certain variations, the main bundle is joined to a stiffer wire or stiffer bundle of wires. This allows the device **200** to have a very flexible distal section with a relatively stiffer proximal section. Fig. 4A above, discusses placement of a joint at a location spaced from the distal section of the device so as to increase a bond strength but not impair the distal section's flexibility. In any case, the device **200** can have a proximal bundle **203** that comprises either the exposed wires or a covering/tube over the wires. In certain variations, the bundle or wire **202**, **203** can be encapsulated with a coating.

[0146] The proximal end of the sheath **106** includes a sheath handle **244**. As discussed herein, axial movement of the bundle **202** or proximal bundle **203** (typically at the handle **242**) results in movement **126**, or translation of the bundle within the sheath **106**. This action moves the distal capture portion **226** (as shown by arrows **126**). In certain variations, the device **200** is loaded into a microcatheter (not shown but discussed above) that is delivered to the site of the obstruction and crosses the obstruction.

[0147] In some variations, the sheath hub **244** includes one or more locking hubs **246**. Where actuation (either axial or rotational) of the locking hub **246** locks the main bundle **202** relative to the sheath handle **244** and sheath **106**. It follows that such locking action also locks the distal capture portion **226** relative to the proximal capture portion **260**. A variety of methods can be employed to increase a frictional interference between the locking hub **246** and the proximal bundle **203**. As a result, when a physician determines a length of an obstruction, the physician can set a spacing between the capturing portions **226** **260** by locking the proximal bundle **203** relative to the sheath hub **244**. Accordingly, the proximal bundle **203** can include any type of incremental markings to allow the physician to readily determine a spacing of the capturing portions. As illustrated, the sheath hub **244**

can include additional injection ports to deliver fluid or other substances through the sheath **106**.

[0148] As noted above, the device **200** can be used with micro-catheter. In those variations it is important that the device **200** is loaded without damaging the distal bundle **202**, capture portions **226 260**, and/or sheath **106**. As a result, the device **200** can include an optional funnel **286** that reduces the proximal capture portion **260** (and /or the distal capture portion **226**) for loading within the microcatheter and/or sheath **106**.

[0149] Another variation of the device **200** includes an insertion tool **280** slidably affixed to the sheath **280**. Because variations of the device **200** can be extremely flexible, the insertion tool **280** can be used to provide column strength to the sheath **106**, bundle **202** or other components as the device **200** is pushed into the microcatheter. The insertion tool comprises a rigid section **282** and a frictional coupler **284**. The rigid section **282** has a column strength that supports the device **200** to prevent buckling. The frictional coupler **284** can be a flexible material that allows an operator to squeeze or grip the coupler **284** to create a temporary frictional interface between the loading tool **280** and the device **200** (typically the sheath **106**). Such an action allows axial advancement of the device **200** as the loading tool **280** is advanced into the microcatheter. Once the rigid section **282** is fully inserted into the microcatheter, the operator releases the frictional coupler **284** and can withdraw the loading tool **280** from the catheter without withdrawing the device **200**. The insertion tool **280** can also include an optional loading tube **286** slidably coupled to the rigid section **282**. When used, the funnel **286** can withdraw the proximal and distal capturing portion **226 260** within the loading tube **286**. The loading tube **286** then couples to a microcatheter allowing the capturing portions to advance therein as the rigid section **282** and frictional coupler **284** advance the device **200** relative to the loading tube **286**.

[0150] Fig. 11A illustrates a funnel catheter **300** useful for retrieving objects from vessels or body lumens. Typically, when a physician captures an obstruction in various retrieval devices, the device and the obstruction are easily removed from the body by withdrawing the device and obstruction into a sheath, guide catheter or introducer ("guide catheter"). However, in some circumstances, a physician has difficulty withdrawing the obstruction loaded device within a sheath, guide catheter or introducer. Specifically, one or more components of the retrieval

device might become caught on an edge of the guide catheter. The concern may still remain even when using a guide catheter having an increased diameter (such as when the retrieval device catches on one edge of the guide catheter tip). Moreover, large guide catheters are difficult to advance within various parts of the anatomy. As a result, the obstruction loaded device must travel further. Movement of the obstruction loaded device within the body creates the risk that the obstruction will detach or break apart and cause additional adverse consequences.

[0151] The funnel catheter **300** includes a first and second slotted funnels **330**, **340** located at the distal end of an inner shaft **302.** Each funnel **330 340** comprises a number of extensions or tines **332 342**. The inner shaft **302** can be cut to produce the first tines **332**. Alternatively, the first tines **332** can be affixed to a portion of the inner shaft **302**. The second slotted funnel **340** is offset in both a proximal and rotational position relative to the first slotted funnel **330**. The purpose of this dual offset is discussed in detail below. As shown, the second funnel **340** can be a slotted tube that is affixed over the inner shaft **302**. In an alternate variation, a plurality of second tines **342** can be located about the inner shaft **302** to form a second slotted funnel **340**. As shown in Fig. 11B, the tines **332 342** can be configured to expand outward (if not restrained) via use of a coil or other spring-type means. Alternatively, they can be actuated to expand outward. However, in most cases, the tines **332 342** can expand passively upon entry of the retrieval device **200**. The expansion of one or both funnels assists in receiving the retrieval device. In additional configurations, one or more funnels can be designed so that they remain in a cylindrical shape rather than expand outwards (as shown in Fig. 11C). Variations of the funnel catheter **300** can include configurations having one or more funnels, or configurations where the tines spaced or adjacent (or a combination thereof).

[0152] Fig. 11C also illustrates the dual offset nature of the dual funnel catheter **300**. The first offset is a linear offset **316** such that the distal ends of the first tines **332** or funnel **330** extends beyond a distal end of the second tines **342** or second funnel **340**. The second offset comprises a rotational offset (denoted by rotational angle **A**). For example, the illustrated rotational offset **A** is 45 degrees. However, the rotational offset can vary depending on the particular application. In most variations, the rotational offset **A** will place the second tines **342** over the gaps or spaces between the first tines **332**. The number of tines can vary depending on the

application. Variations of the funnel catheter can include discontinuous funnels with two or more tines.

[0153] Turning back to Fig. 11A, the funnel catheter **300** can optionally include any number of medical fittings or components. As shown, the catheter **300** includes a hemostasis valve or hub **306** at the proximal end. The hemostasis valve **306** can include a fluid side port **308** for delivery of fluid through the catheter **300**. The catheter **300** can also include one or more radiopaque markers **310** so that the location of the funnel or funnels **330 340** can be identified via non-invasive imaging (e.g., under fluoroscopy). The funnel catheter **300** can also optionally include one or more markers **312**. Such markers are useful to inform a physician (who is only able to view the proximal end of the device **300**) of the distance to the first or second funnel. As a result, the physician will be able to determine whether the funnels are advanced out of the guide catheter. Fig. 11A also shows the funnel catheter **300** as including a loading tool **314**. The loading tool **314** can be advanced over the funnels **330 340** to compress the funnel when loading into a guide catheter or other sheath.

[0154] Figs. 12A to 12C provide an illustrative example where use of a funnel catheter **300** aids in removal of an obstruction **2** loaded within a retrieval device **200**.

[0155] As shown in Fig. 12A, attempting to remove the obstruction **2** when engulfed in the retrieval device **200** creates a risk that one or more portions of the device **200** become caught on the guide sheath or access catheter **108**. In some cases, the physician can simply engage the device **200** against the distal end of the guide sheath **108** and withdraw until the obstruction **6** and device **200** are located in an acceptable area of the body or withdrawn entirely from the body. For example, in certain situations, the obstruction **6** and device **200** can be withdrawn with the guide sheath **108** until all components reach a high flow, non-critical locations (e.g., the groin area). In the case of a clot, a clot dissolving substance (TPA) can then be applied to dissolve and remove the clot. Alternatively, the physician can attempt to aspirate through the guide sheath **108** in an attempt to draw the entire retrieval device **200** and obstruction **2** within the guide sheath **108**. In yet another variation, the physician can advance fibers or guide wires out through the guide sheath **108**, then withdraw the obstruction **2**/retrieval device **200** and attempt to use the fibers or guide wires as a moveable surface to capture the

device **200**. Furthermore, the physician can attempt to use a variety of existing devices (e.g., the FastCath provided by Genesis Medical Inc., the Merci Retriever provided by Concentric Medical Inc., or any commercially available snare or distal protection device) to remove the engulfed obstruction **2** from the body.

[0156] In some variations, the capturing portions discussed above can be constructed to improve their ability to be withdrawn into a guide sheath. For example, increasing the number of petals or flanges on the traversing sections increases the probability that the distal flanges nest within the proximal capturing portion. Alternatively, or in combination, the petals **238** on the distal capturing portion can be staggered in length or position to ease insertion into the proximal capturing portion. In another variation, the petals **238** shape or curvature can be adjusted so that they do not flare outward.

[0157] Fig. 12B shows a distal end of a funnel catheter **300** as it receives an obstruction **2** loaded retrieval device **200**. As shown, the tines **332** of the first funnel **330** receive the device **200**. The tines **332** minimize the likelihood that the device **200** becomes caught. The limited surface area of the tine **332** (combined with the rounded tines **332 342**) produces a tendency for the device **200** to deflect away from the tines as it is withdrawn into the funnels. The second funnel **340**(being rotationally offset from the first funnel **330** provides coverage over the spaces between the first tines **332** thereby assisting in nesting of the device **200** within the funnels. Ultimately, the device **200** and obstruction **2** are withdrawn into a guide sheath **108** and removed from the body.

[0158] Figs. 12 C to 12D show additional variations of funnel catheter **300**. Fig. 12C shows a single funnel **330** having a plurality of tines **332**. Fig. 12D illustrates a dual funnel catheter **300** having a discontinuous first funnel **230** and a second funnel **346**. The second funnel **346** can be a continuous funnel so long as it is able to retract within the guide sheath **108**. As shown, the second funnel **346** can include a single slit **348** that allows the funnel to compress within the guide sheath **108**. In addition, the variation of Fig. 12D can be used without the first discontinuous funnel **330**. Accordingly, as the retrieval device **200** and clot **2** approach the funnel **346** and enters the funnel, further withdrawing the retrieval device **200** causes squeezing of the retrieval device **200** and obstruction **2**. In yet another variation, the funnel **346** can incorporate a drawstring to compress the funnel **346** once the retrieval device **200** and obstruction are located therein.

[0159] Fig. 13A to 13B illustrates another variation of a funnel catheter **350** suited to remove a retrieval device **200** from the body. As shown in Fig. 13A, the funnel catheter **350** includes a first shaft **352** and a second shaft **354** slidably located therein. A mesh **370** is fused to each shaft **352 354** at a distal location **362 364**. Accordingly, relative movement of the shafts **352 354** (either the first shaft **352** can be pushed or the second shaft **354** can be pulled) creates a funnel shape **372** as the mesh portion affixed to the second shaft **354** is inverted within the remainder of the mesh **370**. It is noted that in some variations of the system, the mesh funnel funnels are combined with the tine based funnels described above. Such that one funnel comprises the tines while the other comprises the mesh structure described herein.

[0160] In another variation, a third distally located capture portion (similar to a distal capture portion) can be used to draw the retrieval device within a guide sheath. In such a variation, the third capture portion can be a larger distal capture portion and when the retrieval device engulfs an obstruction, the third basket portion can be proximally withdrawn to capture the retrieval device and obstruction.

[0161] As illustrated in Fig. 13B, as the retrieval device **200** and obstruction **2** approach the funnel catheter **350**, the distal attachment points **362 364** of the shafts **352 354** are moved together to invert the mesh **370** and form a funnel **372**. The retrieval device **200** can then be withdrawn into the funnel. This design allows for the retrieval device **200** to be fully withdrawn into the catheter **350** while the funnel **372** is expanded. Alternatively, the funnel **372** can be used to compress the retrieval device **200** and obstruction **2** prior to withdrawal into the catheter **350**.

[0162] The mesh **370** can include any medically acceptable material such as a nitenol braid. Furthermore, the mesh allows for flow through the vessel or lumen while expanded. However, additional variations of the device can include a solid layer of material substituted for the mesh.

[0163] Figs. 13C to 13E illustrate another variation of a funnel catheter **350** suited to remove a retrieval device **200** from the body. As shown in Fig. 13C, the funnel catheter **350** includes a first shaft **352** and a second shaft **354** slidably located therein. A mesh **370** is joined only the rear shaft **354** at a distal location **362**. The end of the mesh **370** is free at the distal end of the device **350**. The mesh **370** is sized at a distal end **371** to neck down. Accordingly, as the distal shaft moves

rearward, the mesh **370** is unsupported. The necked section **371** of the mesh allows for distal advancement of the device **200** through the neck portion **371**. However, as shown by Fig. 13D, rearward movement of the device **200** causes engagement with the neck portion **371**. Further rearward movement of the device **200** causes the unsupported mesh **370** to form a funnel shape **372** as shown in Fig. 13E. The funnel shape allows for the retrieval device **200** to be fully withdrawn into the catheter **350** while the funnel **372** is expanded. Alternatively, the funnel **372** can be used to compress the retrieval device **200** and obstruction **2** prior to withdrawal into the catheter **350**. To compress the funnel, the device **200** can be advanced out of the funnel and away from the mesh **370**. Next, the distal shaft **352** can be advanced through the neck portion **371** of the mesh **370** to receive the device **200**. In another variation, the device **350** can include a single shaft **354** where the mesh **370** can extend beyond the shaft **354**. The mesh can be heat set to assume a funnel shape upon the application of a current or as it reaches body temperature. In another variation, the mesh **370** can comprise a super-elastic material that assumes the shape shown in Fig. 13E when released from a constraining member.

[0164] Figs. 13F to 13G illustrate yet another variation a funnel catheter **350** suited to remove a retrieval device **200** from the body. In this variation, the funnel catheter **350** includes a single shaft **354** having a mesh **370** is fused to a distal location **364**. The mesh **370** is free at a proximal side. The mesh is also pre-formed to assume a funnel shape as shown in Fig. 13G. Accordingly, upon delivery the mesh **370** can be constrained (e.g., via a sheath, or other removable restraint). Once the restraint is removed, the mesh **370** expands to form a funnel **372**.

[0165] Figs. 14A to 14D illustrate additional concepts for use with various retrieval devices **200**. Fig. 14A illustrates a distal capturing portion **226** and a proximal capturing portion **260** where the proximal capturing portion includes a covering **212** (e.g., a polymeric covering or a wire or fiber wound about the flanges **238**). The covering **212** prevents the flanges **238** of the distal capturing portion **226** from flaring outside of the proximal capturing portion **260**.

[0166] Fig. 14B illustrates a variation of a reentry sleeve where tines **332** of the reentry sleeve **302** include protrusions **214** on an inner surface. The protrusions **214** cause the tines **332** to splay out as the retrieval device **200** is withdrawn within

the tines **332**. As the reentry sleeve **302** is withdrawn in a guide catheter (as discussed above) the protrusions serve to compress the retrieval device **200** even further.

[0167] Fig. 14C and 14D illustrate variations of a wire or fiber **218** affixed to the flanges **238** of a distal capturing portion **226** to assist in compressing the flanges **238** prior to entry within a guide sheath. As shown in Fig. 14C the fiber **218** can be affixed to a suture ring **216**. As the fiber **218** is pulled, the suture ring **216** compresses the flanges **238** to prevent outward flaring. In Fig. 14D, one or more fibers **218** are affixed to one or more flanges **238**. Once the obstruction is captured, the fibers can be pulled to draw the flanges **238** closed.

[0168] Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. Also, any optional feature of the inventive variations may be set forth and claimed independently, or in combination with any one or more of the features described herein. Accordingly, the invention contemplates combinations of various aspects of the embodiments or combinations of the embodiments themselves, where possible. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said," and "the" include plural references unless the context clearly dictates otherwise.

[0169] It is important to note that where possible, aspects of the various described embodiments, or the embodiments themselves can be combined. Where such combinations are intended to be within the scope of this disclosure.

CLAIMS

We claim:

1. A medical device for removing an obstruction from a blood vessel, the medical device comprising:

a main bundle comprising a group of wires having a first end and a second end;

a capturing portion formed by the group of wires and having a translating surface adjacent to a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end;

where the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface, the translating surface, and open proximal end about the main bundle; and

where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than a capturing surface axial strength, wherein application of a tensile force on the main bundle causes axial compression of the capturing surface without causing axial compression and deformation of the translating surface sufficient to deform the translating surface as the capturing portion engages the obstruction.

2. The medical device of claim 1, where the capturing portion is formed such that articulation of the capturing portion relative to the main bundle does not cause the open proximal end to reduce in size.

3. The medical device of claim 1, where the capturing surface is configured to generate a spring force against the translating surface when a proximal force applied by the main bundle of wires compresses the capturing surface against the translating surface when encountering resistance from the obstruction, where the capturing surface is configured to have a sufficient axial stiffness to direct the spring force and proximal force to the open proximal end as the open proximal end engages the obstruction where the capturing surface is also sufficiently flexible to conform to a shape of the vessel.

4. The medical device of claim 1, where the capturing section is configured so that when the open proximal end of the translating section engages resistance equal to or greater than a threshold force, proximal movement of the main bundle inverts the capturing section within the translating section and reduces a size of the capturing section.

5. The medical device of claim 4, where the capturing section and traversing section are configured to invert upon continued proximal movement of the main bundle such that the traversing surface moves distally to the capturing surface.

6. The medical device of claim 1, where the main bundle is joined to a proximal bundle, where the proximal bundle comprises a stiffness greater than the main bundle and where the main bundle extends for a pre-determined distance from the permeable distal end to allow navigation of a distal portion of the medical device within the cerebral vasculature.

7. The medical device of claim 6, where the pre-determined distance is at least 20 cm.

8. The medical device of claim 1, where the capturing surface has an increased frictional resistance as compared to the translating surface, such that the capturing surface engages the obstruction for removal of the obstruction.

9. The medical device of claim 1, where the open proximal end further comprises a plurality of flanges extending from the translating surface.

10. The medical device of claim 9, where the flanges extend radially away from an axis of the capturing portion.

11. The medical device of claim 1, where the capturing portion is self-expandable.

12. The medical device of claim 1, where at least a portion of the capturing surface comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, and a plurality of crossing wires or a combination thereof.

13. The medical device of claim 1, where the main bundle of wires includes at least a first wire and a second wire where the first and second wire each have different characteristics.

14. The medical device of claim 13, where the characteristics are selected from a group consisting of material, cross-sectional shape, and cross-sectional size.

15. The medical device of claim 1, where the main bundle of wires includes at least one shape memory alloy wire.

16. The medical device of claim 1, where the main bundle of wires includes at least one wire selected from the group consisting of a superelastic wire, a polymeric wire, or a metal alloy.

17. The medical device of claim 16, where the metal alloy comprises an alloy selected from the group consisting of stainless steel, titanium, platinum, gold, iridium, tantalum, nitinol, and combinations thereof.

18. The medical device of claim 1, further comprising at least one radiopaque material located on the capturing portion.

19. The medical device of claim 1, where the individual wires in the group of wires each comprise a bundle of smaller wires.

20. The medical device of claim 1, where the individual wire comprises a super-elastic outer shell and an inner core of a radiopaque material.

21. The medical device of claim 20, where the inner core comprises a material selected from a group consisting of platinum, iridium, gold, and tantalum.

22. The medical device of claim 1, where the capturing portion is jointless.

23. The medical device of claim 1, where at least one of the wires from the main bundle returns to the main bundle after forming at least a part of the capturing portion.

24. The medical device of claim 1, where each of the wires from the main bundle returns to the main bundle after forming a part of the capturing portion.

25. The medical device of claim 1, where the main bundle is surrounded by a coil or coiled wire.

26. A retrieval device for removing an obstruction from a body lumen, the retrieval device comprising:

at least one leading wire;

a retrieval body comprising a translating section adjacent to a capturing section, the translating section having an open proximal end and the capturing section having a permeable distal end, where the leading wire extends to a portion of the capturing section to permit articulation of the open proximal end relative to the leading wire; and

where the translating section and capturing section are configured so that a translating section axial strength is greater than a capturing section axial strength, wherein application of a tensile force on the leading wire causes axial compression of the capturing surface without causing axial deformation of the translating surface when the retrieval body engages the obstruction.

27. The retrieval device of claim 26, where the retrieval body is formed such that articulation of the retrieval body relative to the leading wire occurs without narrowing of the open proximal end during articulation.

28. The retrieval device of claim 26, where the capturing section is configured to generate a spring force against the translating section when a proximal force applied by the leading wire compresses the capturing section against the translating section when encountering resistance from the obstruction, where the capturing section is configured to have a sufficient axial stiffness to direct the spring force and proximal force to the open proximal end as the open proximal end engages the obstruction, where the capturing section is also sufficiently flexible to conform to a shape of the body lumen.

29. The retrieval device of claim 26, where the capturing section is configured so that when the open proximal end of the translating section engages resistance equal to or greater than a threshold force, proximal movement of the leading wire inverts the capturing section within the translating section and reduces a size of the capturing section.

30. The retrieval device of claim 29, where the capturing section and traversing section are configured to invert upon continued proximal movement of the leading wire such that the traversing section moves distally to the capturing section.

31. The retrieval device of claim 26, where the at least one leading wire is joined to at least one proximal leading wire, where the proximal leading wire comprises a stiffness greater than the leading wire and where the leading wire extends for a pre-determined distance from the permeable distal end to allow navigation of a distal portion of the retrieval device within the cerebral vasculature.

32. The retrieval device of claim 31, where the pre-determined distance is at least 20 cm.

33. The retrieval device of claim 26, where the leading wire is surrounded by a coil or coiled wire.

34. The retrieval device of claim 26, where the leading wire extends to the permeable distal end.

35. The retrieval device of claim 26, where the capturing portion comprises a structure selected from a group consisting of a laser cut tube, an etched tube, an injection molded structure.

36. The retrieval device of claim 36, where the at least one leading wire is attached to the capturing portion via a joint or junction.

37. The retrieval device of claim 26, where the translating section has a low coverage density relative to the capturing section, thereby lowering frictional resistance of the first portion of the capturing surface when moving over the obstruction.

38. The retrieval device of claim 37, where the at least one leading wire comprises a super-elastic outer shell and an inner core of a radiopaque material.

39. The retrieval device of claim 38, where the inner core comprises a material selected from a group consisting of platinum, iridium, gold, tantalum, alloys or mixtures thereof.

40. The retrieval device of claim 38, where leading wire is continuous with and forms the capturing portion.

41. The retrieval device of claim 26, where the at least one leading wire comprises a group of wires forming a main bundle and where the group of wires forms the capturing portion such that the group of wires diverges from a second end of the main bundle to form the permeable distal end, the group of wires continue to extend to form both the capturing surface and open end.

42. The retrieval device of claim 26, where the at least one leading wire comprises a group of wires forming a main bundle and where the group of wires forms, the capturing portion such that the group of wires diverges from a second end of the main bundle to form the capturing surface, the group of wires continues to extend to form both the permeable distal end and open proximal end.

43. The retrieval device of claim 26, where the at least one leading wire comprises a group of wires forming a main bundle and where at least one individual wire has a cross-sectional shape selected from the group consisting of a circle, an oval, a rectangular shape, a polygon, and a D-shape.

44. The retrieval device of claim 26, where the retrieval body is jointless.

45. The retrieval device of claim 26, where at least a portion of the capturing section comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a plurality of crossing wires, and a combination thereof.

46. The retrieval device of claim 26, where the open proximal end of the translating section further comprises a plurality of flanges extending from the capturing portion

47. The retrieval device of claim 26, where the retrieval body is self-expandable and compresses to fit within a lumen of a catheter.

48. The retrieval device of claim 26, further comprising at least one radiopaque material located on the capturing section.

49. The retrieval device of claim 26, where the leading wire comprise a bundle of smaller wires.

50. The retrieval device of claim 26, where the leading wire comprises a group of wires that diverges towards the permeable distal end of the capturing section.

51. The retrieval device of claim 26, further comprising a proximal capturing portion where the retrieval body is moveable relative to the proximal capturing portion, where the proximal capturing portion comprises an open distal end and a proximal end, where the leading wire extends through the open distal end of the proximal capturing portion, and is moveable relative to the proximal capturing portion such that a distance between the distal open end of the proximal capturing portion and the proximal open end of the retrieval body can be changed.

52. The retrieval device of claim 51, where the proximal end of the proximal capturing portion is permeable.

53. The retrieval device of claim 51, where the proximal end of the proximal capturing portion is non-permeable.

54. The retrieval device of claim 51, further comprising a first plurality of flanges located on the proximal open end of the distal capturing portion and a second plurality of flanges located on the distal open end of the proximal capturing portion, where the first and second plurality of flanges can removably engage each other.

55. The retrieval device of claim 51, where the proximal capturing portion and retrieval body are rotatable relative to each other.

56. The retrieval device of claim 51, where the proximal end of the proximal capturing portion is connected about the leading wire such that the leading wire is moveable therethrough.

57. The retrieval device of claim 51, further comprising a sheath extending over the leading wire, where the proximal end of the proximal capturing portion is affixed to the sheath.

58. The retrieval device of claim 51, where the proximal capturing portion comprises a structure selected from a group consisting of a laser cut tube, an etched tube, an injection molded structure.

59. The retrieval device of claim 58, where the at least one leading wire is attached to the proximal capturing portion via a joint or junction

60. The retrieval device of claim 51, where the proximal capturing portion has a coverage density that increases from the open distal end to the proximal end.

61. The retrieval device of claim 51, where the proximal capturing portion is formed from a wire comprising super-elastic outer shell and an inner core of a radiopaque material.

62. The retrieval device of claim 61, where the inner core comprises a material selected from a group consisting of platinum, iridium, gold, and tantalum or combination thereof.

63. The retrieval device of claim 51, where the proximal capturing portion is jointless.

64. The retrieval device of claim 51, where at least a portion of a surface of the proximal capturing portion comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a plurality of crossing wires, and a combination thereof.

65. A method of removing an obstruction from a blood vessel, the method comprising:

advancing a catheter distal to the obstruction;

deploying a first capturing portion distal of the obstruction, where the first capturing portion comprises a translating surface and a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, and at least one leading wire affixed to the capturing surface and extending through the capturing portion and through the catheter, where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than that of a capturing surface axial strength;

proximally moving the leading wire to compress the capturing surface without compressing the translating surface sufficient to cause axial deformation of the translating surface such that the translating surface gradually advances over the obstruction; and

removing the obstruction and first capturing portion from the blood vessel.

66. The method of claim 65, where pulling on the leading wire causes the capturing surface to apply a spring force against the translating surface such that the open proximal end advances along the obstruction.

67. The method of claim 65, where applying a threshold force on the leading wire while the open proximal end engages the obstruction causes the capturing surface to invert within the capturing portion.

68. The method of claim 67, where applying the threshold force comprises continuing to apply the threshold force to withdraw the capturing surface into the catheter distal end.

69. The method of claim 67, where applying the threshold force comprises continuing to apply the threshold force to invert the capturing portion such that the capturing surface is proximal to the translating surface.

70. The method of claim 65, where pulling on the leading wire to apply the force to the capturing surface comprises applying the force to the permeable distal end.

71. The method of claim 65, where pulling on the leading wire to apply the force to the capturing surface comprises applying the force to the capture surface.

72. The method of claim 65, further comprising a second capturing portion having an open distal end and a proximal end attached axially moveable relative to the first capturing portion, such that moving the first capturing portion over the obstruction causes the open proximal end of the first capturing portion to move towards the open distal end of the second capturing portion to surround the obstruction.

73. The method of claim 72, where the proximal end of the second capturing portion is non-permeable and temporarily occludes or interrupts flow.

74. The method of claim 72, where the proximal end of the second capturing portion is permeable and permits flow during removal of the obstruction.

75. The method of claim 72, further comprising continuing to move the first capturing portion towards the second capturing portion such that the open proximal end and the open distal end can removably engage each other.

76. The method of claim 72, further comprising compressing the second capturing portion about the obstruction to further secure the obstruction.

77. A reentry device for withdrawing an object into a distal end of a sheath, the reentry device comprising:

a elongate member having a distal portion and a lumen extending therethrough; and

a plurality of first tines arranged circumferentially at the distal portion, the plurality of first tines each having a distal end forming a first discontinuous funnel where the distal end of each first tine is spaced from the distal end of an adjacent first tine, wherein the first discontinuous funnel is collapsible upon withdrawal into the distal end of the sheath..

78. The reentry device of claim 77, further comprising:

a second funnel spaced proximal to the first funnel, where the second funnel is collapsible upon withdrawal into the distal end of the sheath; and

wherein a distal perimeter of the first discontinuous funnel shape is distal to a distal perimeter of the second funnel.

79. The reentry device of claim 78, where the second funnel comprises a plurality of second tines arranged circumferentially at the distal portion, the plurality of second tines each having a distal end forming a second discontinuous funnel shape where the distal end of each second tine is spaced from the distal end of an adjacent second tine.

80. The reentry device of claim 79, further comprising at least one protrusion on an inner surface of at least the first or second tine.

81. The reentry device of claim 78, where the second funnel comprises a continuous funnel.

82. The reentry device of claim 77, further comprising a second funnel, where the second funnel comprises a flexible layer.

83. The reentry device of claim 82, where the flexible layer comprises a mesh braid.

84. The reentry device of claim 83, where the mesh braid comprises a Nitinol braid.

85. The reentry device of claim 77, where the second funnel comprises a tapered split tube.

86. A reentry device for withdrawing an object into a distal end of a sheath, the reentry device comprising:

an elongate member having a distal portion and a lumen extending therethrough, the elongate member sized to slidably fit within the sheath;

a first slotted funnel comprising a plurality of first tines each having free ends discontinuous with free ends of adjacent first tines, where the first slotted funnel is collapsible upon withdrawal into the distal end of the sheath; and

a second funnel located proximal to the free ends of the first tines.

87. The reentry device of claim 86, where the second funnel comprises a second slotted funnel comprising a plurality of second tines each having free ends discontinuous with free ends of adjacent second tines, where the first slotted funnel is collapsible upon withdrawal into the distal end of the sheath.

88. The reentry device of claim 87, where the free ends of the second tines are located proximally to the free ends of the first tines relative to the elongate member and where the first and second tines are rotationally offset.

89. The reentry device of claim 86, where the second funnel comprises a second continous funnel, where the second continuous funnel is collapsible upon withdrawal into the distal end of the sheath.

90. The reentry device of claim 86, where the second funnel comprises a tapered split tube.

91. The reentry device of claim 86, where the second funnel comprises a flexible layer.

92. The reentry device of claim 91 where the flexible layer comprises a mesh braid.

93. The reentry device of claim 92, where the mesh braid comprises a Nitinol braid.

94. A retrieval system for withdrawing an object into a distal end of a sheath, the retrieval system comprising:

an elongate member having a distal portion and a lumen extending therethrough; a flexible layer having a portion affixed to the elongate member, where a first end of the flexible layer is configured to form a funnel at the distal portion of the elongate member;

a retrieval device advanceable through the elongate member for engaging the object, where proximal movement of the retrieval device into the flexible causes the flexible layer to engage the retrieval device to assist the retrieval device securing the object to the sheath.

95. The retrieval system of claim 94, where the elongate member comprises a first shaft and a second shaft, where the first and shaft are in telescoping engagement, where a first end of the flexible layer is affixed to the first shaft and a second end of the flexible member is affixed to the second shaft, where moving the first and second shaft to decrease a distance between ends of the flexible member causes the flexible material to form a funnel when the flexible layer further inverts about the second elongate shaft.

96. The retrieval system of claim 94, where the flexible layer is affixed to the elongate member at a single location.

97. The retrieval system of claim 96, where the flexible member is affixed to the elongate member at a distal location, and where the flexible member has a pre-determined funnel shape such that when unrestrained the flexible member forms the funnel shape about the distal end of the elongate member.

98. The retrieval system of claim 96, where the flexible member is affixed to the elongate member at a proximal location, and where the flexible member extends beyond the distal end of the elongate member.

99. The retrieval system of claim 98, where proximal movement of the retrieval device engages he flexible member causing the flexible member to form a funnel shape.

100. The retrieval system of claim 98, where the flexible member has a pre-determined funnel shape such that the flexible member assumes a funnel shape when un-restrained.

101. The retrieval system of claim 94, where the flexible layer comprises a mesh braid.

102. The retrieval system of claim 101, where the mesh braid comprises a Nitinol braid.

103. The retrieval system of claim 94, where the flexible layer comprises a flexible layer of material.

104. The retrieval system of claim 94, further comprising:

a retrieval sheath extending through the second elongate member having a proximal capture portion affixed to a distal end;

at least one leading wire extending through the retrieval sheath, where a distal section of the leading wire comprises a distal stiffness and where a proximal section of the leading wire comprises a proximal stiffness, where the proximal stiffness is greater than the distal stiffness; and

a distal capturing portion at the distal end of the leading wire, the distal capturing portion being axially moveable relative to the proximal capture portion.

105. The retrieval system of claim 104, where the distal section of the leading wire extends proximally for a pre-determined distance from the distal capturing portion to allow navigation of a distal section of the leading wire within the cerebral vasculature.

106. The retrieval system of claim 105, where the pre-determined distance is at least 20 cm.

107. A system for removing a object within a body, the system device comprising:

a sheath having a sheath distal end and a sheath lumen extending therethrough; a reentry device slidably located in the sheath lumen and being advanceable out of the sheath distal end, the reentry device comprising an elongate member having a first slotted funnel and a second slotted funnel, the elongate member having a distal portion and a lumen extending therethrough and being sized to slidably fit within the sheath,

the first slotted funnel and the second slotted funnel each respectively comprising a plurality of first and second tines, each of the tines having a free end discontinuous with the free ends of an adjacent tines, where a distal end of the second slotted funnel is proximal to a distal end of the first slotted funnel and where the first and second tines are rotationally offset such that upon withdrawal into the sheath, the second tines cover a portion off a space between adjacent first tines.

108. The system of claim 107, further comprising a capturing section slidably advanceable through the elongate member.

109. A retrieval system for use with a catheter, the system comprising:

a retrieval sheath;

a proximal capture portion affixed to a distal end of the retrieval sheath;

at least one leading wire extending through the retrieval sheath, where a distal section of the leading wire comprises a distal stiffness and where a proximal section of the leading wire comprises a proximal stiffness, where the proximal stiffness is greater than the distal stiffness; and

a distal capturing portion at the distal end of the leading wire, the distal capturing portion being axially moveable relative to the proximal capture portion.

110. The retrieval system of claim 109, an insertion tool slidably located over the retrieval sheath, the insertion tool comprising a gripping region affixed to a rigid section, where compression of the gripping portion creates a frictional fit between the insertion tool such that when the insertion tool is coupled to the retrieval sheath, compression of the gripping portion and axial movement of the insertion tool advances the retrieval sheath within the catheter.

111. The retrieval system of claim 109, where distal section of the leading wire is joined to the proximal section of the leading wire at a bond region, where the bond region is located a pre-determined distance from distal capture portion to allow navigation of a distal section of the system within the cerebral vasculature.

112. The retrieval system of claim 111, where the pre-determined distance is at least 20 cm.

113. The retrieval system of claim 109, further comprising a funnel slidably located on the sheath, where movement of the proximal capture portion and distal capture portion within the funnel causes the proximal and distal capture portions to compress.

114. The retrieval system of claim 109, where the insertion tool comprises a loading tube such that the proximal capture portion and distal capture portion can compress within the loading tube.

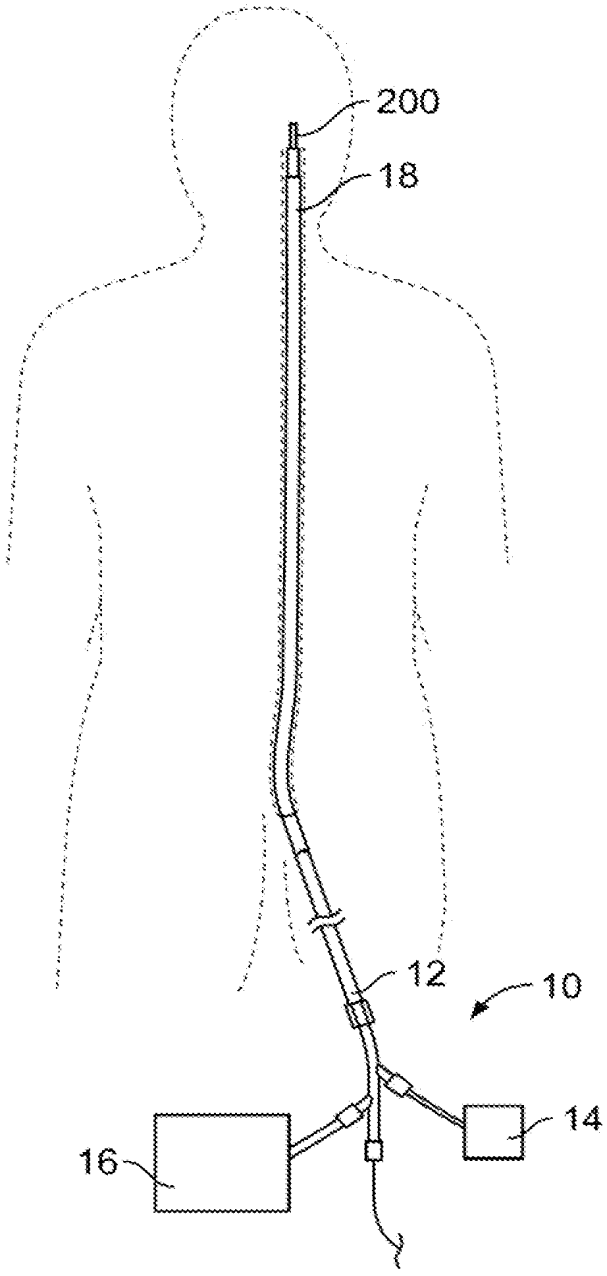

FIG. 1A

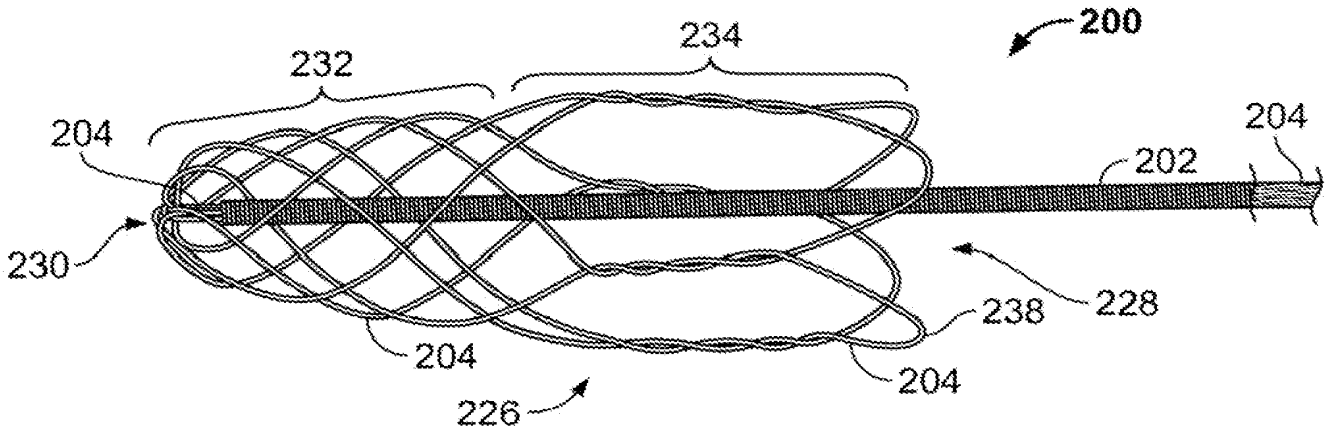
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FIG. 1B

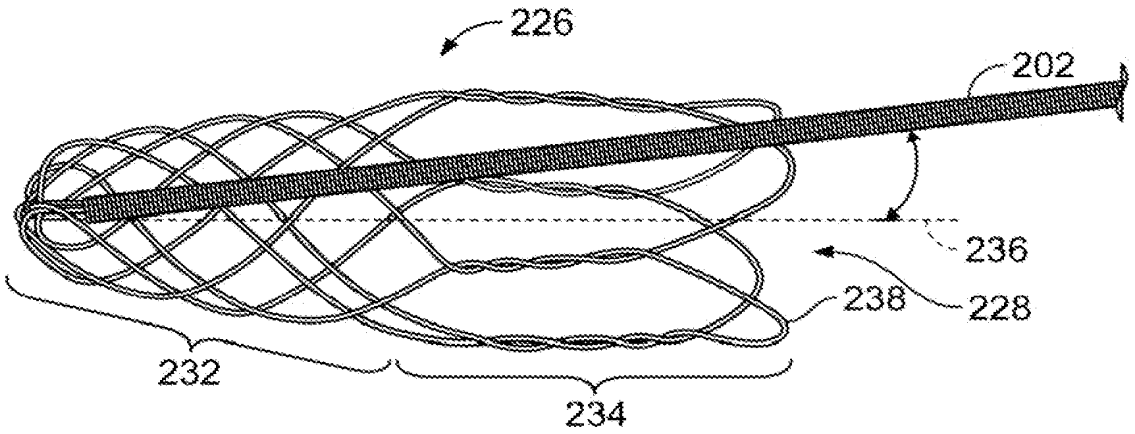
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FIG. 1C

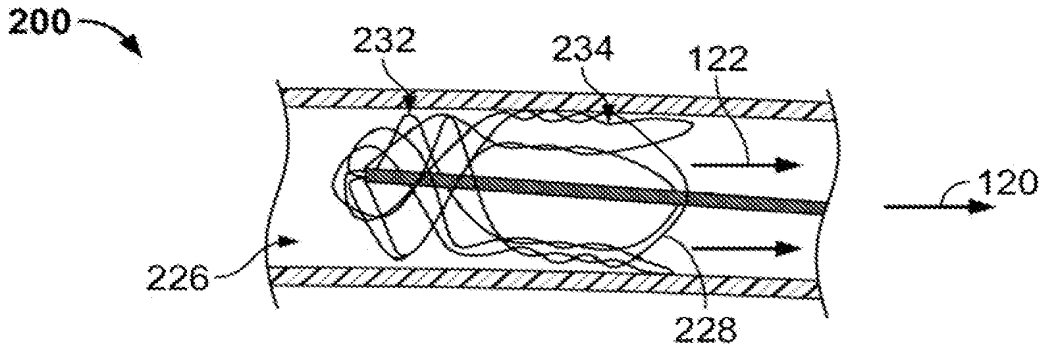

FIG. 2A

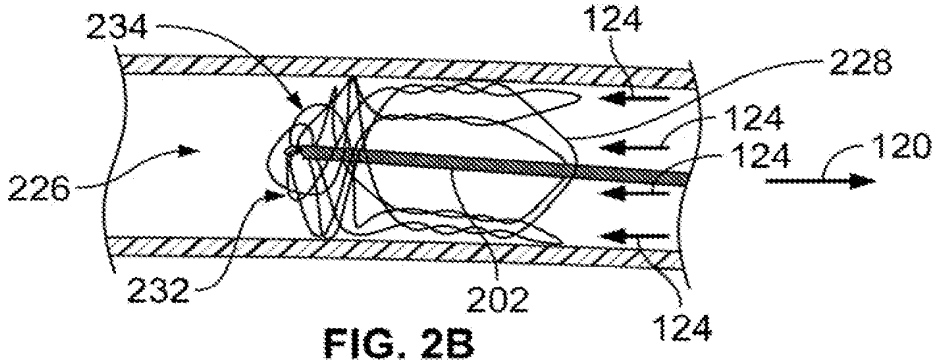

FIG. 2B

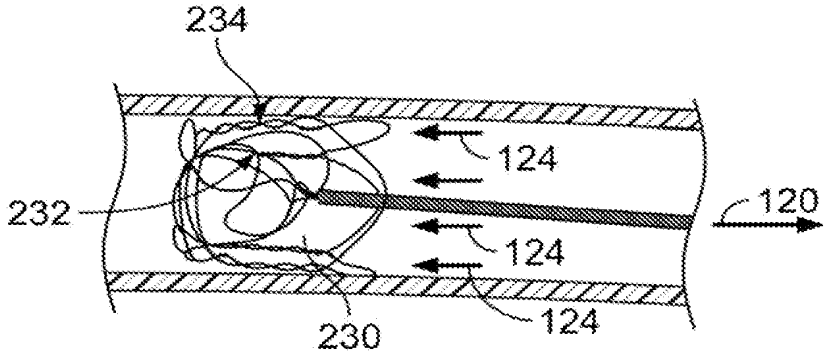

FIG. 2C

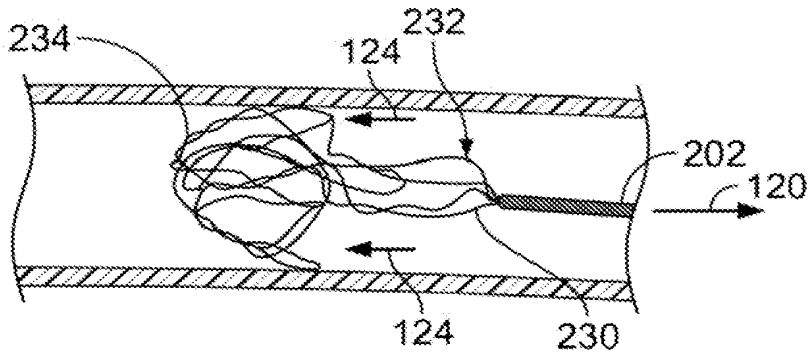

FIG. 2D

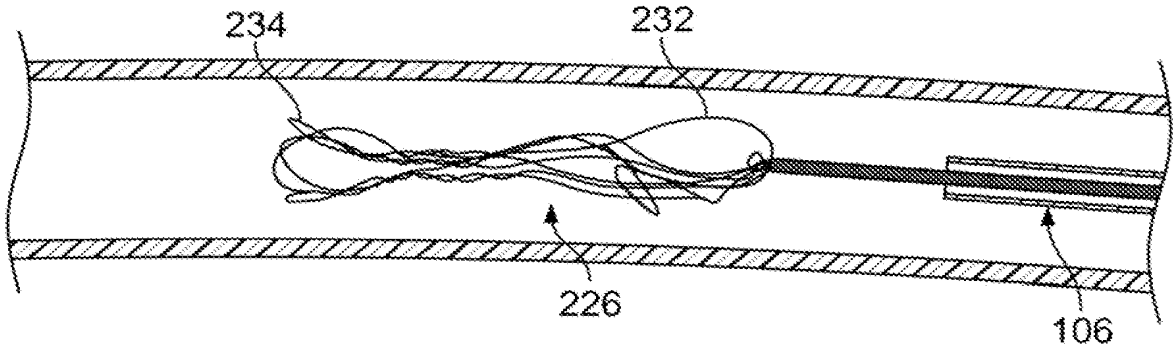

FIG. 2E

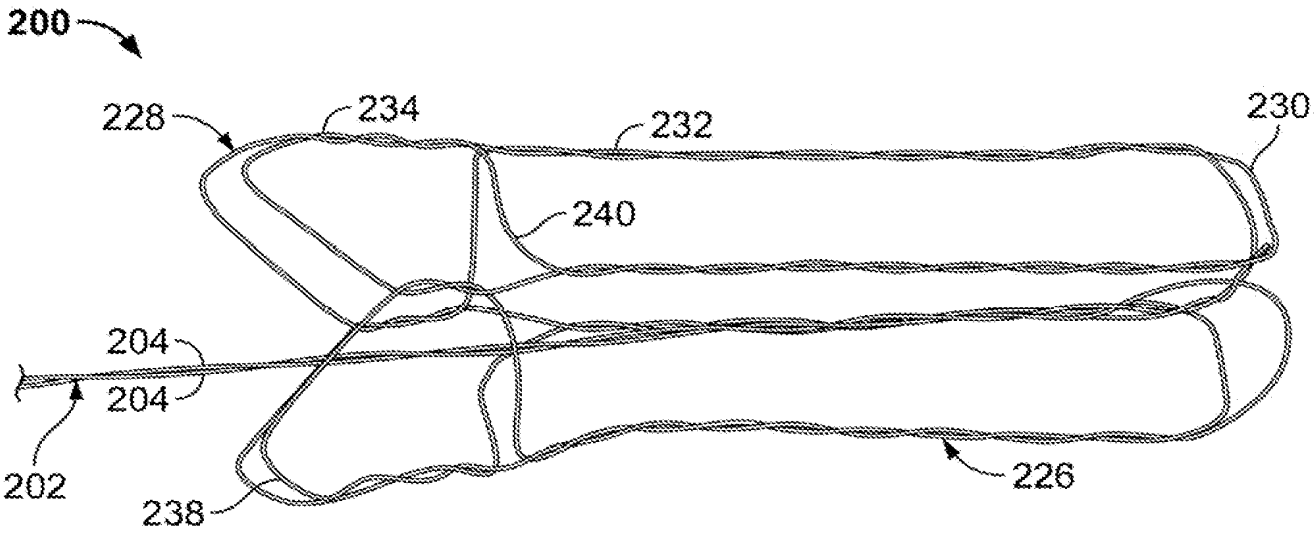
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FIG. 3A

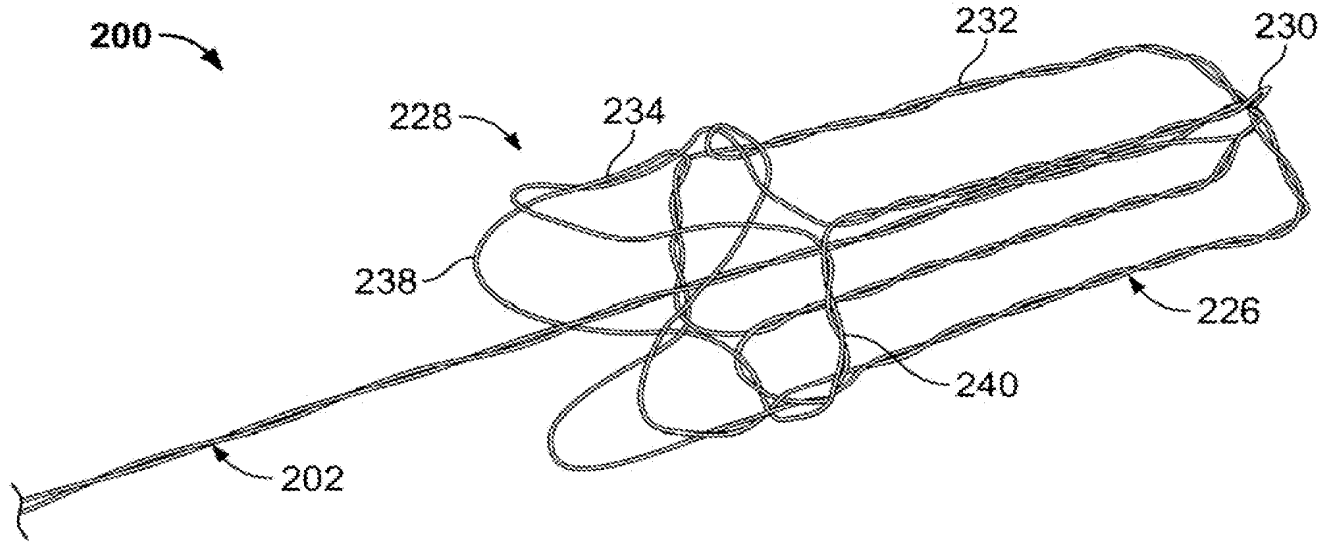
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FIG. 3B

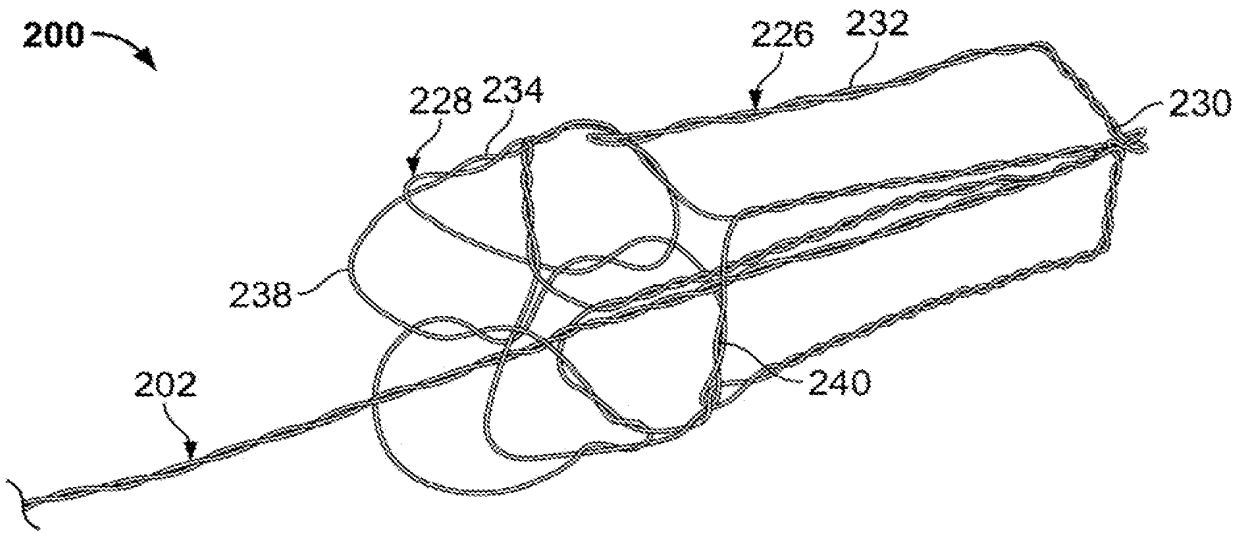

FIG. 3C

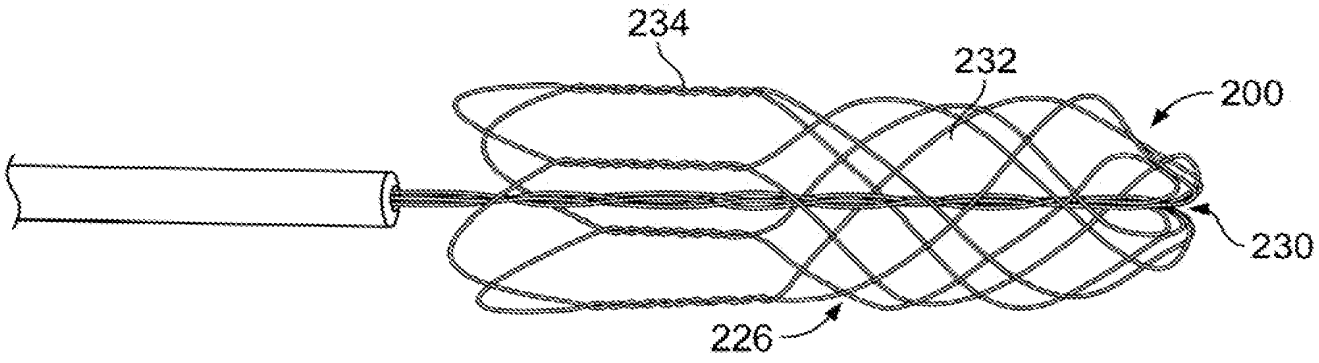

FIG. 3D

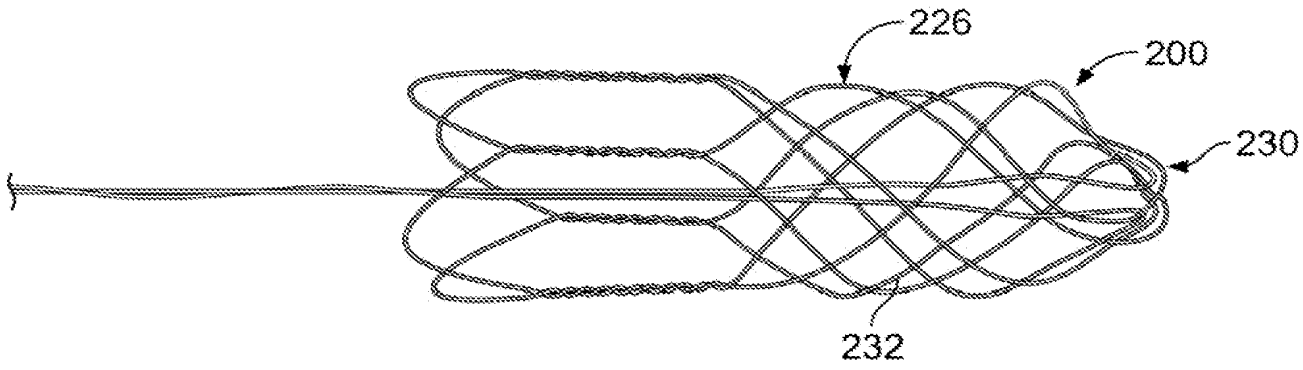

FIG. 3E

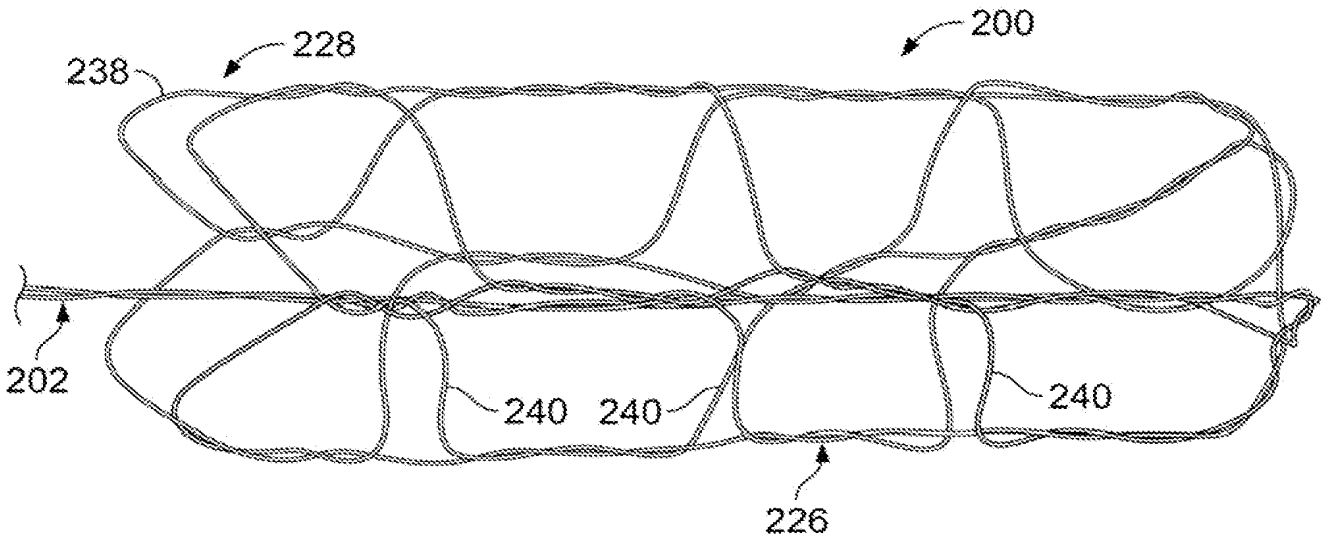

FIG. 3F

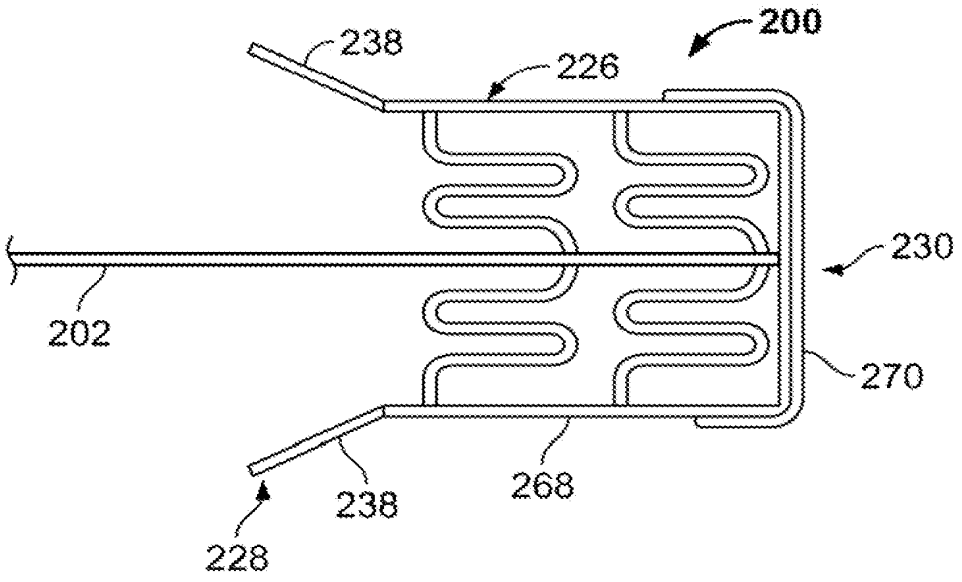

FIG. 3G

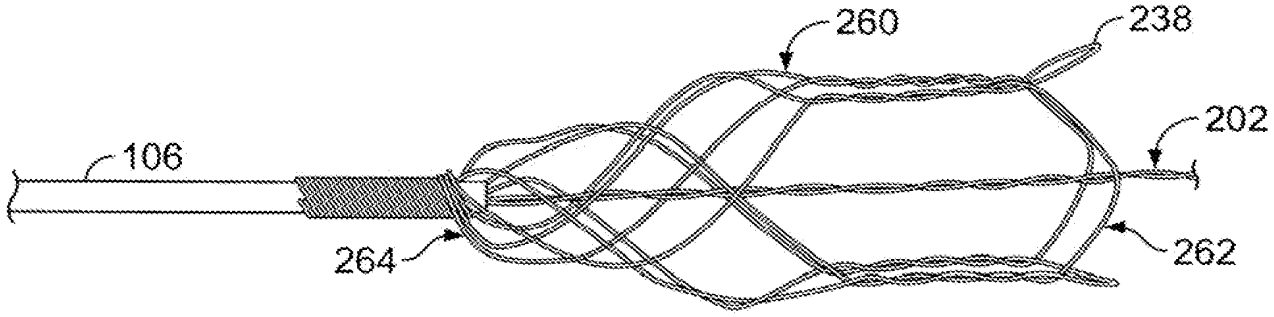

FIG. 3H

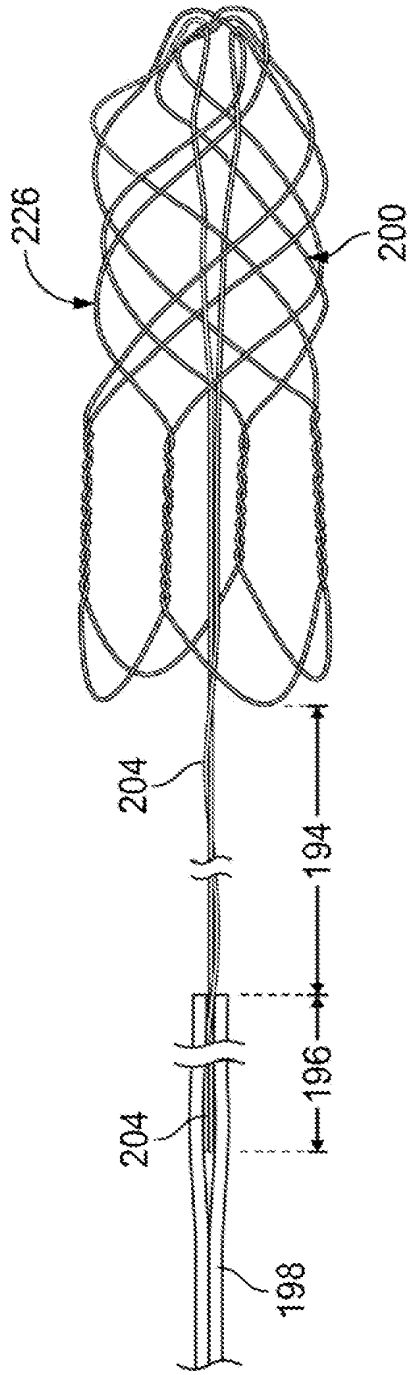

FIG. 4A

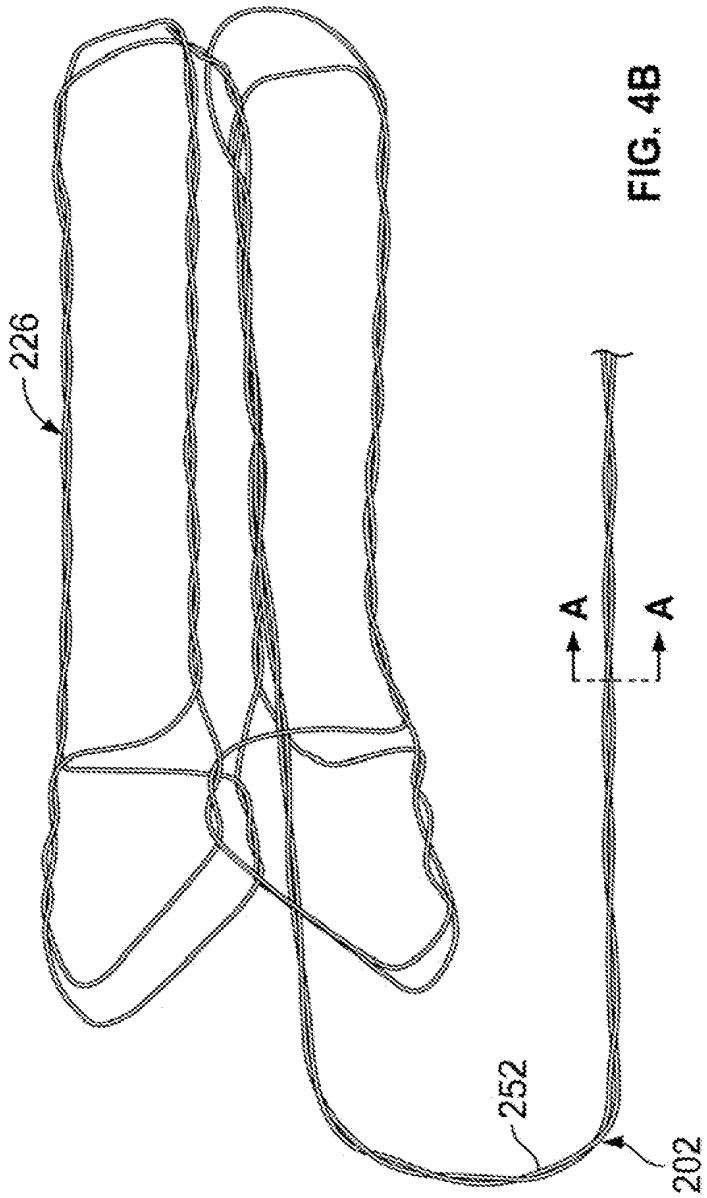

FIG. 4B

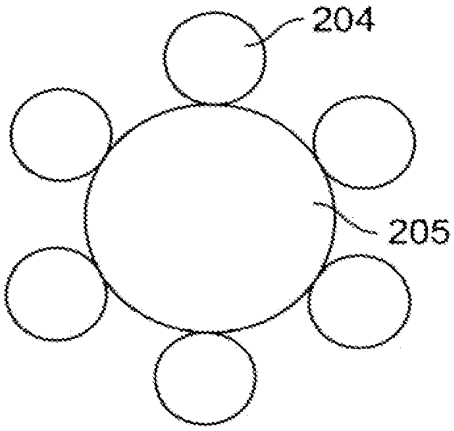

FIG. 4C

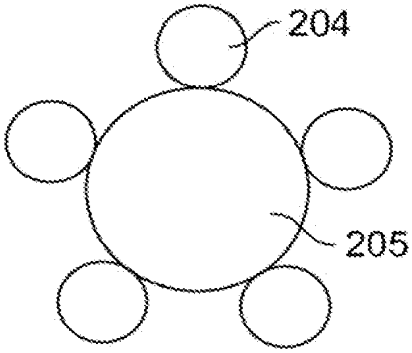

FIG. 4D

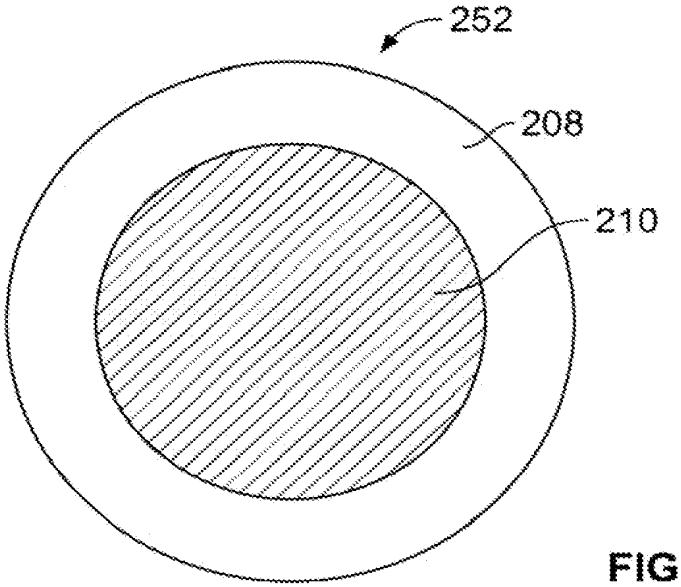

FIG. 4E

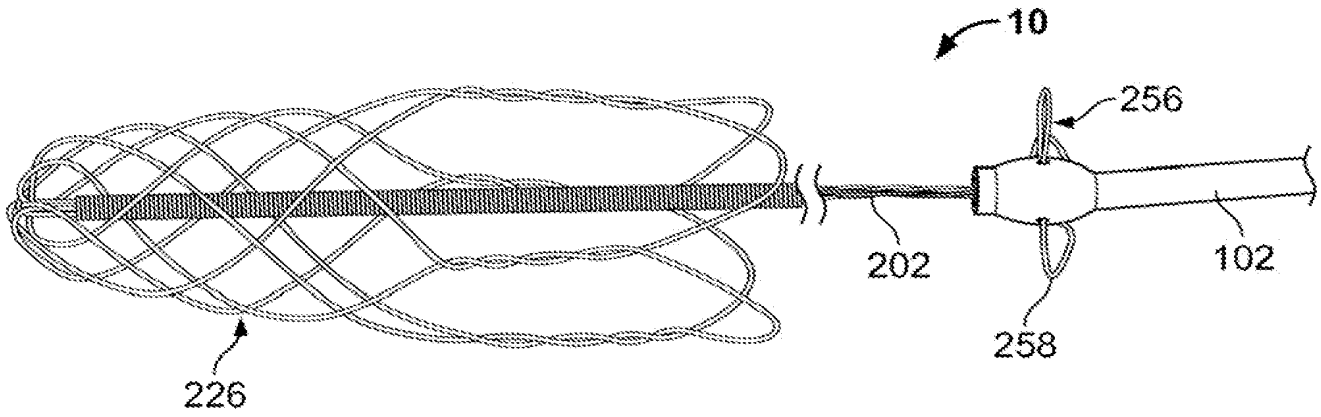

FIG. 5A

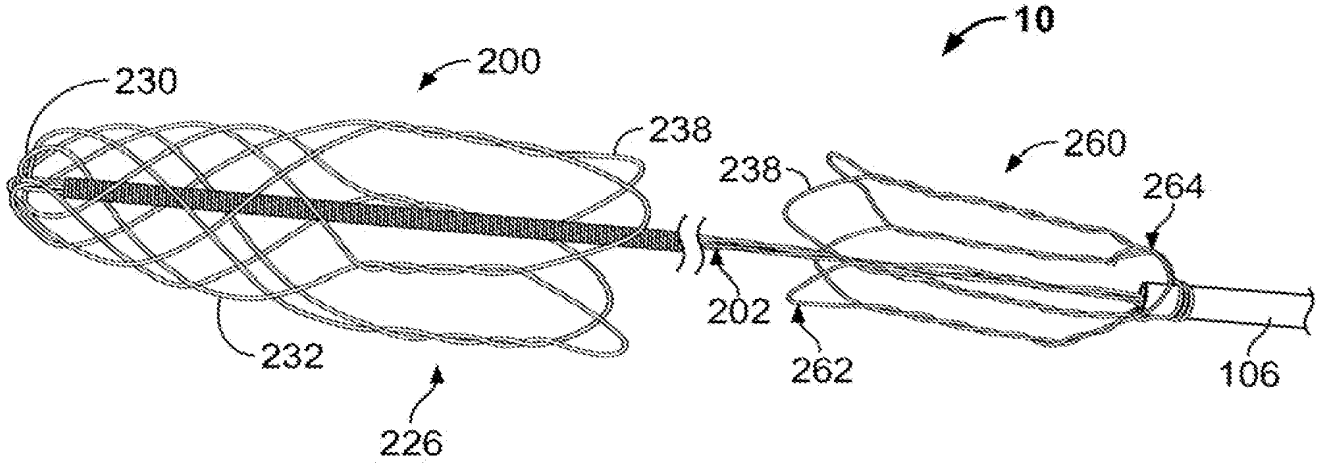

FIG. 5B

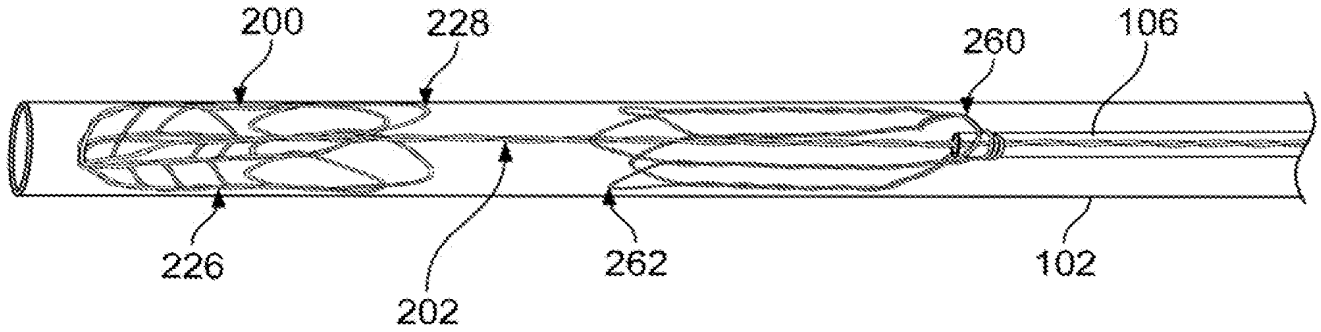

FIG. 5C

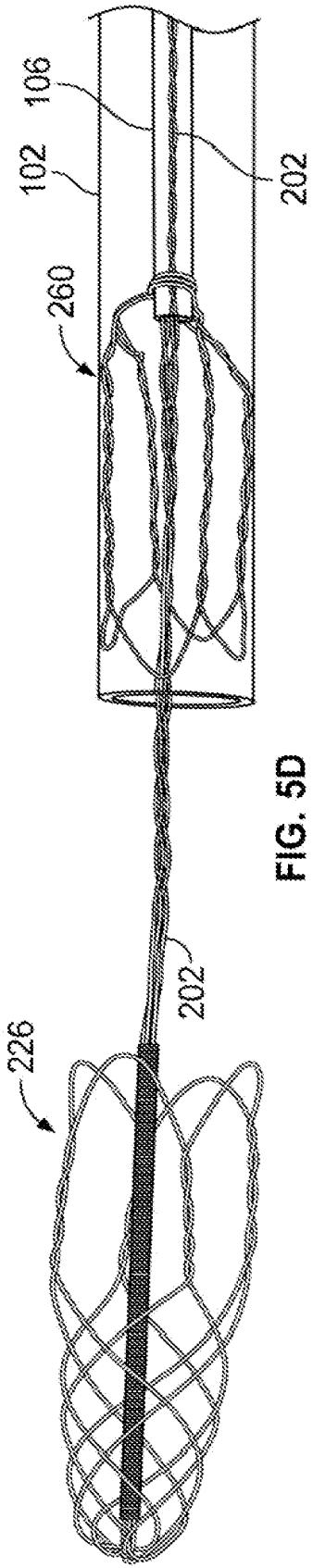

FIG. 5D

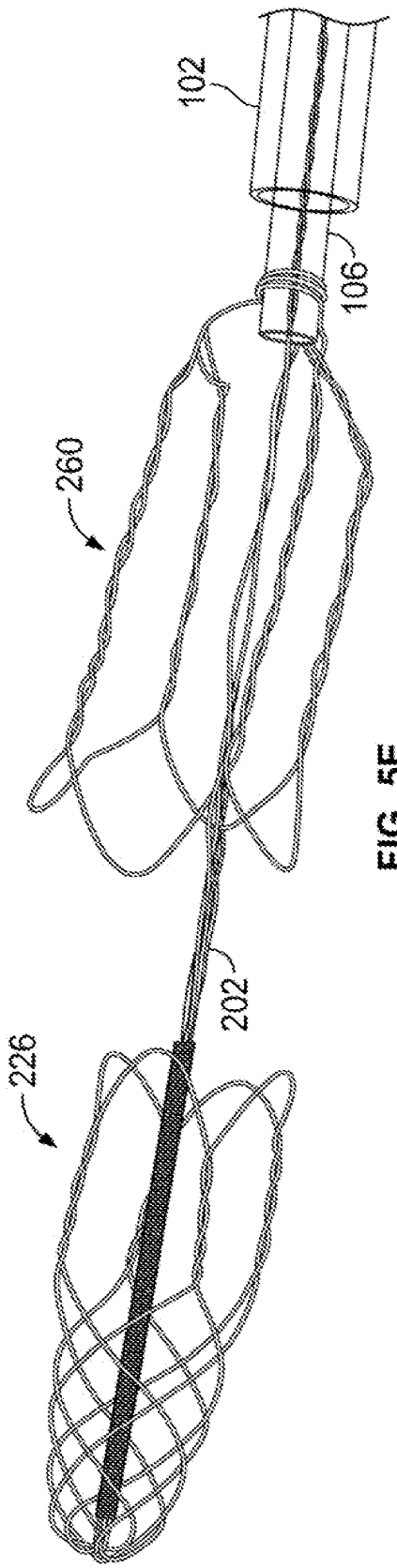

FIG. 5E

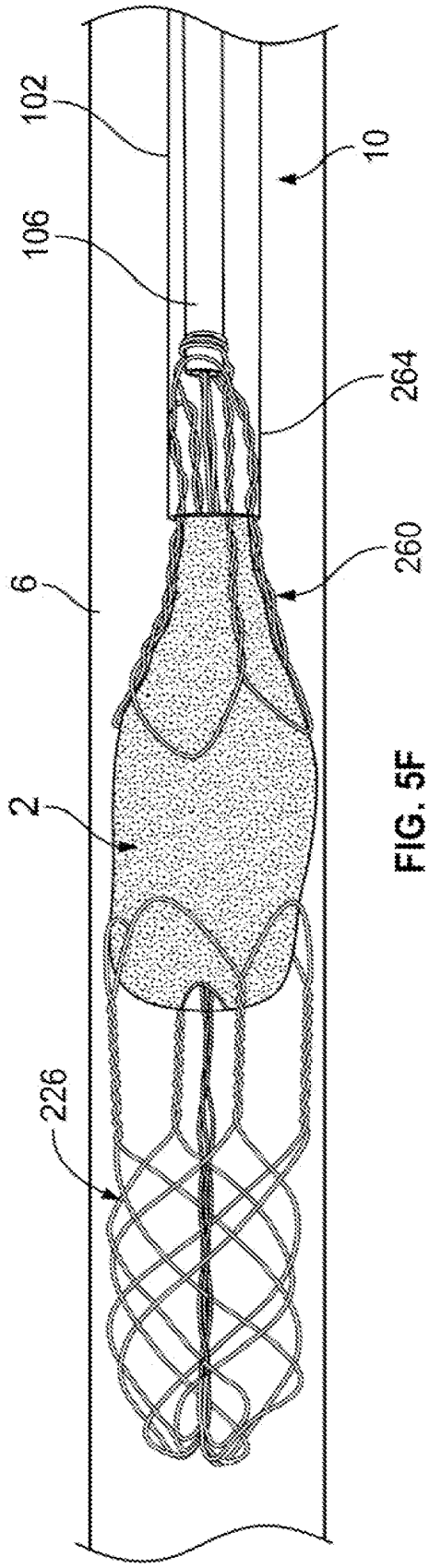

FIG. 5F

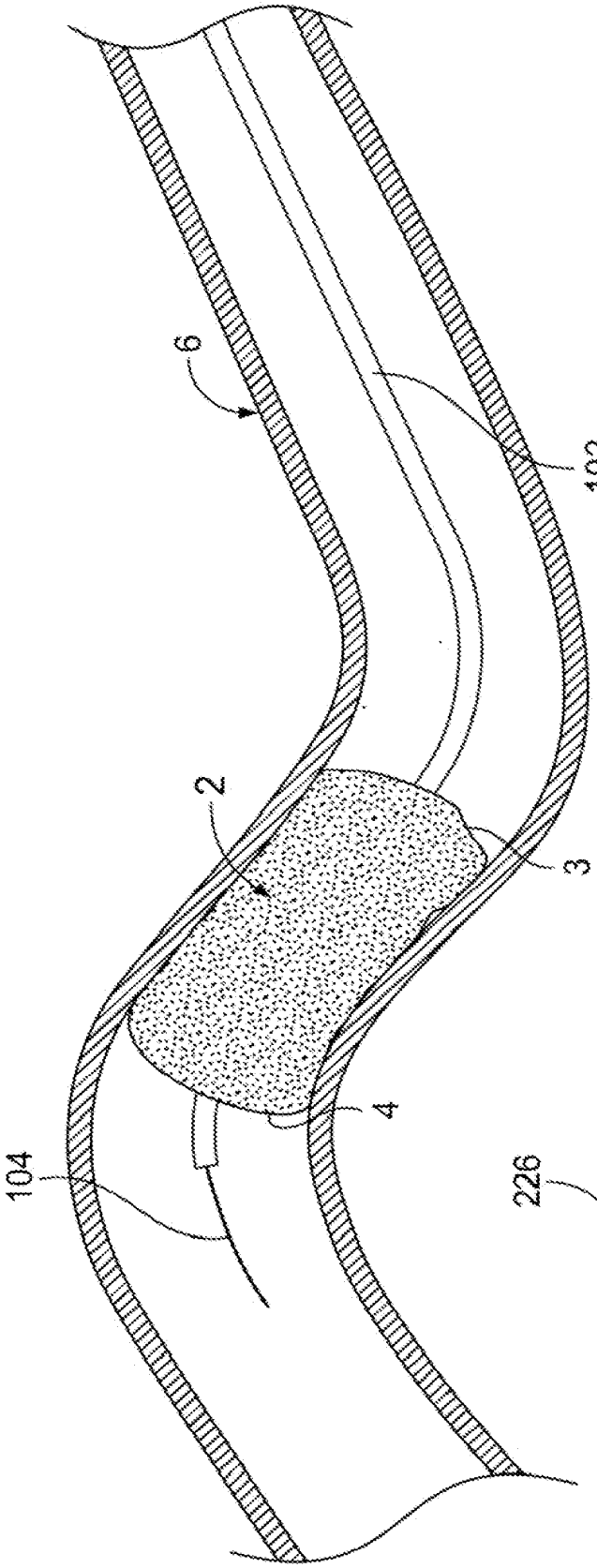

FIG. 6A

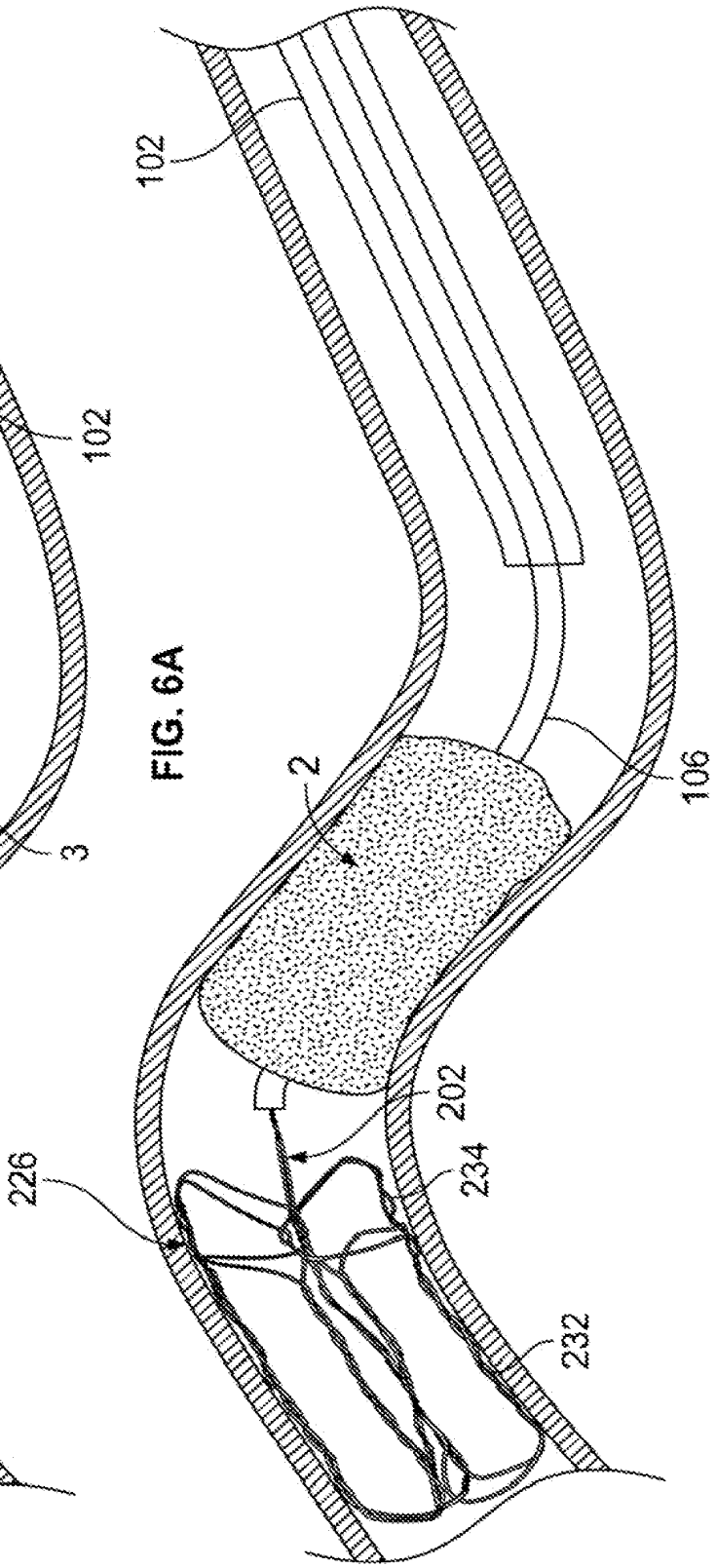

FIG. 6B

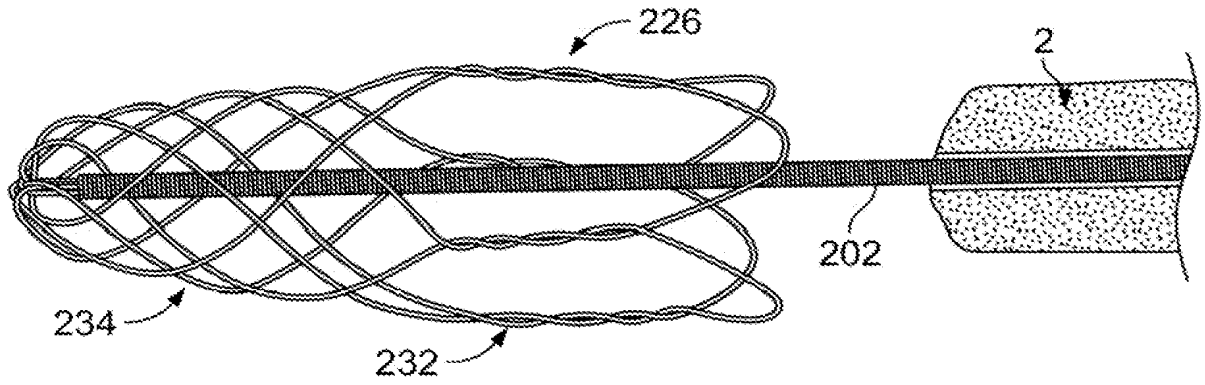

FIG. 7A

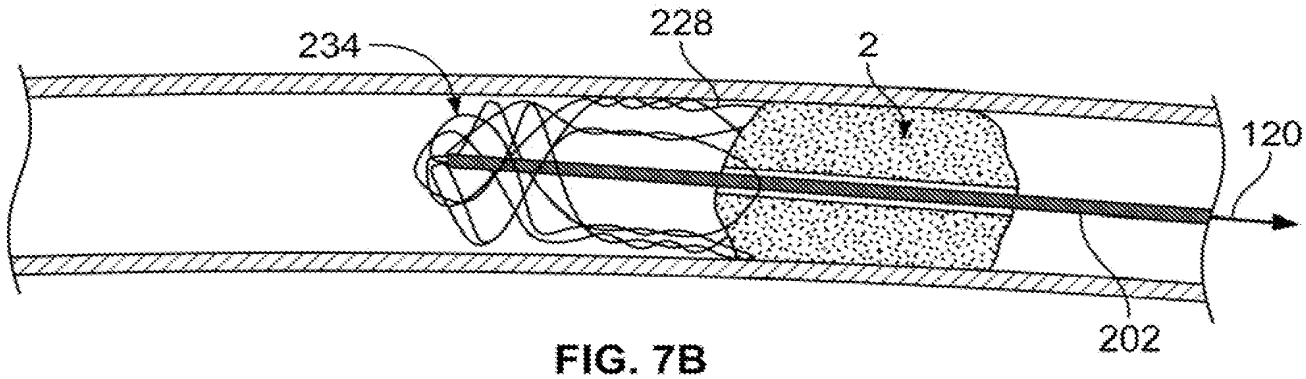

FIG. 7B

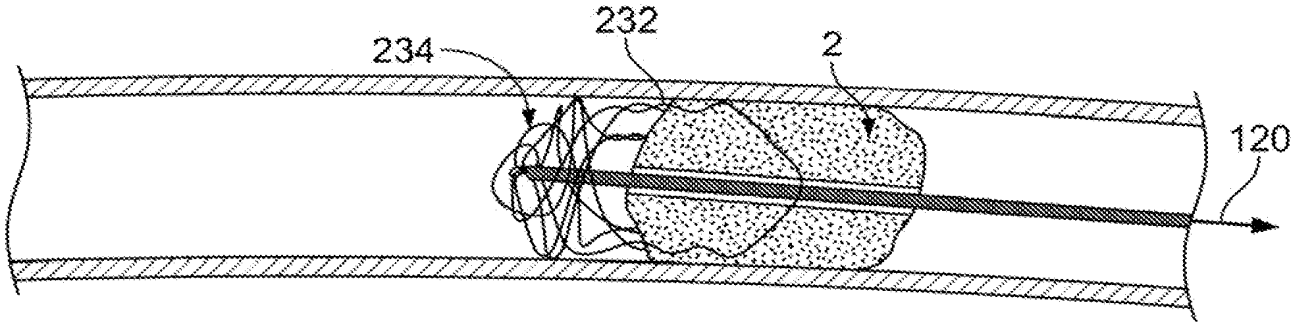

FIG. 7C

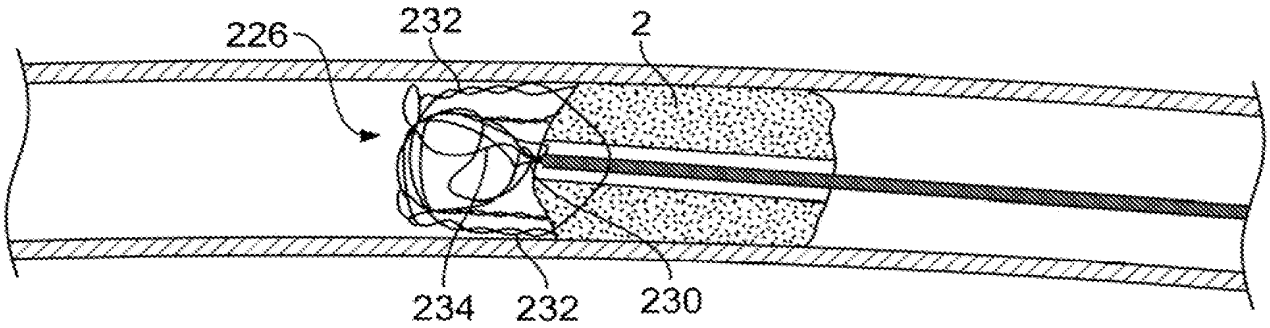

FIG. 7D

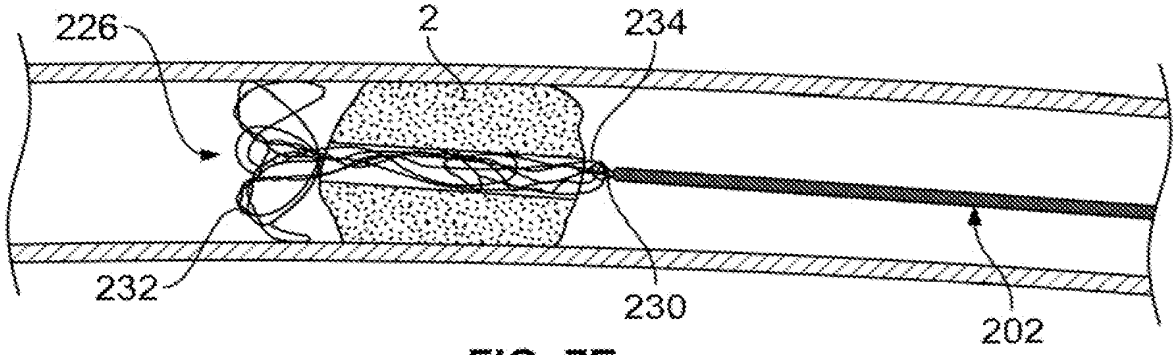

FIG. 7E

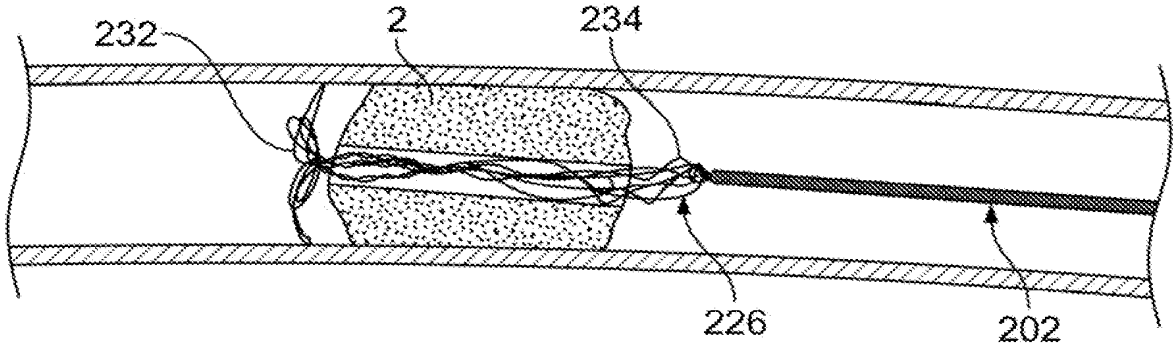

FIG. 7F

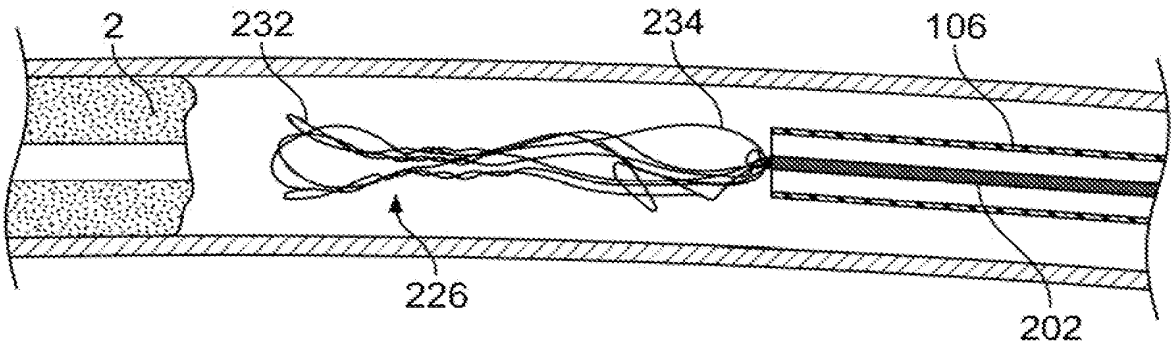

FIG. 7G

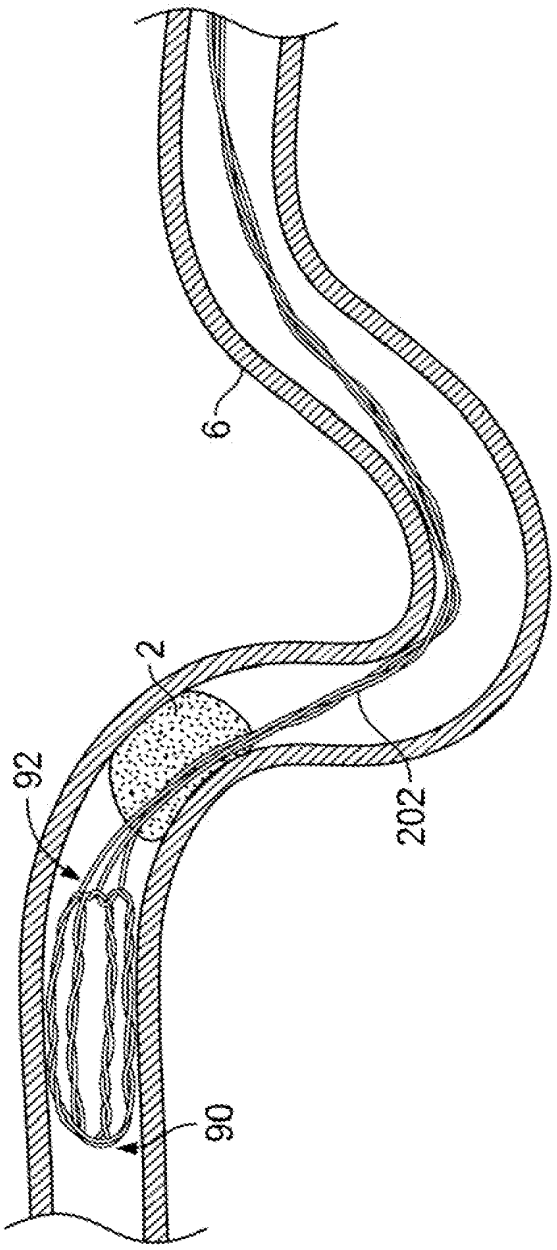

FIG. 8A

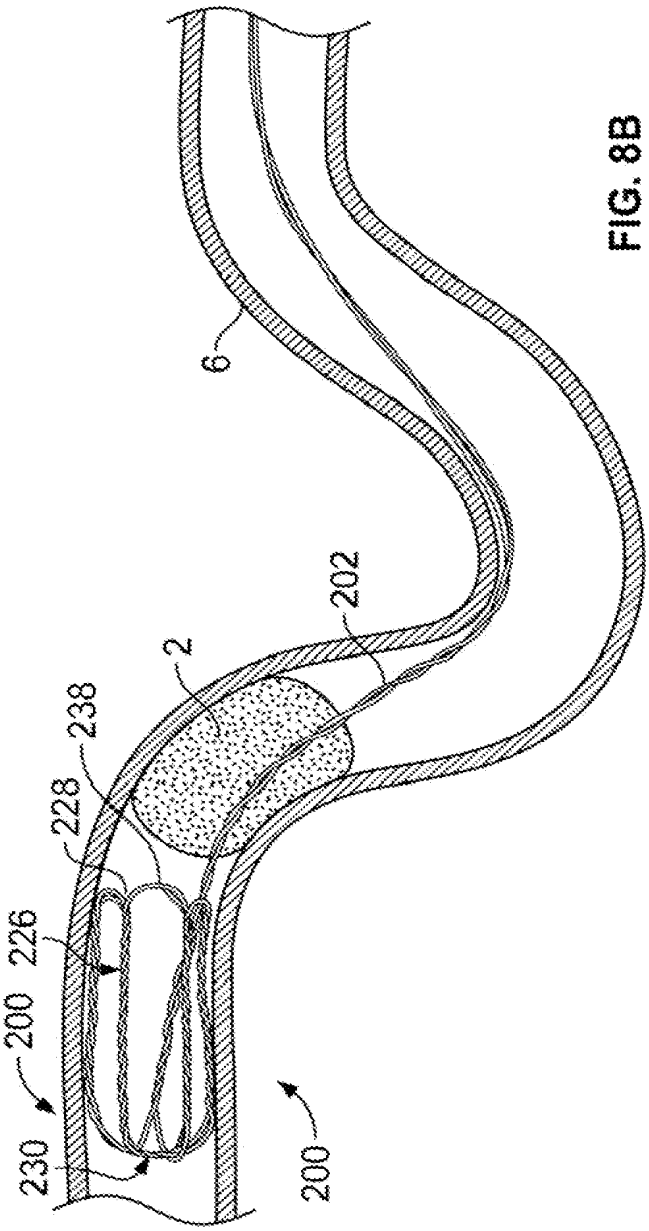

FIG. 8B

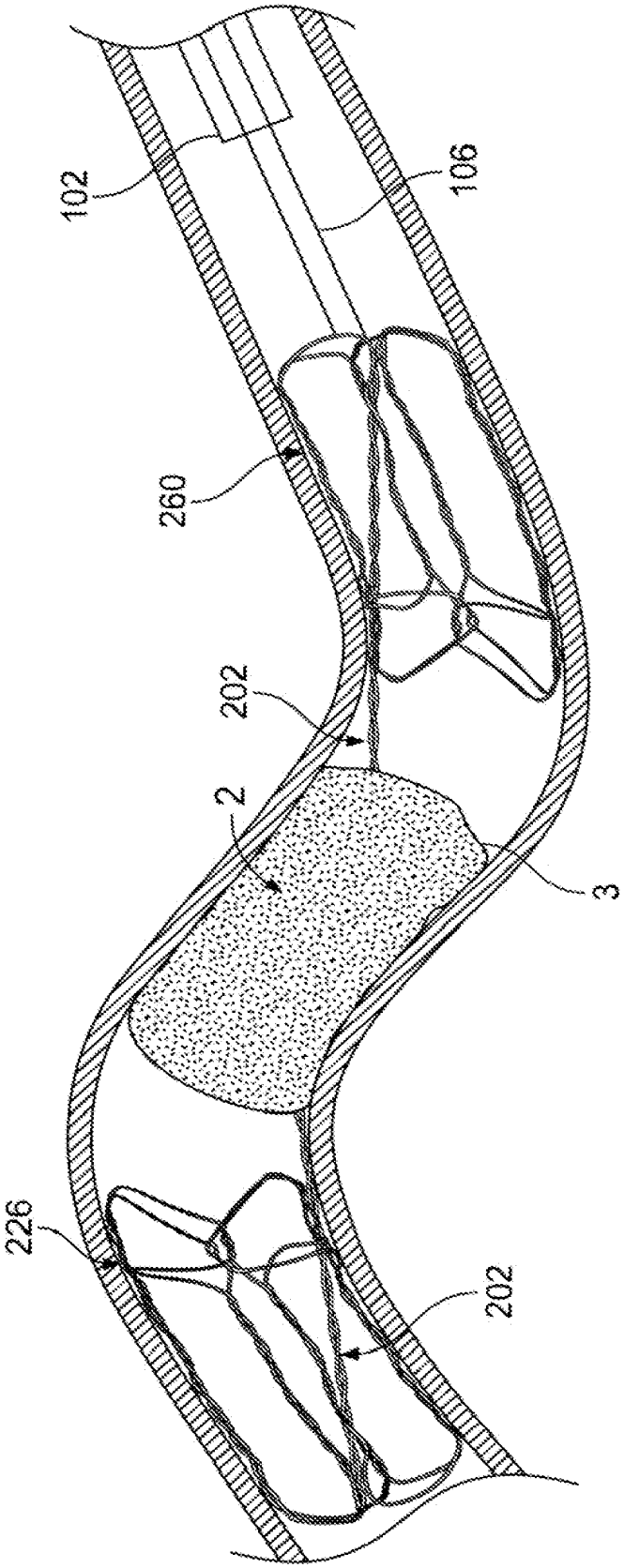

FIG. 8C

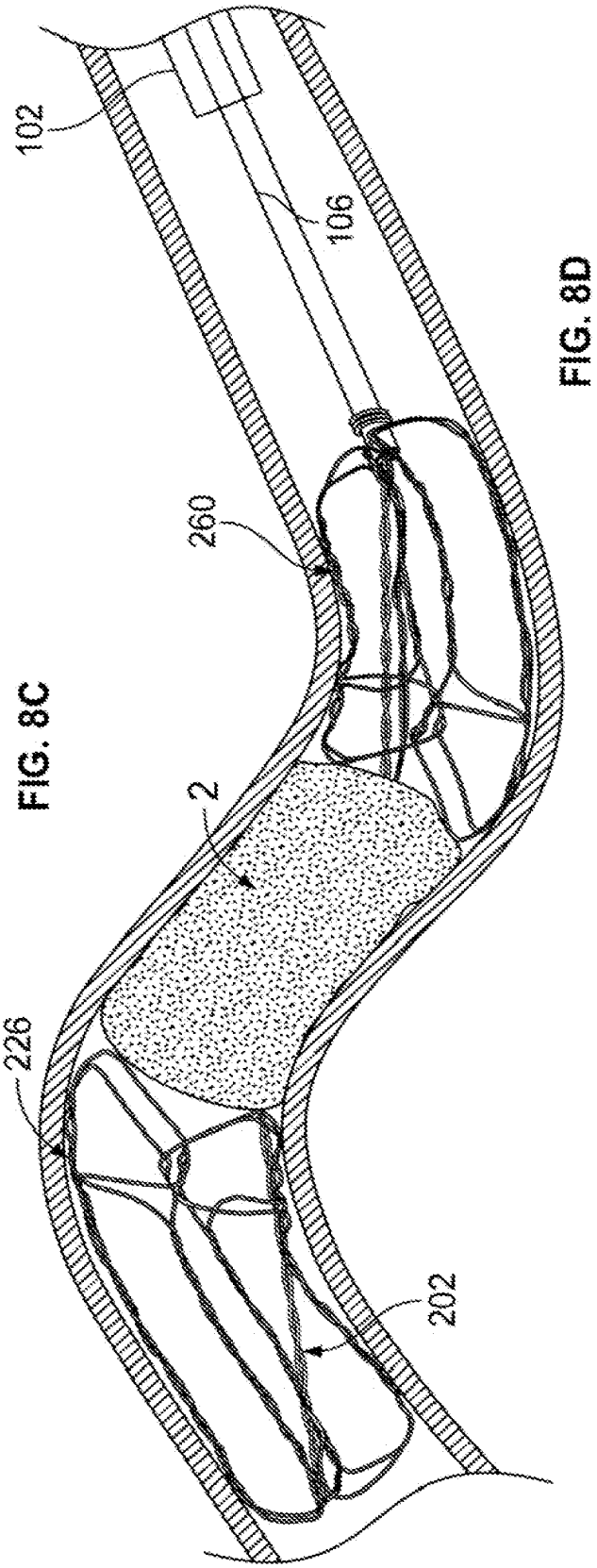

FIG. 8D

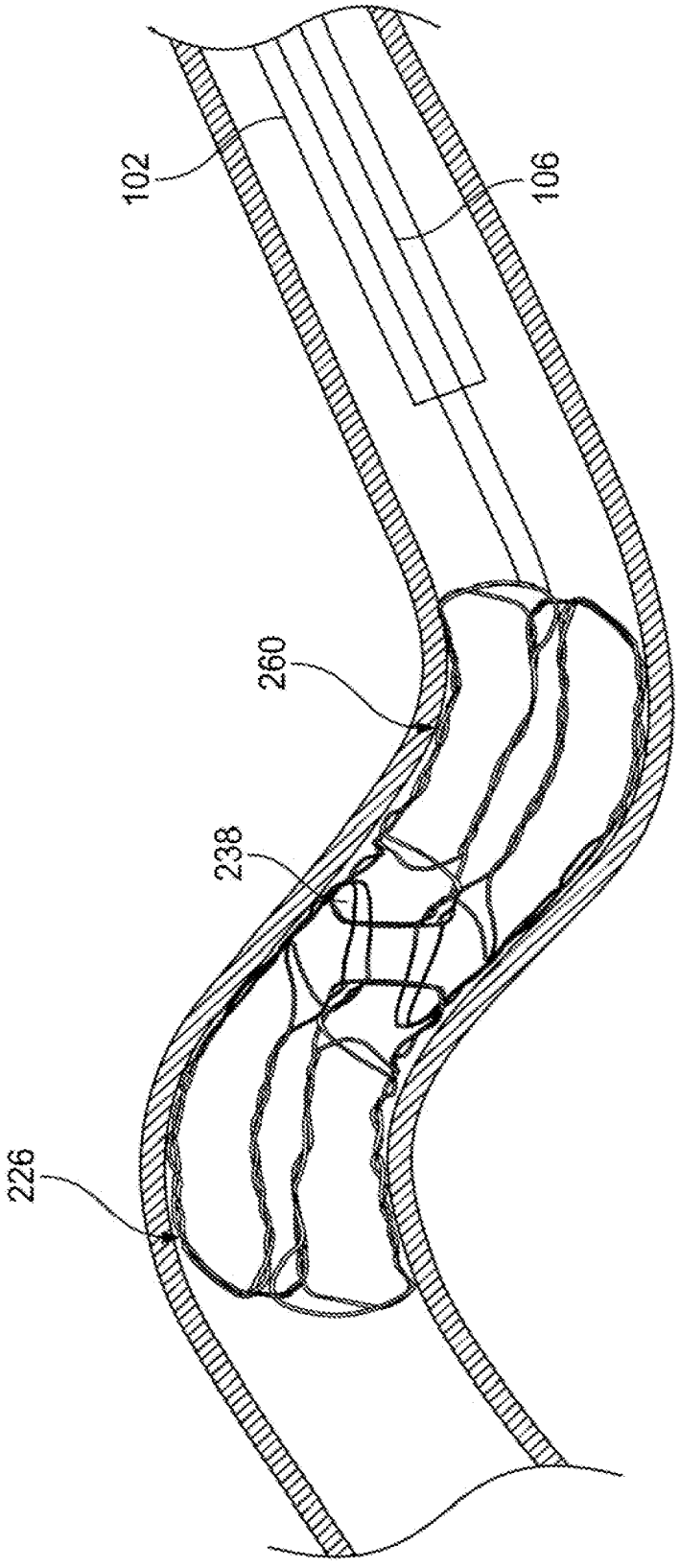

FIG. 8E

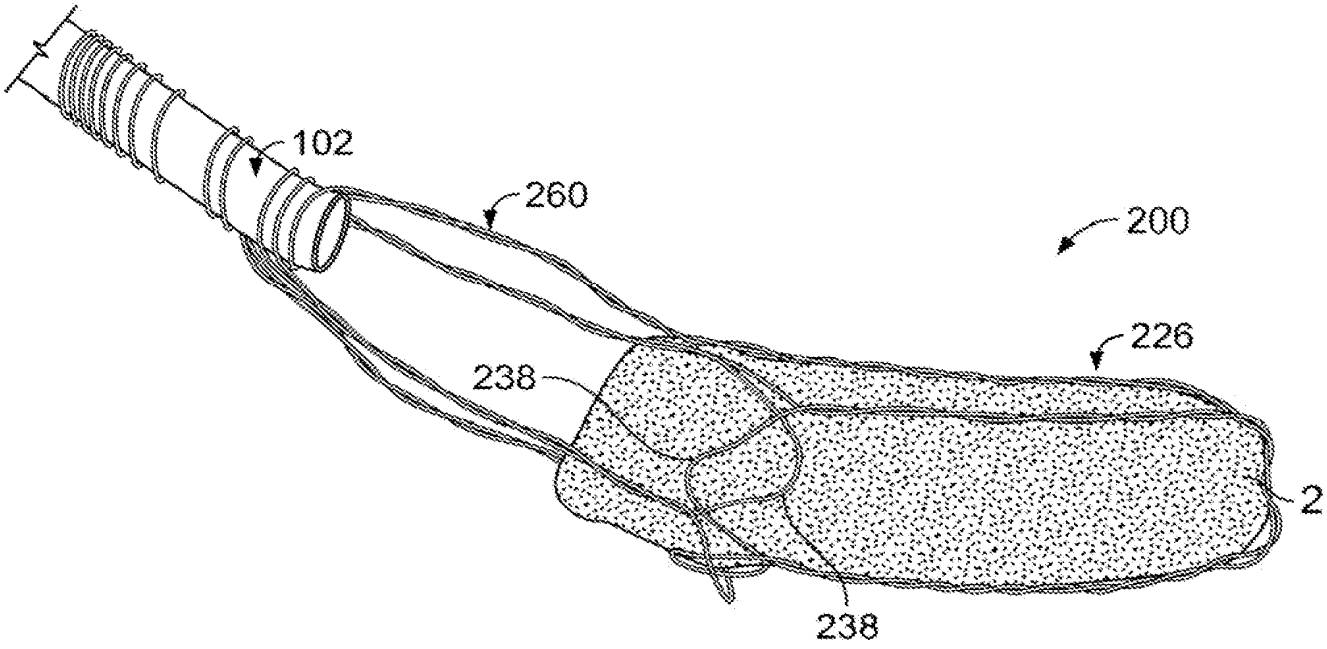

FIG. 8F

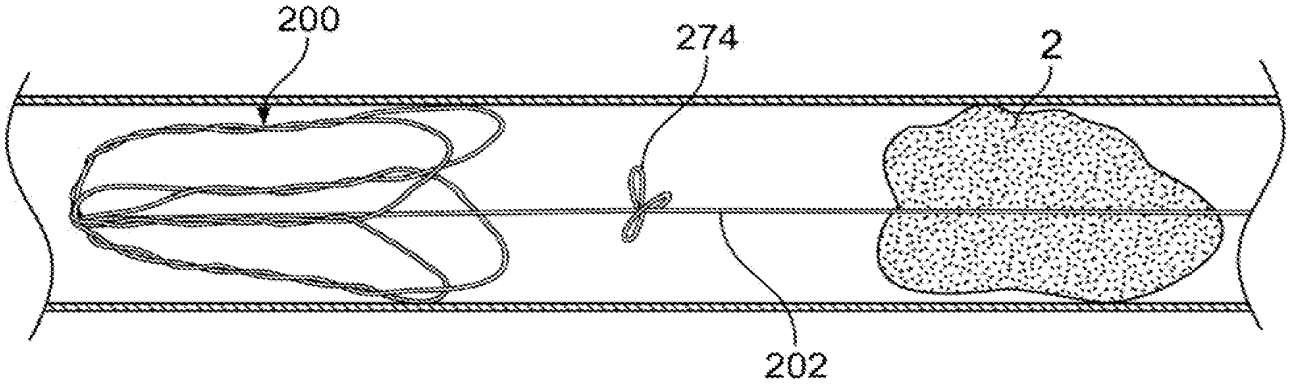

FIG. 9

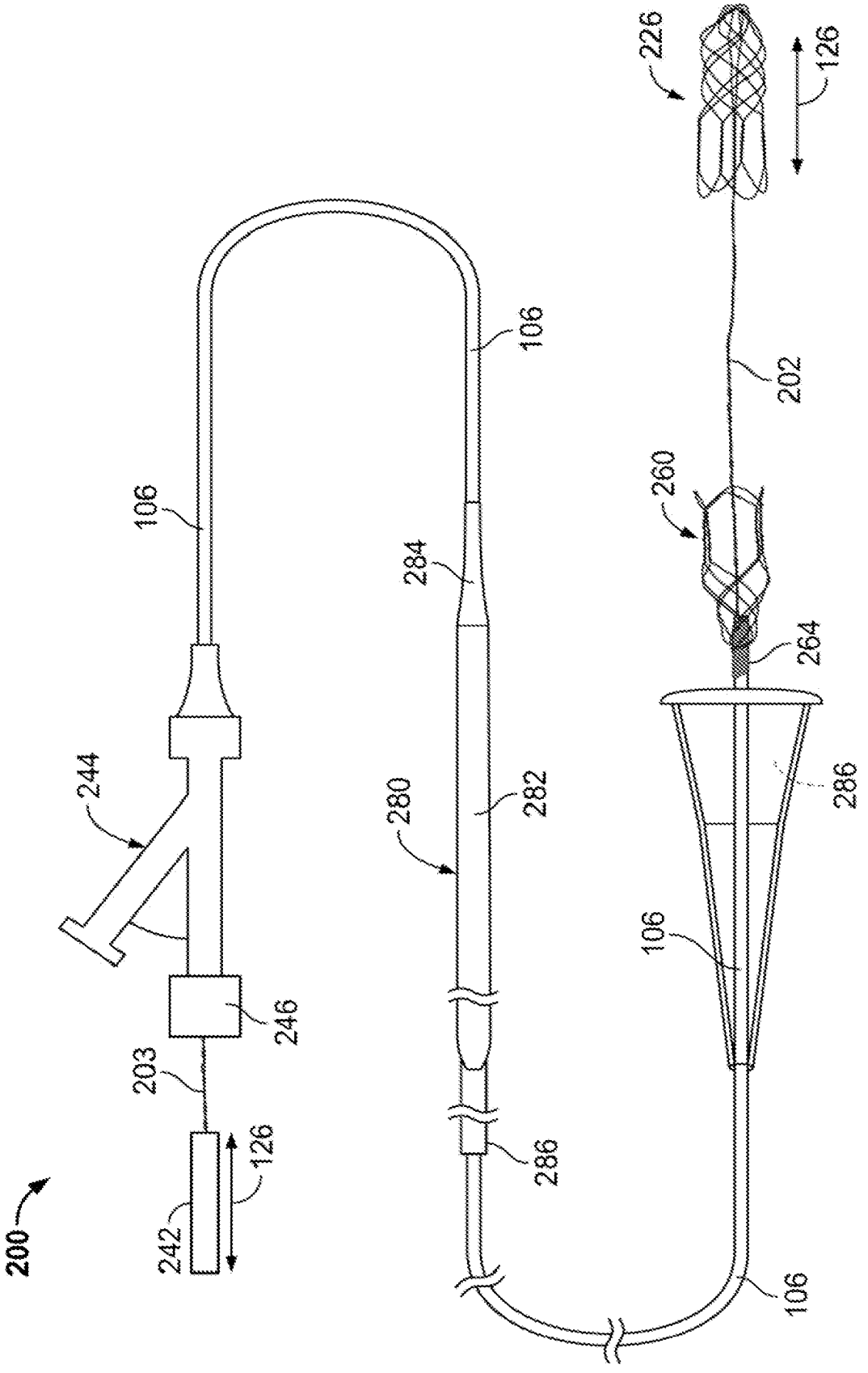
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FIG. 10

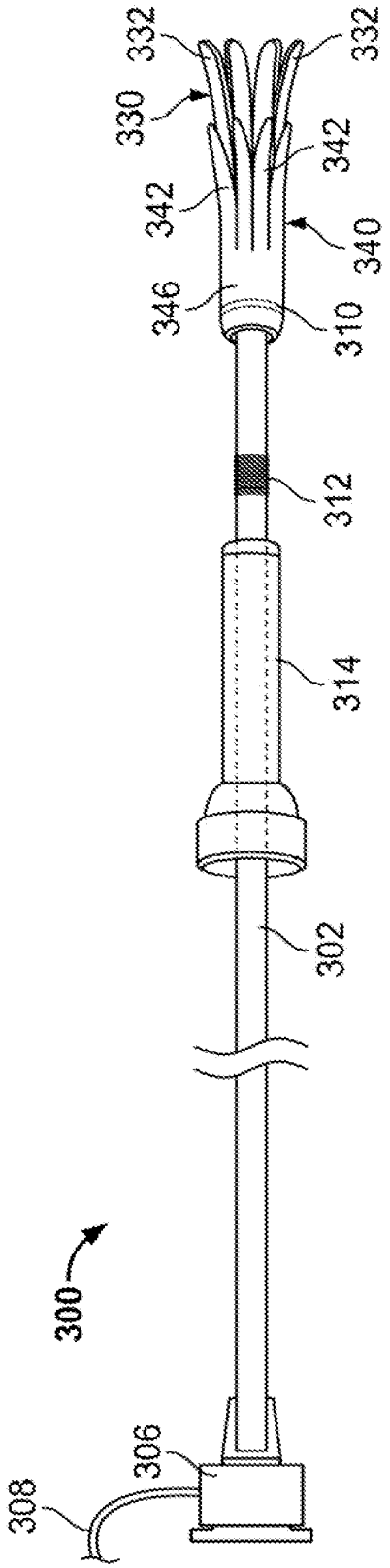

FIG. 11A

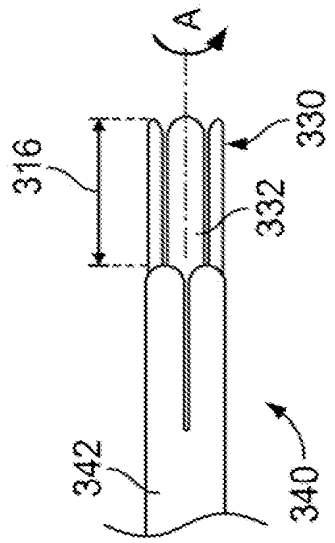

FIG. 11C

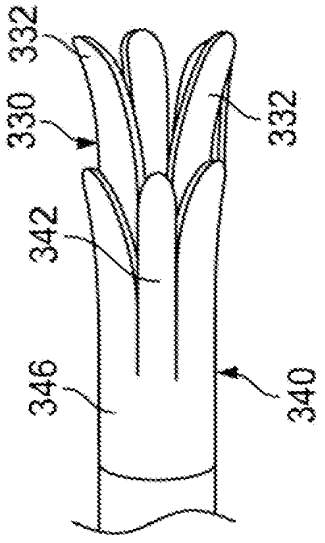

FIG. 11B

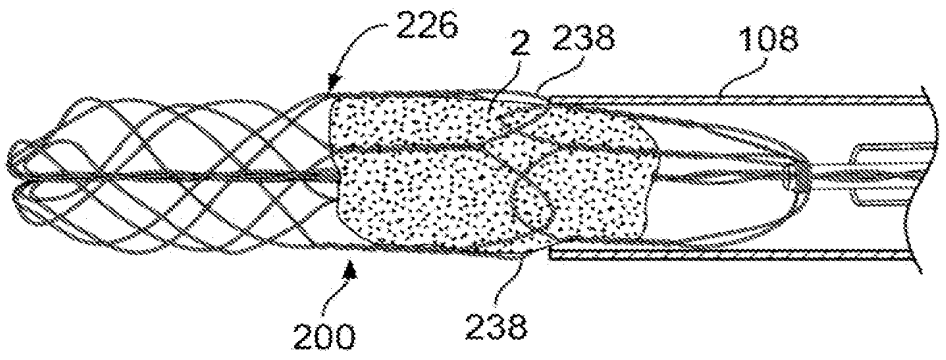

FIG. 12A

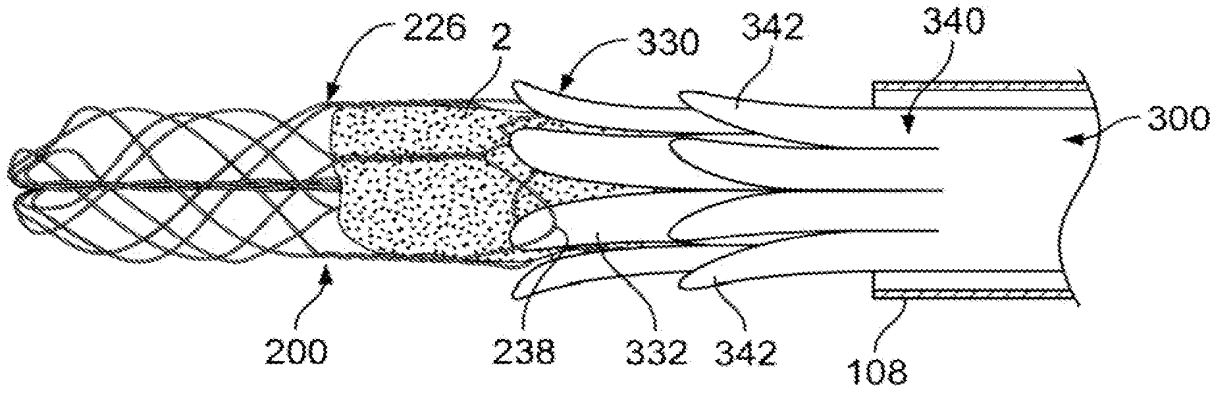

FIG. 12B

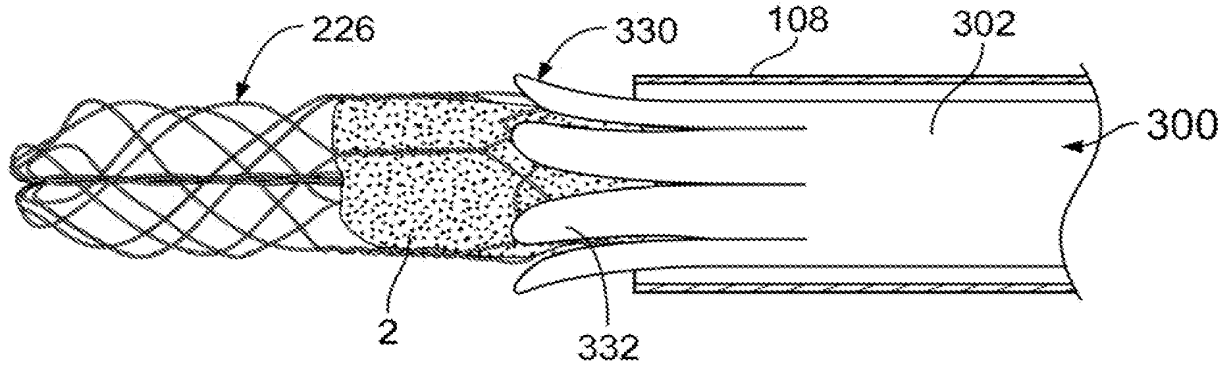

FIG. 12C

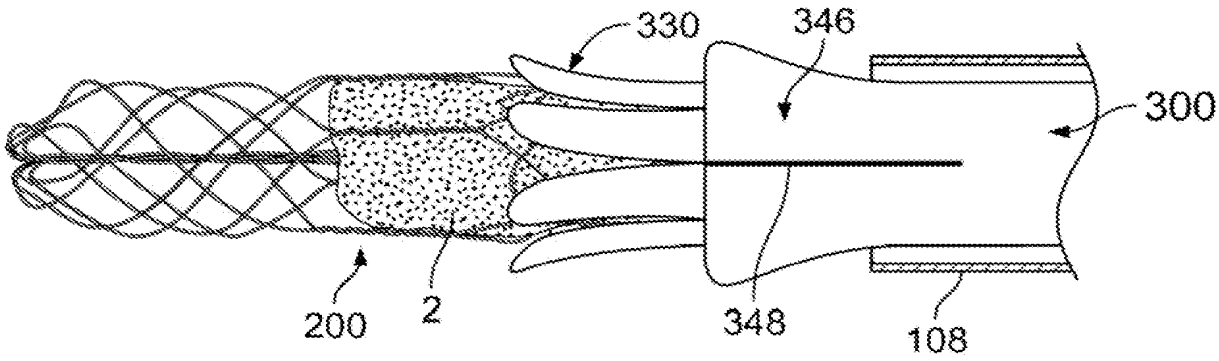

FIG. 12D

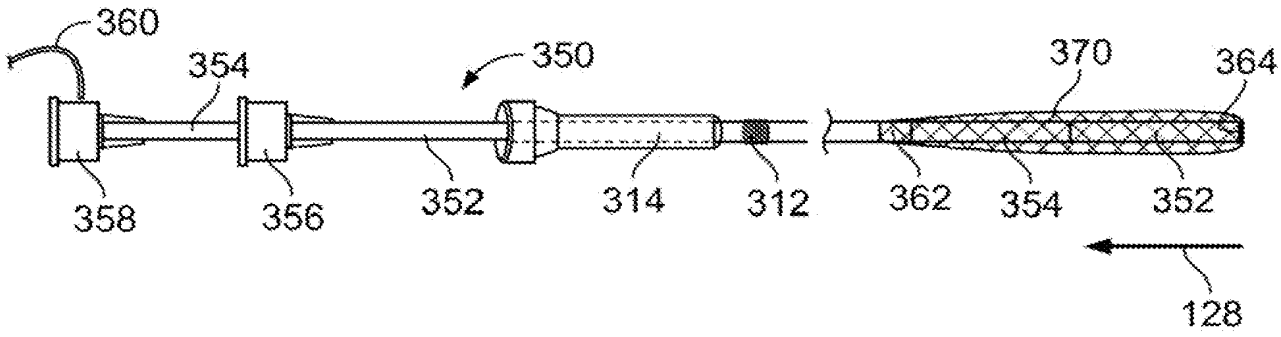

FIG. 13A

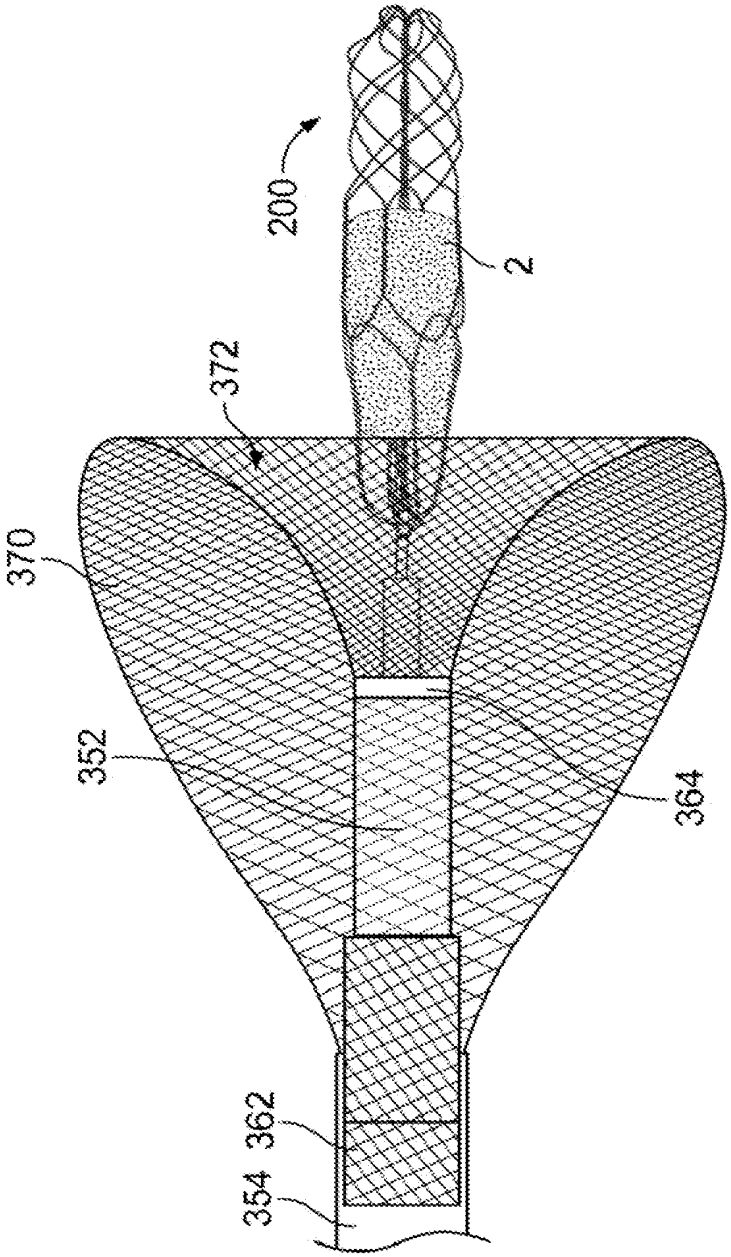

FIG. 13B

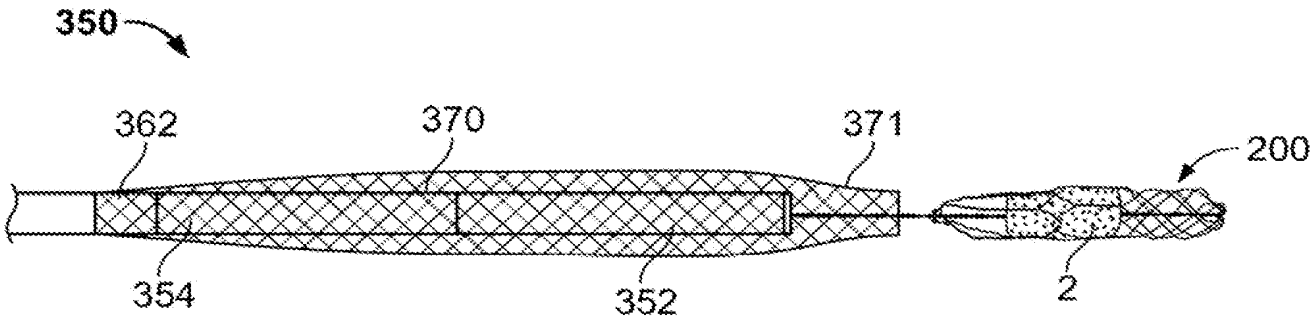

FIG. 13C

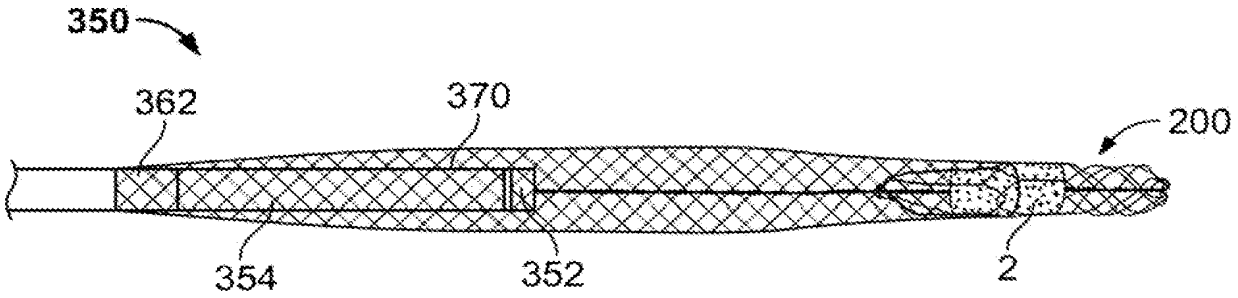

FIG. 13D

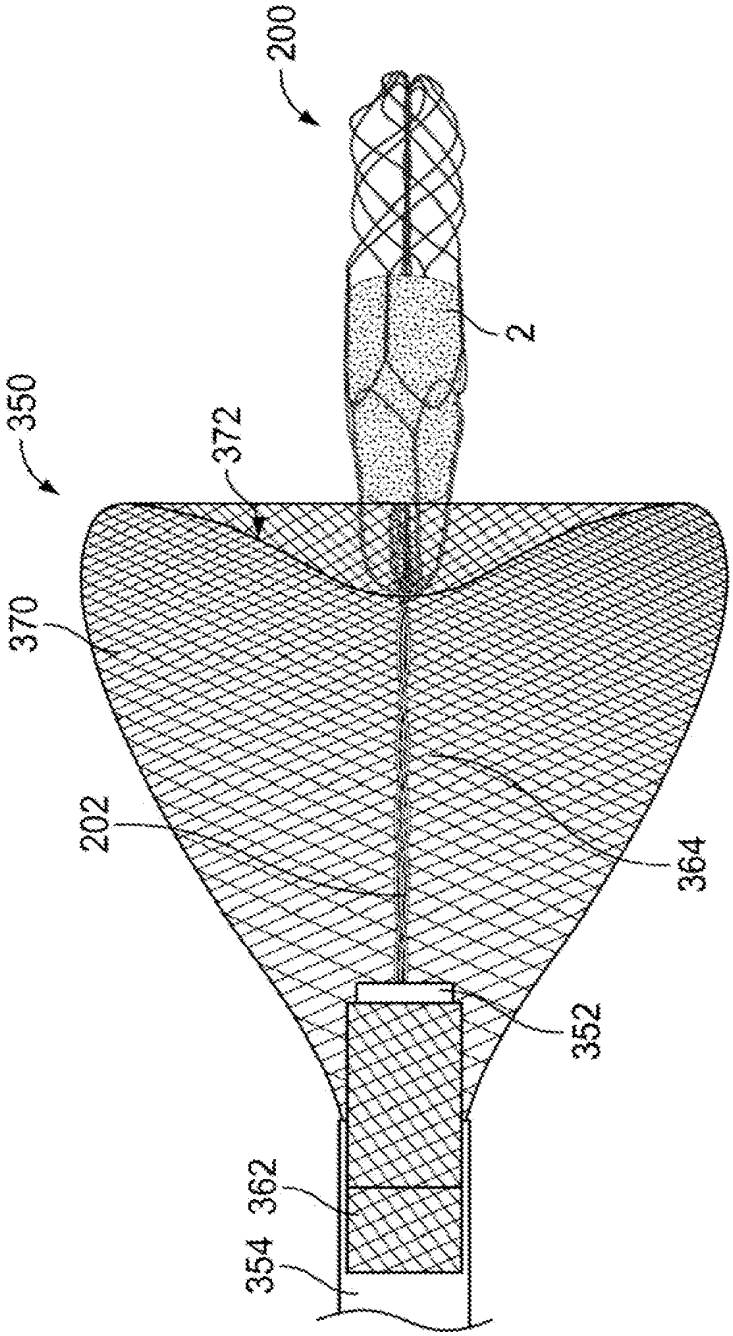

FIG. 13E

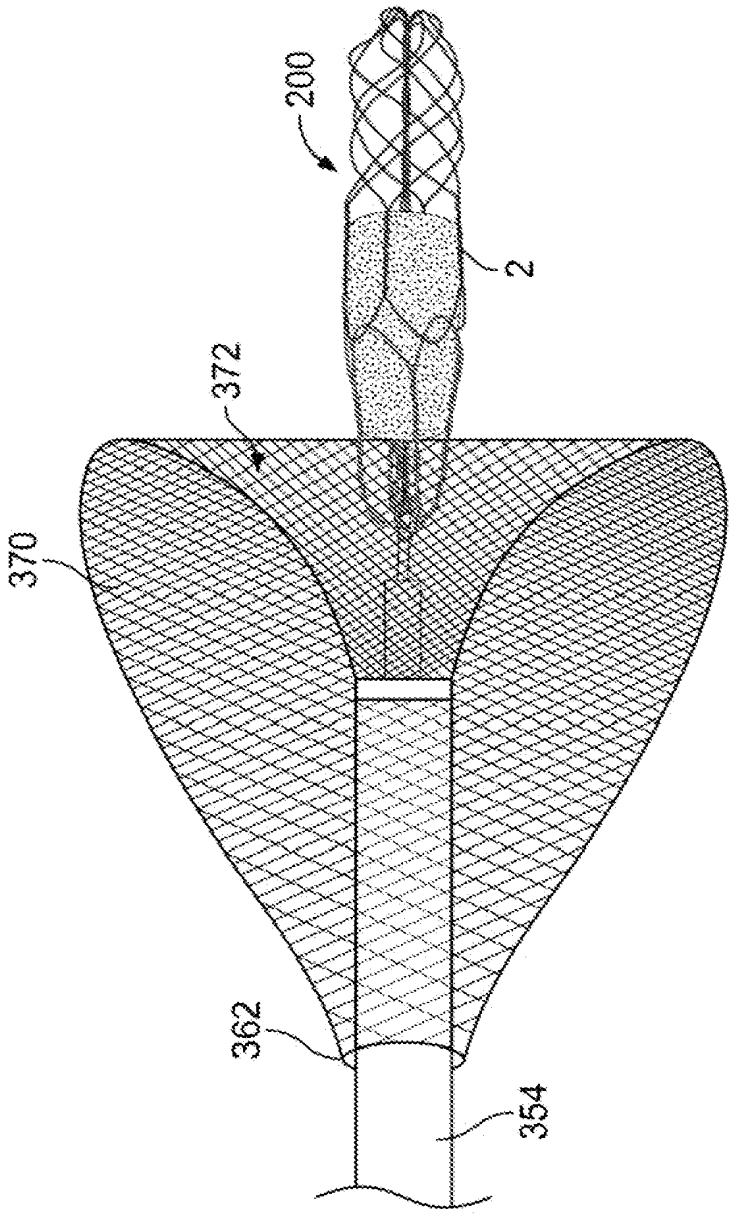

FIG. 13G

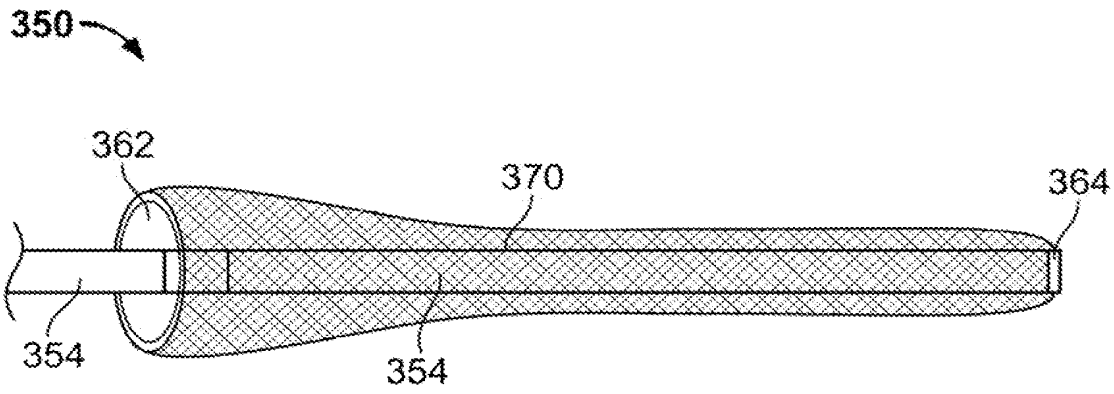

FIG. 13F

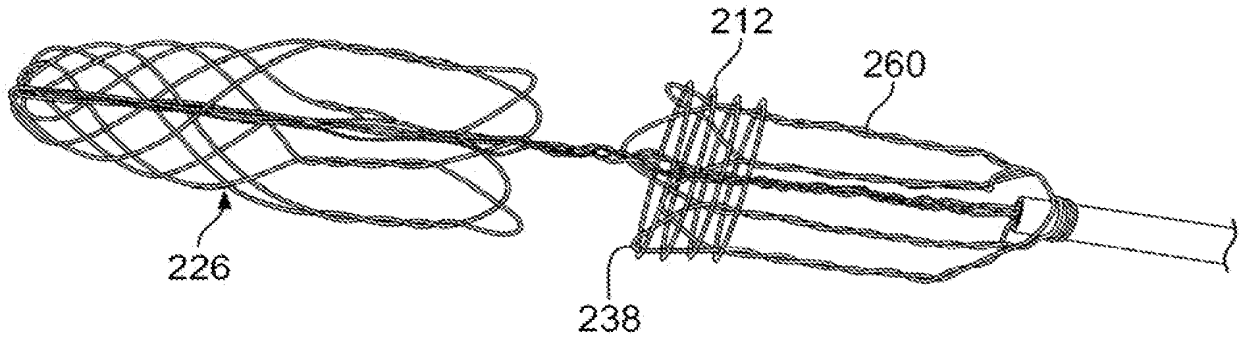

FIG. 14A

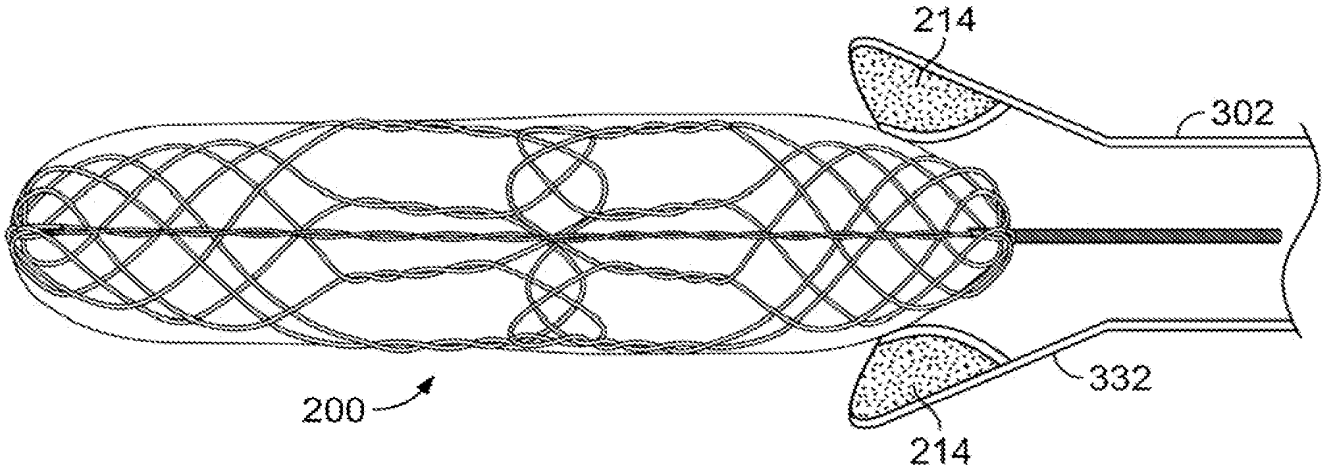

FIG. 14B

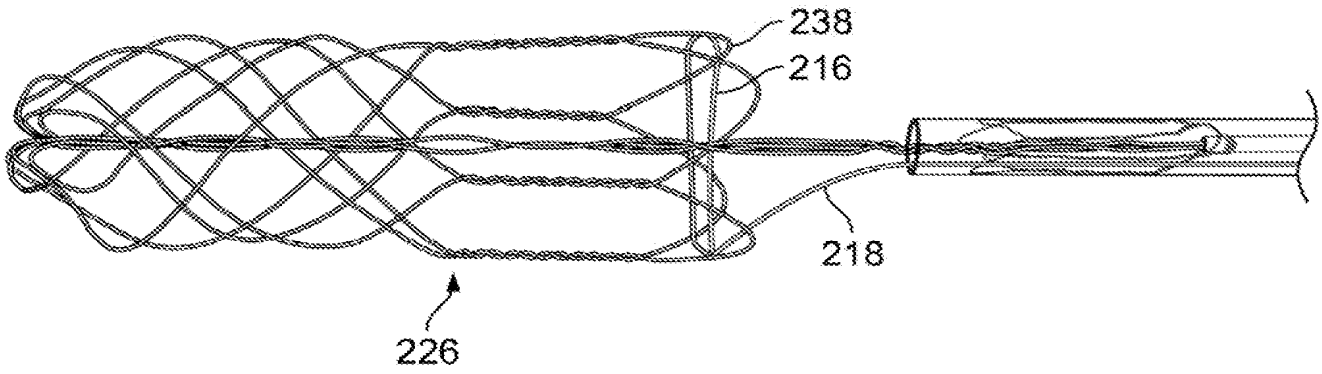

FIG. 14C

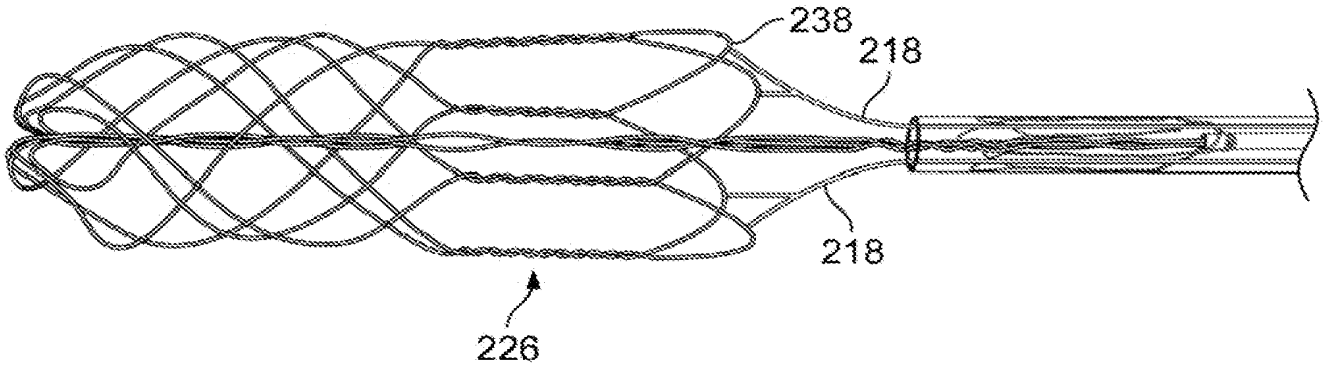

FIG. 14D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/88371

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/22 (2009.01)
USPC - 606/200
According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
606/200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
A61B 17/221 (2009.01)
606/127, 159

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest, Google
Search Terms Used: obstruction, blood vessel,lumen, wire, capture, removal, catheter, retrieval device, friction,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0009784 A1 (Behl et al.) 12 January 2006 (12.01.2006), abstract, para [0009], [0013]-[0014], [0029]-[0030]	1-76, 109-114
Y	US 2007/0225749 A1 (MARTIN et al.) 27 September 2007 (27.09.2007), para [0014]-[0017], [0044], [0082], [0096]-[0098]	1-76, 109-114
Y	US 2005/0090857 A1 (Kusleika et al.) 28 April 2005 (28.04.2005), para [0035] .Fig.4B, para [0066], [0073], [0089]. Fig 8.	18, 20-21, 38-40, 48, 51-64, 66-69, 72-76, 109-114
Y	US 2005/0004594 A1 (Nool et al.) 6 January 2005 (6.01.2005), para [0042], [0077]	53, 73
Y	US 6,221,006 B1 (Dubrul et al.) 24 April 2001 (24.04.2001), Col 16, ln 41-42.	7, 32, 111-112

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 April 2009 (05. 04. 2009)	16 APR 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/88371

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
In order for more that one invention to be examined, the appropriate examination fees must be paid.
There are considered to be 2 inventions as follows:

Group I: claims 1-76 and 109-114 characterized by the axial strength of the capture wire
Group II: claims 77-108 characterized by a funnel

Groups I and II share the technical feature of a retrieval sheath. This generic feature does not avoid the prior art, as evinced by US 2005/0090857 A1 to KUSLEIKA et al which teaches a common example of such a sheath (para [0046]).

The inventions listed above do not relate to a single general inventive concept under PCT rule 13.1 because, under PCT Rule 13.2 the inventions lack the same or corresponding special technical features. Neither of these technical features is common to the other group nor do they correspond to a special technical feature in the other groups.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
claims 1-76 and 109-114

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2007)

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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) **International Patent Classification** 6 :
A61F 2/01, A61M 29/02

A1

(11) **International Publication Number:** **WO 98/51237**

(43) **International Publication Date:** 19 November 1998 (19.11.98)

(21) **International Application Number:** PCT/US98/10220

(22) **International Filing Date:** 15 May 1998 (15.05.98)

(30) **Priority Data:**

60/046,777	16 May 1997 (16.05.97)	US
60/057,439	2 September 1997 (02.09.97)	US

(71)(72) **Applicants and Inventors:** GERTLER, Jonathan [US/US]; 16 Greenridge Road, Weston, MA 02193 (US). KAMM, Roger [US/US]; 31 Nonesuch Road, Weston, MA 02193 (US).

(74) **Agents:** SUNSTEIN, Bruce, D. et al.; Bromberg & Sunstein LLP, 125 Summer Street, Boston, MA 02110–1618 (US).

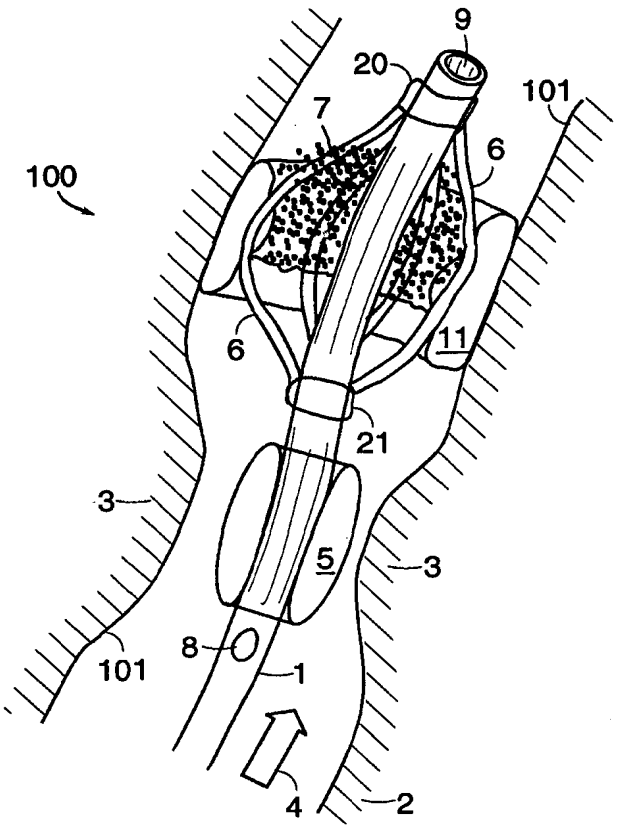
(81) **Designated States:** CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) **Title:** CATHETER–FILTER SET HAVING A COMPLIANT SEAL

(57) **Abstract**

A catheter–filter set in an embodiment may be used in a vas through which a biological fluid may flow. This embodiment includes a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member and having a circumference, for trapping undesired particles. Finally, the embodiment includes a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forms a seal against the interior wall of the vas. Other embodiments are also provided.



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CATHETER-FILTER SET HAVING A COMPLIANT SEAL

Technical Field

The present invention relates to catheter-filter sets, including those for use in angioplasty and other procedures.

Background Art

A large number of medical procedures utilize catheters. A catheter is defined herein and within the appended claims as a tubular, flexible instrument for insertion into a body cavity. Catheters may facilitate the withdrawal or introduction of fluids or other substances and may, in combination with other coupled components, perform a variety of other useful functions.

Catheters coupled with inflatable balloons provide the means to facilitate the unblocking of and the relief of constriction within various body passageways and vessels. Such angioplasty procedures can replace other more invasive surgical procedures and provide acceptable solutions to correct life threatening conditions. However, these procedures carry a risk of serious secondary problems associated with the transmission of unwanted material downstream of the operative site. Any material, such as plaque built up in arterial vessels, which does not adhere to the interior vas wall or is in another way removed from the vessel following treatment becomes a likely source of downstream blockage. In arterial angioplasty, embolic ischemic damage distal to the angioplasty site is a major complication of the procedure. Mobile arterial plaque is a major factor linked with ischemic stroke or end organ/limb infarction. In particular, carotid

artery angioplasty is not a favored practice at present due to the risk of emboli and resulting stroke.

Some catheters coupled with downstream filtering capability have been previously disclosed. Several utilize wire mesh filters which are generally not compliant and do not accommodate localized changes in vessel diameter and shape which may be caused by on-going fluid flow restoration and pulsatility. Other designs contain deployment structures which may make insertion prior to and retraction after completion of a procedure problematic or unduly risky.

Typical prior art catheter arrangements are disclosed in United States patents 4,723,549; 4,794,928; 5,662,671; and 5,695,519. These documents are hereby incorporated herein by reference.

Summary of the Invention

Various embodiments of the present invention solve problems of the prior art by providing radial compliance to accommodate localized changes in vessel diameter and shape which may be caused by on-going fluid flow restoration and pulsatility. Furthermore, some embodiments of the invention provide a device that is biased to return to its lowest profile condition in the absence of active operator input to facilitate making arterial angioplasty, particularly in the cerebral and coronary beds, more fail-safe. Various embodiments of the invention avoid asperities or protrusions which can traumatize or otherwise damage or irritate interior vas walls. Similarly various embodiments provide for cushioning of the filter element against the vas wall when it is deployed. This cushioning effect is balanced with the requirement of effective sealing of the vas to prevent any unwanted downstream flow of matter.

Accordingly, in a first embodiment of the invention there is provided a catheter-filter set for use in a vas through which a biological fluid may flow. This embodiment includes a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member and having a circumference, for trapping undesired particles. (Unless the context otherwise requires, the term

"particles" as used in this description and the accompanying claims refers to substances to be removed from a vas, and may include thrombotic material.) Finally, the embodiment includes a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall of the vas. In further embodiments, the resilient member may be inflatable, such as a balloon, or alternatively may be an O-ring or sleeve. The outer surface of the resilient member may form the seal with the interior wall or may otherwise effectuate the seal. In a related embodiment the resilient member is a balloon having an anterior for receiving an inflation fluid and a shape so that when the balloon is inflated there is provided a passageway permitting fluid flow through the filter. In accordance with another related embodiment, the balloon is toroidal in shape and may have anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent. Alternatively or in addition, the catheter-filter set may include an elastic member coupled to the balloon and the tubular member for causing the balloon to be radially confined when not deployed. In yet another variation, regardless whether a balloon is utilized, the filter has a stowed position where the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, where the filter is radially expanded.

Various embodiments of the present invention have a range of potential applications. The application of embodiments to angioplasty procedures wii be apparent to those skilled in the art. In addition, through either standard open technique or laparoscopic technique, retrieval of common duct stones in the biliary tree is facilitated by catheter passage utilizing embodiments herein. Similarly, through either standard open technique or cystographic technique, retrieval of ureteral and bladder duct stones is, also, facilitated by catheter passage via endoscopic or surgical methods. A catheter coupled with an inflatable balloon may also be utilized to effect balloon sphincteroplasty and stone retrieval. Embodiments herein provide improved devices to effectively retrieve such stones and to avoid their further passage or migration downstream.

Embodiments herein may also employable as a temporary filtering device for the vena cava. In the process of lytic treatment for deep venous thrombosis, there is a risk of clot (thrombus) breaking loose and causing pulmonary embolism, a potentially fatal event. Although filters exist for vena cava use, these are permanent structures with attendant long term morbidity. Having an effective and retractable filter which is in place only for the time of significant risk, *i.e.*, during deep venous clot lysis, would allow protection from pulmonary embolism and avoidance of the long term sequelae of a permanent filter insertion.

Discussion of medical procedures and associated devices in this description may focus, for example, upon arterial (blood circulation), biliary, and ureteral systems. This focus in no way limits the applicability of embodiments herein to any and all other uses for catheters with filtration capability known to those skilled in the art.

In another embodiment, there is provided a catheter-filter set having a tubular member, which has a first lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position and a deployed position, and a non-inflatable actuator, coupled to the filter, for causing the filter to move from the stowed position to the deployed position, wherein, absent operation of the actuator, the filter is biased to be in the stowed position. In a related embodiment, the set also includes a vas conditions-modifying element located upstream from the filter; this element may be an angioplasty balloon. In yet another related embodiment, the tubular member has a second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter. In further embodiment, the set has a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a stowed condition in which they are parallel to the

longitudinal axis and a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member. Each rib may have a second end slidably mounted on the tubular member and coupled to the actuator. The catheter-filter set may further include a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall of the vas.

In another embodiment in accordance with the present invention, there is provided a catheter-filter set having:

a. a tubular member, having a lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto; and

b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded.

Brief Description of the Drawings

Figs. 1A and 1B are longitudinal views of a catheter-filter set, in the deployed and the stowed conditions, respectively, used in a vas as part of an angioplasty device and using a toroidal balloon according to an embodiment of the invention.

Figs. 2A and 2B are longitudinal views of a portion of a catheter-filter set, in the stowed and the deployed conditions, respectively, illustrating generally filter deployment according to an embodiment of the invention utilizing ribs for structuring the filter.

Figs. 3A and 3B are longitudinal views of a catheter-filter set, in accordance with a tether deployment embodiment of the invention, showing stowed and deployed conditions, respectively.

Figs. 4A and 4B are longitudinal views of a catheter-filter set, in accordance with a balloon deployment embodiment of the invention, showing stowed and deployed conditions, respectively.

Fig. 5 is a longitudinal view of a catheter-filter set in accordance with an embodiment using balloon deployment wherein elastic bands bias the set in a stowed condition.

Figs. 6A and 6B are stowed and deployed conditions respectively of an embodiment similar to that of Figs. 4A and 4B, but wherein the ribs are normally twisted in a stowed condition, in which the embodiment is biased.

Fig. 7A is a cross-sectional view of a catheter-filter set in the deployed condition illustrating a balloon deployment design according to an embodiment of the invention in which the balloon has a passageway to permit fluid flow therethrough. Figs. 7B and 7C are longitudinal views of the same embodiment in the stowed and the deployed conditions, respectively.

Fig. 8A is a cross-sectional view of a catheter-filter set according to an embodiment of the invention, using for deployment a balloon 11 that is asymmetrically disposed with respect to the tubular member. Fig. 8B is a longitudinal view of the same embodiment in the deployed condition. Fig. 8C shows detail of the catheter-balloon interface.

Fig. 9 is a view of a catheter-filter set according to an embodiment of the invention utilizing a retractable O-ring.

Fig. 10 is a perspective view of a catheter-filter set according to an embodiment of the invention that is similar to the embodiment of Fig. 9, but utilizing a sleeve in lieu of the O-ring.

Fig. 11A is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a tethered O-ring, shown in the deployed condition. Fig. 11B is a longitudinal view of the same embodiment in the stowed condition.

Detailed Description of Specific Embodiments

Various embodiments of the catheter-filter set described herein address a number of shortcomings inherent in previous designs. Some desirable features

for the filter portion of the set are that it be easily confined in a radial direction for ease of set insertion and removal, that it be capable of capturing and safely removing all particles flowing downstream in a vas, and additionally, it should be designed so as to minimize the risk of accidental deployment and to collapse into position for removal in the event of failure. It should be atraumatic to the native vas wall and should accommodate changes in vas diameter.

Figs. 1A and 1B are longitudinal views of a catheter-filter set, in the deployed and the stowed conditions, respectively, used in a vas as part of an angioplasty device and using a toroidal balloon according to an embodiment of the invention. Fig. 1A shows a catheter **1** inserted into a vas **2**. The vas may be constricted or otherwise blocked at a location **3**. Downstream fluid flow is indicated by arrow **4**. An angioplasty balloon **5** affixed to the catheter and inflatable (by means well known in the art) is positioned proximate to location **3**. During and after the angioplasty balloon **5** inflation process, unwanted particles may flow downstream from location **3**. A plurality of resilient ribs **6** (four are shown in this view) are coupled to the catheter **1** by two collars, one collar **20** at a downstream end and the other collar **21** at an opposing, upstream end of the catheter. In this embodiment, one of collars **20** and **21** is fixed relative to the catheter **1** and the other of the collars is free to slide along the catheter **1**. The ribs **6** and both collars **20** and **21** are positioned at a location downstream from location **3** and the angioplasty balloon **5**. A filter **7** is shown attached to the ribs **6** and to the catheter **1**. A toroidal balloon **11**, which is distinct from the angioplasty balloon **5**, is attached to the ribs **6**. In this embodiment, the toroidal balloon **11** is mounted approximately midway along the length of the ribs **6** and positioned radially outward from the catheter **1**. (The filter **7** is represented in this figure and figures below by a dot or hash pattern; for clarity of representation, the dot or hash pattern is not shown to occupy the entire region occupied by the filter. It will be understood, however, that when deployed the filter, together with any accompanying structure, such as the balloon **11**, will occupy the entire cross section of the vas so as to operate in an effective manner known in the art.)

Fig. 1B shows that, in accordance with the embodiment in the stowed condition, the ribs parallel to the longitudinal axis of the catheter **1** facilitating set **100** insertion into and retraction out of the vas **2** minimizing trauma to the vas wall **101**. During insertion and retraction of set **100** and catheter **1** into and out of the vas **2**, the uninflated toroidal balloon **11** is collapsed and radially confined against the ribs **6** and the uninflated angioplasty balloon **5** is collapsed against the catheter **1**. As illustrated in Fig. 1A, when the toroidal balloon **11** is inflated (in accordance with means well known in the art), one of collars **20** and **21** slides toward the other collar causing at least a portion of each of the ribs **6** and the filter **7** to be disposed radially outward from the catheter **1**. The toroidal balloon **11** effectively spans any radial distance between, on the one hand, the vas wall **101**, and on the other hand, the ribs **6** with the expanded filter **7**. The toroidal balloon **11** thus forms a compliant seal between the set **100** and the vas wall **101**.

After this compliant seal has been established, the angioplasty balloon **5** may then be inflated to unblock the vas **2** at location **3**. The deployed filter **7** may then capture unwanted particles flowing downstream during and after operation and subsequent deflation of the angioplasty balloon **5**. After the procedure, the toroidal balloon **11** is deflated, and the set **100** returns to the position shown in Fig. 1B for retraction from the vas **2**. Unwanted particles are trapped within the filter **7** and are safely removed from the vas **2** upon retraction of the set **100**. Additionally, biasing components (for example, as discussed below in connection with later figures) may be used in connection with the set **100** to insure the return to the position shown in Fig. 1B after deflation of the toroidal balloon **11**. These components may include, and are not limited to, elastic bands coupled to one or more elements of the ribs **6**, the filter **7**, and collars **20** and **21**.

Also shown in Fig. 1A, an inlet port **8** is provided by the catheter **1** at a location upstream from the angioplasty balloon **5** and an outlet port **9** is provided downstream from the filter **7**. The ports are in communication with a lumen of the catheter; the lumen may be the same as the lumen used for other purposes or may be a separate dedicated lumen. The result of this structure is an auto-perfusion pathway from inlet port **8** through a catheter lumen to the outlet port **9**

to permit the unimpeded flow of a quantity of fluid during the time in which the medical procedure is being performed. The feature is advantageous when deleterious results may occur from even short intervals of downstream fluid starvation or depletion. Hypoperfusion during angioplasty balloon inflation is primarily relevant to the cerebral and coronary beds. Carotid artery angioplasty, in which the brain is immediately downstream from the location **3**, is a prime example of a procedure benefiting from an auto-perfusion pathway. In many arterial applications, given the normal magnitude of blood pressures, there may be provided a lumen having an internal diameter of 1 to 2 mm. Even when blood flow is not as high as normal, the reduced rate of flow may nevertheless significantly reduce the risk of tissue damage caused by a complete interruption of flow in the cerebral and coronary beds.

Figs. 2A and 2B are longitudinal views of a portion of a catheter-filter set, in the stowed and the deployed conditions, respectively, illustrating generally filter deployment according to an embodiment of the invention utilizing ribs **6** for structuring the filter **7**. Fig. 2A shows the ribs **6** and the filter **7** coupled to and juxtaposed with the catheter **1** in conjunction with the downstream collar **20**. In Fig. 2B the ribs **6**, which are resilient, are expanded radially from the catheter **1** to form a convex shape. The expanded ribs **6** support the filter **7** as shown. Preferably, the ribs **6** are free from asperities. The ribs **6** may be made of any resilient material with sufficient rigidity to support and to enable deployment of the filter **7**. The number of ribs **6** may be selected to be sufficiently large to facilitate a seal of the filter **7** with the interior wall of the vas **2** but not so numerous as to significantly obstruct fluid flow or convenient operation of the set. In the embodiment of Figs. 2A and 2B, the ribs **6** are disposed radially outward from the filter **7**. In other embodiments of the invention, the ribs **6** may be disposed radially inward from the filter **7**, so that, when stowed, the resilient ribs **6** lie immediately adjacent to the catheter **1**. Such other embodiments may deploy in a fashion analogous to opening of an umbrella. The ribs **6** may have one free end as in Figs. 2A and 2B, or be coupled to the catheter **1** at both ends and bow in the middle for deployment as for example in Figs 1A and 1B. The

filter **7** may beneficially be made of a porous, compliant material in a manner known in the art. Suitable materials may include, but are not limited to, woven nylon, plastic resins such as PTFE sold under the Teflon trademark by Dupont of Wilmington, Delaware, other woven polymer, porous silicone rubber and latex rubber. Suitable materials are sufficiently porous to permit a small downstream flow of fluid yet capable of collecting any dangerous particles. For example, calculations suggest that, for an arterial application, a woven material with a fiber porosity of 90% and a spacing of 200 microns may pose little impediment to normal blood flow while trapping undesirable particles..

Figs. 3A and 3B are longitudinal views of a catheter-filter set, in accordance with a tether deployment embodiment of the invention, showing stowed and deployed conditions, respectively. As shown in Fig. 3B, the ribs **6** of this embodiment are attached to the catheter **1** at both ends by collars **20** and **21**. The upstream end collar **21** is free to slide along the catheter **1** while the downstream end collar **20** is fixed. Collar **21** is tethered with line **30** so that an operator can, by applying an upstream force to line **30** slide collar **21** downstream toward collar **20.** This action urges the ribs **6** to form a convex shape and to expand radially from the catheter **1**. As Figs. 3A and 3B show, tethering may be accomplished by attaching one end of line **30** to collar **21**, feeding the line **30** through a port **31** provided by the catheter **1** at a position downstream from collar **21.** The line passes into a lumen of the catheter and exits the catheter **1** upstream at its retraction end. The ribs **6** may expand to the full radial extent of the vas **2**. Other material, as discussed in connection with other figures, may be coupled to the ribs **6** proximate to their approximate midpoint in length to provide better sealing action and cushioning at the interface with the vas wall **101**. (For example, the toroidal balloon of Figs. 1A and 1B may be employed; alternatively, any suitable resilient sleeve or O-ring may be utilized.) The ribs **6** will return to the stowed position of Fig. 3A, in accordance with the embodiment of the invention, with the elimination of the applied upstream force on line **30**. This provides a set **100** which is biased to remain in and revert to the stowed position. Such bias provides for assured collapsibility upon retraction and offers

a high degree of fail-safe operation by minimizing the chance of accidental deployment.

Another embodiment according to the invention provides a filter deployment technique using an inflatable toroidal balloon **11** with ribs **6** which have their upstream end uncoupled to the catheter **1**. The stowed position is shown in Fig. 4A; the deployed position in Fig. 4B. Operation of this embodiment is similar to that of Figs. 1A and 1B with respect to the use of a toroidal balloon and to that of Figs. 2A and 2B with respect to the ribs **6**. A tube **40** is provided for inflation fluid communication between a lumen disposed within the catheter **1** and the toroidal balloon **11**. The opposing ends of tube **40** are, respectively, inserted and remain within ports **41**, provided by the catheter **1**, and **42**, provided by the toroidal balloon **11**. The ends of tube **40** may be secured in the ports **41** and **42** with adhesives or using other methods in a manner known in the art. The uninflated toroidal balloon **11**, as shown in Fig. 4A is coupled to the upstream ends of the ribs **6** and juxtaposed with the catheter **1**. As shown in Fig. 4B, with inflation of the toroidal balloon **11**, the resilient ribs **6** expand radially from the catheter **1** to form a convex shape supporting the filter **7**. At its most radially outward extent, the inflated toroidal balloon **11** effects a compliant seal between the set **100** and the vas wall **101**. The toroidal balloon **11** may be made by wrapping fiber around it so that its expansion will be constrained in such a way that the diameter of its inflatable cross-section increases to a lesser degree than its radial (perpendicular to the catheter axis) dimension. In fact, this mode of inflation can be produced by any material that is anisotropic having a high stiffness (or Young's modulus) in the direction of the fiber wrapping and a low stiffness in the direction perpendicular to the wrapping. The inflation of the toroidal balloon provides the necessary structural rigidity needed to withstand the forces associated with downstream fluid flow (in particular, arterial blood flow) while the set **100** is in the deployed condition.

Fig. 5 is a longitudinal view of a catheter-filter set in accordance with an embodiment using balloon deployment wherein elastic bands **50** are employed to bias the set in a stowed condition. The bands **50** are coupled to an upstream collar

51 and a second downstream collar 52. Both collars 51 and 52 are coupled to the catheter 1; the second downstream collar 52 is positioned at a distance farther downstream along the catheter 1 than collar 20 to which optional ribs 6 may be coupled. This embodiment provides a set 100 which is biased to revert to the stowed condition. On deflation of the toroidal balloon 11, the bands 50 act to force the balloon 11, the ribs 6, and the filter 7, with any entrapped particles within, to revert to the stowed condition for safe retraction.

Figs. 6A and 6B are stowed and deployed conditions respectively of an embodiment similar to that of Figs. 4A and 4B, but wherein the ribs are normally twisted in a stowed condition, in which the embodiment is biased. The ribs 6 (which are here differently shaded to permit differentiation in the figure), when in a relaxed, unstressed configuration, fit snugly about the catheter 1 bore in a helical arrangement, as shown in Fig. 6A. The filter 7 is gathered together inside the ribs while the cushioning balloon 11 lies outside the ribs 6 but deflated into a collapsed configuration. The ribs 6 in this embodiment are attached at both the upstream and downstream ends to collars 21 and 20 respectively. The collars 21 and 20 are constrained so as to prevent movement in the longitudinal direction, but the downstream collar 20 can be rotated by rotation of a stiff line 60 threaded through a lumen 61 of the catheter 1. Rotation of the downstream collar 20 causes the ribs 6 to bow outward into the deployed position illustrated in Fig. 6B. Once deployed, the balloon 11 can be inflated to provide a resilient seal against the interior wall of the vas 101 while maintaining an open space between the balloon 11 and catheter 1 for fluid flow. Bowing of the ribs deploys the filter 7 attached to the inner surface of the balloon 11 so that it can function as a trap for debris released from an upstream site. Retraction of the ribs 6 occurs when the stiff line 60 is allowed to rotate back to its original position and the balloon 11 is deflated. The filter set is therefore biased closed in that when pressure is relieved from the balloon 11 and the torque exerted on the stiff line 60 is released, the ribs 6 and filter 7 revert to their stowed position.

Fig. 7A is a cross-sectional view of a catheter-filter set in the deployed condition illustrating a balloon deployment design according to an embodiment

of the invention in which the balloon has a passageway to permit fluid flow therethrough. Figs. 7B and 7C are longitudinal views of the same embodiment in the stowed and the deployed conditions, respectively. In this embodiment, the inflation balloon **11** takes on the shape of two "Ds" back-to-back. The advantage of this embodiment is that the catheter **1** passes directly through the inflatable portion of the balloon **11**, avoiding the need for a separate inflation line that might be prone to rupture because of its small diameter. Fig. 7A shows the balloon in a view along the axis of the vas **2** looking in the downstream direction. The catheter **1** can be seen passing through at the center, and is sealed to the balloon at the points where it passes through the balloon membrane. The catheter has a port inside the balloon **11** that is used for balloon inflation. The filter **7** is seen in Fig. 7A through the openings in the balloon **11** through which the fluid is free to flow. Fig. 7B shows the balloon **11** in the retracted or stowed position. Elastic bands **50** hold the deflated balloon **11**, so that it is radially confined, tight against the catheter **1**. The filter **7** is gathered together and held against the catheter **1** in part by the elastic bands **50**. Deployment is accomplished by inflation of the balloon **11**, a process that forces the balloon **11** into its double-D shape shown in longitudinal view in Fig. 7C. The inflated balloon **11** of Fig. 7C forms a flexible seal against the vas wall **101** and deploys the filter **7**. The filter in this embodiment is firmly tethered to the catheter at its downstream end to aid in gathering the filter **7** to the catheter on balloon deflation. The balloon **11** is made from a flexible but relatively inextensible polymer so that on inflation, it takes the shape shown.

Fig. 8A is a cross-sectional view of a catheter-filter set according to an embodiment of the invention, using for deployment a balloon **11** that is asymmetrically disposed with respect to the tubular member. Fig. 8B is a longitudinal view of the same embodiment in the deployed condition. Fig. 8C shows detail of the catheter-balloon interface. This embodiment increases the area available for flow through the "doughnut hole" of the balloon **11** and, like the embodiment of Figs. 7A through 7C, avoids the need for a separate inflation tube connecting the balloon **11** with the catheter **1**. In this embodiment, the

catheter **1** passes through the toroidal balloon **11** at location **80** on its circumference; a seal is provided between the balloon **11** and the catheter so that the balloon can be inflated through a port as in the embodiment of Figure 7. In the stowed position, shown in Figure 8A, an elastic band **50** attached to the balloon 11 at a point diametrically opposite to the inflation site **80** draws the balloon **11** in the upstream direction. When and as the balloon **11** is deflated, it and filter **7** are collapsed radially against the catheter 1 bore under the force of the elastic band **50**. Additional elastic bands may be optionally used on the downstream side to help gather together the filter **7** on deflation. The filter is deployed by inflation of balloon **11** through the port at location **80** as illustrated in Figure 8B. Balloon inflation also seals the balloon **11** in a flexible manner against the wall of the vas. In the process of balloon inflation, the catheter **1** is displaced off center toward the wall of the vas so as to increase the area available for flow. All flow still passes through the filter **7**.

Fig. 9 is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a retractable O-ring. The downstream end of the catheter **1** is pictured at a location downstream of a suitable vas-modifying element. The filter **7** is fastened to an O-ring **90** which in turn, is coupled to a set of resilient ribs **6** (four of which are shown). When in the deployed position (shown) the ribs **6** are pushed out of the downstream end of the catheter **1**. The resilience of the O-ring **90** (optionally, in combination with shape memory of the ribs **6**) causes the ribs **6** to separate as the O-ring **90** deploys into its natural circular shape, producing a seal against the wall of the vas. In so doing, the O-ring **90** expands the filter **7** so that it can trap debris released from an upstream location. The filter **7** is returned to its original undeployed position by retracting the ribs **6** into the catheter **1**, exerting a radially-inward force on the O-ring **90**, causing it to buckle into a

multi-lobed pattern with outside radial dimension much smaller than in the deployed position. The ribs **6** can be drawn into the catheter **1** by means of a stiff tether line **91** attached to the ribs **6** at their upstream end **92** within the catheter lumen. The tether line **91** must be sufficiently rigid that it can exert the force

needed to deploy the filter **7** and the O-ring **90**. For ease of retrieval, the filter **7** can be sheathed by a second catheter that slides on the outer bore of the catheter **1**, slipping over the buckled O-ring **90** and filter **7**.

Fig. 10 is a perspective view of a catheter-filter set according to an embodiment of the invention that is similar to the embodiment of Fig. 9, but utilizing a cylindrical sleeve **93** in lieu of the O-ring **90**. An advantage of the sleeve is that the filter **7** can be entirely contained within the sleeve **93** when the ribs and filter are in the retracted position, thus eliminating the necessity for a second catheter.

Fig. 11A is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a tethered O-ring, shown in the deployed condition. Fig. 11B is a longitudinal view of the same embodiment in the stowed condition. This embodiment shows that an O-ring **191** may be employed in situations in which the filter **7** is attached upstream of the end of the catheter **1**. Deployment, in this embodiment, is accomplished when the operator relaxes the force applied by the line **121** which passes through the wall of the catheter **1** at point **122**. The line **121** is attached to a collar **21** that can slide freely along the bore of the catheter **1**. When force is relaxed, the resilience of the O-ring **191** that exerts a tension in a plurality of tether lines **200** (two are shown) pulls the collar **21** in the downstream direction. The O-ring **191**, selected to be of an outer diameter when fully extended slightly larger than the normal diameter of the vas, provides a flexible seal against the wall of the vas when the tension force in tethers **200** is reduced. A filter **7** is attached around the circumference of the O-ring **191** and is deployed when the O-ring is allowed to expand to fill the vas. The O-ring **191** is also attached to a plurality of additional tethers **201** (two are shown) that are rigidly fixed to the downstream collar **20**. All tether lines **200** and **201** are inextensible and, in this embodiment, are attached at points distributed roughly equidistant around the circumference of the O-ring **191.** To retract and stow the filter, the operator pulls on the line **121** and the O-ring buckles into the configuration shown in Figure 11B due to the alternating

attachments of the tether lines **200** and **201**. The buckling of the O-ring **191** also helps to gather together the filter **7**.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art that various modifications can be made without departing from the spirit and the scope of the invention, as set forth in the claims hereinbelow.

What is claimed is:

1. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

a. a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto;

b. a filter, coupled to the tubular member and having a circumference, for trapping undesired particles; and

c. a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall.

2. A catheter-filter set according to claim 1, wherein the resilient member is an O-ring.

3. A catheter-filter set according to claim 1, wherein the resilient member is a sleeve.

4. A catheter-filter set according to claim 1, wherein the resilient member is a balloon having an interior for receiving an inflation fluid and a shape so that when the balloon is inflated there is provided a passageway permitting fluid flow through the filter.

5. A catheter-filter set according to claim 4, further comprising an elastic member coupled to the balloon and the tubular member for causing the balloon to be radially confined when not deployed.

6. A catheter-filter set according to claim 4, wherein the balloon is toroidal and its interior has a cross-section.

7. A catheter-filter set according to claim 6, wherein the resilient balloon has anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent.

8. A catheter filter set according to claim 1, such that the filter has a stowed position where the filter is radially confined and disposed in the lumen so that

the catheter-filter set may be inserted into and removed from the vas, and a deployed position, where the filter is radially expanded.

9. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

a. a tubular member, having a first lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto;

b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded; and

c. a non-inflatable actuator, coupled to the filter, for causing the filter to move from the stowed position to the deployed position;

wherein, absent operation of the actuator, the filter is biased to be in the stowed position.

10. A catheter-filter set according to claim 9, further comprising:

d. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.

11. A catheter-filter set according to claim 9 wherein element (d) is an angioplasty balloon.

12. A catheter-filter set according to claim 9, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.

13. A catheter-filter set according to claim 12, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.

14. A catheter-filter set according to claim 9, further comprising:

d. a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a stowed condition in which they are parallel to the longitudinal axis and having a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member.

15. A catheter-filter set according to claim 14, wherein the filter, in the deployed position, has a maximum radial extent and each rib, in the deployed condition, radially extends a distance less than the maximum radial extent of the filter.

16. A catheter-filter set according to claim 14, wherein each rib has a second end slidably mounted on the tubular member and coupled to the actuator.

17. A catheter-filter set according to claim 16, wherein each rib is coupled to a collar slidably mounted on the tubular member.

18. A catheter-filter set according to claim 14, further comprising:

e. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.

19. A catheter-filter set according to claim 18 wherein element (e) is an angioplasty balloon.

20. A catheter-filter set according to claim 18, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.

21. A catheter-filter set according to claim 20, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.

22. A catheter-filter set according to claim 9, further comprising:

d. a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall.

23. A catheter-filter set according to claim 22, further comprising:

e. a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a

stowed condition in which they are parallel to the longitudinal axis and having a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member.

24. A catheter-filter set according to claim 23, wherein the filter, in the deployed position, has a maximum radial extent and each rib, in the deployed condition, radially extends a distance less than the maximum radial extent of the filter.

25. A catheter-filter set according to claim 23, wherein each rib has a second end slidably mounted on the tubular member and coupled to the actuator.

26. A catheter-filter set according to claim 25, wherein each rib is coupled to a collar slidably mounted on the tubular member.

27. A catheter-filter set according to claim 23, further comprising:

f. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.

28. A catheter-filter set according to claim 27 wherein element (f) is an angioplasty balloon.

29. A catheter-filter set according to claim 23, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.

30. A catheter-filter set according to claim 29, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.

31. A catheter-filter set according to claim 22, wherein the resilient member is an O-ring.

32. A catheter-filter set according to claim 22, wherein the resilient member is a sleeve.

33. A catheter-filter set according to claim 22, wherein the resilient member is a resilient balloon having an interior for receiving an inflation fluid and a shape so that when the resilient balloon is inflated there is provided a passageway permitting fluid flow through the filter.

34. A catheter-filter set according to claim 33, wherein the resilient balloon is toroidal and its interior has a cross-section.

35. A catheter-filter set according to claim 34, wherein the resilient balloon has anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent.

36. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

a. a tubular member, having a lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto; and

b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded.

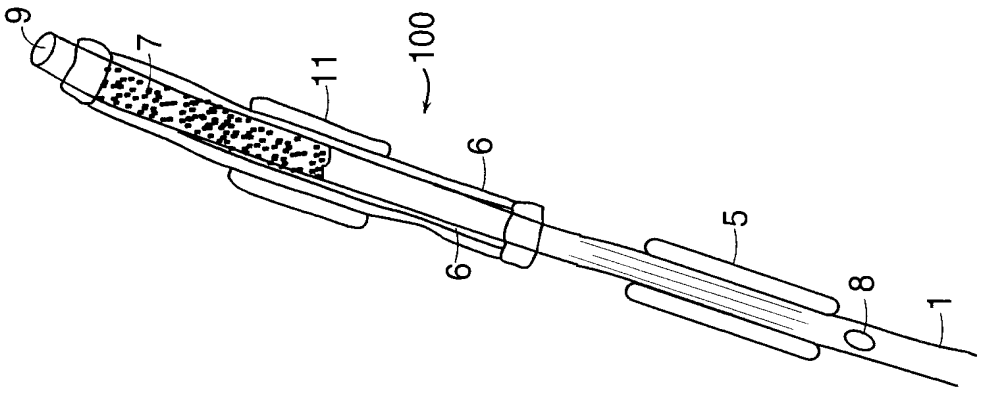

FIG. 1B

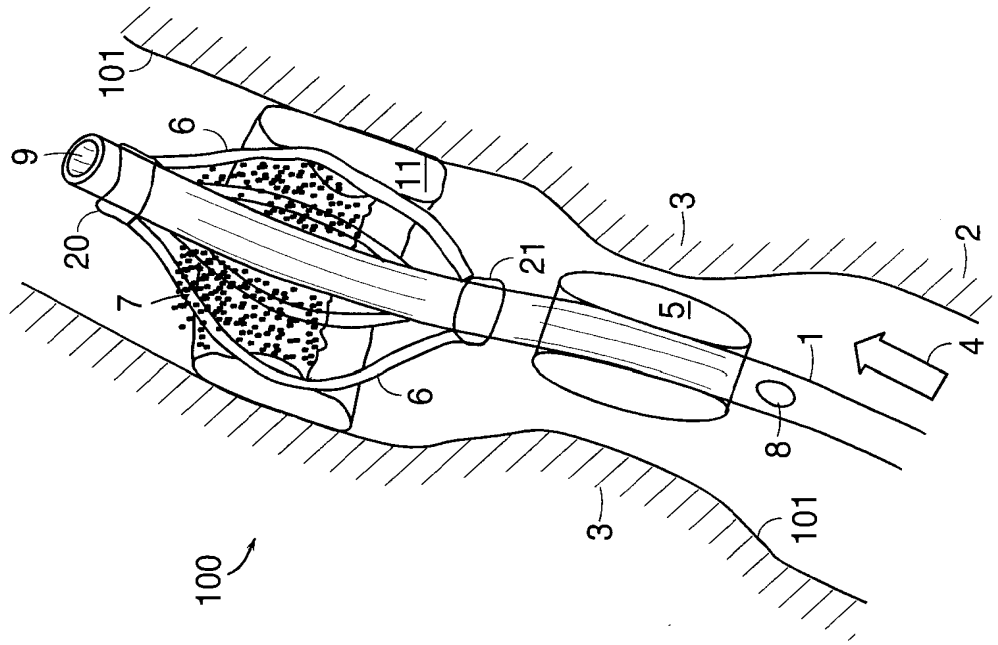

FIG. 1A

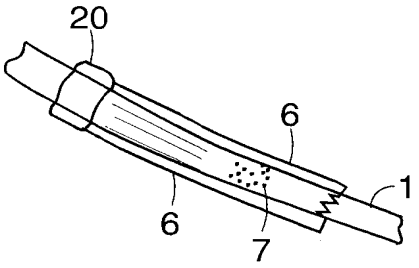

FIG. 2A

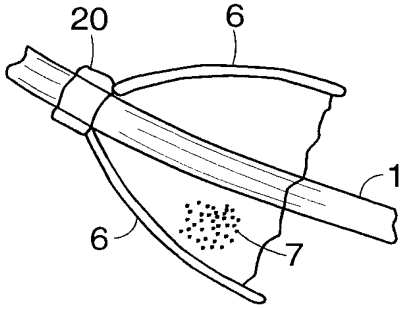

FIG. 2B

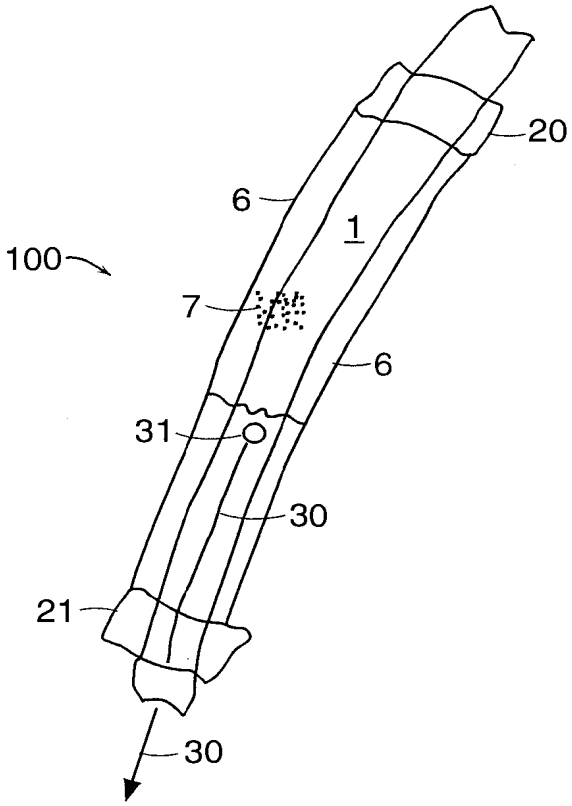

FIG. 3A

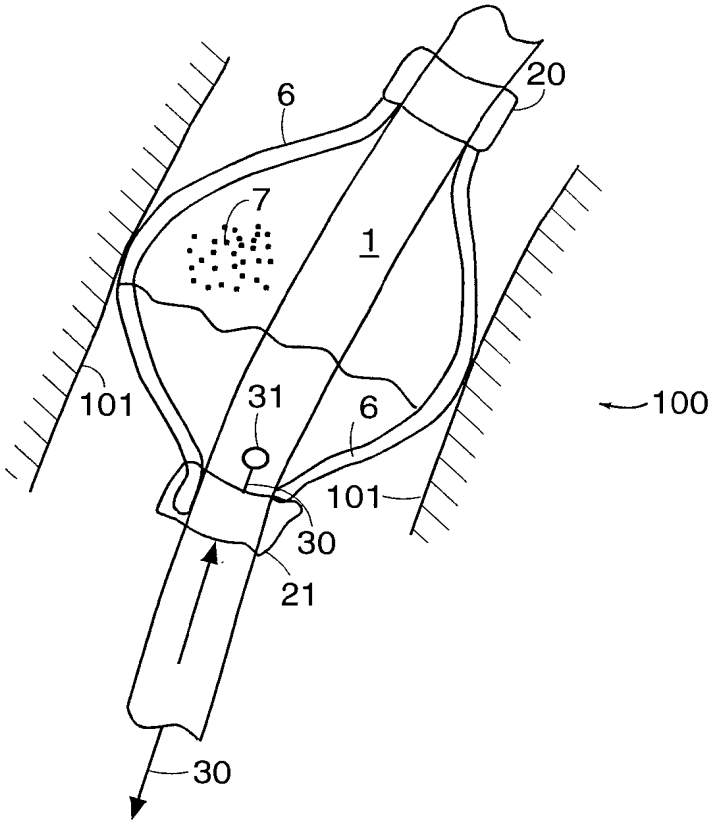

FIG. 3B

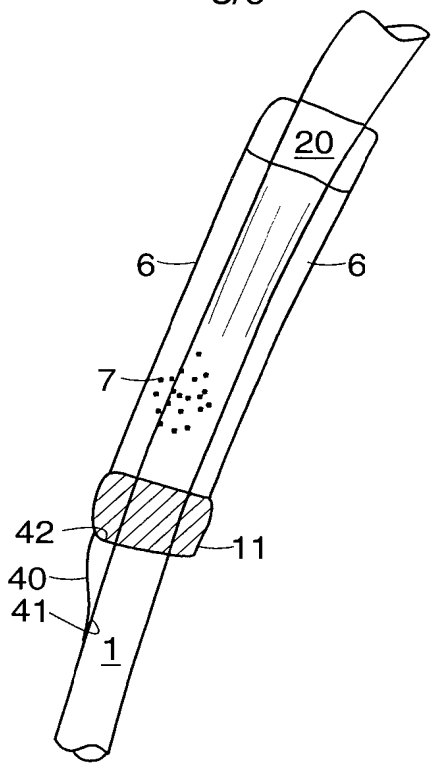

FIG. 4A

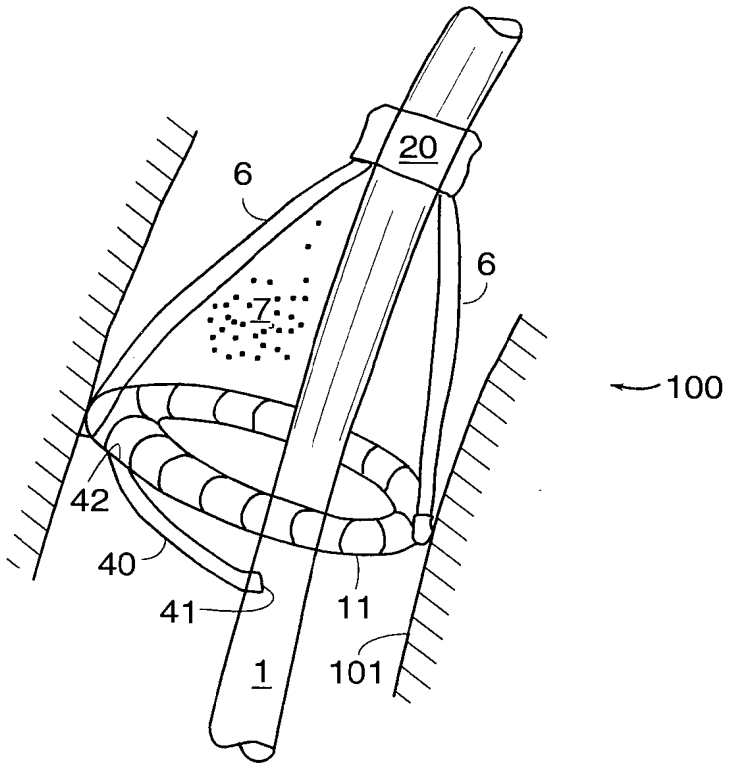

FIG. 4B

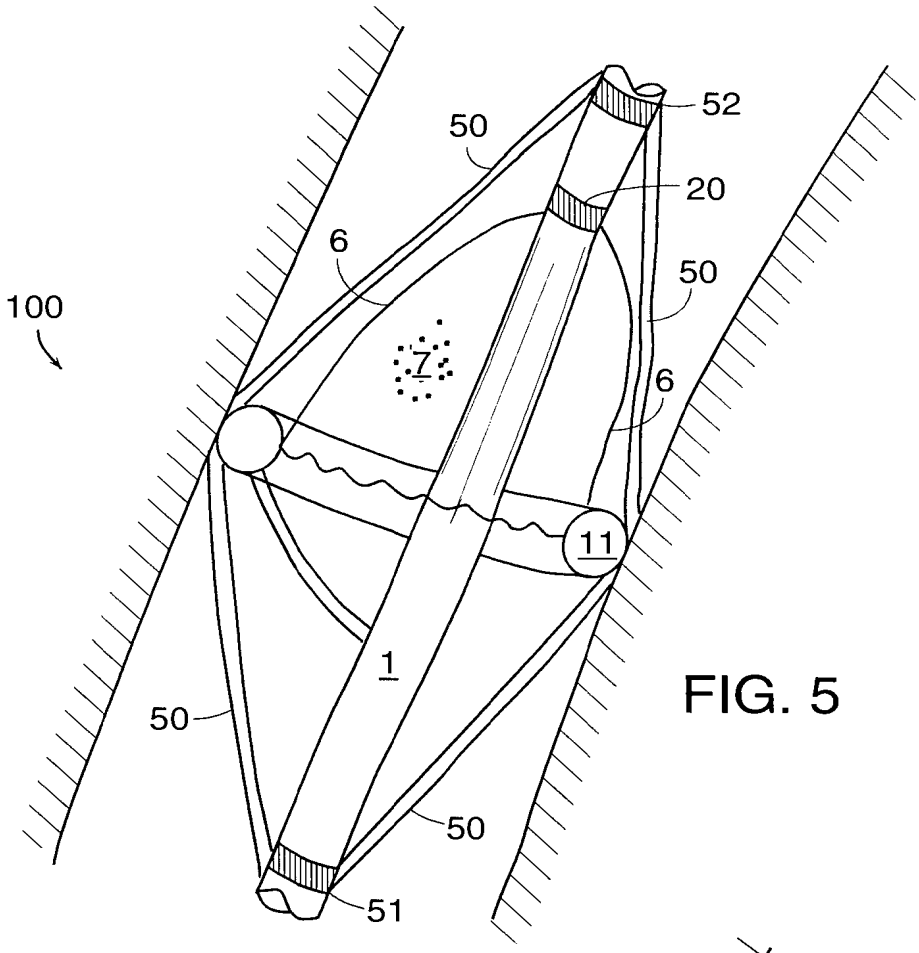

FIG. 5

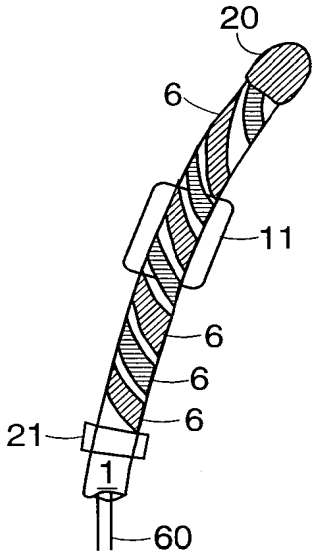

FIG. 6A

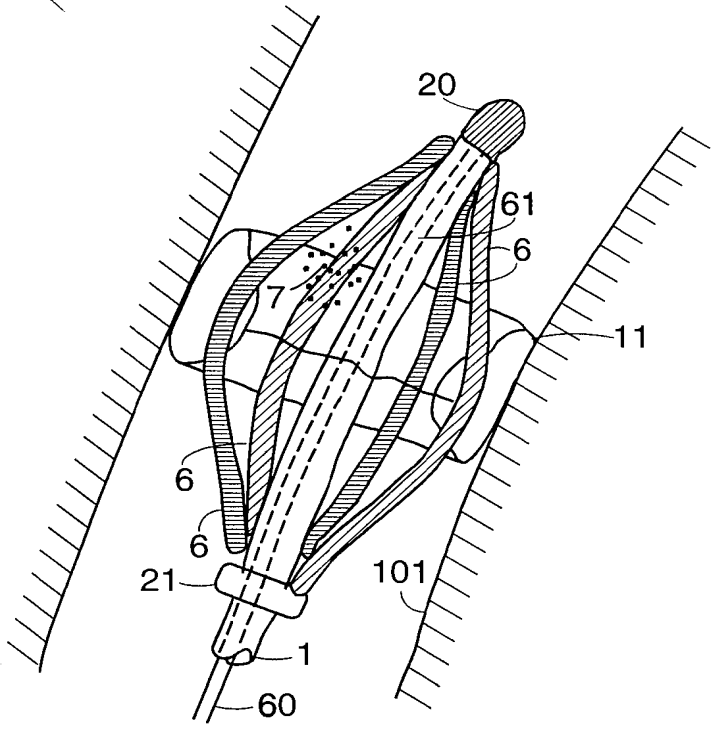

FIG. 6B

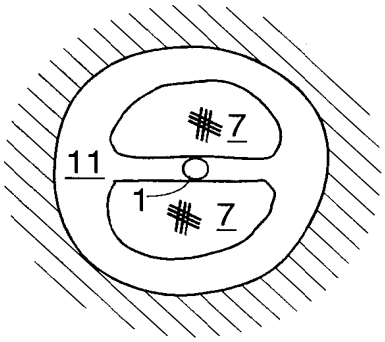

FIG. 7A

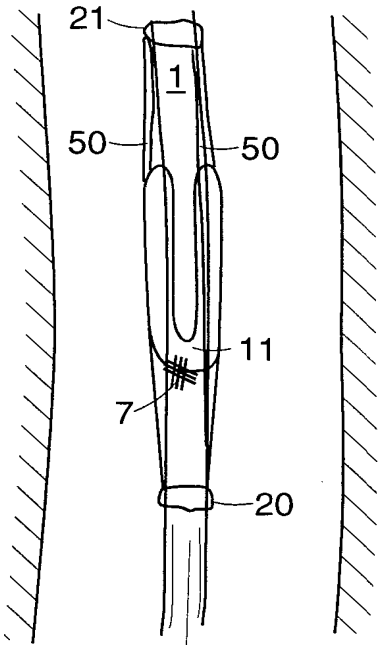

FIG. 7B

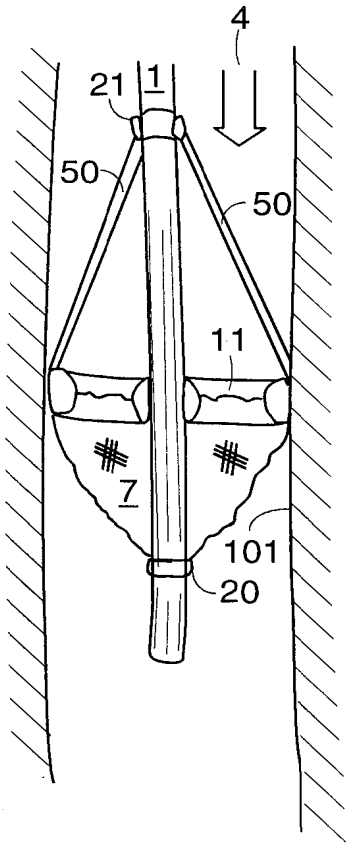

FIG. 7C

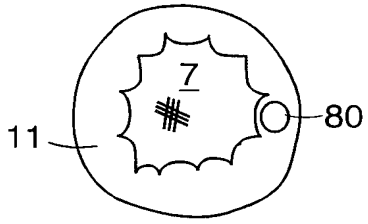

FIG. 8A

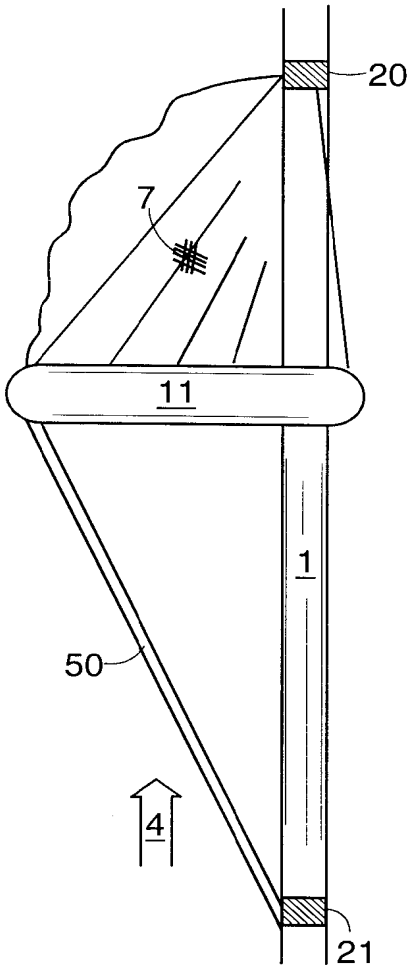

FIG. 8B

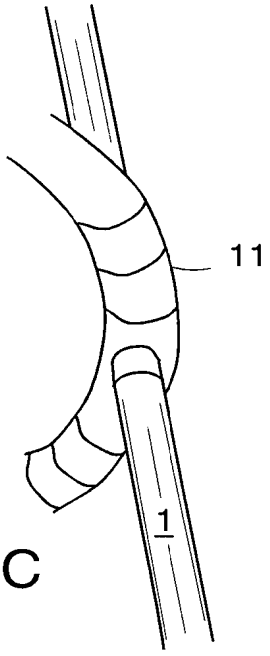

FIG. 8C

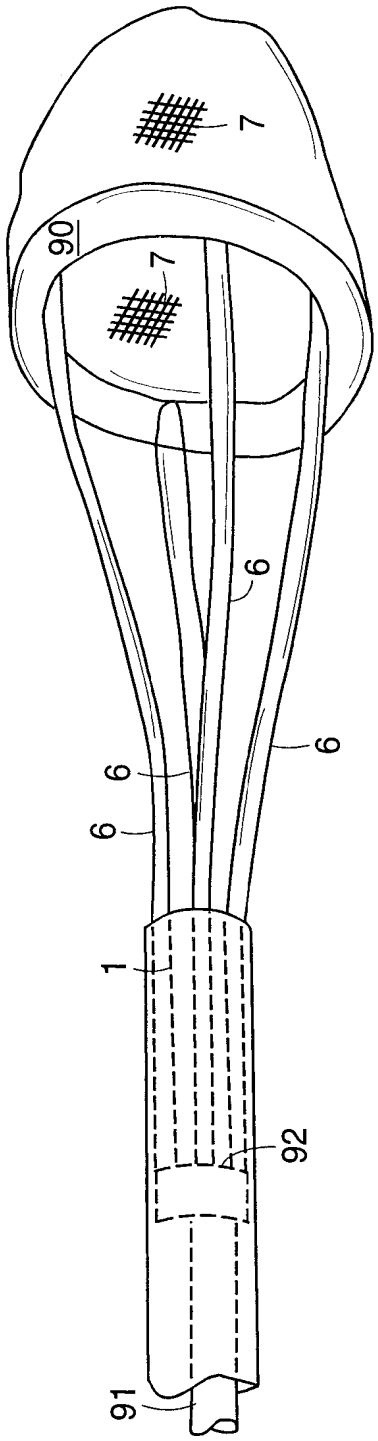

FIG. 9

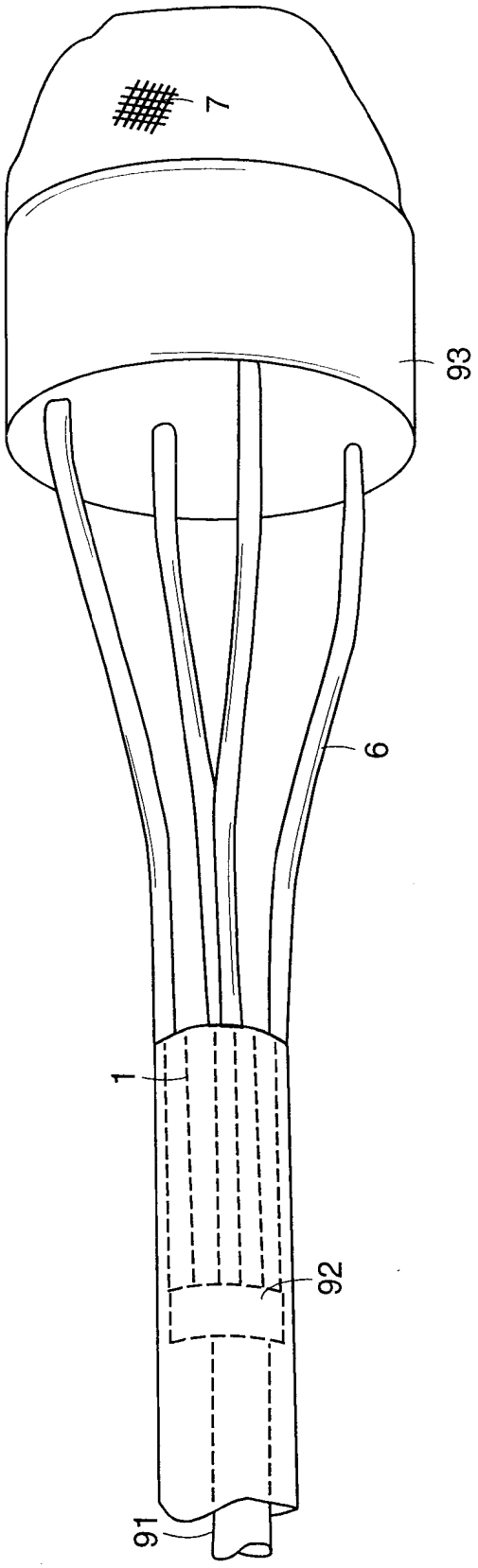

FIG. 10

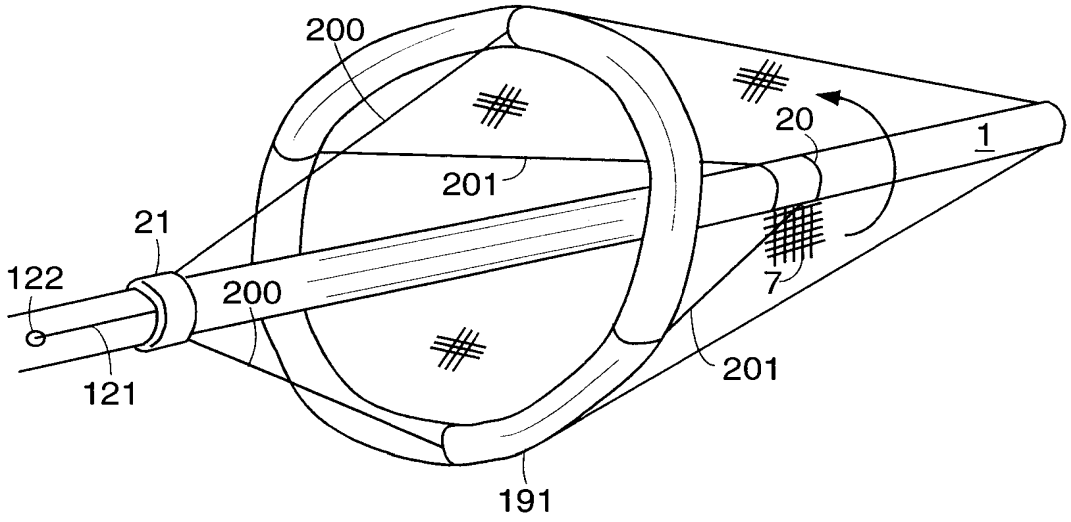

FIG. 11A

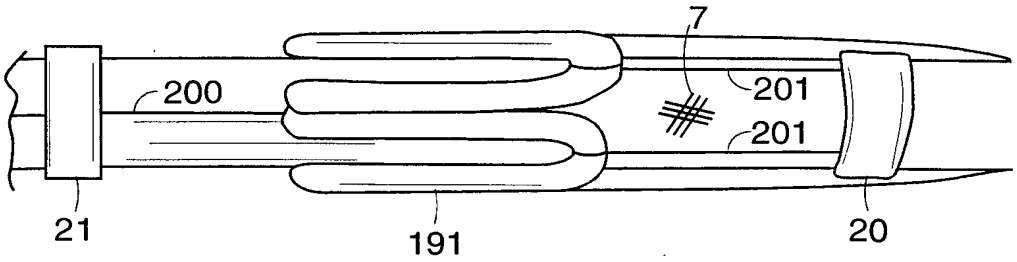

FIG. 11B

INTERNATIONAL SEARCH REPORT

In..ational Application No
PCT/US 98/10220

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/01 A61M29/02

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 95 05209 A (TECH. DEV. CENTER) 23 February 1995 see page 13, line 29 - page 15, line 11 see page 7, line 6 - line 10; figures 1,13-15	1-4,6-8, 36 5,9-35
Y	US 4 723 549 A (WHOLEY ET AL.) 9 February 1988 cited in the application see column 3, line 2 - line 66; figures 1-6	5,9-35

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 August 1998	02/09/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Moers, R

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/10220

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Week 8122 8 July 1981 Derwent Publications Ltd., London, GB; AN 78-70163A XP002075206 & SU 764 684 A (CHELY MED. INST.) see abstract; figures 1-5	1-3,9,36
X A	US 5 053 008 A (BAJAJ) 1 October 1991 see column 7, line 55 - column 8, line 47; figures 1-4	1,36 3,7,32, 35
A	US 5 470 314 A (WALINSKY PAUL) 28 November 1995 see column 7, line 13 - line 18	7,35

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Ir. .ational Application No
PCT/US 98/10220

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9505209 A	23-02-1995	AU 7567394 A	14-03-1995
US 4723549 A	09-02-1988	NONE	
US 5053008 A	01-10-1991	NONE	
US 5470314 A	28-11-1995	NONE	

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16 August 2018 (16.08.2018)

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(30) Priority Data:

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15/687,789	28 August 2017 (28.08.2017)	US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:
— *with international search report (Art. 21(3))*

WO 2018/148174 A1

(54) Title: AXIAL LENGTHENING THROMBUS CAPTURE SYSTEM

(57) Abstract: Systems and methods can remove material of interest, including blood clots, from a body region, including but not limited to the circulatory system for the treatment of pulmonary embolism (PE), deep vein thrombosis (DVT), cerebrovascular embolism, and other vascular occlusions.

AXIAL LENGTHENING THROMBUS CAPTURE SYSTEM

PRIORITY CLAIM

[0001] Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application. This application claims the benefit under 35 U.S.C. § 120 as continuation of U.S. nonprovisional application no. 15/604531, filed May 24, 2017, which is a continuation-in-part application of U.S. Pat. App. No. 15/428,076 filed on February 8, 2017, which is a continuation-in-part application of U.S. Pat. App. No. 15/230,109 filed on August 5, 2016, which claims the benefit under 35 U.S.C. § 119(e) as a nonprovisional application of each of U.S. Provisional App. Nos. 62/202,074 filed on August 6, 2015, 62/273,418 filed on December 30, 2015, and 62/345,863 filed on June 6, 2016. Each of the aforementioned priority applications is hereby incorporated by reference in their entireties.

BACKGROUND

Field of the Invention

[0002] The invention relates to, in some aspects, systems and methods to remove materials of interest, including blood clots, from a body region, including but not limited to the circulatory system for the treatment of pulmonary embolism (PE), deep vein thrombosis (DVT), cerebrovascular embolism, and other vascular occlusions.

Description of the Related Art

[0003] It is understood that undesirable materials such as blood clots (which could be referred to as thrombi, thromboemboli, or emboli herein) in the blood vessels may partially or completely occlude blood vessels in areas of the coronary, cerebrovascular, pulmonary, peripheral venous, and peripheral arterial circulation resulting in myocardial infarction, stroke, pulmonary embolism, deep vein thrombosis, and infarction of an extremity respectively.

[0004] Various therapies and devices are known to either dissolve, debulk and/or aspirate the thromboemboli. For instance, anticoagulant agents such as heparin and warfarin help stabilize blood clots and prevent further forming of clots while thrombolytic agents such

as urokinase, streptokinase, and tPA assist in dissolving blood clots. These agents can be delivered via systemic infusion or catheter-based infusion to the intended location. While thrombolytic agents can be effective in dissolving blood clots, they require a long time duration in order for the agents to dissolve the blood clots; thus patients may need to remain in the hospital intensive care unit (ICU) during thrombolytic infusion. Relatively long lengths of stay can increase healthcare costs significantly. A major limitation for these thrombolytic agents is that they can potentially cause intracranial, gastrointestinal, retroperitoneal, and pericardial bleeding, among other sites, which can be often life-threatening and cause significant morbidity and mortality risks.

[0005] Mechanical debulking and/or aspiration devices can be used to remove the obstruction. These mechanical techniques can either macerate, aspirate, or a combination thereof in order to remove the blood clots. An advantage of mechanical therapy is that it can remove thrombus directly from the blockage area and immediately eliminates the obstruction and may be superior to thrombolytic agents in some cases. However, current mechanical therapies have some major limitations. There is minimal to no flow during the procedure thus there is little time before patients may become hemodynamically instable. The debris removed from mechanical treatment can travel distally creating additional embolization. The small size devices are unable to remove large amount of blood clots in short time periods thus patients may become hemodynamically instable.

[0006] Catheter-based removal of blood clots from larger blood vessels (e.g., pulmonary arteries) have had limited success compared to smaller blood vessels (e.g., coronary arteries). Catheter pulmonary embolectomy is where pulmonary emboli are removed percutaneously using several techniques. Fragmentation thrombectomy breaks blood clots into smaller pieces, most of which travel further downstream, resulting in distal embolization. It is sometimes used in combination with thrombolytics. With the rheolytic thrombectomy, high velocity saline jets create a Venturi effect and draw the fragments of the clot into the catheter. This method poses risk of hemolysis. Finally the aspiration techniques draw the clot into a catheter via suction. All of these techniques rely on the catheter used to remove the clots from blood vessels. The users use small catheters to remove or break up large amounts of blood clot. This procedure is therefore time-consuming and inefficient. Once the blood clots are broken into small pieces, the debris can migrate distally and create

unwanted emboli. Rheolytic therapy poses the risk of hemolysis. Additionally, the ability to suction is limited due the small catheter size suctioning large emboli. These limitations cause in some cases unnecessary duress to the user and risk to the patient.

[0007] Catheter-based removal of blood clots in general also has a major limitation when distal working space within a body lumen is limited. Conventional devices may require full axial and/or radial deployment and expansion to be functional, and as such flexibility to use such devices for a variety of clinical situations involving differing clot or other material sizes to be removed can be very limited. Therefore, conditions where there is limited distal space of blood vessels can render these conventional devices ineffective.

[0008] It is evident that all of the therapeutic options available to patients with blood clots or other undesirable material in blood vessels and other body lumens have limitations. Anticoagulation only limits propagation of clots but does not actively remove it. Thrombolytic therapy poses a risk of major bleeding. Catheter embolectomy is not effective to manage removal of material in large vessels. Additionally, these devices require distal space to fully deploy to be functional thus ineffective in tight distal spaces. Surgical embolectomy can be highly effective but highly invasive, and has a high rate of morbidity and mortality. There is a need for a direct mechanical treatment that is as or more effective as surgical embolectomy removing large blood clots but can be performed using endovascular techniques and restore immediate blood flow, and cause a lower incidence of complications.

SUMMARY

[0009] In some embodiments, disclosed herein is a capture system for selected materials within a body. The capture system can include a capture assembly configured to isolate unwanted material, e.g., a blood clot that can include a shape memory body such as made of, for example, a mesh material and having a distal end connected to a capture guide having a distal opening. The shape memory body can further include a proximal end connected to a first shaft, and a tubular sidewall between the proximal end and the distal end. The capture assembly can be configured to expand the capture guide and the distal opening end when the shape memory body proximal end is compressed in the delivery system. The shape memory body can be movable from a first configuration having a first axial length and a second configuration having a second axial length. The shape memory body can be

configured to roll out, invert, evert, and/or variably lengthen proximally or distally from the first configuration to the second configuration. The second axial length can be different from the first axial length. The width of the capture assembly can, in some cases not substantially change from the first configuration to the second configuration. The capture system can also include a control line configured to independently move the capture assembly from the first configuration to the second configuration. The first shaft can extend within the longitudinal axis of the capture assembly.

[0010] In some embodiments, disclosed herein is a material, e.g., a clot capture system. The system can include a first, outer tubular shaft comprising a central lumen, the first outer tubular shaft comprising a proximal portion and a distal portion, the distal portion more radially expandable than the proximal portion. The system can also include a second tubular shaft configured to be positioned within the central lumen of the first shaft. The system can also include a third tubular shaft configured to be positioned within a central lumen of the second shaft. The shape memory tubular body can include a first end, a second end, and an axial length therebetween, the first end having a proximal-facing opening and a ring-shaped capture guide attached to a circumference of the proximal-facing opening, the capture guide operably attached to the second tubular shaft, the second end attached to an outer wall of the third tubular shaft. The shape memory tubular body can be compressed within the central lumen of the second tubular shaft in a first delivery configuration. The shape memory tubular body can be transformable to a second configuration in which the first end and the capture guide is radially expanded up to a dynamic fold point, but the second end and a segment of the shape memory tubular body extends in a different direction, such as proximally past the dynamic fold point, and remains radially compressed within the central lumen of the second tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular mesh body has a first expanded axial length. The shape memory tubular body can be transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, and a width of the shape memory tubular shaft along its second expanded axial length is the same or substantially the same as a width of the shape memory tubular shaft along its first expanded axial length. The first tubular shaft can be configured to be reversibly coupled with respect to the second tubular shaft in the delivery configuration and axially

movable with respect to the third tubular shaft in the second configuration. In some embodiments, the second expanded axial length is about or at least about, for example, 105%, 110%, 115%, 120%, 125%, 130%, 150%, 200%, 250%, 300%, 350%, 400%, 450%, 500%, or more of the first axial length. The capture system of Claim 1, wherein the shape memory body can be porous, semi-permeable, and non-porous, and include nitinol braided, woven, or non-woven mesh, or nitinol wire. In some embodiments, the tubular body is coated with a hydrophilic or hydrophobic agent, or noncoated, and may not include a shape memory metal or material. In some embodiments, the tubular mesh body is configured to invert, evert, or roll out with respect to the first, second, and/or third shaft. The system can also include a control line extending proximally from the capture guide, either terminating on a sleeve on one of the shafts or extending proximally to the proximal end of the system. In some embodiments, the system includes a suction element configured to operably connect with the proximal opening of the shape memory tubular body. The system can also include a mechanical thrombectomy element, such as a macerator. The system can also include a filter collection chamber configured to collect and filter blood obtained from the suction element.

[0011] The system can further include an expanding guide catheter configured to receive the capture assembly in the form of a kit. The expanding guide element can include an open funnel distal tip, that can be porous in some embodiments to allow flow around the funnel distal tip.

[0012] In some embodiments, disclosed herein is a material, such as a clot capture system that can include a first, outer tubular shaft comprising a central lumen; a second tubular shaft configured to be positioned within the central lumen of the first shaft, the second tubular shaft comprising a proximal portion and a distal portion, the distal portion more radially expandable than the proximal portion; a third tubular shaft configured to be positioned within a central lumen of the second shaft; a tubular mesh comprising a first end, a second end, and an axial length therebetween, the first end having a proximal-facing opening and a ring-shaped capture guide attached to a circumference of the proximal-facing opening, the capture guide operably attached to the second tubular shaft, the second end attached to an outer wall of the third tubular shaft. The tubular mesh can be compressed within the central lumen of the second tubular shaft in a delivery configuration. The tubular mesh can also be transformable to a second configuration in which the first end and the

capture guide is radially expanded but the second end and a portion, such as a minority, half, or a majority of the tubular mesh remains radially compressed within the central lumen of the second tubular shaft and the second end is positioned proximal to the first end and the tubular mesh has a first expanded axial length. The tubular mesh can be transformable to a third configuration in which the tubular mesh has a second expanded axial length greater than the first expanded axial length, wherein a width of the tubular mesh along its second expanded axial length is substantially the same as a width of the tubular mesh along its first expanded axial length, wherein the third tubular shaft extends distally through the proximal end opening as well as the second axial expanded length of the shape memory tubular body. In some embodiments, the tubular mesh is not under tension or substantially under tension in the second configuration or the third configuration defining an axial working range of the tubular mesh.

[0013] In some embodiments, a material, such as a clot capture system includes a first, outer tubular shaft comprising a central lumen; a second tubular shaft configured to be positioned within the central lumen of the first shaft, the second tubular shaft comprising a proximal portion and a distal portion, the distal portion more radially expandable than the proximal portion; a third tubular shaft configured to be positioned within a central lumen of the second shaft; a tubular body that may include shape memory materials that includes a first end, a second end, and an axial length therebetween, the first end having a proximal-facing opening and a ring-shaped capture guide attached to a circumference of the proximal-facing opening, the capture guide operably attached to the second tubular shaft via a sleeve circumscribing a portion of the second tubular shaft, the second end attached to an outer wall of the third tubular shaft. The shape memory tubular body can be compressed within the central lumen of the second tubular shaft in a delivery configuration. The shape memory tubular body can be transformable to a second configuration by axial movement of the second tubular shaft with respect to the first tubular shaft, in which the first end and the capture guide is radially expanded but the second end and a segment of the shape memory tubular body remains radially compressed within the central lumen of the second tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular mesh body has a first expanded axial length. The shape memory tubular body can be transformable to a third configuration by movement of the second tubular shaft with respect

to the third tubular shaft, in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular shaft along its second expanded axial length is substantially the same as a width of the shape memory tubular shaft along its first expanded axial length, wherein the third tubular shaft extends distally through the proximal end opening as well as the second axial expanded length of the shape memory tubular body. The shape memory tubular body can, in some cases, be transformable to a fourth configuration by movement of the second tubular shaft with respect to the third tubular shaft. The shape memory tubular body can have a third expanded axial length greater than the second expanded axial length, wherein a width of the shape memory tubular shaft along its third expanded axial length is less than the width of the shape memory tubular shaft along its second expanded axial length. The clot capture system can also include a sleeve that includes a metal or polymer, and the sleeve can be partially or fully radiopaque or radiolucent under fluoroscopy or other imaging.

[0014] Also disclosed herein is a method of performing a thrombectomy. The method can include, for example, accessing the interior of a blood vessel; advancing a thrombus capture device comprising a capture assembly through the blood vessel; positioning the thrombus capture device such that a distal end of the device is distal to the thrombus; actuating the capture assembly to isolate the thrombus within the capture device, wherein the capture assembly is movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial length being different from the first axial length, wherein the width of the capture assembly does not substantially change from the first configuration to the second configuration; and suctioning, macerating, and/or mechanically removing the thrombus.

[0015] In some embodiments, a method of performing a thrombectomy can include, for example, accessing the interior of a blood vessel; advancing an expanding guiding catheter through the blood vessel; positioning the expanding guiding catheter such that a distal end of the device is proximal to a thrombus; retracting the expanding guide catheter outer member to expand a funnel tip and exposing an expandable inner member; advancing a thrombus capture device comprising a capture assembly through the expanding guide catheter; positioning the thrombus capture device such that a distal end of the device is distal to or within the thrombus; and actuating the capture assembly to isolate the thrombus

within the capture device. The capture assembly can be movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial length being different from the first axial length. The width of the capture assembly may not substantially change from the first configuration to the second configuration. The method can also include retracting the capture assembly with the thrombus into an expanding guide catheter funnel tip and expandable inner body. The method can also include axially lengthening the thrombus capture device distally and retracting the thrombus into the funnel tip of the expanding guide catheter. The method can further include radially shortening the thrombus capture device to compress the thrombus and promote removal of the thrombus.

[0016] In some embodiments, disclosed herein is a clot capture system that can include a capture assembly configured to isolate a blood clot. The system can include a shape memory body that has a distal end connected to a capture guide comprising a distal or proximal opening. The shape memory body can also include a proximal end connected to a first shaft, and a sidewall between the proximal end and the distal end. The capture guide and the distal zone of the shape memory body opening end can also be fully or partially recaptured inside the outer sheath. The capture assembly can be configured to radially expand the capture guide and a distal zone of the shape memory body opening end while the shape memory body proximal end remains compressed in the delivery configuration. The capture assembly can be movable from a first configuration having a first axial length to a second configuration having a second axial length. The shape memory body can be configured to roll out, invert, evert, and/or variably lengthen proximally from the first configuration to the second configuration. The second axial length can be different from the first axial length. The width of the capture assembly can in some cases not substantially change from the first configuration to the second configuration.

[0017] Also disclosed herein is a capture assembly configured to isolate a blood clot including a shape memory body including a proximal end and a distal end connected to a capture guide including a distal opening, a proximal end connected to a shaft, and a sidewall between the proximal end and the distal end. The capture assembly can be configured to expand the capture guide and the distal shape memory body opening end while the shape memory body proximal end is compressed in the delivery configuration between a first shaft

and a second shaft, and movable from a first configuration having a first axial length and a second configuration having a second axial length. The shape memory body can be configured to roll out/unroll, invert, evert, and/or variably lengthen proximally from the first configuration to the second configuration. The second axial length can be different from the first axial length. In some cases, the width of the capture assembly does not substantially change from the first configuration to the second configuration. Furthermore, the shape memory body can be fully or partially recaptured inside the outer sheath once deployed. The system can also include a sleeve coupled a control line connected to the second shaft configured to move the capture assembly from the first configuration to the second configuration. The first shaft and the second shaft can be off-axis with respect to the capture assembly.

[0018] Also disclosed herein is a method of performing a thrombectomy. The method can include any number of the following: accessing the interior of a blood vessel; advancing a thrombus capture device comprising a capture assembly through the blood vessel; positioning the thrombus capture device such that a distal end of the device is distal to the thrombus; actuating the capture assembly to isolate the thrombus within the capture device, wherein the capture assembly is movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial length being different from the first axial length, wherein the width of the capture assembly does not substantially change from the first configuration to the second configuration; and suctioning the thrombus.

[0019] In some embodiments, the methods can include any number of the following: accessing the interior of a blood vessel; advancing an expanding guiding catheter through the blood vessel; positioning the expanding guiding catheter such that a distal end of the device is proximal to a thrombus; retracting the expanding guide catheter outer member to expand a funnel tip and exposing an expandable inner member; advancing a thrombus capture device comprising a capture assembly through the expanding guide catheter; positioning the thrombus capture device such that a distal end of the device is distal to or within the thrombus; actuating the capture assembly to isolate the thrombus within the capture device, wherein the capture assembly is movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial

length being different from the first axial length wherein the width of the capture assembly does not substantially change from the first configuration to the second configuration; and retracting the thrombus into an expanding guide catheter funnel tip and expandable inner body. In some embodiments, the capture guide is first recaptured into the outer sheath of the delivery catheter and then retract into the expanding guide catheter funnel tip and expandable inner body.

[0020] In some embodiments, disclosed herein is a clot capture system. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to the second tubular member. In some embodiments, at least part of the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains radially compressed within the central lumen of the first tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0021] The system can include a capture guide attached to the first end opening. In some embodiments, the capture guide at least partially circumscribes the first end opening. In some embodiments, the capture guide fully partially circumscribes the first end opening. The system can include an expandable cover element circumscribing the capture guide. In some embodiments, the expandable cover element is inflatable. The system can include a control line extending proximally from the capture guide. The system can include a sleeve attached to the first tubular shaft and the first end opening of the shape memory tubular body. In some embodiments, the shape memory tubular body is configured to invert, evert, or roll

out with respect to the first tubular shaft or the second tubular shaft. In some embodiments, the end opening of the shape memory tubular body is proximal-facing. In some embodiments, the shape memory tubular body comprises a mesh. In some embodiments, the shape memory tubular body is configured to allow fluid flow therethrough. In some embodiments, the second tubular member comprises a central lumen. The system can include an expanding guide element configured to receive the capture assembly. In some embodiments, the expanding guide element comprises an open funnel distal tip. In some embodiments, the open funnel distal tip is porous to allow flow. In some embodiments, the shape memory tubular body has a maximal length of between about 0.5cm and about 125cm. In some embodiments, the shape memory tubular body is transformable to a fourth configuration wherein the shape memory tubular body has a third axial expanded length greater than the second axial expanded length, wherein a width of the shape memory tubular body along its third expanded axial length is less than the width of the shape memory tubular body along its second expanded axial length.

[0022] In some embodiments, disclosed herein is a system for capturing material of interest within a body lumen. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to an outer wall of the second tubular member. In some embodiments, the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end opening and a first segment of the shape memory tubular body extending axially in a first direction from the first end opening is radially expanded to a fold point, while a second segment of the shape memory tubular body extends axially from the fold point to the second end of the shape memory tubular body in a second direction opposite the first direction, the second segment relatively radially compressed with respect to the first segment, the second end positioned proximal to the first end. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the axial length of the first segment increases by a first amount, the shape memory tubular body has a second expanded

axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0023] In some embodiments, disclosed herein is a clot capture system. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to an outer wall of the second tubular member. In some embodiments, the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end opening and a first segment of the shape memory tubular body extending axially in a first direction from the first end opening is radially expanded to a fold point, while a second segment of the shape memory tubular body extends axially from the fold point in a second direction opposite the first direction to the second end, the second segment radially compressed with respect to the first segment, the second end positioned proximal to the first end. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the axial length of the first segment increases by a first amount, the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0024] In some embodiments, disclosed herein is a clot capture system. The system can include an outer sheath comprising a central lumen. The system can include a dual lumen shaft configured to be positioned within the central lumen of the outer sheath. The system can include an inner pusher configured to be positioned within a first lumen of the dual lumen shaft. The system can include an anchor pusher configured to be positioned within a second lumen of the dual lumen shaft. The system can include an anchor coupled to the anchor pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a

capture guide attached to a portion of the opening. In some embodiments, the shape memory tubular body and the anchor are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed within the lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor in the third configuration.

[0025] The system can include, for example, one, two, or more anchors. The anchors can have any desired configuration to stabilize or associate with a clot to facilitate removal, including a J-hook shape in some cases. The anchors can penetrate a clot or other material to be captured in some embodiments, or do not penetrate but rather circumscribe or otherwise stabilize or reversibly secure at least a portion of the clot or other material to be captured. In some embodiments, the anchors have a central longitudinal axis that is coaxial. The system can include three anchors, or more. In some embodiments, the cross-section of the anchor is round, ovoid, square, rectangular, or another cross section. In some embodiments, the anchor comprises nitinol. In some embodiments, the anchor forms an angle with the anchor pusher, wherein the angle is approximately 90 degrees. In some embodiments, the anchor forms an angle with the anchor pusher, wherein the angle is approximately 45 degrees. In some embodiments, the anchor forms an angle with the anchor pusher, wherein the angle is between 5 degrees and 135 degrees. In some embodiments, the diameter of the anchor is less than the diameter of the shape memory tubular body when radially expanded. In some embodiments, a portion of the anchor pusher is crescent shaped. In some embodiments, the capture guide comprises nitinol. In some embodiments, the capture guide comprises a central longitudinal axis and wherein the dual lumen shaft is offset from the central longitudinal axis. In some embodiments, the second end of the shape memory tubular body is coupled to the inner pusher. In some embodiments, the capture guide

forms a continuous loop. In some embodiments, the capture guide forms a non-continuous loop.

[0026] In some embodiments, disclosed herein is a clot capture system. The system can include an inner pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to at least a portion of the opening, the second end coupled to the inner pusher. In some embodiments, the shape memory tubular body and the capture guide are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some embodiments, the capture guide forms a continuous loop. In some embodiments, the capture guide forms a non-continuous loop.

[0027] Also disclosed herein is a method of using a clot capture system. The method can include any number of the following: positioning a system near a blood clot in the first configuration; transforming the shape memory tubular body to the second configuration; and transforming the shape memory tubular body to the third configuration to encapsulate the clot. The system can include an inner pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to at least a portion of the opening, the second end coupled to the inner pusher. In some embodiments, the shape memory tubular body and the capture guide are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the

capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some embodiments, the blood clot is within the CNS.

[0028] Also disclosed herein is a method of using a clot capture system. The method can include any number of the following: positioning a system near a blood clot; transforming the shape memory tubular body to the second configuration; expanding the anchor; and transforming the shape memory tubular body to the third configuration to encapsulate the anchor. The system can include an outer sheath comprising a central lumen. The system can include a dual lumen shaft configured to be positioned within the central lumen of the outer sheath. The system can include an inner pusher configured to be positioned within a first lumen of the dual lumen shaft. The system can include an anchor pusher configured to be positioned within a second lumen of the dual lumen shaft. The system can include an anchor coupled to the anchor pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to a portion of the opening. In some embodiments, the shape memory tubular body and the anchor are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed within the lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor in the third configuration. In some embodiments, deploying the anchor comprises securing the anchor within the clot. In some embodiments, transforming the shape memory tubular body to the third configuration to encapsulate the anchor further comprises encapsulating the clot. In some embodiments, the blood clot is a neurological blood clot.

[0029] In some embodiments, disclosed herein is a clot capture system. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a plurality of axially spaced-apart anchors extending radially outwardly from the first tubular member or the second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to the second tubular member. In some embodiments, at least part of the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains radially compressed within the central lumen of the first tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0030] In some embodiments, disclosed herein is a clot capture system. The system can include an anchor. The system can include a tubular body comprising a first end, a second end, and an axial length therebetween. The first end can have an opening. The tubular body and the anchor can be compressed in a delivery configuration. The tubular body and the anchor can be transformable to a deployed configuration in which the anchor and the shape memory tubular body first end are expanded but the shape memory tubular body second end and a majority of the shape memory tubular body remains compressed and the tubular body has a first expanded axial length. The shape memory tubular body can transformable to a capture configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. The shape memory tubular body can encapsulate the anchor, or a portion thereof, in the capture configuration. In some embodiments, the system can include two or more anchors. In some embodiments, the

two anchors have a central longitudinal axis that is coaxial. In some embodiments, the anchor is a stent like structure. In some embodiments, the anchor is a balloon. In some embodiments, the anchor is a disk. In some embodiments, the anchor comprises nitinol. In some embodiments, the anchor comprises a spherical balloon. In some embodiments, the anchor is configured to entangle a clot. In some embodiments, the anchor is coupled to the shape memory tubular body. In some embodiments, the anchor is a funnel. In some embodiments, the anchor is tapered from the distal end to the proximal end of the anchor. In some embodiments, the shape memory tubular body comprises a central longitudinal axis and wherein the anchor is offset from the central longitudinal axis. In some embodiments, the second end of the shape memory tubular body is coupled to an inner pusher.

[0031] In some embodiments, disclosed herein is a clot capture system. The system can include an anchor. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween. The first end can have an opening. The shape memory tubular body and the anchor can be configured to be compressed during delivery. The first end of the shape memory tubular body and the anchor can be configured to be expanded while the second end and a majority of the shape memory tubular body remains compressed. The shape memory tubular body can have a first expanded axial length with a first cross-section. The shape memory tubular body can be configured to be axially lengthened. In some embodiments, the system can include a pusher, wherein the second end of the shape memory tubular body is coupled to the pusher. In some embodiments, the anchor and the shape memory tubular body are fixed together.

[0032] In some embodiments, disclosed herein is a method of using a clot capture system. The method can include positioning any clot capture system disclosed herein near a blood clot. The method can include expanding the shape memory tubular body and the anchor. The method can include axially lengthening the shape memory tubular body to encapsulate the clot. In some embodiments, the blood clot is within the central nervous system.

[0033] In some embodiments, disclosed herein is a method of using a clot capture. The method can include positioning any clot capture system disclosed herein near a blood clot. The method can include transforming the shape memory tubular body and the

anchor to the deployed configuration. The method can include transforming the shape memory tubular body and the anchor to the capture configuration to encapsulate the anchor.

[0034] In some embodiments, disclosed herein is a clot capture system. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains compressed within the first lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section. In some embodiments, the first cross-section is substantially similar to a cross-section of the capture guide. In some embodiments, the cross-section of the shape memory tubular body is round. In some embodiments, the anchor forms an angle with the anchor pusher when expanded, wherein the angle is approximately 90 degrees. In some embodiments, the anchor forms an angle with the anchor pusher when expanded, wherein the angle is approximately 45 degrees. In some embodiments, the anchor forms an angle with the anchor pusher when expanded, wherein the angle is approximately 5 degrees. In some embodiments, wherein a diameter of the anchor is less than a diameter of the shape memory tubular body when expanded. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains compressed and the shape memory tubular body has a first expanded axial length with a first cross-section. In some embodiments, the first cross-section is substantially similar to a cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains compressed within the central lumen of the first tubular member and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length. In some embodiments, a width of the shape memory tubular body along the second expanded axial length is substantially the same as a width of the shape memory tubular body along the first expanded axial length. In some embodiments, disclosed herein is a method of using a clot capture system. The method can include transforming the shape memory tubular body to the third configuration to encapsulate the blood clot. In some embodiments, the blood clot is within the central nervous system. In some embodiments, expanding the anchor

comprises securing the anchor within the blood clot. In some embodiments, transforming the shape memory tubular body to the third configuration to encapsulate the anchor further comprises encapsulating the blood clot.

[0035] In some embodiments, disclosed herein is a clot capture system. The system can include a shaft. The system can include a plurality of axially spaced-apart anchors comprising a reduced configuration and an expanded configuration. In some embodiments, the plurality of axially spaced-apart anchors extend radially outward from the shaft in the expanded configuration. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween. In some embodiments, the first end can include an opening. In some embodiments, the shape memory tubular body can be compressed in a compressed configuration. In some embodiments, the shape memory tubular body can be transformable to a first expanded configuration in which the first end is expanded. In some embodiments, the second end and a portion of the shape memory tubular body can be compressed in the first expanded configuration. In some embodiments, the shape memory tubular body can have a first expanded axial length in the first expanded configuration. In some embodiments, the shape memory tubular body can be transformable to a second expanded configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some embodiments, the shape memory tubular body circumscribes the plurality of axially spaced-apart anchors in the second expanded configuration. In some embodiments, the plurality of axially spaced-apart anchors comprise three or more anchors. In some embodiments, the plurality of axially spaced-apart anchors are coaxial. In some embodiments, the plurality of axially spaced-apart anchors comprise nitinol. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when expanded, wherein the angle is approximately 90 degrees. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when expanded, wherein the angle is approximately 45 degrees. In some embodiments, a cross-section of an anchor of the plurality of axially spaced-apart anchors is less than a cross-section of the first end of the shape memory tubular body when expanded. In some embodiments, the plurality of axially spaced-apart anchors are coupled to an anchor pusher. In some embodiments, the second end of the shape memory tubular body is coupled to an inner pusher.

[0036] In some embodiments, disclosed herein is clot capture system. The system can include a shaft. The system can include an anchor comprising a reduced configuration and an expanded configuration. In some embodiments, the anchor extends outward from the shaft in the expanded configuration. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, In some embodiments, the first end can have an opening. In some embodiments, the shape memory tubular body can be compressed in a compressed configuration. In some embodiments, the shape memory tubular body can be transformable to a first expanded configuration wherein the first end is expanded. In some embodiments, the second end and a portion of the shape memory tubular body can be compressed in the first expanded configuration. In some embodiments, the shape memory tubular body can have a first expanded axial length. In some embodiments, the shape memory tubular body can be transformable to a second expanded configuration in which the shape memory tubular body has a second expanded axial length. In some embodiments, the second expanded axial length is greater than the first expanded axial length. In some embodiments, the first cross-section is round. In some embodiments, the anchor forms an angle with an anchor pusher when expanded, wherein the angle is between 5 degrees and 135 degrees. In some embodiments, the system can include a second anchor. In some embodiments, the anchors are coaxial. In some embodiments, the second end of the shape memory tubular body is coupled to an inner pusher.

[0037] In some embodiments, disclosed herein is clot capture system. The system can include a shaft. The system can include an anchor configured to expand outwardly from the shaft. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween. In some embodiments, the first end can have an opening. In some embodiments, the shape memory tubular body can be compressed in a compressed configuration. In some embodiments, the shape memory tubular body can be transformable to a first expanded configuration wherein the first end is expanded while the second end and a portion of the shape memory tubular body remains compressed. In some embodiments, the shape memory tubular body can have a first expanded axial length in the first expanded configuration. In some embodiments, the shape memory tubular body can be transformable to a second expanded configuration wherein the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some

embodiments, the shape memory tubular body surrounds the anchor in the second expanded configuration. In some embodiments, the system can include a second anchor. In some embodiments, the anchors are spaced axially apart along the longitudinal axis of the shaft. In some embodiments, the anchor is configured to entangle a clot. In some embodiments, a cross-section of the anchor is less than a cross-section of the first end of the shape memory tubular body when expanded.

[0038] In some embodiments, the shape memory tubular body can have a first expanded axial length in the first expanded configuration extending from the first end to a fold. In some embodiments, the fold forms the distal end of the shape memory tubular body in the first expanded configuration. In some embodiments, the first end and the second end are proximal to the distal end in the first expanded configuration. In some embodiments, the shape memory tubular body can circumscribes at least one anchor of the plurality of axially spaced-apart anchors in the second expanded configuration. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when the anchor is expanded, wherein the angle is approximately 90 degrees. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when the anchor is expanded, wherein the angle is approximately 45 degrees. In some embodiments, a cross-section of each of the plurality of axially spaced-apart anchors is less than a cross-section of the first end of the shape memory tubular body when the plurality of axially spaced-apart anchors and the first end of the shape memory tubular body are expanded. In some embodiments, the shape memory tubular body comprises a distal end in the first expanded configuration. In some embodiments, the first end and the second end are proximal to the distal end in the first expanded configuration. In some embodiments, a cross-section of the shape memory tubular body is round when the shape memory tubular body is expanded. In some embodiments, the anchor forms an angle with an anchor pusher when the anchor is expanded, wherein the angle is between 5 degrees and 135 degrees. In some embodiments, the first anchor and the second anchor are coaxial. In some embodiments, an anchor can be configured to expand. In some embodiments, the shape memory tubular body comprises a dynamic fold point between the first end and the second end in the first expanded configuration. In some embodiments, the first end and the second end are proximal to the dynamic fold point in the first expanded configuration. In some

embodiments wherein the first anchor and the second anchor are spaced axially apart along the longitudinal axis of a shaft. In some embodiments, a cross-section of the anchor is less than a cross-section of the first end of the shape memory tubular body when the anchor and the first end are expanded.

[0039] In some embodiments, the shape memory tubular body and the at least one anchor can be transformable to a second configuration in which the at least one anchor and the first end of the shape memory tubular body are expanded but the second end of the shape memory tubular body and a portion of the shape memory tubular body remains compressed such that the second end is positioned proximal to the first end and the first end overlaps with the portion of the shape memory tubular body that remains compressed. In some embodiments, the first end overlaps with the portion of the shape memory tubular body that remains compressed. In some embodiments, the shape memory tubular body can be transformable to a configuration in which the opening is expanded and a first segment of the shape memory body extending axially in a first direction from the opening is expanded to a fold point, the first segment having a first expanded axial length, and a second segment of the shape memory body extending axially from the fold point to the second end of the shape memory body in a second direction opposite the first direction such that the second segment of the shape memory tubular body extends at least partially within the first segment of the shape memory tubular body. In some embodiments, the second segment is relatively compressed with respect to the first segment. In some embodiments, the second end positioned proximal to the first end. In some embodiments, the second segment of the shape memory tubular body extends at least partially within the first segment of the shape memory tubular body.

BRIEF DESCRIPTION OF THE FIGURES

[0040] Figure 1 illustrates examples of a catheter system, and various possible elements that can be included in a material capture system, according to some embodiments of the invention.

[0041] Figure 2 illustrates a close-up view of the thrombus capture systems of Figures 1 and 2.

[0042] Figure 3 illustrates an axially-lengthening thrombus capture (ALTC) system in the initial deployment configuration with the ALTC device expanded, according to some embodiments of the invention.

[0043] Figure 4 illustrates a close up view of the ALTC system distal segment position in the delivery configuration indicating the outer sheath and nose tip, according to some embodiments of the invention.

[0044] Figure 5 illustrates the distal end of an axial lengthening thrombus capture device at the initial deployment position, according to some embodiments of the invention.

[0045] Figure 6 illustrates the axial lengthen thrombus capture device retracting proximally to deploy and lengthen, according to some embodiments of the invention.

[0046] Figure 7 illustrates the axial lengthen thrombus capture device is fully deployed and the funnel tip of the guide catheter is positioned within the ALTC device, according to some embodiments of the invention.

[0047] Figures 8 and 9 illustrate different views of the initial deployment position of the ALTC Device and the funnel tip of the suction catheter, according to some embodiments of the invention.

[0048] Figure 10 illustrates the partially deployed ALTC Device, according to some embodiments of the invention.

[0049] Figure 11 illustrates an ALTC device deployed configuration where the funnel tip of the suction catheter is positioned inside the ALTC device, according to some embodiments of the invention.

[0050] Figure 12 illustrates the Axial Lengthening Thrombus Capture (ALTC) assembly wherein the distal end of the ALTC device is in the expanded (deployed) configuration and is fixed to the thrombus capture guide and capture pullwire, according to some embodiments of the invention. For purpose of illustration, the proximal end is in a collapsed configuration and extends proximally.

[0051] Figure 13 illustrates the axial lengthening thrombus capture device in the initial deployed configuration, according to some embodiments of the invention.

[0052] Figure 14 illustrates the thrombus capture element of the ALTC device that can include a stent or braided mesh, according to some embodiments of the invention.

[0053] Figures 15A-C illustrate an embodiment of the ALTC system, a distal portion of the ALTC System and a proximal portion of the ALTC System respectively.

[0054] Figure 16A illustrates another embodiment of the axial lengthening thrombus capture device in the delivery configuration, according to some embodiments of the invention.

[0055] Figure 16B illustrates the axial lengthening thrombus capture device in the initial deployed configuration wherein the outer sheath is retracted to expanded the axial lengthen thrombus capture device. The loop is coupled to the sleeve wherein it is coupled to the capture catheter shaft, according to some embodiments of the invention.

[0056] Figure 16C illustrates the axial lengthening thrombus capture device retracting proximally and lengthening, according to some embodiments of the invention.

[0057] Figure 16D illustrates the lengthening of the axial lengthening thrombus capture device and in some cases at full deployment, according to some embodiments of the invention.

[0058] Figures 17A-D illustrate different configurations of the ALTC device, according to some embodiments of the invention.

[0059] Figures 18A-B illustrate an embodiment of a distal portion of the axially-lengthening thrombus capture system with a cover element radially outward of, and partially or completely circumscribing the capture guide of the ALTC device, which can be in the shape of a ring as illustrated.

[0060] Figures 19A-C illustrates an embodiment of an axially-lengthening thrombus capture system, configured to allow the guidewire to distally exit the system prior to exiting the luer port at the proximal end of the system.

[0061] Figure 20A illustrates the expanding guide catheter system in the delivery configuration, according to some embodiments of the invention.

[0062] Figure 20B illustrates the expanding guide catheter system wherein the funnel tip is in deployed position and the obturator is positioned in the expanding guide catheter lumen, according to some embodiments of the invention.

[0063] Figure 20C illustrates the expanding guide catheter having a funnel tip, expanding distal segment and non-expanding proximal segment, according to some embodiments of the invention.

[0064] Figure 20D illustrates an obturator, according to some embodiments of the invention.

[0065] Figures 21A-C illustrate the expanding guide catheter system including the expanding guide catheter, outer cover and obturator, according to some embodiments of the invention.

[0066] Figure 21D illustrates an embodiment wherein a cover tip encapsulates the distal end of the outer cover of the expanding guide catheter system, according to some embodiments of the invention. Figures 21E-F illustrate an embodiment of a hemostasis valve for use within a hemostasis guide catheter system.

[0067] Figure 22 illustrates the outer sheath assembly of the capture device, according to some embodiments of the invention.

[0068] Figures 23 and 24 illustrate the distal end and proximal end of the outer sheath assembly respectively.

[0069] Figure 25 illustrates the capture catheter assembly, according to some embodiments of the invention.

[0070] Figure 26 illustrates the proximal end of the capture catheter, according to some embodiments of the invention.

[0071] Figure 27 illustrates an embodiment of a key cap feature to enable an anti-rotation of the hypotube pusher.

[0072] Figures 28 and 29 illustrates the suction catheter that can include a funnel tip, catheter shaft, and connector with seal, according to some embodiments of the invention.

[0073] Figure 30 illustrates the distal end of the suction catheter indicating the funnel tip and catheter shaft, according to some embodiments of the invention.

[0074] Figure 31 illustrates the proximal end of the suction catheter indicating the connector with seal and ports for use with filter chamber and access to flush catheter lumen, according to some embodiments of the invention.

[0075] Figures 32–41 illustrate different macerator designs and shapes, according to some embodiments of the invention.

[0076] Figure 42 illustrates a filter collection chamber that can include an inflow port to connect to a syringe, an outflow port to connect to the suction catheter, a plunger, a

filter to filter blood clot or debris and retain in the chamber and a chamber to collect blood clot or debris, according to some embodiments of the invention.

[0077] Figure 43 illustrates a blood clot lodging in the left side of pulmonary system, according to some embodiments of the invention.

[0078] Figure 44A and 44B illustrate blood clots residing in the left side pulmonary system and the capture device respectively, according to some embodiments of the invention.

[0079] Figure 45 illustrates the initial deployment configuration of the axial lengthening thrombus capture device positioned distal to the thrombus occluded area and a funnel tip positioned proximal to the thrombus occlusion, according to some embodiments of the invention.

[0080] Figure 46 illustrates the axial lengthening thrombus capture device lengthening proximally to capture the thrombus, according to some embodiments of the invention.

[0081] Figure 47 illustrates the axial lengthening thrombus capture device completely capturing the thrombus, and a funnel tip is inside the axial lengthening thrombus capture device.

[0082] Figure 48A illustrates the delivery configuration of the capture catheter device, according to some embodiments of the invention.

[0083] Figure 48B illustrates the initial deployment position of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0084] Figure 48C illustrates the lengthening of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0085] Figure 48D illustrate the final deployment of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0086] Figures 49A and 49B illustrate another embodiment of the axial lengthening thrombus capture device wherein the guidewire lumen and capture catheter is offset to the longitudinal axis of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0087] Figures 50A – 50G illustrate an embodiment of the retrieval of thrombus into the expanding guide catheter wherein the ALTC device lengthens distally and creates

additional space and the thrombus is redistributed and enable better retrieval into the expanding guide catheter. The funnel tip and expanding section of the expanding guide catheter also facilitate the ease of thrombus retrieval.

[0088] Figure 51 illustrates an embodiment of a system for removing blood clots.

[0089] Figure 52 illustrates the distal end of the capture device of the system of Figure 51 in the deployed configuration.

[0090] Figure 53 illustrates the distal end of the capture device of the system of Figure 51 in an initial deployed configuration.

[0091] Figure 54 illustrates the distal end of the capture device of the system of Figure 51 in a second configuration.

[0092] Figure 55 illustrates the distal end of the capture device of the system of Figure 51 in a third configuration.

[0093] Figure 56 illustrates an embodiment of the basket mesh element of the system of Figure 51. The basket mesh element can made of metallic materials such as Nitinol. The mesh element can be braided or laser cut.

[0094] Figure 57 illustrates an embodiment of a capture device element of the system of Figure 51.

[0095] Figures 58A- 58B illustrate embodiments of an expandable loop element of the system of Figure 51.

[0096] Figure 59 illustrates a view of a capture device opening for a system for neuro thrombus.

[0097] Figure 60 illustrates another view of a capture device opening of Figure 59.

[0098] Figure 61 illustrates an embodiment of a system.

[0099] Figure 62 illustrates a distal end of the capture device system of the system of Figure 61.

[0100] Figure 63 illustrates a proximal end of the system of Figure 61.

[0101] Figure 64 illustrates an anchor assembly of the system of Figure 61.

[0102] Figure 65 illustrates a side view of a distal end of the capture device and anchors of the system of Figure 61.

[0103] Figure 66 illustrates a top view of a distal end of the capture device and anchors of the system of Figure 61.

[0104] Figure 67 illustrates a front view of a distal end of the capture device of the system of Figure 61.

[0105] Figure 68A illustrates the capture device of the system of Figure 61 in an initial deployed configuration.

[0106] Figure 68B illustrates the capture device and first anchor release of the system of Figure 61 when the outer sheath retracts proximally.

[0107] Figure 68C illustrates the capture device, first anchor, and second anchor release of the system of Figure 61 when the outer sheath is retracted.

[0108] Figure 68D illustrates the capture device, first anchor, second anchor, and third anchor release of the system of Figure 61 when the outer sheath is retracted.

[0109] Figure 69A illustrates the capture device of the system of Figure 61 in an initial deployed configuration and the anchors are fully released.

[0110] Figure 69B illustrates the capture device of the system of Figure 61 lengthened proximally to encapsulate the first anchor.

[0111] Figure 69C illustrates the capture device of the system of Figure 61 lengthened proximally to encapsulate the anchors.

[0112] Figures 70A and 70B illustrate views of an embodiment of a pusher lock system.

[0113] Figures 71A-71D illustrate views of a pusher lock of the pusher lock system of Figure 70A.

[0114] Figure 72 illustrates a method of assembly an ALTC device to a capture guide.

[0115] Figure 73 illustrates an embodiment of an anchor.

[0116] Figure 74 illustrates an embodiment of an anchor.

[0117] Figure 75 illustrates a distal end of a capture device system including the anchor in a vessel of Figure 73.

[0118] Figure 76A illustrates the capture device of the system of Figure 75 in an initial deployed configuration and the anchor is fully expanded.

[0119] Figure 76B illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate a portion of the anchor.

[0120] Figure 76C illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate the anchor.

[0121] Figure 77A illustrates the capture device of the system of Figure 75 in an initial deployed configuration and the anchor is fully expanded.

[0122] Figure 77B illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate a portion of the anchor.

[0123] Figure 77C illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate the anchor.

[0124] Figure 78 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0125] Figure 79 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0126] Figure 80 illustrates the capture device system in a vessel of Figure 79.

[0127] Figure 81 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0128] Figure 82 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0129] Figure 83 illustrates the capture device system in a vessel of Figure 82.

[0130] Figure 84 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0131] Figure 85 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0132] Figure 86 illustrates the capture device system in a vessel of Figure 85.

[0133] Figure 87 illustrates a capture device system in a vessel.

[0134] Figures 88A-88R illustrate embodiments of an anchor.

[0135] Figure 89 illustrates an embodiment of a system designed for removing a blood clot.

[0136] Figure 90 illustrates a distal end of the system of Figure 89.

[0137] Figure 91 illustrates a distal end of a system including an embodiment of an anchor.

[0138] Figure 92 illustrates a distal end of a system including an embodiment of an anchor.

[0139] Figure 93 illustrates a distal end of a system including an embodiment of an anchor.

[0140] Figure 94 illustrates the capture device of the system of Figure 93 lengthened proximally to encapsulate the anchor.

[0141] Figure 95 illustrates a distal end of a system including an embodiment of an anchor.

[0142] Figures 96A-96B illustrate an embodiment of an expandable guide catheter.

DETAILED DESCRIPTION

[0143] The present invention provides, in some embodiments, systems and methods that can be delivered percutaneously in a body to retrieve and removal materials including blood clots, stones/calculi, and/or foreign materials in a body lumen, including a blood vessel, such as an arterial vessel or a venous vessel within the circulatory system. The present invention can, in some embodiments, also apply to nonvascular areas to treat, for example, gallstones, kidney stones, common bile duct stones, and the like.

[0144] Systems can be delivered percutaneously, via a cut-down approach, a thoracoscopic approach, or via other approaches, for example, using a catheter system 35, of which a perspective view of an embodiment is shown in Figure 1. Figure 1 also illustrates examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 1, included in some embodiments are any number of, such as one, two, or more of the following components: a first tubular member, such as an outer sheath 1, a second tubular member, such as a capture catheter 12, a third tubular member, such as a guidewire tube 6 an axial lengthening thrombus capture device 8, a suction catheter 2, and a filter collection chamber 5. The outer sheath 1 can, in some embodiments, be an elongate tubular member with a central lumen therethrough, and have a proximal end 1000 and a distal end 1001. The distal end 1001 of the

outer sheath 1 can be operably connected to a capture device (e.g., tubular mesh 8), which can be movably axially with respect to the outer sheath 1. In some embodiments, the outer sheath 1 has a relatively rigid proximal portion and a distal portion that is more flexible than the relatively rigid proximal portion, which can be advantageous to flexibly expand if necessary to accommodate the passage of large clots and/or other materials. The proximal end 1000 of the outer sheath 1 can connect to a proximal hub 1003 that may include any number of: the suction catheter 2, capture catheter 12, guidewire tube 6, and filter collection chamber 5. Non-limiting examples of other optional elements that can be included in the system (not shown in Figure 1) include a macerator tool (described elsewhere herein) and a discrete expanding guide catheter (described elsewhere herein. In some embodiments, the outer sheath 1 has a lumen configured to house the suction catheter 2, which in turn has a lumen configured to house the capture catheter 4, which in turn has a lumen configured to house the guidewire tube/guidewire lumen assembly 6 and the axial lengthening thrombus capture device (ALTC device) 8, which in turn has a lumen configured to house a guidewire (not shown) therethrough. An ALTC device as defined herein can include any structure, such as a net-like structure for example, configured to capture materials within a body location and axially lengthen and shorten through a working range, with or without radially shortening in width or diameter throughout that working range depending on the desired clinical result. In some embodiments, the outer sheath 1 has an inner diameter configured to house the capture catheter 12 coaxially therein, and the capture catheter 12, which in turn has a lumen configured to house the guidewire tube 6 and the body of the ALTC device 8. The ALTC device 8 can in some embodiments including a mesh net-like structure with a proximal-facing opening at one end that can be made of a shape memory metal or polymer, a non-shape memory metal such as stainless steel, or another non-shape memory fabric, embodiments of which are described in detail elsewhere herein. In some embodiments, conventional net-like structures such as used in IVC and other embolic filters can be utilized with systems and methods herein. In some embodiments, a thrombus capture device can be configured in some embodiments to axially lengthen throughout a working range, with or without radially shortening the device throughout the working range.

[0145] Figure 2 illustrates a close-up view of the proximal end 1000 of the thrombus capture systems of Figure 1. Illustrated is outer sheath 1 configured to, in some

embodiments, house suction catheter 2 therethrough. Also illustrated is the proximal end of the outer sheath 1 which can terminate in a connector 17 and hemostasis seal 190, of which another tube, such as the suction catheter 2 (and/or capture catheter 4) can be inserted coaxially into. The proximal end of the suction catheter 2 can also include a connector 3 having a seal, and a lumen of which the capture catheter 12 can be inserted into. The capture catheter 4 can also include a connector with a seal 18 at its proximal end. The guidewire tube 6 with a lumen to house a guidewire therethrough can be configured to fit coaxially within the capture catheter shaft 12. Also illustrated is an optional filter collection chamber 5 with a lumen fluidly connected to a lumen of the suction catheter 2. A proximal hub 17 is also illustrated, as well as a flush port 20. In some embodiments, suction is not required (and as such a suction catheter 2 is not included in the system), and the clot or other materials can be captured either mechanically, hydraulically and/or maceration via the ALTC device 8.

[0146] Figure 3 illustrates an axially-lengthening thrombus capture system 35 in the initial deployment configuration with the ALTC device 8 radially expanded, according to some embodiments of the invention. Also illustrated is nose tip 7 distal to the ALTC device 8. Relative axial movement of the outer tube 1 with respect to capture catheter 4 can allow for transformation of a first end (e.g., an expanded proximal end with a proximal-facing opening, or distal or laterally facing opening in other embodiments) of the ALTC device 8 from a radially compressed to a radially expanded configuration. In some embodiments, the proximal end opening of the ALTC device 8 includes a capture guide 11 that takes the form of, in some embodiments, a radially expandable shape memory partial or full ring-like annular structure that expands once free of the sidewall of the outer tube 1 along with a portion of the ALTC device mesh 8 attached to the capture guide 11. In the illustrated configuration, however, a significant portion of the surface area and/or the axial length of the mesh of the ALTC device remains in a compressed configuration within the lumen of the capture catheter 4, as the other end of the ALTC device mesh 8 is still operably attached, such as fixed to the outer diameter sidewall of the guidewire catheter 6.

[0147] Figure 4 illustrates a close up view of the distal end of the ALTC catheter system 35 in the delivery configuration including the distal end 1001 of the outer sheath 1 and nose tip 7, which can be atraumatic and tapered as shown, according to some embodiments of the invention.

[0148] The ALTC Device 8 can function to retrieve and capture materials such as thromboemboli. The capture catheter 4 is shown, along with the ALTC Device 8, capture catheter shaft body 12, pull wire 10, and thrombus capture guide 11.

[0149] As illustrated in Figures 5-9 for example, a thrombus capture guide 11 can attach to a portion, such as an open end of the ALTC Device 8 and one, two, or more capture pull wires 10 where the capture pull wires are positioned inside the side lumen of the suction catheter 2 or outside of the lumen in other embodiments, and extends proximally. The distal end of the capture pullwire 10 can be connected to the proximal end of the ALTC device 8 at the capture guide 11 as illustrated. The capture pullwire 10 can extend proximally through the length of the outer sheath 1, and the proximal end of the pullwire 10 can be pushed or pulled allow a user to control, such as adjust the axial length of the ALTC device 8, for example when axially elongating the ALTC device in a proximal direction. In some embodiments, the capture pullwire 10 and the capture guide 11 are the only elements attached to the proximal end of the ALTC device 8. In some embodiments, the capture pullwire 10 and the capture guide 11 can be made into a single component such as a Loop. In some other embodiments, the capture guide and the proximal end of the ALTC device is sutured in place using silk or polymeric filaments such as Ultra-High Molecular Weight polyethylene, Nylon, PET, PTFE. In some embodiments, the open end of the ALTC device is covered with a low durometer film or coating and is then folded over the capture guide 11 and suture to secure the assembly. In another embodiment, the open end of the ALTC device 8, capture guide 11 and sutured assembly is coated with a low durometer polymeric materials. Another method to secure the wire ends is to apply polymeric fabric either on the outer or inner surface of the tubular structure and secure via suturing in place with suture filaments. The fabric can be at least one piece initially wrapped either on the inner or outer surface of the tubular structure and then folded over to the opposite side to secure and protect with wire ends. The two sides of the fabric can secured to the tubular structure using suture filament. Other means of securing the fabric to the tubular structure such as thermal bonding, press, lamination, chemicals, mechanical securement, and lasers can be used in some embodiments. The closed end of the ALTC device can be attached to an outer surface of the guidewire tube 6, which in turn can be positioned within a lumen of the capture catheter shaft 12. As such, axial elongation of the ALTC device in a distal direction can be achieved by, for

example, movement of the guidewire tube 6 and pullwire 10 distally with respect to the capture catheter shaft 12. The axial elongation of the ALTC device in a proximal direction can be achieved by, for example, movement of the capture pullwire and capture catheter shaft proximally. The Thrombus Capture Guide 11 can be formed, for example, from metallic, shape memory, or other appropriate materials. In some embodiment, the thrombus capture guide 11 can include a loop configuration and be formed from nitinol shape memory wire of various geometries such as round, oval, elliptical, flat, and the like. The thrombus capture guide 11 can be formed of different shapes such as a circular loop, oval loop, z-shape, etc. In some embodiment, the loop 11 can be shaped set either into coils, multiple full circles, full circle or partial circles where the ends of the wire formed into two legs. The partial circle can be from, for example, 180 degrees to 359 degrees or 220 degrees to 359 degrees. The legs can be configured to be off-axis to the loop such that it can be right angle, acute or obtuse angle relative to the loop. It can be arcuate and form a partial or full ring as illustrated, and can circumscribe or otherwise form an outer diameter, and define the proximal-most end of the ALTC Device 8. The thrombus capture guide 11 can in some embodiments include a single loop or multiple loops positioned along the length of the ALTC Device 8 and not necessarily be present or have the entire guide 11 at the proximal-facing end opening end of the ALTC device 8. In some embodiments, the thrombus capture guide 11 does not include a loop. The ALTC Device tubular structure can be configured to be compressed and positioned within the Capture Catheter Shaft 12 lumen during introduction into the vascular system where the Capture Catheter Shaft 12 is configured to be positioned coaxially within and extend through the tubular structure and thrombus capture guide 11.

[0150] As illustrated in Figure 5, the Axial Lengthening Thrombus Capture Device (ALTC Device) 8 can be in some embodiments a generally tubular net-like mesh structure that is collapsible, expandable and configured to axially lengthen or shorten, such as within a working range, while maintaining or substantially maintaining its diameter within the working range to retrieve and capture foreign or otherwise unwanted materials within the body, including the vascular system such as blood clots, thrombus and/or foreign materials.

[0151] As shown, for example, in Figure 6, it can also be possible to lengthen the ALTC Device 8 in an appropriate direction, such as distally, by pushing the capture catheter 12 relative to the guidewire shaft 6, thereby allowing additional reserve radially compressed

length of the tubular mesh 8 to radially expand out of the confines of the lumen of the capture catheter 12 to axially lengthen the Thrombus Capture Device 8 and maintain its constant or substantially constant diameter through a working range. The other end of the ALTC device 8 at its radially compressed end can be fixed to the outer sidewall of the guidewire tube 6. A combination technique of, for example, manipulating the Capture Pull wire 10 attached to the Capture Catheter shaft 12 movement (Figure 6) can position the ALTC device at a desired location within the body lumen, and movement of the guidewire catheter 6 axially with respect to the capture catheter shaft 12 will also axially lengthen or shorten the ALTC Device 8 while maintaining its diameter through a working range. When the ALTC Device 8 is in the deployed (expanded) configuration, the ALTC Device 8 can also be stretched beyond the working range to an extended axial length to reduce its diameter.

[0152] Figure 7 illustrates the axial lengthening thrombus capture device 8 is fully deployed such that the attachment site 128 of the ALTC device 8 on the guidewire lumen 6 outer diameter is distal to the distal end of the capture catheter shaft 12 and the funnel tip 9 of the suction catheter is positioned within the ALTC, according to some embodiments of the invention.

[0153] Figures 8 and 9 illustrate different views of the initial deployment position of the ALTC Device 8 and the funnel tip of the optional suction catheter 2, according to some embodiments of the invention.

[0154] Figure 10 illustrates the partially deployed ALTC Device, according to some embodiments of the invention, where the ALTC device 8 is axially lengthened while maintaining its width normal to the axial direction.

[0155] Figure 11 illustrates an ALTC device deployed configuration where the funnel tip of the suction catheter is positioned inside the ALTC device, according to some embodiments of the invention.

[0156] As illustrated, a Guidewire Lumen Assembly 6 can include a nose tip 7, shaft, lumen, and a proximal connector and port where a guidewire can be inserted therethrough. The central lumen can have a distal opening in some embodiments The guidewire tube 6 can be used to navigate and track over the guidewire in the vascular system. The guidewire tube 6 can extend coaxially within the lumen of the catheter shaft 12. A nose tip 7 can form or otherwise connect to the distal end of the guidewire tube 6 6 shaft to aid

tracking the system through the vascular system, and can be atraumatic in some embodiments. The guidewire tube 6 can be made of polymeric materials such as, and not limited to Polyimide, Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE or ePTFE. The guidewire tube 6 can have, in some embodiments, radiopaque markers along its length for use to indicate the location of the ALTC Device, initial deployment, partial deployment, final deployment, the percent of length deployed and/or any combination thereof.

[0157] Figure 12 illustrates the Axial Lengthening Thrombus Capture (ALTC) assembly 8 without the outer sheath, capture catheter 4, or guidewire catheter 6 present for clarity. As illustrated, end 800 with proximal-facing opening 802 of the ALTC device 8 is in the expanded (deployed) configuration and is fixed to the thrombus capture guide 11 and capture pullwire 10, according to some embodiments of the invention. For purpose of illustration, a reserve portion of unexpanded mesh 81 including end 804 is in a collapsed configuration and extends proximally toward attachment site 128.

[0158] In some embodiments, the tubular mesh structure 8 can axially lengthen or shorten without reducing or substantially reducing its diameter through a working length/axial range because the radially expanded portion of the tubular mesh structure is subject to none or minimal tension as it elongates or shortens axially through that axial working range. Not to be limited by theory, this can be accomplished at least in part because the tubular mesh structure can elongate axially throughout the working range by unrolling, everting, or otherwise expanding or transforming a radially compressed reserve segment of tubular mesh, such as unexpanded mesh 81. As such, an expanded "end" opposite the end of the radially expanded device with the capture guide and proximal end opening, such as dynamic fold point 88 of the radially expanded portion of the tubular mesh 8 may not be the absolute end of the tubular mesh fixed to a tubular shaft at zone 128, but rather an intermediate dynamic fold point 88 that is not fixed at that point to a tubular shaft, and as such not under any, or not substantially under any tension. The radially compressed reserve segment of tubular mesh 81 thus extends back in a different or the opposite direction (e.g., proximally in some cases) and ends at the terminal fixation point to the tubular shaft (e.g., at location 128). If it has not exceeded the working length of the expanded tubular shaft, the distance between the dynamic fold point 88 and the distal end of the entire catheter system

(e.g., the nose tip) can increase as the radially expanded portion of the tubular mesh 8 lengthens, and the radially compressed reserve segment is used up.

[0159] Once the compressed reserve segment 81 of tubular mesh 8 is nearly or completely expanded to, or almost to its actual end at 128 and the tubular mesh 8 is axially elongated beyond its working length range, further axial elongation can start to exert significantly increased tension on the fully axially expanded tubular mesh structure 8, causing it to assume a configuration in which it radially contracts as it further axially lengthens.

[0160] A tubular net-like structure with one open end as disclosed above and elsewhere herein can be highly advantageous as a relatively small axial segment of the tubular mesh can be radially expanded and be fully functional to capture emboli and/or other materials in tight working environments, such as in obstructed body lumens with limited space to maneuver distal to the treatment location of interest. If it is desired that a greater axial length of radially expanded tubular mesh is required, such as to capture a relatively long length thromboemboli, the compressed reserve segment of tubular mesh can be unrolled, everted or otherwise expanded or transformed to a specific axial length as desired. Having a compressed reserve segment that can be stored along the length of the catheter system in a compact manner can be very advantageous in providing a long effective capture length tubular mesh without requiring the entire capture system to have a long fixed length as would be required in conventional filters/nets, which can be fixed at both ends and thus are functional and fully radially expanded when the first end is spaced apart from the second end at a single specific axial distance.

[0161] As illustrated in Figure 12, some or most of the axial length of the ALTC device, e.g., the tubular mesh structure 8 remains radially compressed as part of the reserve segment between the outer diameter of the guidewire catheter 6 and the inner diameter of the shaft 12 of the capture catheter (distance between of which is length L12B), with the radially expanded portion of the tubular mesh structure 8 being defined along the axial length between proximal end 800 with proximal-facing opening 802 and the dynamic fold point 88 (distance between of which is length L12A), the sum of L12A and L12B amounting to the absolute length of the tubular mesh 8. In this initial configuration, the length L12B of the

radially compressed reserve segment 81 can be about, or at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or more of the absolute length of the tubular mesh 8.

[0162] Figure 13 illustrates the axial lengthening thrombus capture device 35 in the initial deployed configuration, according to some embodiments of the invention, with the radially expanded segment of the mesh 8 between end 800 and dynamic fold point 88 and the reserve compressed segment (not shown) extending axially proximally past end 800 to fixation point 128 on the outer surface of the guidewire shaft (not shown). Figure 14 illustrates the thrombus capture element 15 of the ALTC device that can include a stent, braided, woven, laser cut, or other mesh such as a net-like structure, according to some embodiments of the invention. The tubular mesh structure need not necessarily be porous, and can be covered by nonporous or other layers. The ALTC Device tubular mesh structure 8 can be made of any suitable polymeric materials such as but not limited to polyethylene terephthalate (PET), polyethylene (PE) polypropylene (PP), nylon, silk, UHMWPE, PTFE, Kevlar, cotton, and/or metallic materials including superelastic material, nitinol, stainless steel, cobalt-chromium-nickel-molybdenum-iron alloy, or cobalt-chrome alloy, Chronichrome, or Elgiloy. The tubular structure can be braided, extruded, woven, knitted, laser cut, dip, film cast from a polymeric and/or metallic flat sheet, metallic filaments, polymeric filament or fabric in some embodiments. The tubular structure can be film cast with laser cut holes in some embodiments. The tubular structure can also be braided from polymeric and/or metallic filaments or any combination thereof. In some cases, the tubular structure can be made of nitinol wire mesh having multiple wire strands. Furthermore, the tubular structure can include at least one wire strand made of high radiopaque material such as tantalum, platinum, gold or nitinol drawn filler tube with a platinum core to enable viewing the tubular structure under fluoroscopy. In some embodiments, the tubular structure can include one, two, or more radiopaque markers. Depending of the diameter of the ALTC device, the number of wire strands can range from, for example, 1 to 576 wire strands. The ALTC Device can have 2, 4, 144, 288, or another number of wire strands in some embodiments. In some embodiment, the ALTC device is configured to have one wire strand. The wire strand diameter can range from, for example, .0002" up to .015". In some embodiments, the wire strand diameter is about 0.001". The tubular structure can be impermeable in some sections, permeable in other sections and/or a combination thereof. The

tubular structure can be non-coated, or coated with one, two, or more anti-thrombogenic agents such as heparin to prevent clotting, or other therapeutic agents. The tubular structure can also be coated with a hydrophilic or hydrophobic agent. The tubular structure can have different pore sizes to assist with capturing small emboli or larger pore sizes to allow perfusion or blood flow. The tubular structure can have uniform pore sizes through the entire length or a combination of different pore sizes along its entire length. For example, when utilized as a cerebral protection filter, the ALTC device pore size can be sufficiently large to capture clinical relevant emboli size as small as, for example, about 200, 175, 150, 125, 100, 75, 50 microns or less while maintaining perfusion or blood flow. During retrieval, the ALTC device 8 can be repositioned to a particular section of the tubular structure that has smaller pore size and retrieve the blood clots/thrombus. In some embodiments, the ALTC device can deploy and enmesh within the blood clot to capture the blood clot in, for example, the neurovascular system. During retrieval, the ALTC device can lengthen sufficiently beyond the captured thrombus to create a protection filter distal to the captured thrombus. This can be clinically beneficial to prevent thrombus from dislodging during retrieval and thereby prevent secondary stroke. The ALTC Device tubular structure **8** proximal end can, in some embodiments, attach to the guidewire tube **6** outer surface, such as near attachment site 128. In some embodiments the proximal end of the ALTC Device tubular structure can be wrapped and sutured with polymeric filaments and encapsulated with low durometer polymeric material to fixably secure the wire ends to the shaft, such as the guidewire lumen assembly. Other means of attachment to secure the wire ends such as mechanically, thermally or chemically bonding the polymer to secure the wire ends can be used. In another embodiment, the ALTC Device proximal end can be fixed to the outer surface of the guidewire shaft using adhesive and is sandwiched between the outer surface of the guidewire shaft and cover tubes.

[0163] Figures 15A-C illustrate another embodiment of a clot capture system, a distal portion of the ALTC System and a proximal portion of the ALTC System respectively. Figure 15A schematically illustrates the catheter system 35, while Figure 15B shows the distal nose tip 7 operably connected to the distal end of the guidewire shaft 6 that includes a lumen for a guidewire to pass therethrough. One end of the ALTC device 8 can be fixably attached to the guidewire shaft 6 at one or more locations 128 and the other end 800 that

includes proximal or distal-facing opening 802 is attached to capture guide 11, such as in the form of a loop 11, and it is movable axially distally and proximally via capture guide 11 Loop can include, for example, one, two, or more linear segments that extend proximally from the loop 11 onto the capture catheter shaft 12, which are in turn secured proximally to the capture catheter shaft 12 by a the sleeve 30. The sleeve 30 in some embodiments can be present instead of the pullwire(s) extending proximally all the way through the device. This can in some cases be advantageous ergonomically and allow for more streamlined control at the proximal end for a user. . The axially expanded length of the tubular mesh 8 is shown extending from end 800 to dynamic fold point 88, with the reserve length of compressed tubular mesh (not shown) running proximally along the outer sidewall of the guidewire shaft 6 to its end at fixation point 128. Figure 15C illustrates an embodiment of the proximal end of the system, including one or more flush ports 13, hub 55 of the outer sheath 1, hub 155 of the capture catheter 12, and hypotube pusher 14, and proximal-most hub 15 with a lumen configured to slide a guidewire therethrough. The hypotube pusher 14 can in some embodiments be coextensive with, such as welded or otherwise attached to the third tubular member (e.g., the guidewire tube 6), and when manipulated by an operator effect axial movement of the guidewire tube 6 in a proximal or distal direction. In some embodiments, there can be an integral guidewire tube 6 from the proximal most hub 15 to the distal nose tip 7. The third tubular member 14 can be configured to be placed within a lumen of a second tubular member (e.g., capture catheter shaft 12), such as at its proximal end at hub 155. The second tubular member can be configured to be placed within a lumen of a first tubular member (e.g., outer sheath 1), such as its proximal end at hub 55. In some embodiments, hub 55 and hub 155 can include complementary threads or other reversible locking features to allow for the outer sheath 1 to be reversibly coupled to the capture catheter 12 to allow for axial movement of the two tubular members in concert with each other. Uncoupling the hubs 55, 155 can allow for axial movement of the capture catheter 12 with respect to the outer sheath 1 and vice versa.

[0164] Still referring to Figures 15A-C, in some embodiments as illustrated, if a sleeve 30 is present, no separate pullwire extends from the capture guide 11 proximally to the proximal end of the system. In some such embodiments, axial movement of the capture catheter shaft 12 proximally with respect to the guidewire tube shaft 6 facilitates radial

expansion of at least a portion of the ALTC device 8 and positioning of the ALTC device 8 within a body lumen. Axial lengthening and/or shortening of the ALTC device 8 in some embodiments can be effectuated by movement of the guidewire tube 6 (of which the other end of the ALTC device not attached to the capture catheter 12 via sleeve 30 is attached to, such as at attachment site 128) with respect to the capture catheter 12 and/or movement of the capture catheter 12 with respect to the guidewire tube 6.

[0165] Figure 16A illustrates another embodiment of a distal portion of the axial lengthening thrombus capture device 35 in the delivery configuration, according to some embodiments of the invention.

[0166] Figure 16B illustrates the axial lengthening thrombus capture device in the initial deployed configuration wherein the outer sheath 1 is retracted, e.g., proximally to radially expand an end that includes the proximal-facing opening 802 of the axial lengthen thrombus capture device (e.g., tubular mesh 8) to dynamic fold point 88 which serves as the effective expanded distal end of the tubular mesh 8. The capture guide 11 and associated terminal wires 10 are operably coupled to the sleeve 30, and the sleeve 30 is coupled to the outer wall of the capture catheter shaft 12, according to some embodiments of the invention. The compressed reserve length segment (not shown) of the tubular mesh, such as about or at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% or more of the absolute axial length of the ALTC device 8 (e.g., tubular mesh) taking into account folds remains inverted, rolled up, and/or otherwise radially compressed and circumscribed by the inner sidewall of the capture catheter shaft 12, up to the point where the other end of the ALTC device 8 is attached on an outer diameter of the guidewire tube 6 at attachment site 128. As illustrated, the dynamic fold point 88 varies along the length of the tubular mesh 8 depending on the length of the compressed reserve length segment that is expanded. The dynamic fold point 88 "floats" and is not directly attached to the guidewire shaft 6 nor the capture catheter shaft 12, and as such moves axially proximally when the expanded segment of the tubular mesh 8 axially lengthens.

[0167] As such, when the guidewire shaft 6 with distal nose tip 7 is maintained in a constant position, axial elongation of the expanded tubular mesh 8 results in an increase in the axial distance D between the distal nose tip 7 and the dynamic fold point 88, so distance D3 is greater than D2, which is in turn greater than D1. Furthermore, as shown in Figure 16B

the first end 800 of the tubular mesh is distal to the unexpanded end of the tubular mesh (at location 128) fixed to the outer sidewall of the guidewire tube 6, but moves closer proximally in Figure 16C and becomes proximal to the unexpanded end of the tubular mesh at Figure 16D while the dynamic fold point 88 moves proximally but is still slightly distal to the unexpanded distal end of the tubular mesh 8 in Figure 16D, where the expanded axial length is even greater, or in some cases at its maximum working length. As noted, the diameter/width of the expanded tubular mesh remains constant or relatively constant between Figures 16A-D. Upon exhaustion of the compressed reserve segment which has transformed into expanded tubular mesh, continued axial expansion can result in increased tensile forces on the tubular mesh, resulting in a configuration in which radial contraction begins to occur.

[0168] Figures 17A-D illustrate different configurations of the ALTC device, according to some embodiments of the invention. During delivery, the capture guide 11 (e.g., ring-shaped in some embodiments) connected to the expanded end 800 of the tubular mesh 8 can be configured to collapse within the outer sheath 1 lumen during introduction into the vascular system and is configured to radially expand first when the outer sheath 1 retracts proximally while the length of reserve tubular mesh structure 81 of the ALTC device 8 extending proximally from the dynamic fold point 88 to fixation point 128 on the guidewire shaft 6 remains compressed in the capture catheter shaft 12 lumen. The dynamic fold point 88 serves as the effective expanded distal end of the tubular mesh 8. Upon further retracting the thrombus capture guide 11 via pulling the Capture Pull Wire 10 (or sleeve 30 as shown) and capture catheter shaft 12 proximally, the portion of the ALTC Device 8 tubular structure that is compressed within the Capture Catheter Shaft 12 lumen expands and can transform via, e.g., roll out proximally, inversion, and/or eversion, and axially lengthening the ALTC Device 8. Advance of the Capture Catheter Shaft 12 distally can collapse at least a portion of the ALTC Device 8 tubular structure into the Capture Catheter Shaft 12 lumen, as previously shown in Figures 7 - 9. The ALTC Device's ability to expand, roll out, axially lengthen and maintaining a substantially constant diameter through a working range creates a cavity (or pocket) within the sidewall of the radially expanded segment of the ALTC Device 8 to retrieve and capture foreign materials such as, for example, blood clots/thrombus. In another embodiment a sleeve **30** (Figures 16A-D and 17A-D) can be used to couple, such as permanently, the Capture Pull Wire **10** to a portion of the Capture Catheter shaft **12** to enable

both components to operate together. Coupling the Capture Pull Wire 10 and the Capture Catheter shaft 12 can allow the user to manage the capture device more efficiently and easily. In another embodiment, the capture guide 11 takes the form of a loop and can attach to the Sleeve 30, which is coupled to the Capture Catheter Shaft 12.

[0169] Figures 18A-B illustrate an embodiment of a distal portion of the axially-lengthening thrombus capture system with a cover element 80 radially outward of, and partially or completely circumscribing the capture catheter shaft 12 or loop 11 of the ALTC device, which can be in the shape of a ring as illustrated. In some embodiments, the cover element 80 can function to protect one or more of the capture guide, ALTC device, and the luminal wall of the lumen being treated. The ring 80 can also be configured to provide a seal against the luminal wall, e.g., of the vessel, to prevent leakage or migration or embolization of unwanted material around the tubular mesh 8. In some embodiments, the cover 80 can also include a skirt portion. The cover 80 can be axially and/or radially expandable, such as an inflatable balloon, a soft polymer, a gel, a foam, a textile fabric, shape memory, and/or include other materials. If the cover 80 is expandable, it can be configured to reversibly contract to allow for fluid flow around the cover 80 once the procedure is completed. Also as illustrated is sleeve 30 serving to attach the capture guide 11 connected to one or more wires 10. Sleeve 30 can include one or more apertures 307 that serve as relatively radiolucent markers, and/or the sleeve 30 could be made of a radiopaque material in some embodiments. Also as illustrated, the capture catheter 12 as well as guidewire tube 6 can extend through the tubular mesh 6 from first end 800 through dynamic fold point 88. The reserve segment of compressed tubular mesh is not shown for clarity.

[0170] Figures 19A-C illustrate an embodiment of an axially-lengthening thrombus capture system, configured to allow the guidewire 350 to distally exit the system prior to exiting the luer/proximal-most port 15 at the proximal end of the system. The guidewire's proximal end can exit the system through an aperture or slot 351 in the sidewall once it passes the reversibly couplable hemostasis seals 55, 155 of the outer sheath 1 assembly and the capture catheter 12 respectively. In some embodiments, the guidewire 350 is configured to exit sideways, that is laterally. In some embodiments, a keyed cap 36 is positioned distal to the hemostasis seals 55, 155, which is in turn proximal to a shaft 14, which can serve as a hypotube pusher connected to or coextensive with the guidewire tube

and be made of metal in some embodiments. The shaft 34 can include a sidewall groove 351 fully or partially axially from the port 15 to the hub 155 and/or one, two, or more discrete slots as illustrated.

[0171] Such embodiments can be advantageous, for example, to utilize a shorter length guidewire needed when the delivery system overall length increases. In some embodiments, when the ALTC capture device increase in length, the hypotube is also lengthened to accommodate thus increase the distance for user to manage the guidewire and system. The side guidewire feature can minimize the distance resulting in better handling, and the proximal end of the guidewire 350 need not necessarily extend past the proximal end of the entire system, such as at port 15. As such, the guidewire as part of the system can advantageously have a total length in some embodiments that is the same as, or even less than the axial length of the entire material capture system from proximal port 15 to distal nose tip 7, which may otherwise not be possible.

[0172] The guidewire 350 can be located near the hemostasis seals 55, 155 area during the procedure, and as such the entire procedure/operation can be done with the user not needing to look down to see where the components are located. As such, the user can hold the hemostasis seals 55, 155 housing in one hand while at the same time manipulating the guidewire 350 and hypotube pusher 14 with the other hand in the general area without substantially moving away from the area. The users can hold and maneuver the hypotube pusher 14 or hold and maneuver the guidewire 350 or hold both the hypotube pusher 14 and guidewire 350 at the same time. In some embodiments, the inner diameter of the shaft 14 with groove can be generally larger than the guidewire 350 that allows the guidewire 350 to exit laterally. The keyed cap 36 with a boss profile can mate to the groove of the metal shaft 14 to prevent the metal shaft 14 from rotating and still allow the shaft 34 to slide back and forth axially.

[0173] In some embodiments, an Expanding Guide Catheter 50 (shown in Figures 20-21 for example) is a discrete catheter that can be utilized together with the clot capture system, and functions to assist in retrieving the ALTC Device 8 (and associated catheter system 35) and capture blood clots and other undesired materials. In some embodiments, the Expanding Guide Catheter 50 can include a first tubular member, such as an outer sheath 49 with a proximal end, a distal end, a lumen extending from the proximal end and the distal

end, and a port on the proximal end, which can be coaxial as illustrated or offset from the longitudinal axis of the outer sheath 49. A second tubular member, such as inner catheter 54 can have a proximal end, a distal end, and a lumen extending from the proximal end to the distal end and can be configured to be placed within the lumen of the outer sheath 49. The inner catheter 54 can also have a proximal port, a removable obturator 51 positionable in the inner catheter lumen, distal expandable funnel tip 52, expandable shaft section 53 proximal to the funnel tip 52, an inner shaft 54, and connectors with seal 55. The obturator 51 can be used to aid in inserting and navigating the Expanding Guide Catheter 50 in the vascular system. The obturator 51 can be made of polymeric materials such as Polyethylene, Nylon, Pebax, Polyurethane, PET or PTFE for example. The obturator 51 can have a tapered distal end in some embodiments to aid in introducing the Expanding Guide Catheter 50 in the vasculature or other body lumen. Alternatively, other embodiments of the obturator 51 includes an expandable member such as a balloon operably connected to the distal end. Expansion of the expandable member, such as inflating the balloon can create a smooth tip transition. The balloon can be made of polymeric materials such Nylon, Polyurethane, PET, etc. Inflating the balloon can also secure the balloon obturator to the guide catheter such that when applying axial load proximally to the obturator shaft will articulate the tip of guiding catheter. The funnel tip 52, illustrated for example in Figures 20B-C, can include a distal funnel-like segment, and be adjacent to an expandable proximal segment 53 wherein it is connected to a more proximal portion of the inner shaft 54. The funnel tip 52 can be, in some embodiments, made of either polymeric and/or metallic materials. It can be either tubular in shape, woven or braided. The braid configurations can be, in some cases, 1x1 or 1x2 or 2x1 or 2x2 or any combination thereof. The picks per inch (PPI) can range from, in some embodiments, 5 to 60. The number can be, in some embodiments, from one wire filament up to 288 wire filaments. The wire shape can be, e.g., round, flat, oval, rectangular or square. The wire diameter can be, e.g., from .0005" up to .015". The flat wire thickness can be, e.g., from .0005" up to .010" and the wire width can be, e.g., from .001" up to .030". The funnel tip 52 distal segment can have various shapes or configurations to allow better retrieving the blood clots or thrombus. In some embodiments, the funnel tip 52 distal segment has a large open end where it contacts the vessel wall when expanded and transitions to smaller opening proximal segment 53. The distal segment open end can range from, in some embodiments,

about 5 mm to about 80 mm in diameter. The funnel tip distal segment 52 also has, in some embodiments, openings or holes (perforations) along the side to allow blood flow. The funnel distal segment 52 can have either one layer of braid or multiple layers. In some embodiments, the funnel distal segment has two layers. In some one layer embodiments, the most distal open end of the funnel does not have the wire end terminate or exposed such that the wire ends are located at the proximal end of the funnel assembly. The funnel tip proximal segment 53 can be configured such that it is capable of expanding and receive the ALTC device and captured blood clots or thrombus. The proximal segment 53 can be configured to expand to receive object that is larger than its inner diameter and recovery after passage. The proximal segment 53 can include a PTFE inner layer and compliance and/or low durometer polymeric materials such as Polyurethane, Silicone, Tecoflex, Pebax 25D and/or 35D or braid and/or non-braided such as Pebax/Propel/BaSO4 outer layer. The proximal segment 53 can also include other lower durometer polymeric materials. The composite funnel tip and proximal segment can be laminated via dipped coat, spray or reflow process or any combination thereof. The braid materials can be either metallic and/or polymer and/or combination thereof. The braid configurations can be, e.g., 1x1 or 1x2 or 2x1 or 2x2 or any combination thereof. The picks per inch (PPI) can range from, for example, 5 to 60. The number can be, e.g., from one wire filament up to 288 wire filaments. The wire cross-sectional shape can be, for example, round, flat, oval, rectangular or square. The wire diameter can be, e.g., from .0005" up to .015". The flat wire thickness can be, e.g., from .0005" up to .010" and the wire width can be, e.g., from .001" up to .030". In some embodiments, an advantageous feature is the ability to expand and contract without buckling under compression. The inner diameter can range from, e.g., 2F to 30F. In some embodiments, the inner diameter can range from, e.g., 6F to 18F. The expanded length section can be up to the entire catheter length. In some embodiments, the length is about 20cm. The funnel distal 52 and proximal segment 53 can also be made as one component wherein the braid configuration is continuous. Coupled to or continuous with the funnel tip proximal segment 53, the inner shaft 54 can be made from materials such as and not limited to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, or ePTFE. The inner shaft 54 can be braided or non-braided. The outer shaft 49 can function to slide over and collapses the funnel tip and provide support during introduction into the vasculature. The outer shaft 49

retracts to deploy the funnel tip. The outer shaft 49 can be made of polymeric materials such as Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, FEP or combination thereof. The outer shaft 49 diameter can range from, e.g., 4F to 34F. The outer shaft 49 inner diameter can range from, for example, 3F to 32F. In some embodiments, the inner diameter has substantially the same throughout the lumen shaft. In some embodiments, the inner diameter at the distal end is larger than the proximal end inner diameter. The change in inner diameter can be in one location, two or more locations. The outer diameter is substantially the same throughout the entire length of the outer sheath shaft. In some embodiments, the outer shaft 49 is about 22F or smaller in diameter. The outer shaft 49 can include a radiopaque marker at the distal end or radiopaque filler along its shaft length for visibility under fluoroscopy. In some embodiment, the outer shaft can be deflectable (via, for example, one, two, or more pullwires on the distal end) at various locations and multiple deflectable directions along the shaft length to accommodate various tortuous paths such as entry into the right atrium, right ventricle, main pulmonary artery, and left and right pulmonary artery for pulmonary embolism applications.

[0174] Still referring to Figures 20A-20D, in some embodiments the expanding guide catheter 50 can be utilized to retrieve blood clots or thrombus. The expanding guide catheter 50 and obturator 51 can be introduced over a wire into the vasculature and advanced near the treatment area. The obturator 51 is removed. The outer member 49 of the expanding guide catheter is retracted proximally to expand the funnel tip 52 and the expandable section 53 of the guide catheter 50. In some embodiments, the guide outer shaft 49 is inserted into the vessel together with the obturator 51 and the obturator 51 is removed once the outer shaft 49 is in a desired position. The inner guide member can include the funnel tip 52, proximal segment 53 and the inner shaft 54 is then inserted into the outer shaft 49 up to the distal tip of the outer shaft 49. The outer shaft 49 can then be retracted (or the inner shaft 54 advanced) to expand and deploy the distal funnel 52 and the proximal segment 53. The capture catheter system 35 is inserted over the wire and through the lumen of the expanding inner guide member 54. Once the ALTC Device 8 is deployed and captures the blood clots, the ALTC Device 8 is retracted along with the captured blood clots into the funnel tip 52 and expanding guide inner member 53, (shown later in Figure 50). When high resistance is encountered at the funnel tip due to the large blood clot position at the tip, the guidewire lumen can

advances distally to lengthen the ALTC Device. Lengthening the ALTC device can create additional space within the ALTC device such that the blood clot volume is redistributed thereby reduces the large blood clots pooled at the tip of expanding guide catheter. The expanding guide catheter distal section also allows larger clots to be captured due to its expandability increasing the lumen size. Continuing to retract the ALTC device will retrieve additional captured blood clots inside the expanding guide catheter. Repeated lengthening of the ALTC during the procedure will continue to redistribute the clot and retrieve inside the Expanding Guide Catheter, advantageously allowing for improved thrombus processing and redistribution. In some embodiments, a kit can include a capture catheter system 35 as described herein and configured to be reversibly placed within, and move axially with respect to an inner lumen of a discrete expanding guide catheter system 50 as described herein.

[0175] Figure 21D illustrates an embodiment wherein a cover tip 710 encapsulates the distal end of the outer cover of the expanding guide catheter system, according to some embodiments of the invention. In some embodiments, a guide catheter is part of a hemostasis guide system that can includes one or more obturators, an inner shaft member, an outer shaft member, and a hemostasis valve disposed within a housing of the system. The inner shaft member can include a non-expandable braided proximal segment, a distal expandable segment and a braided funnel distal end which can be as described elsewhere herein. The inner shaft member can be positioned within the lumen of the outer shaft member. The outer shaft member can have, for example, a braided polymeric configuration with a flexible kink resistance distal segment. The inner shaft and outer shaft member can be attached to the housing body. The housing body can be, for example, at a proximal end of the guide catheter system. The hemostasis valve can be disposed within the housing body. The hemostasis valve can be in some embodiments a flexible disc-like valve. The hemostasis valve can be configured to provide hemostasis and prevent leakage, such as with nothing inside. In some embodiments, the system can be configured for use with a 0.035" guidewire, 5Fr catheter, and include sizes between about 12F and about 17F, such as about 12F, 16F, or 17F. The hemostasis valve can include two surfaces, an upper surface and a lower surface. The upper surface and lower surface can be opposing surfaces in some embodiments. The upper surface can include a slit extending partially across the upper surface and a depth into the valve without protruding all the way through the thickness of the

lower surface. The lower surface can include a slit extending across the lower surface and a depth into the valve without protruding all the way through the thickness of the upper surface. In some embodiments, the valve has a diameter of between about 0.50" and about 1.00", such as about 0.5", 0.6", 0.7", 0.8", 0.9", or 1.0". In some embodiments, the valve has a thickness of between about 0.050" and about .0100", such as about 0.075". In some embodiments, the slits can have a depth/thickness of between about 0.020" and about 0.060", such as about 0.040". The midpoint of a slit can be in some cases at or proximate the center of the surface of the disc. The upper slit and the lower slits can intersect at, for example, a point location within the valve. The slits can extend beyond the intersection point by a desired distance, such as between about .001" and about .010" or approximately .005" beyond the intersection point. In some embodiments, the arrangement of the slits along the valve permits insertion and removal of shafts therethrough while preventing leakage of blood or air back across the valve. The upper and lower slits can have long axes that intersect at an angle. The angle could be in some embodiments between about 45 degrees and about 135 degrees, or about 45, 60, 75, or 90 degrees in some cases.

[0176] Figures 22-24 illustrate the outer sheath assembly 1 of the capture device, according to some embodiments of the invention. The outer sheath 1 can function to contain, protect, and deliver the Axial Lengthening Thrombus Capture Device (tubular mesh 8 (not shown) to the desired anatomical location, such as in a radially compressed configuration. As shown in Figure 22, the Outer Sheath 1 can include a soft atraumatic distal tip, a shaft body that can be tubular in some embodiments, an interior channel/lumen configured to house and reversibly couple at its proximal end a second tubular member, such as a capture catheter as described elsewhere herein, and a proximal connector with a seal 55 and flush tube/port 13. The Outer Sheath 1 can be made from suitable medical grade materials, including but not limited to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, PEEK, PEBAX/Propell and polypropylene. The polymeric materials can include radiopaque materials such as, for example, barium sulfate, bismuth subcarbonate or bismuth trioxide to enable viewing under fluoroscopy. The radiopaque materials can form one, two, or more discrete marker elements in some embodiments, such as at the distal tip, and/or spaced apart at regular or irregular intervals along the length of the outer sheath 1. The outer diameter of the outer sheath 1 can range from, for example, 3F to 30F. The inner diameter of the outer

sheath 1 can range from, for example, 2F to 28F. In some embodiments, the inner diameter is substantially constant throughout the interior channel, e.g., the lumen shaft. In some embodiments, the inner diameter at the distal end is about or at least about 10%, 20%, 30%, 40%, 50%, or more than the proximal end. The change in inner diameter can be, for example, stepwise or gradual in one location or two or more locations. The outer diameter can be substantially the same the entire length of the catheter, in some embodiments. The outer sheath 1 working length can be, in some cases, from about 10cm to about 150cm. In some embodiment, the Outer Sheath 1 working length is about 135cm in some embodiments. The Outer Sheath 1 shaft can be braided or non-braided. In some embodiments, the Outer Sheath 1 shaft can be deflectable (via, for example, one, two, or more pullwires on the distal end) at various locations and multiple deflectable directions along the shaft length to accommodate various tortuous paths such as entry into a left or right heart atrium, heart ventricle, main pulmonary artery, and left and right pulmonary artery for pulmonary embolism applications, or a vein such as the great saphenous vein, superficial femoral, common femoral, SVC, IVC, or other upper or lower extremity, visceral, or other superficial or deep veins for deep venous thrombosis removal applications. The distal end of the shaft of the outer sheath 1 can be configured to deflect up to 360 degrees in some cases. Additionally, the distal tip of the Outer Sheath 1 can be configured to deflect or bias toward or away from the vessel wall. The distal tip of the outer sheath 1 can include one, two, or more radiopaque markers to indicate tip location. Alternatively, the distal tip can include radiopaque materials such as, for example, Barium Sulfate, Bismuth Subcarbonate or Bismuth Trioxide. Figure 23 and 24 illustrate the distal end and proximal end of the outer sheath assembly respectively. As shown in Figure 26, the proximal end of the outer sheath 1 connects to the outer sheath connector 55 with seal and coupler to a capture catheter connector, and flush port 13.

[0177] Figure 25 illustrates the capture catheter assembly 12, according to some embodiments of the invention, showing catheter shaft 12 and outer sheath 1. Figure 26 illustrates the proximal end of the capture catheter, according to some embodiments of the invention, showing a connector with seal 155 operably connected to a flush port 13.

[0178] Figure 27 illustrates an embodiment of a key cap 36 feature to prevent or inhibit rotation of the hypotube pusher 14. As illustrated, the key cap 36 can be a tubular member with a lumen to fit the hypotube pusher 14 therethrough. The lumen is non-circular

in some embodiments, and/or have a non-circular zone, or otherwise configured to prevent or limit rotation. In some embodiments, the lumen includes teeth or other projections into the lumen as shown to prevent undesired rotation of the hypotube pusher. In some embodiments, the lumen or a portion thereof has a square, rectangular, triangular, oval, pentagonal, hexagonal, or other non-circular geometry, and configured to limit rotation.

[0179] In some embodiments, as illustrated in Figures 28-29 for example, an optional suction catheter 2 can function to aspirate thrombus within the ALTC Device 8. The suction catheter 2 can include in some embodiments a distal funnel tip 9, elongate shaft body 16, and proximal connector with seal 3. Figure 30 illustrates a close-up view of the funnel tip 9 which can be attached at the suction catheter shaft 16 distal end to aid in retrieving the thrombus and allow efficient suction. The funnel tip 9 can be made of, for example either polymeric and/or metallic materials. It can be tubular in shape, woven or braided, in some embodiments. Funnel tip 9 can be in various configurations to allow better retrieval and suction. In some embodiments, the funnel tip 9 has a funnel shape with a first, larger distal diameter, a transition section, and a second, smaller proximal diameter as illustrated. The suction catheter shaft 16 creates a pathway for the aspirated thrombus to travel proximally and exit the body and in some embodiments into the optional filter collection chamber. The shaft can be of various diameters, lengths and/or geometries to aid in the removal of materials such as blood clots. The suction catheter shaft can be made from suitable materials such as and not limited to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, PEEK, and polypropylene. In some embodiments, the suction catheter Shaft distal end is expandable so to accommodate large amount of blood clots. The suction catheter 2 can attach to the proximal end of filter collection chamber 5 to enable thrombus aspiration (or removal). In some embodiments, the suction catheter shaft 16 is deflectable at one, two, or more locations along the shaft length to accommodate various tortuous paths such as entry into the right atrium, right ventricle, main pulmonary artery, and left and right pulmonary artery. A proximal flush port 13 is also illustrated.

[0180] In some embodiments, a mechanical thrombectomy tool such as macerator 19 shown in Figures 32-41 for example, can function to disrupt and break up the thrombus within the ALTC Device 8. The macerator 20 can include a disruptor 19, shaft 22 and proximal connector with seal 21. Adjustable Touhy knob 23 distally is also shown just

proximal to disruptor 19. The disruptor 19 can be attached to the distal end of the shaft 22. The macerator 20 can have various end effector tip configurations as illustrated in Figures 35-41 depending on the desired clinical result to break up the thrombus within the ALTC Device 8, including a bulbous shape (Figure 36), proximal and distal bulbs with a narrow waist (Figure 37), a plurality of proximal and distal bulbs with a narrow waist each offset by an angle, such as about 90 degrees (Figure 38), a flower petal design with petals radiating radially outwardly from a central hub (Figure 39), a hemi-petal design (Figure 40), or a substantially linear design orthogonal from the longitudinal axis of the shaft 22 (Figure 41). The disruptor 19 collapses during insertion through the suction catheter 2 system and expands once exiting the catheter. The disruptor 19 can be made of, for example, metallic materials such as stainless steel, Nitinol, cobalt chrome, etc. The macerator can be activated either by manual rotation, manipulation and/or a motorized handle.

[0181] To macerate the thrombus, the macerator 19 is inserted through the suction catheter 2 and position within the ALTC Device 8. A manual technique applies to the luer connector 21 of the macerator 19 by rotating the luer connector 21 causing the disruptor 20 to rotate thereby breaking up the thrombus. Alternatively, the macerator 19 can be used with a motorized handle (not shown). Traversing the disruptor 20 axially through the entire length of the ALTC device 8 can aid in breaking up the thrombus.

[0182] The filter collection chamber 5 (Figure 42) can function to suction and collect the blood clots. The filter collection chamber 5 can include, for example, a collection chamber 325, filter 324, plunger 323, inflow port 327 and outflow port 326. The filter collection chamber 5 can have an outflow port 326 attaching to the suction catheter 2 connector and an inflow port 327 where a syringe or a similar device can attach for aspiration. The collection chamber 325 has a filter system 324 residing inside the chamber 325 to allow filtering the blood and thrombus. The chamber 325 also has a plunger 323 for use in injecting fluid such as saline to fill the chamber 325 and push filtered blood back into the vasculature. The plunger 323 can serve as a seal on one side of the chamber.

[0183] To aspirate the thrombus from the system, the suction catheter 2 is attached to the filter collection chamber 5 (Figure 42). A large syringe attaches to the proximal end of the filter collection chamber 5. Applying suction using the syringe causes the thrombus and blood clots to migrate into the filter collection chamber 5. Once all the

thrombus is contained within the chamber 5, close stopcock, detach the syringe and fill with saline and reattach the syringe to the filter collection chamber 5. Alternatively, an extension tube and external saline filled syringe can be used to fill saline into the suction syringe. Injecting via the syringe will push saline into the chamber 325 causing the plunger 323 to push the blood back into the vasculature. The chamber 325 will return the blood and leave the thrombus inside the chamber 325. Alternatively, the filter collection chamber 5 can be detached without returning filtered blood to the system. Once the thrombus is removed, retract the suction catheter 2 inside the outer sheath 1. Retract the ALTC Device 8 into the outer sheath 1 and remove the entire system from the body.

[0184] Catheter systems as described herein can be utilized for a variety of indications depending on the desired clinical result. In some embodiments, the use is not limited to venous systems and can apply to other arterial, venous, or nonvascular areas such as neurovascular, peripheral vascular, cardiovascular, temporary embolic protection device for a cardiovascular procedure such as valve replacement, carotid protection, pulmonary protection during deep vein thrombectomy or embolectomy), or retrieval of an implant, medical device, or other material.

[0185] Figure 43 illustrates a blood clot lodging in the left side of the pulmonary system. Shown is the right pulmonary artery 251, left pulmonary artery 252, inferior vena cava 253, left iliac artery 254, right iliac artery 255, a pulmonary embolus 256 in the left pulmonary artery 252 distally, and the superior vena cava 257.

[0186] Figure 44A and 44B illustrate blood clots residing in the left side pulmonary system and the capture device respectively, according to some embodiments of the invention. In addition to the anatomical features illustrated in Figure 43, also shown is the guide catheter 264, right ventricle 266, and right atrium 267. As shown in Figure 44B, capture devices as described and illustrated herein can advantageously be utilized when there is very limited distal space, as the device is functional throughout a wide working axial range as discussed elsewhere herein.

[0187] Figures 45-47 illustrate capture of a thrombus within a vessel, according to some embodiments. Figure 45 illustrates the initial deployed configuration of the axial lengthening thrombus capture device (e.g., tubular mesh) 8 with end 800, dynamic fold point 88, and reserve radially compressed segment (not shown) terminating proximally at point

128 where the radially compressed segment is fixably attached to the outer sidewall of the guidewire lumen 6 is shown. The expanded segment of the tubular mesh 8 is positioned distal to the thrombus 73 occluded area and the expanding guide catheter 50 including distal funnel tip 52 with proximal expandable section, inner catheter 54 and outer catheter 49, or in some embodiments suction catheter funnel tip positioned proximal to the thrombus occlusion 73, according to some embodiments of the invention. In some embodiments, expanding guide catheter 50 as described elsewhere herein or a suction catheter can be utilized depending on if suction is desired. Also shown proximally is inner sheath 54 and outer sheath 49 of expanding guide catheter 50. Actuation of capture pullwire 10 alone or with capture catheter 12 such as axially in an appropriate direction (or capture catheter coupled to the outer sheath (not shown) in embodiments with a sleeve as previously described) can result in axial lengthening or shortening of the ALTC device 8 depending on the desired clinical result. Figure 46 illustrates the axial lengthening tubular mesh 8 expandable segment lengthening proximally to capture the thrombus, according to some embodiments of the invention, with the associated radially compressed segment shortening reciprocally. Figure 47 illustrates the axial lengthening thrombus capture device completely capturing the thrombus, and the expanding guide catheter funnel tip or alternatively the suction catheter funnel tip is inside the axial lengthening thrombus capture device. Subsequent suction via the suction catheter 2 in embodiments where suction is utilized can be performed to remove the blood clot or thrombus. The ALTC Device can lengthen to have a maximal length that covers the entire length of catheter system from, e.g., about 0.5cm to about 125cm. In some embodiments, the ALTC device may lengthen to about or at least about 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 20, or more centimeters. Depending on vessel diameter, the outer diameter of the ALTC device can range from, in some embodiments, about 1 millimeter up to about 80 millimeters. For example, large vessels such as the inferior vena cava, superior vena cava, descending, and ascending aorta, the diameter can range up to about 60, 70, 80, 90, 100 millimeters or more. Small vessels in the neurovascular system can be, for example, as small as about or less than about 5, 4.5, 4, 4.5, 3, 2.5, 2, 1.5, 1, 0.5, or less millimeters in diameter. The diameter of the ALTC device can achieve the similar effect of reducing or stretching the ALTC device diameter. In some embodiments, suction is not utilized or required, and the ALTC device envelops the clot, which can be mechanically pulled back into the capture

catheter. In some embodiments, the ALTC device can be utilized to treat, for example, a clot in the carotid or cerebral arterial or venous circulation. The vessels to be treated could include, for example, the Circle of Willis, left or right common carotid or internal carotid arteries, anterior cerebral arteries, anterior communicating arteries, middle cerebral artery, posterior communicating arteries, carotid siphon, basilar arteries, vertebral arteries, or ophthalmic arteries for example, or any branches thereof. In some embodiments, the ALTC device can be utilized to treat, for example, a femoral vein, a brachial vein, a pulmonary vein, a breast vein, a cerebral vein, a brain sinus vein, a renal vein, a portal vein, a jugular vein, or another vein.

[0188] Figure 48A illustrates another delivery configuration of the clot capture system 35 that can include features as previously described, according to some embodiments of the invention. Figure 48B illustrates the initial deployment position of the axial lengthening thrombus capture device, according to some embodiments of the invention, and reversible coupling of the hub 55 of the capture catheter 155 to the hub 55 of the outer sheath. Figure 48C illustrates the further lengthening of the expanded segment of the axial lengthening thrombus capture device, according to some embodiments of the invention, with reciprocal shortening of the reserve compressed segment 81. As illustrated, the guidewire tube 6 with nose tip 7 is maintained in position while the capture catheter reversibly coupled to the outer sheath can be withdrawn proximally. Figure 48D illustrate the final deployment of the axial lengthening thrombus capture device at its maximal working length, according to some embodiments of the invention.

[0189] In some embodiments, systems and devices as disclosed herein can involve a general percutaneous technique, a cut-down procedure, or minimally invasive technique such as transapical, thoracoscopic, laparoscopic, or other techniques, for example, and not limited to transfemoral, transradial and/or internal jugular venous access. The technique can also apply to the arterial system, including neurovascular, cardiovascular, and peripheral vascular applications, as well as for use as an embolic protection device such as for a cardiovascular procedure such as valve replacement or repair for example. In some embodiments, a thrombectomy system can be delivered downstream of the aortic root, such as prior to the aortic arch, and a variable-length shape memory mesh structure such as an ALTC device with an open proximal end and closed distal end expanded prior to the index

cardiovascular procedure, to capture downstream emboli, calcifications, or other debris. In some embodiments, the system can be deployed to prevent embolization during a deep vein thrombectomy or pulmonary embolectomy, for example. In another embodiment, the system can be deployed to prevent embolization or retrieval during acute ischemic stroke. Systems and methods as disclosed herein can also be utilized in non-vascular anatomy such as the biliary tree to capture gallstones, common bile duct stones, and pancreatic duct stones, for example, in the ureters or bladder to capture kidney stones, or in the fallopian tubes to capture ova or other materials, or in the gastrointestinal tract such as the esophagus, stomach, duodenum, jejunum, ileum, or colon to capture, for example, foreign bodies. Described herein are some embodiments of using the venous system to access the pulmonary artery to treat pulmonary embolism. The technique can also apply to other areas of the vasculature. Initial puncture to access the femoral vein. A short access guidewire is inserted into the femoral vein. Next, an appropriate 5F or 6F introducer sheath is inserted. The guidewire is exchanged for a 180cm, 260cm or 300cm guidewire and advance pass the inferior vena cava, right atrium, right ventricle and the pulmonary artery to access the occluded treatment area. A longer length introducer/guiding catheter may be necessary to cross the tricuspid and pulmonary valve. Once the guidewire passes through the occluded treatment area, the 5F or 6F introducer sheath is exchanged for a long guiding catheter and position proximally near the occluded area. The catheter system 35 is inserted over the wire and through the guiding catheter and advance distally to the occluded area. The catheter system 35 can also utilize the outer sheath deflectable features to navigate through the vasculature without the use of a guiding catheter. Next, the catheter system's nose tip 7 passes through the occluded treatment area and positioned distal to the occluded treatment area. The Outer Sheath 1 is retracted to deploy the thrombus capture guide 11. The outer sheath 1 is retracted past the thrombus and positioned proximal to the thrombus (occluded area). The Suction Catheter 2 advances distally outside the Outer Sheath 1 and positions proximally to the occluded area, if suction is utilized.

[0190] To retrieve and capture materials such as blood clots or thrombus, the Thrombus Capture Guide 11 retracts by pulling the Capture Pullwire 10 proximally while push/pull Capture Catheter 12 to axially lengthen the ALTC Device 8 over the thrombus without substantially decreasing the device diameter. As needed, advancing the Capture

Catheter shaft 12 distally while pulling the Capture Pullwire will allow the ALTC Device 8 to axially lengthen to capture the thrombus. Furthermore, the expandable Funnel Tip 9 of the Suction Catheter 2 (or the funnel tip of the expanding guide catheter) can be positioned at the proximal end of the occluded area to support and minimized thrombus movement. This maneuver continues until all thrombus is inside the ALTC Device 8. Once the thrombus is completely within the ALTC Device 8, pulling the ALTC Device 8 away from the occluded area can restore immediate blood flow while containing the thrombus inside the ALTC Device 8.

[0191] In some embodiments, the capture catheter shaft 12 and the guidewire tube 6 are configured to be positioned side-by-side adjacent (e.g., offset and not coaxial, and not passing within the opening 802 or other radially expanded portion of the tubular mesh 6) to the ALTC Device 8 and capture guide (shown, for example, in Figures 49A and 49B). Also illustrated is the dynamic fold point 88, reserve radially compressed segment 81 and compressed end at 128 fixed to the outer wall of the guidewire tube 6.

[0192] Figures 50A – 50G illustrate the retrieval of thrombus into the expanding guide catheter wherein the ALTC device lengthens distally and creates additional space and the thrombus is redistributed and enable better retrieval into the expanding guide catheter. The funnel tip 52 and expanding section 53 of the expanding guide catheter also facilitate the ease of thrombus retrieval. For example, when the ALTC Device (e.g., tubular mesh 8) captures the blood clot inside, the ALTC Device 8 can advantageously stretch axially and compress radially beyond its working length (e.g., when the reserve radially compressed segment has been completely expanded, and/or by distal advance of the guidewire tube 6), effectively squeezing the blood clot radially to decrease its diameter/width. Fresh blood clots are typically soft and deformable. Applying axial stretching to the ALTC device can squeeze out the fluid that is within the blood clot, thereby reducing the size of blood clot and allowing blood clots to be removed from the vascular system more easily. The ability of the ALTC Device to lengthen dynamically also provides another clinically effective way to remove the large clot burden by redistributing the volume of blood clot or thrombus, as shown, for example, in Figure 50A – 50G. For example, with respect to current interventional devices such as filters and baskets, when blood clots or thrombus is collected and retrieved into a catheter such as a guiding catheter or sheath, the blood clot or thrombus can gather together

or pooled at base of the filter or basket into a large "ball-like" shape and prevent the large "ball-like" thrombus to enter the lumen of the guiding catheter or sheath. A similar effect can occur when aspiration/suction is attempted using a smaller inner diameter guide catheter. However, the ALTC device can lengthen serially from the distal end to create additional length and space within the ALTC Device (as shown, for example, in Figures 50B, 50D, and 50F). By lengthening the ALTC Device's distal end, the blood clot or thrombus is redistributed within the ALTC device thereby reducing the ball-like size of the blood clot, thrombus, or other material for better retrievable inside the guiding catheter lumen (Figures 50C, 50E, 50G). These steps can be repeated for about or at least about 2, 3, 4, 5, or more cycles until all the blood clot and thrombus is retrieved in the catheter in a compacted form. Furthermore, the use of an expanding guide catheter with an expandable distal section in concert with the ALTC device can allow more efficient blood clot or thrombus removal, as illustrated, for example, in Figures 50A and 50C. The effectiveness of the ALTC Device 8 can be further demonstrated in an extreme vascular condition where there is minimal to no distal space available for conventional thrombectomy catheters to fully axially expand in order to be functional. The distal space beyond the distal end of the thrombectomy system can be in some cases less than about 3cm, 2cm, 1cm, 5mm, or less. In other words, the ALTC Device 8 can be delivered in a first, radially compressed configuration, and compressed by the outer sheath. Upon removal of the outer sheath, the ALTC Device 8 can transform into a radially expanded configuration and configured to capture thromboemboli even though the device may be in an axially compressed configuration. The ALTC Device 8 can then be axially expanded, such as, for example, at least about 1.25x, 1.5x, 2x, 2.5x, 3x, 3.5x, 4x, 4.5x, 5x, 5.5x, 6x, 6.5x, 7x, 8x, 9x, 10x, or more with respect to its fully functional axially compressed length while still maintaining a constant or substantially constant radially expanded diameter through a working range, such as between about 1cm and about 50cm, between about 1cm and about 20cm, between about 1cm and about 10cm, between about 1cm and about 5cm, or between about 1cm and about 3cm in some embodiments. In some embodiments, the ALTC device 8 has an open proximal end during delivery, and/or throughout its working axial length. The Thrombus Capture Guide 11 can advantageously deploy initially in the tight space while the ALTC device body remains inside the Capture Catheter shaft 12. Subsequently, the Thrombus Capture Guide retracts proximally to begin

deploying the ALTC Device 8. The potential axially expanded length of the ALTC Device 8 is not necessarily limited and in some embodiments could extend to the entire length of the catheter system. The ALTC Device 8 can be collapsed and contained within the Capture Catheter shaft 12 and Outer Sheath 1 during introduction into the vasculature and expands when the Outer Sheath 1 retracts proximally to deploy the ALTC Device 8. The Capture Catheter shaft 12 can be made from suitable materials such as and not limit to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, PEEK, polypropylene. It is also advantageous and possible in some embodiments that the Capture Catheter shaft 12 is deflectable at various locations and multiple deflectable directions along the shaft length to accommodate various tortuous paths such as entry into the right atrium, right ventricle, main pulmonary artery, left and right pulmonary artery as previously described.

[0193] A perspective view of another embodiment of a capture system is shown in Figure 51. Figure 51 also illustrates non-limiting examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 51, included in some embodiments are any number of, such as one, two, or more of the following components: a thrombus capturing device or ALTC device 201 having any of the features described herein, e.g., a pusher wire or inner pusher 202, a first tubular member such as an outer sheath 203, a loop or capture guide 204, and a coupler 205. The ALTC device 201 can attach to the capture guide 204. In some embodiments, the capture guide 204 comprises a metallic material, such as Nitinol. The capture guide 204 can be in the form of, for example, a loop, as shown, or any closed shape including an oval, ellipse, or polygon. The capture guide 204 can be in the form of an open shape such as any linear or non-linear segment. The ALTC device 201 and the capture guide 204 can be coupled such as being sutured together. The ALTC device 201 and the capture guide 204 can be encapsulated in a low durometer polymeric material. The capture guide 204 can be coupled to the outer sheath 203 via the coupler 205. The proximal end of the ALTC device 201 (not shown) can be coupled to the inner pusher 202.

[0194] The outer sheath 203 can, in some embodiments, be an elongate tubular member with a central lumen therethrough, and have a proximal end 2000 and a distal end 2001, both shown in Figure 51. The distal end 2001 of the outer sheath 203 can be operably connected to a capture device (e.g., tubular mesh as described herein), which can be movably

axially with respect to the outer sheath 203. The proximal end 2000 can include any number of, such as one, two, or more of the following components: a hemostasis assembly 206, a flush port 207, and a collapsed segment 208. The outer sheath 203 extends proximally and can be coupled to the hemostasis assembly 206. The inner pusher 202 extends proximally and can be coupled to a luer. In some embodiments, the inner pusher 202 can have a lumen to allow passage of a guidewire. In some embodiments, the inner pusher 202 is a solid shaft.

[0195] Figure 52 shows the distal end 2001 of the ALTC device 201 in a deployed configuration. In some embodiments, the ALTC device 201 in the initial deployed configuration has a low profile. A portion of the ALTC device 201 is extended while the remaining length of the ALTC device 201 is collapsed and contained within the outer sheath 203 as previously described. In some methods of use, the ALTC device 201 can be collapsed and tracked through a sheath or guide catheter (not shown) to the intended treatment area. In some embodiments, the guide catheter can be retracted proximally to initially deploy the ALTC device 201 and the capture guide 204. For instance, the retraction of the guide catheter can cause the capture guide 204 to expand. The capture guide 204 can include a compressed or constrained configuration while within the guide catheter. During the initial deployment, the capture guide 204 is released from a constrained position to a neutral position. In the neutral position, the capture guide 204 creates a perimeter for the ALTC device 201. In the case of a loop or other circular configuration, the capture guide 204 can create a constant diameter. In the case of other shapes or configurations, the capture guide 204 can create a constant cross-section. Alternatively or in combination, in other methods of use, the ALTC device 201 can be advanced distally from the guide catheter to deploy the ALTC device 201.

[0196] In some cases, only a small fractional portion of the ALTC device 201, such as less than about 50%, 45%, 40%, 35%, 30%, 25%, 20%, 15%, 10%, 5%, or less of the axial length of the device can be initially deployed and fully functional. The small portion can correspond to an amount of the ALTC device 201 which allows the capture guide 204 to assume the neutral position. During the deployment of the capture guide 204, a length of the ALTC device 201 can be retained within the outer sheath 203. The ALTC device 201 can follow a curve from the capture guide 204 to the outer sheath 203. Retracting the outer sheath 203 can lengthen the ALTC device 201 while maintaining a constant diameter or cross-section provided by the capture guide 204.

[0197] Figure 53 illustrates an embodiment of an ALTC device 201 in the initially deployed configuration. As illustrated in Figure 53, the ALTC device 201 can be in some embodiments a generally tubular structure, and in some cases a net-like mesh structure that is collapsible within the outer sheath 203. The ALTC device 201 is expandable to the diameter or cross-section provided by the capture guide 204. The ALTC device 201 can be axially lengthened or shortened, such as within a working range, by releasing the ALTC device 201 from the outer sheath 203. The ALTC device 201 can be axially lengthened or shortened while maintaining or substantially maintaining the diameter or cross-section provided by the capture guide 204. The ALTC device 201 can be deployed to form a generally tubular or cylindrical shape of varying axial lengths. The ALTC device 201 can be axially lengthened or shortened to retrieve and capture foreign or otherwise unwanted materials within the body, including the vascular system such as blood clots, thrombus and/or foreign materials. In some embodiments, an outer sheath is not present and a loader can be utilized to prepare the ALTC device 201 for delivery in a low crossing-profile configuration.

[0198] As shown, for example, in Figures 54 and 55, the ALTC device 201 can be axially lengthened. Figure 54 illustrates the ALTC device 201 in a second configuration. The ALTC device 201 is in the second configuration wherein the deployed and expanded ALTC device 201 is longer than the initial deployed configuration in the axial direction. The remaining collapsed ALTC device 201 length resides inside the outer sheath 203 and is shorter than the initial deployed configuration. The outer sheath 203 can be retracted to axially lengthen the ALTC device 201. As the outer sheath 203 is retracted, the capture guide 204 is retracted since the capture guide 204 is coupled to the outer sheath 203 via the coupler 205. As the capture guide 204 is retracted, the ALTC device 201 is advance from the collapsed portion 208 to the expanded portion. The outer sheath 203 can be retracted proximally to axially lengthen the ALTC device 201. Alternatively or in combination, in other methods of use, the capture guide 204 can be retracted to axially lengthen the ALTC device 201, such as be retracting the outer sheath 203. The diameter or cross-section of the ALTC device 201 can remain constant or substantially constant between the initial deployed configuration and the second configuration.

[0199] Alternatively or in combination, in other methods of use, the inner pusher 202 is advanced distally to advance the proximal end of the ALTC device 201. As described

herein, the proximal end of the ALTC device 201 is coupled to the inner pusher 202. In the second configuration, the inner pusher 202 is advanced distally to release a portion of ALTC device 201 from the outer sheath 203.

[0200] Figure 55 illustrates an embodiment of an ALTC device 201 in a third configuration. The ALTC device 201 is in the third configuration wherein the deployed and expanded ALTC device 201 is longer than the second configuration in the axial direction. The remaining collapsed ALTC device 201 length resides inside the outer sheath 203 and is shorter than the second configuration. The outer sheath 203 can be retracted proximally to axially lengthen the ALTC device 201. The diameter or cross-section of the ALTC device 201 can remain constant or substantially constant between the second configuration and the third configuration. Alternatively or in combination, in other methods of use, in the third configuration, the inner pusher 202 is advanced distally to a greater extent. In the third configuration, the inner pusher 202 is advanced distally to release a longer portion of ALTC device 201 from the outer sheath 203.

[0201] Figure 56 illustrates an embodiment of the material capture, e.g., basket mesh element 209. The basket mesh element 209 can be a component of the ALTC device 201. The basket mesh element 209 can be a structural mesh that provides an appropriate shape as described herein. The basket mesh element 209 can comprise Nitinol or other materials. The basket element can be braided, weave, wireform or laser cut. The basket mesh element 209 can include a first end that couples to the capture guide 204. The basket mesh element 209 can be coupled to the capture guide 204 via a suture or other mechanical means including welding, clips, flanges, adhesive, lamination, etc. The basket mesh element 209 and the capture guide 204 can be encapsulated within a low durometer polymeric material. The second end of the basket mesh element 209 can be coupled to the inner pusher 202. The second end can be folded inward to couple to the inner pusher 202. The second end can be inverted to couple to the inner pusher 202. The second end 202 can form a tube within a tube configuration of the ALTC device 201.

[0202] Figure 57 illustrates an embodiment of the ALTC device 201. The ALTC device 201 has an expanded portion when the ALTC device 201 is deployed (e.g., initial deployed configuration, second configuration, third configuration, etc.). The expanded portion has a constant diameter or cross-section as described herein. The expanded portion,

or a portion thereof, is coupled to the capture guide 204. The expanded portion is coupled to the outer sheath 203 via the capture guide 204 and the coupler 205. The ALTC device 201 has a collapsed portion 208. The collapsed portion 208 can reside within the lumen of the outer sheath 203. The collapsed portion 208 can be retained within the outer sheath 203 when the expanded portion is in the deployed configuration. The collapsed portion 208, or a portion thereof, can be coupled to the inner pusher 202. The collapsed portion 208 is everted as shown. During axial lengthening of the ALTC device 201, a portion of the collapsed portion 208 can roll-out at a distal region to transition between the collapsed portion 208 and the expanded portion.

[0203] Figures 58A and 58B illustrate embodiments of the capture guide 204. Figure 58A illustrates the capture guide 204. Figure 58B illustrates the capture guide 244, which can include any of the features of capture guide 204. The capture guide 204 can form a continuous shape. The capture guide 204 can include leg elements 210. The leg elements 210 can transition the capture guide 204 from an axial direction to a perimeter shape. The perimeter shape can be circular as shown in Figure 58A. The capture guide 204 can form a continuous loop. The capture guide 244 can include a non-continuous perimeter. As shown in Figure 58B, the capture guide 244 can include a non-continuous loop. The capture guide 204, 244 can be made of a metallic material. In some embodiments, the capture guide 204, 244 is formed of a shape-memory material. In some embodiments, the capture guide 204, 244 is formed from Nitinol. The capture guide 204, 244 can be formed of a spring-like material such as a metal. The capture guide 204, 244 can be circular, elliptical, semi-circular, or any combination thereof. The capture guide 204, 244 can include a pre-shaped curve. The pre-shaped curve can be formed during the manufacturing of the capture guide 204, 244. The pre-shaped curve can be a neutral or expanded shape of the capture guide 204, 244. Upon release of a constraint, the capture guide 204, 244 will assume the pre-shaped curve. The capture guide 204, 244 can have any curved shape. The capture guide 204, 244 can have a single radius of curvature or multiple portions having different radii of curvature. The capture guide 204, 244 can be considered spring loaded based in part of the material and the shape of the capture guide 204, 244. In some embodiments, the anchors can include non-continuous shapes, such as hooks with sharp or atraumatic segments or tips in some cases.

[0204] The capture guide 204, 244 can have two or more leg elements 210. The leg elements 210 can be adjacent or adjoining within the guide catheter during delivery. The leg elements 210 can be relatively parallel or side-by-side during delivery in the collapsed configuration. The collapsed leg elements 210 can define a different diameter or cross-section as compared to the fully expanded or neutral configuration of the capture guide 204, 244. In some embodiments, the collapsed leg elements 210 enable the capture guide 204, 244 to have a smaller diameter or cross-section while collapsed within the guide catheter. For example, when the capture guide 204, 244 is fully expanded, the circular portion of the capture guide 204, 244 defines a diameter. For non-circular capture guide 204, 244, the capture guide 204, 244 can define a cross-section when fully expanded. Upon collapsing the leg elements 210, the circular portion of the capture guide 204, 244 defines a diameter that is smaller than the previous expanded configuration. The capture guide 204 can comprise one segment as shown in Figure 58A with two ends that form a continuous loop configuration. The capture guide 244 can comprise multiple segments as shown in Figure 58B and form a non-continuous loop.

[0205] During expansion, the leg elements 210 can bias the capture guide 204, 244 outward to assume the neutral configuration of the capture guide 204, 244. The leg elements 210 can be positioned at an angle relative to each other in the neutral configuration of the capture guide 204, 244. The leg elements 210 can include one or more bends to facilitate folding of the capture guide 204, 244. The one or more bends can enable the capture guide 204, 244 to fold in a low profile configuration along the longitudinal axis of the guide catheter.

[0206] Figure 59 shows one aspect of the opening of the ALTC device 201. The end of the ALTC device 201, or a portion thereof, attaches to the capture guide 204. While the capture guide 204 is shown in Figure 59, any capture guide or feature thereof can be coupled to the end of the ALTC device 201. The end of the ALTC device 201 and the capture guide 204 form an assembly. The assembly can be encapsulated within a low durometer polymeric material to form a polymeric coating or ring 245. The polymeric coating can encapsulate the assembly completely or a portion thereof. In the illustrated embodiment, the polymeric coating encapsulates a portion of the end of the ALTC device 201 and the capture guide 204. The polymeric coating can encapsulate the rounded portion of

the capture guide 204 having a constant or substantially constant diameter. The polymeric coating can encapsulate the entire ALTC device 201, or any portion thereof. The area where the polymeric coating is void/not present can allow for easy movement. For instance, the area between the leg elements can be void. The void area can facilitate collapse of the capture guide 204. In some embodiments, the polymeric coating can be selectively applied. In some embodiments, the polymeric coating can form a ring or a portion of a ring. The polymeric coating can be applied to the outside of the material capture element, e.g., basket mesh element 208. The polymeric coating can be applied to the inside of the basket mesh element 208. The polymeric coating can be applied to the entire basket mesh element 208 to encapsulate the basket mesh element 208.

[0207] Figure 60 shows one aspect of the opening of the ALTC device 201. The ALTC device 201 can include a central, longitudinal axis. The outer sheath 203 can include a longitudinal axis. The inner pusher 202 can extend along the longitudinal axis of the outer sheath 203. The central, longitudinal axis of the ALTC device 201 can be offset from the longitudinal axis of the outer sheath 203. The central, longitudinal axis of the ALTC device 201 can be offset from the longitudinal axis of the inner pusher 202. The capture guide 204 can define the offset. For instance, the central, longitudinal axis of the ALTC device 201 can include the central point of the circle created by the capture guide 204. The central point of the capture guide 204 can be offset from the outer sheath 203. As described herein, the end of the ALTC device 201 is coupled to the inner pusher 202. The ALTC device 201 axially lengthens by releasing a portion of the ALTC device 201 from the outer sheath 203. The ALTC device 201 that is released follows a portion of the inner pusher 202 as shown in Figure 59. The released portion of the ALTC device 201 curves outward and assumes the diameter of the capture guide 204. The ALTC device 201 can form an everted shape with a portion of the ALTC device 201 collapsed near the inner pusher 202 and a portion of the ALTC device 201 expanded to the diameter or cross-section of the capture guide 204. In some embodiments, the shape of the ALTC device 201 can resemble a tube within a tube. In some embodiments, the ALTC device 201 can be considered telescoping.

[0208] A perspective view of another system is shown in Figure 61. Figure 62 shows the proximal end of the system and Figure 63 shows the distal end of the system. Figure 64 shows a subassembly of the system. Figures 61-64 also illustrates non-limiting

examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 61, included in some embodiments are any number of, such as one, two, or more of the following components: an anchor assembly 221, a corewire and basket assembly 222, an anchor and pusher assembly 223, a proximal catheter assembly 224, and a distal catheter assembly 225. The anchor assembly 221 can include about or at least about one, two, three, four, five, or more anchors 241 configured to secure a clot. The anchor and pusher assembly 223 includes one or more anchors 241 and the anchor pusher 240. The anchors can be coupled to the pusher as described herein. The corewire and basket assembly 222 can include a corewire 242 and the ALTC device 201. The proximal catheter assembly 224 can include a shaft with one, two, or more lumens, e.g., the dual lumen shaft 243. Figure 61 illustrates a dual lumen shaft 243 of the system. The dual lumen shaft 243 can be attached to the hemostasis housing 206 described herein. The dual lumen shaft 243 can be coupled to the capture guide 204 via the coupling 205. The illustrated embodiment shows a dual lumen shaft, but other configurations are contemplated. In some embodiments, the shaft has a single lumen. In some embodiments, the shaft is a multi-lumen shaft. The shaft can have about or more than about one lumen, two lumens, three lumens, four lumens, five lumens, six lumens, seven lumens, etc. In some embodiments, the anchor 241 is a single loop. In some embodiments, the anchor 241 is a continuous loop. In some embodiments, the anchor 241 has a closed perimeter. In some embodiments, the anchor 241 has an open perimeter. In some embodiments, the anchor 241 forms a circular shape. In some embodiments, the anchor 241 forms an oval. In some embodiments, the anchor 241 forms any round, closed shape.

[0209] Figure 62 illustrates the proximal end of the system including the corewire and basket assembly 222, the anchor and pusher assembly 223, and the proximal catheter assembly 224. The corewire and basket assembly 222 and the anchor and pusher assembly 223 can reside in separate lumens of the dual lumen shaft 243. The system can include the corewire 242. The corewire 242 can include any of the features or function as the inner pusher 202. The corewire 242 can be coupled to a pusher lock 246. The anchor pusher 240 can extend through the pusher lock 246. The pusher lock 246 can be movable along the shaft of the anchor pusher 240. In some embodiments, the pusher lock 246 can limit the expansion of the anchors 241. In some embodiments, the pusher lock 246 can provide a tactile response

when the anchors 241 are deployed by abutting the anchor and pusher assembly 223 with the pusher lock 246.

[0210] Figure 63 illustrates the distal catheter assembly 225. The distal catheter assembly 225 can include any of the features described herein. The distal catheter assembly 225 can include the ALTC device 201. The distal catheter assembly 225 can include the coupler 205 between the outer shaft 203 and the capture guide 204.

[0211] Figure 64 illustrates the anchor assembly 221. The anchor assembly 221 can comprise one or more anchors 241. The anchor assembly 221 can comprise about or at least about one anchor, two anchors, three anchors, four anchors, five anchors, six anchors, seven anchors, eight anchors, nine anchors, ten anchors, or more than ten anchors 241. The illustrated embodiment shows three anchors, but other configurations are contemplated. The anchor assembly 221 can include the anchor pusher 240. The anchor pusher 240 can include an elongate member comprising a shaft. The anchor pusher 240 can be extended proximally within the dual lumen shaft 243. The anchor pusher 240, or a portion thereof, can pass proximally through the proximal catheter assembly 224. The anchor pusher 240, or a portion thereof, can pass proximally through the pusher lock 246. The anchor pusher 240, or a portion thereof, can be connected to the luer hub. The anchor assembly 221 can be contained in the dual lumen shaft 243. The one or more anchors 241 can be coupled at a distal end of the anchor pusher 240. The one or more anchors 241 can be one anchor or a plurality of anchors 241. The anchors can be connected to the anchor pusher 240 in series, and regularly or irregularly spaced apart. In some embodiment, the diameter of the anchor 241 when expanded is smaller than the diameter of the capture guide 204 when expanded. In some embodiment, the diameter of the anchor 241 when expanded is smaller than the ALTC device 201 when expanded. The anchor 241 can be designed to fit within the ALTC device 201 when the ALTC device 201 is expanded. In some embodiments, the anchors can form symmetric or asymmetric loop shapes to circumscribe and stabilize a portion of the clot. In some embodiments, the anchors can be an mesh or braided element. In some embodiments, the anchor can be a balloon. In some embodiment, there can be a combination of braided mesh and balloon. In some embodiments, the anchors 241 can have a portion that extend radially outwardly from the elongate member in which they are attached.

[0212] Figure 65 illustrates a side view of the distal end of the ALTC device 201 and the anchors 241. The anchors 241 can include or be similar to any of the features of capture guide 204, 244 described herein. Each anchor 241 can form a continuous shape, or a discontinuous shape in other embodiments. Each anchor 241 can include leg elements 228. The leg elements 228 can transition the anchor 241 from an axial direction to a perimeter shape. The perimeter shape can be circular as shown in Figure 64. The anchor 241 can form a continuous loop. The anchor 241 can include a non-continuous perimeter such as a non-continuous loop. The anchor 241 can be made of a metallic material. In some embodiments, the anchor 241 is formed of a shape-memory metal such as Nitinol. The anchor 241 can be circular, elliptical, semi-circular, or any combination thereof. Each anchor 241 can include a pre-shaped curve. Two or more anchors 241 can have the same pre-shaped curve. Two or more anchors 241 can have a different pre-shaped curve. The pre-shaped curve can be formed during the manufacturing of the anchors 241. The pre-shaped curve can be a neutral or expanded shape of the anchors 241. Upon release of a constraint, the anchors 241 can assume the pre-shaped curve. The pre-shaped curve of the anchors 241 can be similar to the pre-shaped curve of the capture guide 204. The anchors 241 can have a different radius of curvature from the capture guide 204. As described herein, the anchors 241 can have a smaller diameter than the capture guide 204. Alternatively, the anchors can have the same or larger diameter than the capture guide. In some embodiments, the anchors include barbed elements to attach to a clot. In some embodiments, the anchors are atraumatic and do not include any barbed or other sharp surfaces.

[0213] The anchor 241 can have two or more leg elements 228. The leg elements 228 can be adjacent or adjoining within the guide catheter during delivery, and relatively parallel to the . The leg elements 228 can be relatively parallel or side-by-side during delivery in the collapsed configuration. The collapsed leg elements 228 can define a different diameter or cross-section as compared to the fully expanded or neutral configuration of the anchor 241. In some embodiments, the collapsed leg elements 228 allow the anchor 241 to have a smaller diameter or cross-section while collapsed within the guide catheter. For example, when the anchor 241 is fully expanded, the circular portion of the anchor 241 defines a diameter. For non-circular anchors 241, the anchor 241 can define a cross-section when fully expanded. Upon collapsing the leg elements, the circular portion of the anchor

241 defines a diameter that is smaller than the previous expanded configuration. The anchor 241 can comprise one segment as shown in Figure 64 that forms a continuous loop configuration. The anchor 241 can comprise multiple segments similar to capture guide 244 shown in Figure 58B. The anchors 241 have a outwardly curving shape relative to the two or more leg elements 228.

[0214] The anchor 241 can include an expanded position as shown in Figure 65. In the case of a shape memory material the expanded position can be a neutral position of the material. The anchor 241 can be configured to fold or bend during delivery. The anchor 241 can assume a low-profile configuration during delivery. The expanded anchor 241 can have any shape including round, circular, elliptical, etc. The anchors 241 expand to their pre-formed shape upon removal of a constraint, such as outer sheath 203, delivery catheter, or other constraining structure.

[0215] The expanded position of an anchor 241 can be defined by angle theta θ. In some embodiments, the angle theta is measured from the leg element 228 to the circular portion of the anchor 241. In some embodiments, the angle theta is measured from the horizontal to the vertical extension of the anchor 241. In some embodiments, the angle theta is measured from the dual lumen shaft 243 to the expanded portion of the anchor 241. In some embodiments, the angle theta determines the vertical or substantially vertical orientation of the anchor 241. Each anchor 241 of a plurality of anchors 241 can have the same angle theta. If the anchors 241 are arranged in a series, the angle theta can be uniformly the same. Two or more anchors 241 can have the same angle theta, or angles that are within about 30, 25, 20, 15, 10, 5, 4, 3, 2, 1, or less degrees of each other.

[0216] Each anchor 241 of a plurality of anchors 241 can have a different angle theta. Two or more anchors 241 can have the different angle theta. If the anchors 241 are arranged in a series, the series of anchors 241 can also have different variations in the angle theta. For example, the first anchor 241 can have a first angle theta such as about or at least about 45 degrees, such as between about 0 and 90 degrees, between about 15 and 75 degrees, or between about 30 and 60 degrees in some cases. The next or immediately adjacent anchor 241 can have a second angle theta such as 135 degrees. The next or immediately adjacent anchor 241 can have a third angle theta such as 45 degrees. The series can continue to

alternate between 45 degrees and 135 degrees or other desired angles. In some embodiments, the series of anchors can have different diameter.

[0217] In some embodiments, two or more anchors 241 can form a mirror image. In some embodiments, two or more anchors 241, 241 can extend from the dual lumen shaft 243 such that the circular portion of one anchor 241 substantially projects onto the circular portion of the other anchor 241. In some embodiments, two or more anchors 241 can be identical or substantially identical in orientation. In some embodiments, two or more anchors 241 can be coaxial. In some embodiments, two or more anchors 241 have different orientations relative to the dual lumen shaft 243. In some embodiments, two or more anchors 241 are not coaxial. In some embodiments, a first anchor 241 has a first axis extending through the circular portion of the first anchor 241 and the second anchor 241 has a second axis extending through the circular portion of the second anchor 241. In some embodiments, the first axis and the second axis can be skewed. In some embodiments, the first axis and the second axis are perpendicular. In some embodiments, the first axis and the second axis are parallel. In some embodiments, the first axis and the second axis are coaxial.

[0218] In some embodiments, the angle theta can range from 5 degrees to 175 degrees. Examples of the angle theta include 5 degrees, 10 degrees, 15 degrees, 20 degrees, 25 degrees, 30 degrees, 35 degrees, 40 degrees, 45 degrees, 50 degrees, 55 degrees, 60 degrees, 65 degrees, 70 degrees, 75 degrees, 80 degrees, 85 degrees, 90 degrees, 95 degrees, 100 degrees, 105 degrees, 110 degrees, 115 degrees, 120 degrees, 125 degrees, 130 degrees, 135 degrees, 140 degrees, 145 degrees, 150 degrees, 155 degrees, 160 degrees, 165 degrees, 170 degrees, 175 degrees, etc., and ranges incorporating any two of the aforementioned values. Examples of the angle theta can be in the range of 0-20 degrees, 20-40 degrees, 40-60 degrees, 60-80 degrees, 80-100 degrees, 100-120 degrees, 120-140 degrees, 140-160 degrees, 160-180 degrees, etc. In some embodiments, the angle theta can be approximately 90 degrees. In such embodiment, the anchor 241 can be approximately vertical relative to the dual lumen shaft 243. In some embodiments, the angle theta can be approximately 45 degrees. In such embodiment, the anchor 241 can form an acute angle relative to the dual lumen shaft 243. In some embodiments, the angle theta can be approximately 135 degrees. In such embodiment, the anchor 241 can form an obtuse angle relative to the dual lumen shaft 243.

[0219] The anchor and pusher assembly 223, or a portion thereof, can be moved within the dual lumen shaft 243. In some embodiments, the anchor and pusher assembly 223 can be moved coaxially within a lumen of the dual lumen shaft 243. The anchor and pusher assembly 223 can be moved independently from the corewire and basket assembly 222. In some embodiments, the anchor and pusher assembly 223 can be moved simultaneously with the corewire and basket assembly 222. In some embodiments, the anchor and pusher assembly 223 can be advanced distally or proximally relative to the dual lumen shaft 243. In some embodiments, the anchor and pusher assembly 223 does not impact the movement of the ALTC device 201. The one or more anchors 241 can be moved independently of the ALTC device 201. As described herein, the one or more anchors 241 can be moved relative to a stationary ALTC device 201. As described herein, the ALTC device 201 can be moved relative to a stationary anchor 241.

[0220] Figure 66 illustrates a top view of the distal end of the ALTC device 201 and the anchors 241. The one or more anchors 241 can be coupled to a distal pusher 226. In some embodiments, the leg extensions 228 of the anchors 241 are coupled to the distal pusher 226. In some embodiments, the angle theta is measured from the distal pusher 226 to the expanded portion of the anchor 241. In the illustrated embodiment, each anchor 241 is coupled to the distal pusher 226. The movement of the distal pusher 226 causes simultaneous movement of all anchors 241 coupled thereto. In alternative embodiments, two or more distal pushers 226 are provided. Each of the two or more distal pushers 226 controls the movement of one or more anchors 241. The two or more distal pushers 226 can move independently such that two or more anchors 241 can move independently. Other configurations are contemplated. The distal pusher 226 can be coupled to a crescent pusher 227. In some embodiments, the crescent pusher 227 can provide rigidity to the distal pusher 226. The distal pusher 226 and the crescent pusher 227 can be affixed via welding, adhesive, mechanical interference, etc.

[0221] Figure 67 illustrates a front view of the distal end of the ALTC device 201 and the anchors 241. The dual lumen shaft 243 is shown in cross section. In some embodiments, the dual lumen shaft 243 provides a lumen for the anchor and pusher assembly 223 and a lumen for the corewire and basket assembly 222. The two lumens can be separated

such that movement of one assembly does not impact the movement of the other assembly. Other configurations are contemplated.

[0222] The corewire and basket assembly 222 includes the corewire 242. The corewire 242 is shown disposed in one lumen of the dual lumen shaft 243. The corewire 242 can include any of the feature or functions of the inner pusher 202 described herein. The compressed basket or compressed ALTC device 201 is disposed in the same lumen of the dual lumen shaft 243 as the corewire 242. The compressed ALTC device 201 can have any of the features or function as the collapsed segment 208 described herein. The outer shaft of the dual lumen shaft 243 is shown.

[0223] The anchor and pusher assembly 223 can include the distal pusher 226 and the crescent pusher 227 described herein. The crescent pusher 227 can be coupled to the anchor pusher 240, described herein. In some embodiments, the distal pusher 226, the crescent pusher 227, and the anchor pusher 240 are integrally or monolithically formed. In some embodiments, the distal pusher 226 is a portion of the anchor pusher 240. The crescent shape of the crescent pusher 227 may prevent rotation of the crescent pusher 227 within the dual lumen shaft 243. The crescent pusher 227 is shown a lumen of the dual lumen shaft 243.

[0224] The anchors 241 can be coupled to the anchor pusher 240, such that movement of the anchor pusher 240 causes movement of the one or more anchors 241. The anchors 241 can be coupled to the distal pusher 226, such that movement of the distal pusher 226 causes movement of the one or more anchors 241. In some embodiments, the anchors 241 can be welded to the distal pusher 226. The anchors 241 are arranged such that the anchors 241 are coaxial along central longitudinal axis 230. As shown in the illustrated embodiment, only one anchor is visible from the front view due to the coaxial nature of the anchors 241.

[0225] The ALTC device 201 is expanded as shown in Figure 67. The outer diameter 232 of the anchor 241 can be smaller than the inner diameter 233 of the basket or ALTC device 201 in order for the ALTC device 201 to capture the anchors 241. The ALTC device 201 can capture one or more anchors depending on the axial length of the ALTC device 201. The axial length of the ALTC device 201 is adjustable based on the release of the ALTC device 201 from the dual lumen shaft 243. As a longer portion of the ALTC device 201 is released, the ALTC device 201 axially lengthens. As described herein, the ALTC

device 201 remains at a constant diameter or cross-section as the ALTC device 201 lengthens. The capture guide 204 maintains the shape of the expanded ALTC device 201 as the ALTC device 201 axially lengthens. The capture guide 204 is smaller in diameter than the outer diameter 232 of the anchor 241.

[0226] The capture guide 204 can function as a centering device to center the system within the vessel. The capture guide 204 can be a similar diameter or cross-sectional shape as the vessel. In some methods of use, the capture guide 204 is smaller than the diameter of the blood vessel when the capture guide 204 is expanded. In some methods of use, the capture guide 204 is approximately equal to the diameter of the blood vessel when the capture guide 204 is expanded. In some methods of use, the ALTC device 201 is smaller than the diameter of the blood vessel when the ALTC device 201 is expanded. In some methods of use, the ALTC device 201 is approximately equal to the diameter of the blood vessel when the ALTC device 201 is expanded. In some methods of use, the ALTC device 201 contacts the vessel wall of the blood vessel. In some methods of use, the ALTC device 201 does not contact the vessel wall.

[0227] The capture guide 204 can include the central longitudinal axis 231. In some embodiments, the dual lumen shaft 243 can be offset from the central longitudinal axis 231. In some embodiments, the dual lumen shaft 243 can be coaxial with the central longitudinal axis 231 (not shown). The anchor 241 can include the central longitudinal axis 230. In some embodiments, the dual lumen shaft 243 can be offset from the central longitudinal axis 230. In some embodiments, the dual lumen shaft 243 can be coaxial with the central longitudinal axis 230 (not shown). In some embodiments, the central longitudinal axis 230 of the anchor 241 can be offset from the central longitudinal axis 231 of the capture guide 204. In some embodiments, the central longitudinal axis 230 of the anchor 241 can be coaxial with the central longitudinal axis 231 of the capture guide 204 (not shown). In some embodiments, the dual lumen shaft 243 can be positioned near an edge of the capture guide 203. Other configurations are contemplated.

[0228] Figures 68A-69C illustrate capture of a clot within a vessel, according to some embodiments. Figure 68A illustrates the ALTC device 201 in the initially deployed configuration. As illustrated in Figure 68A, the ALTC device 201 can be in some embodiments a generally semi-spherical mesh structure when initially deployed. The mesh

structure is initially collapsible within a guide catheter or outer sheath 203. The guide catheter delivers the ALTC device 201 to the desired location within the body of the patient. The capture guide 204 is released from the constrained condition within the guide catheter or outer sheath 203. The capture guide 204 expands to have a cross-sectional shape. In some embodiments, the capture guide expands to a round or circular shape.

[0229] The ALTC device 201 is expandable to the diameter or cross-section provided by the capture guide 204. In some methods of use the ALTC device 201 is expanded by removal of a constraint. The ALTC device 201 can be released from a guide catheter. The guide catheter can be retracted to allow the capture guide 204 to expand. In some methods of use, the ALTC device 201 can be released from within the dual lumen shaft 243 by retraction of the dual lumen shaft. As described herein, one end portion of the ALTC device 201 is coupled to the capture guide 204. The ALTC device 201 can include a tubular mesh with a distal end. The ALTC device 201 can include a dynamic fold point as described herein such that the tubular mesh becomes everted upon release from the dual lumen shaft 243. The ALTC device 201 can include a reserve radially compressed segment within the dual lumen shaft terminating proximally at a point coupled to the inner pusher 202. In some methods of use, the expanded segment of the ALTC device 201 is positioned distal to the blood clot. The outer sheath 203 is positioned proximally, within, or adjacent to the blood clot.

[0230] Figure 68B shows the ALTC device 201 in the initially deployed configuration. As described herein, the corewire and basket assembly and the anchor and pusher assembly can be independently actuated. The first anchor 241 can be released when the outer sheath 203 retracts proximally. The first anchor 241 can include a shape memory material such that the first anchor 241 assumes an expanded configuration. The first anchor 241 can expand such that the first anchor 241 is defined by the angle theta. The first anchor 241 expands from a low profile configuration to an expanded configuration. The low profile configuration can enable the anchor 241 to reside within the outer sheath 203 during delivery. In some additionally or alternative methods of use, the first anchor 241 can be released when the anchor pusher 240 advances distally.

[0231] The released anchor can be firmly secured to the clot. In some methods of use, the first anchor 241 can become entangled in the clot. In some methods of use, the first

anchor 241 can reside against the clot. In some methods of use, the first anchor 241 can be designed to push the clot. In some methods of use, the first anchor 241 can be designed to perform a sweeping motion through the clot. The sweeping motion can be over an arc of the angle theta, or a portion thereof. The sweeping motion can break the clot, or a portion thereof.

[0232] Figure 68C shows the ALTC device 201 in the initially deployed configuration. The second anchor 241 can be released when the outer sheath 203 retracts proximally. In some methods of use, the second anchor 241 can be released when the anchor pusher 240 advances distally. The second anchor 241 can include a shape memory material such that the second anchor 241 assumes an expanded configuration. The second anchor 241 can expand such that the second anchor 241 is defined by the angle theta. As described herein, the first anchor 241 and the second anchor 241 can have the same or different orientation for the angle theta.

[0233] Figure 68D shows the ALTC device 201 in the initially deployed configuration. In some methods of use, the third anchor 241 can be released when the outer sheath 203 retracts proximally. In additional or alternative embodiments, the third anchor 241 can be released when the anchor pusher 240 is advanced distally. The third anchor 241 can include a shape memory material such that the third anchor assumes an expanded configuration. The third anchor 241 can expand such that the third anchor 241 is defined by the angle theta. As described herein, the first anchor 241, the second anchor 241 and the third anchor 241 can have the same or different orientation for the angle theta.

[0234] The first anchor 241, the second anchor 241 and the third anchor 241 can be designed to be secured to the clot. The arrangement of the anchors 241 can be designed to facilitate engagement with the clot. For instance, the number of anchors, the spacing of the anchors, the cross-section dimension of the anchors, the shape of the anchors, the orientation of the anchors relative to the anchor pusher, the angle theta, the shape of the leg extension, the rapidness of the shape memory material to assume the neutral shape, the stiffness of the material, as well as other factors can be optimized to facilitate engagement of the anchors 241 with the clot.

[0235] The ALTC device 201 and the anchors 241 can retract proximally to remove the clot. In some methods of use, the ALTC device 201 can catch emboli or debris

that dislodges during removal of the clot. In some methods of use, the ALTC device 201 is positioned downstream in a vessel to catch debris. The curved distal end of the ALTC device 201 can function as a net. In some methods of use, the anchors 241 can disrupt the clot to enable easier removal of the clot. In some methods of use, the sweeping motion of deploying the anchors 241 can break apart the clot.

[0236] Figures 69A-69C illustrates the axial lengthening sequence of the ALTC device 201, according to some embodiments. The dual lumen sheath 243 can be retracted to axially lengthen the ALTC device 201. As the dual lumen sheath 243 is retracted, the capture guide 204 is retracted since the capture guide 204 is coupled to the dual lumen sheath 243 via the coupler 205. As the capture guide 204 is retracted, the collapsed portion 208 becomes the expanded portion. The dual lumen sheath 243 can be retracted proximally to axially lengthen the ALTC device 201. Alternatively or in combination, in other methods of use, the capture guide 204 can be retracted to axially lengthen the ALTC device 201, such as be retracting the dual lumen sheath 243. The diameter or cross-section of the ALTC device 201 remains constant between the initial deployed configuration shown in Figure 69A and the expanded configurations shown in 69B and 69C. In additional or alternative methods of use, the corewire 242 can be actuated to axially lengthen the ALTC device 201. The corewire 242 can be positioned within the dual lumen shaft 243. Actuation of the corewire 242 such as axially in the appropriate direction will release the constrained portion of the ALTC device 201. The movement of the corewire 242 can result in axial lengthening or shortening of the ALTC device 201.

[0237] Figure 69A illustrates the system after deployment of the anchors 241. In some methods of use, the anchors 241 are deployed before axial lengthening of the ALTC device 201. In some methods of use, one or more steps of releasing an anchor and axially lengthening can occur in any order. In some methods of use, the first anchor is deployed and then the ALTC device 201 is axially lengthened to cover the first anchor. In some methods of use, the first and second anchors are deployed before the ALTC device 201 is axially lengthened to cover the first anchor or the second anchor. In some methods of use, the first, second, and third anchors are deployed before the ALTC device 201 is axially lengthened to cover the first anchor, the second anchor, or the third anchor. In some embodiments, two or more steps can occur simultaneously. In some methods of use, the first anchor is deployed

and the ALTC device 201 is axially lengthened to cover the first anchor simultaneously. In some methods of use, the first and second anchor are deployed and the ALTC device 201 is axially lengthened to cover either the first anchor or the second anchor simultaneously. In some methods of use, the first, second, and third anchors are deployed and the ALTC device 201 is axially lengthened to cover the first anchor, the second anchor, or the third anchor simultaneously.

[0238] Figure 69B illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally to capture the clot secured by the first anchor 241. The compressed or constrained segment of the ALTC device 201 is shortening within the dual lumen shaft 243 reciprocally. The dual lumen sheath 243 can be retracted to axially lengthen the ALTC device 201, as described herein. The ALTC device 201 can encapsulate the first anchor 241. The first anchor 241 can be sized to fit within the ALTC device 201 once the ALTC device 201 is axially lengthened.

[0239] Figure 69C illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally to capture the clot secured by the first anchor 241, the second anchor 241, and the third anchor 241. The compressed or constrained segment of the ALTC device 201 is shortening within the dual lumen shaft 243 reciprocally. Figure 69C illustrates the axial lengthening ALTC device 201 is sufficient to completely capture the clot. The ALTC device 201 and the anchors 241 can retract proximally to remove the clot.

[0240] The ALTC device 201 can be axially lengthened, such as within a working range, by releasing the ALTC device 201 from the sheath, which can have one, two, or more lumens in the sheath 243. The ALTC device 201 can be axially lengthened or shortened while maintaining or substantially maintaining the diameter or cross-section provided by the capture guide 204. The ALTC device 201 can be axially lengthened or shortened to retrieve and capture foreign or otherwise unwanted materials within the body, including the neurovascular system such as blood clots, thrombus and/or foreign materials.

[0241] The ALTC device 201 described herein can be sized to fit within a vessel of the neurovascular system, including any vessel noted elsewhere herein. As one example, the ALTC device 201 can be used to treat arteries, veins, and non-vascular lumens or regions. In some embodiments, the device can be configured to treat cerebral venous sinus thrombosis

and cavernous sinus thrombosis. A thrombus, commonly called a clot, is the product of blood coagulation due to aggregated platelets and red blood cells connected by a fibrin protein to block a blood vessel. The thrombus can travel (embolize), such as propagating toward the heart, lungs or other organs. The removal of thrombus can reduce the risk of a stroke, myocardial infarction, and/or pulmonary embolisms. The ALTC device 201 can lengthen to have a maximal length that covers the entire length of anchors 241, e.g., from about 0.01 mm to about 100 mm. Depending on vessel diameter, the outer diameter of the ALTC device 201 can range from, in some embodiments, from about 0.01 millimeter up to about 10 millimeters. The diameter of the ALTC device can achieve the similar effect of reducing or stretching the ALTC device diameter. In some embodiments, suction is not utilized or required, and the ALTC device envelops the clot, which can be mechanically pulled back into the capture catheter. In some embodiments, the mechanical thrombectomy systems and methods as disclosed herein can be used in combination with, and/or coated with a therapeutic agent such as, for example, one or more anti-thrombotic or anti-platelet agents such as heparin, hirudin, warfarin, dabigatran, and/or enoxaparin; tPA, streptokinase, or urokinase, an anti-proliferative agent such as paclitaxel (Taxol), rapamycin (Sirolimus), zotarolimus, or tacrolimus; and the like depending on the desired clinical result.

[0242] Figures 70A and 70B illustrate views of an embodiment of a pusher lock system. The pusher lock system can be utilized with any of the system described herein. Figure 70A also illustrates non-limiting examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 70A, included in some embodiments are any number of, such as one, two, or more of the following components: a hemostasis seal 260, a pusher lock 261, and a pusher 262. The hemostasis seal 260 can include a plurality of seals at spaced apart locations in the pusher lock system. The hemostasis seal 260 can be similar to the seals shown in Figure 21E and 21F. The pusher lock 261 can include any of the features of pusher lock 246 described herein. The pusher 262 can include any of the features of the inner pusher 202. The pusher 262 can include any of the features of the corewire 242 described herein. The pusher 262 can include any of the features of the anchor pusher 240 described herein.

[0243] Referring first to the system shown in Figures 70A-B, the pusher 262 can include any of the features of the inner pusher 202 described herein. The pusher 262 can

extend from the proximal end to the distal end. In some embodiments, the pusher extends from the nosetip of the catheter to the proximal end. In some embodiments, the pusher 262 is a single shaft. In some embodiments, the pusher 262 comprises one or more subcomponents. The pusher 262 can include an inner guidewire lumen shaft extending from the distal end toward the proximal end. The pusher 262 can include a pusher tube extending from the proximal end. The inner guidewire lumen shaft can be attached to a pusher tube to form a unitary structure. Other configurations are contemplated. The pusher 262 can comprise any material suitable to axially lengthen the ALTC device 201, as described herein. In some embodiments, the pusher 262 or a component thereof, comprises a metal such as stainless steel or titanium. In some embodiments, pusher tube can comprise stainless steel.

[0244] The pusher 262 can be positioned coaxially within a shaft. In some embodiments, the pusher 262 is placed within a middle shaft. The guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the middle shaft. The pusher tube is extended beyond the middle shaft. The pusher tube can slide coaxially with respect to the middle shaft to either lengthen or shorten the ALTC device 201. During clinical use, if there is no locking mechanism for the pusher 262, the user can inadvertently actuate the pusher tube or the middle shaft prematurely, which will deploy the ALTC device 201. The pusher lock 261 helps to secure the pusher tube to the middle shaft during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked when the user is ready for lengthening the ALTC device 201.

[0245] In some alternative and additionally embodiments, the guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the outer sheath 203. The pusher tube is extended beyond the outer sheath 203. The pusher tube can slide coaxially with respect to the outer sheath 203 to either lengthen or shorten the ALTC device 201. In some embodiments, the pusher tube extends beyond the outer sheath 203, as shown in Figure 51. During clinical use, if there is no locking mechanism for the pusher 252, the user can inadvertently actuate the pusher tube or the outer sheath 203 prematurely, which will deploy the ALTC device 201. The pusher lock 251 helps to secure the pusher tube to the outer sheath 203 during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked when the user is ready for lengthening the ALTC device 201.

[0246] Referring now to the system shown in Figure 62, the pusher 262 can include any of the features of the corewire 242 described herein. The pusher 262 can include any of the features of the anchor pusher 240 described herein. The pusher 262 can extend from the proximal end to the distal end. The pusher 262 can include an inner guidewire lumen shaft extending from the distal end toward the proximal end. The pusher 262 can include a pusher tube extending from the proximal end. Other configurations are contemplated.

[0247] The pusher 262 is positioned coaxially within a shaft. In some embodiments, the pusher 262 is placed within a middle shaft of the dual lumen shaft 243. The guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the middle shaft. The pusher tube is extended beyond the middle shaft. The pusher tube can slide coaxially with respect to the middle shaft to either lengthen or shorten the ALTC device 201. During clinical use, if there is no locking mechanism for the pusher 262, the user can inadvertently actuate the pusher tube or the middle shaft of the dual lumen shaft 243 prematurely, which will deploy the ALTC device 201. The pusher lock 261 helps to secure the pusher tube to the middle shaft during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked when the user is ready for lengthening the ALTC device 201.

[0248] In some alternative or additional embodiments, the pusher 262 is placed within an upper shaft of the dual lumen shaft 243. The guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the upper shaft. The pusher tube is extended beyond the upper shaft. The pusher tube can slide coaxially with respect to the upper shaft to deploy the anchors 241. During clinical use, if there is no locking mechanism for the pusher 262, the user can inadvertently actuate the pusher tube or the dual lumen shaft 243 prematurely, which will deploy the anchors 241. The pusher lock 261 helps to secure the pusher tube to the dual lumen shaft 243 after during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked after unsheathing the first anchor 241. The pusher lock 261 can be unlocked when the user is ready to deploy the anchors 241.

[0249] The method can include one or more of the following steps in any order. The delivery catheter can be prepared. The delivery catheter can be prepared at the bedside of

a patient. The delivery catheter can be prepared according to one or more instructions. In some methods of use, the pusher lock 261 can be locked in position. The pusher lock 261 can be locked in position on the pusher 262. In some embodiments, the pusher lock 261 is locked in position by rotating the lock cap 263. In some embodiments, the pusher lock 261 can be locked by rotating clockwise. In some embodiments, the pusher lock 261 can be locked by rotating counterclockwise.

[0250] In some methods of use, a guidewire is positioned within a patient. In some methods of use, the inner guidewire lumen shaft of the pusher 262 can be guided over the guidewire. In some methods of use, the pusher tube of the pusher 262 can be guided over the guidewire. In some methods of use, the system is advanced over the guidewire. In some methods of use, the delivery catheter is advanced to the intended area for treatment. In some methods of use, the delivery catheter is retracted. In some methods of use, the outer sheath 203 is retracted to deploy the ALTC device 201.

[0251] In some methods of use, the pusher lock 251 is unlocked. In some methods of use, the pusher lock 261 is unlocked by rotating the lock cap 263 counterclockwise. In some methods of use, the pusher lock 261 is unlocked by rotating the lock cap 263 in an opposite direction. Upon unlocking the pusher lock 261, the ALTC device 201 can be lengthened. In some methods of use, the ALTC device is lengthened by axially actuating the middle shaft. In some methods of use, the ALTC device is lengthened by axially actuating the pusher tube. In some methods of use, the ALTC device is lengthened by axially actuating the outer sheath. In some methods of use, the ALTC device is lengthened by axially actuating the dual lumen shaft. The pusher lock 261 can be used to affix the pusher tube to the middle shaft as needed.

[0252] Figures 71A-71D illustrate views of a pusher lock 261 of the pusher lock system of Figure 70A. As illustrated in Figure 71A-71D, included in some embodiments are any number of, such as one, two, or more of the following components: the lock cap 263, a collet 264, and a lock body 265. The lock cap 263 and the lock body can include mating threads. In the illustrated embodiment, the lock cap 263 includes female threads and the lock body 265 includes male threads. The collet 264 is disposed between the lock cap 263 and the lock body 265. The pusher 252, or a portion thereof, is designed to be placed within the collet 264. The pusher 252 can extend through an opening in the lock cap 263, through the collet

264, and through an opening in the lock body 265. The lock cap 263 also includes a ramped surface designed to interact with the collet. As the lock cap 262 is rotated, the collet 264 can be brought into engagement with the ramped surface. Further rotation can cause the collet to collapse or tighten onto the pusher 252. Other configurations are contemplated.

[0253] Figure 72 illustrates a flow chart of an embodiment of a method 300. In some embodiments, the method can assemble the end of the ALTC device 201 to the capture guide 204. The method can include one or more of the following steps, in any order. The step 301 can include mixing a thermoplastic and/or polyurethane, e.g., Pellethane solution. The solution is mixed using, e.g., a thermoplastic polyurethane, e.g., Pellethane and, e.g., a cyclic ester such as Tetrahydrofuran (THF). The mixture of Pellethane and Tetrahydrofuran (THF) ratio can range from, e.g., between about 1:1 and about 1:20 of Pellethane to THF. The ratio of Pellethane to Tetrahydrofuran can be, for example, about, at least about, or no more than about 1:1, 1:2, 1:3, 1:4, 1:5, 1:6, 1:7, 1:8, 1:9, 1:10, 1:11, 1:12, 1:13, 1:14, 1:15, 1:16, 1:17, 1:18, 1.19; 1:20, or ranges including any two of the aforementioned values. The step 302 can include trimming the ALTC device 201. The end of the ALTC device 201 can be squared trim. The step 302 can include loading the ALTC device 201 on the dipping mandrel. The dipping mandrel can be made of polymeric and/or metallic materials such as HDPE, PTFE, stainless steel, etc. The mandrel can be non-coated or coated to allow ease of manufacturing. The step 303 can include dipping the ALTC device 201 in the solution. The ALTC device mounted on a dipping mandrel is slowly dipped into the Pellethane/THF solution. The step 303 can include drying the ALTC device 201. The ALTC device 201 can hang to allow to dry, or dried using other mechanisms. The step 304 can involve removing the ALTC device 201. The step 304 can involve trimming the excess Pellethane. The dipped end of the ALTC device 201 can encapsulate and fix the wire ends of the basket mesh element 209 from movement. The dipped end can prevent the wire ends of the basket mesh element 209 from being exposed. The ALTC device 201 is removed from the dipping mandrel. The excess Pellethane is trimmed close to the edge of the ALTC device 201.

[0254] The step 305 can include punching or otherwise creating one or more apertures in the Pellethane coating. The dipped area of ALTC device 201 can be punched to create holes at predetermine location to allow placement of the capture guide. Other methods of making holes in the coating are contemplated. The step 306 can include inserting the

capture guide 204 into the punched hole. The capture guide 204 is inserted into the punched hole. The capture guide 204 can be woven through two or more holes. The capture guide can be threaded from one side of the ALTC device 201 to the other side of the ALTC device 201. The step 307 can include folding the edge of the ALTC device to cover the capture guide 204. The dipped coat edge of the ALTC device 201 is folded to cover the wire loop of the capture guide 204. The folding can protect and prevent the encapsulated wire ends of the basket mesh element 209 from protruding. The step 308 can include suturing the ALTC device 201 and the capture guide 204. The ALTC device 201 is sutured to the capture guide 204 using suture materials. Suture materials can include, for example, PET, PTFE, HMWPE, or other materials known in the art. The step 309 can include suturing around the edge of the ALTC device. The step 309 can include suture the back stitch around the edge.

[0255] The step 310 can include loading the ALTC device onto the forming mandrel. When the suturing is completed, the ALTC device 201 in then loaded onto the forming mandrel. The step 311 can include thermally forming the stitched ALTC edge. The step 311 can include thermally forming the stitched ALTC device edge using appropriate heating. The forming mandrel can be either polymeric or metallic materials such as PTFE, stainless steel, etc. The step 312 can include dipping the ALTC device and capture device. The ALTC device and capture device can be dipped in the Pellethane solution from step 301. The ALTC device and capture device can be dipped in another solution. The dipping process can include dipping the ALTC device 201 and capture guide 204 into the Pellethane/THF solution. The dipping can secure the assembly of the ALTC device 201 and capture device 204. The step 312 can include loading the assembly of the ALTC device 201 and capture device 204 onto the dipping mandrel. The dipping mandrel can be the same dipping mandrel of steps 302, 303. The dipping mandrel can be a different mandrel. The dipping mandrel for this step 312 can be made of polymeric and/or metallic materials such as HDPE, PTFE, stainless steel, etc. The mandrel for this step 312 can be non-coated or coated to allow ease of manufacturing. In some methods of use, a film or sheet of material can be used in addition or in place of one or more dipping steps. The film can be an extruded polymeric film. The sheet can be a sheet of low durometer polymer such as pellethane, polyurethane, tecothane, etc. The film or sheet can be used and place over the end of the ALTC device. In some methods of use, a film or sheet of material can be used in addition thermally forming the edge of the

ALTC device 201. The film or sheet can be thermally fused. The film or sheet can be laminated together. Other manufacturing methods are contemplated.

[0256] Figures 73-94 illustrate embodiments of anchors. The anchors described herein can be used in conjunction with, or in place of, anchors 241. The one or more anchors described herein can form an anchor assembly 221 described herein. The anchor assembly 221 can include about or at least about one, two, three, four, five, or more anchors configured to secure a clot. In some embodiments, two or more anchors of the anchor assembly 221 can be the same. In some embodiments, two or more anchors of the anchor assembly 221 can be different. In some embodiments, two or more anchors of the anchor assembly 221 can be selected from anchors described herein. In some embodiment, the diameter of the anchor when expanded is smaller than the ALTC device 201 when expanded. In some embodiment, the anchor can be designed to fit within the ALTC device 201 when the ALTC device 201 is expanded. In some embodiments, the anchor can be designed to substantially the same or larger than the ALTC device 201. In some embodiments, the distal end of the ALTC device 201 has a flexible, atraumatic extension forming the distal end of the system. In some embodiments, the distal end of the ALTC device 201 has an anchor. In some embodiments, the anchor can have any shape to entangle a portion of the clot. In some embodiments, the anchor can have any shape to stabilize a portion of the clot. In some embodiments, the anchor can have any shape to provide radial support to the clot. In some embodiments, the anchor can have any shape to provide axial support to the clot. In some embodiments, the anchor can have any shape to move a portion of the clot, such as distally toward the ALTC device 201 or proximally away from the ALTC device 201. In some embodiments, the anchor can rotate. In some embodiments, the anchor can move axial to break up the clot.

[0257] The systems described herein can include the guidewire lumen 6, which can advance distally to lengthen the ALTC device 201. Referring to Figure 5, the outer sheath 1 has an inner diameter configured to house the capture catheter 12 coaxially therein, and the capture catheter 12, which in turn has a lumen configured to house the guidewire tube 6 and the body of the ALTC device 8. The systems described herein can include the pusher 202 or corewire 242. Alternatively or in combination, in other methods of use, an end of the ALTC device 201 is coupled to the inner pusher 202. In the second configuration, the inner pusher 202 is advanced distally to release a portion of ALTC device 201 from a sheath.

As the inner pusher 202 is advanced distally, a portion of the collapsed portion 208 becomes the expanded portion of the ALTC device 201. As the inner pusher 202 is advanced distally, the ALTC device 201 is axially lengthened. In additional or alternative methods of use, the corewire 242 can be actuated to axially lengthen the ALTC device 201. The corewire 242 can be positioned within the dual lumen shaft 243. Actuation of the corewire 242 such as axially in the appropriate direction will release the constrained portion of the ALTC device 201. The movement of the corewire 242 can result in axial lengthening or shortening of the ALTC device 201. In some embodiments, the systems described herein can include a fixed guidewire. In some embodiments, the systems described herein can be advanced along a guidewire. In some embodiments, the systems described herein can slide along a guidewire. In some embodiments, the systems described herein can include a lumen configured to slide along a guidewire. In some embodiments, the guidewire is a shaft. In some embodiments, the guidewire has a lumen. In some embodiments, the guidewire is a needle. In some embodiments, the guidewire is solid. In some embodiments, the guidewire is flexible. In some embodiments, the guidewire functions to guide the system within the body of the patient. In some embodiments, the guidewire functions to deploy one or more components of the device.

[0258] The system can include a dual axial lengthening basket and anchor capture device as described here. The anchors can be any configuration such as stent-like, balloon, coils, loops, wire forms into various geometric shapes (not shown), etc. such as the embodiments described herein. In some methods of use, the anchors can function to secure the emboli, thrombus or debris and allow for removal. In some methods of use, the anchors can function to break up the emboli, thrombus or debris. In some embodiments, the ALTC device 201 and the one or more anchors move or translate together. In some embodiments, the ALTC device 201 and the one or more anchors move or translate independently or separately. In some embodiments, one or more anchors can move as a unit with another anchor. In some embodiments, one or more anchors can move independently or separately from another anchor.

[0259] Figure 73 illustrates an embodiment of an anchor 401. The anchor 401 can include any of the features of anchors described herein. In some embodiments, the anchor 401 can comprise symmetric loop shapes. In some embodiments, the anchor 401 can

comprise asymmetric loop shapes. In some embodiments, the anchor 401 can comprise polygonal shapes or generally polygonal shapes. In some embodiments, the anchor 401 comprises generally hexagonal shapes. In some embodiments, the anchor 401 has a constant diameter. In some embodiments, the anchor 401 has two or more diameters. In the illustrated embodiments, the anchor 401 has an alternating larger diameter and smaller diameter. In some embodiments, the smaller diameter is more than 50% of the larger diameter, the smaller diameter is more than 60% of the larger diameter, the smaller diameter is more than 70% of the larger diameter, the smaller diameter is more than 80% of the larger diameter, the smaller diameter is more than 90% of the larger diameter, the smaller diameter is approximately equal to the larger diameter, etc. It is also understood the anchor can have various length. For example, the anchor can have sufficient length such that the anchor is partially deploy to accommodate the length of the clot. Furthermore, the remainder of the anchor is compressed with the delivery catheter and can be lengthen and expand to accommodate longer length clot as needed.

[0260] In some embodiments, the anchor 401 can be a mesh, braid or other network of wire or thread. In some embodiments, the anchor 401 can have an interlaced structure. In some embodiments, the anchor 401 can be formed from parallel or axial wires or threads 402. The parallel or axial wires or threads can be coupled or otherwise connected at junctions 403. The junctions 403 can couple two or more wires or threads 402 together. In some embodiments, the junctions 403can be staggered to form the mesh structure. In some embodiments, the anchor 401 forms a helix. In some embodiments, the anchor 401 forms a double helix. In some embodiments, the anchor 401 forms a helical structure. In some embodiments, the anchor 401 forms an irregular mesh. In some embodiments, the anchor 401 forms a regular mesh. In some embodiments, the anchor 401 forms a fully connected structure. The anchor 401 can comprise a repeating or tessellating shape such as triangles, squares, or hexagons. The anchor can be laser-cut.

[0261] The anchor 401 can include an flexible tip 404. The flexible tip 404 can function as atraumatic soft tip. The opposite end of the anchor 401 is attached to the anchor pusher 240 and function in a similar manner described herein. The flexible tip 404 can be disposed within the outer sheath 203 described herein. The anchor pusher 240 can be disposed within the dual lumen shaft 243 described herein. The anchor pusher 240 can be

disposed within any lumen of any device, shaft or catheter described herein. The anchor can be offset to the ALTC device. The anchor can be coaxial to the ALTC device. The anchor pusher 240 and the anchor 401 can be coupled together such that movement of the anchor pusher 240 causes movement of the anchor 401. In some embodiments, the flexible tip 404, anchor 401 and the anchor pusher 240 is cannulated for an "over the wire" configuration. The anchor pusher 240 can be guided over a guidewire for placement of the anchor 401.

[0262] Figure 74 illustrates an embodiment of an anchor 405. The anchor 405 can include any of the features of anchors described herein, including anchor 401. In some embodiments, the anchor 405 can be a mesh, braid, laser cut or other network of wire or thread 406. In some embodiment, the anchor is made from one wire or thread. In some embodiments, the anchor 405 can be formed from parallel or axial wires or threads 406. The parallel or axial wires or threads can be coupled or otherwise connected at junctions 407. The junctions 407 can couple two or more wires or threads 406 together. In some embodiments, the junctions 407 can be staggered to form the mesh structure. In some embodiments, the junctions 407 can couple all of the wires or threads 406 together. In some embodiments, the junctions 407 can form a plurality of discrete subsections. In the illustrated embodiments, the anchor 405 can include three subsections formed from two junctions 407. Other configurations are contemplated (e.g., the anchor 405 includes two subsections formed from one junction 407, the anchor 405 can include four subsections formed from three junctions 407, the anchor 405 include five subsections formed from four junctions 407, etc.). In the illustrated embodiments, the anchor 405 has an alternating larger diameter and smaller diameter formed by the junctions 407. In some embodiments, the smaller diameter is less than 50% of the larger diameter, the smaller diameter is less than 40% of the larger diameter, the smaller diameter is less than 30% of the larger diameter, the smaller diameter is less than 20% of the larger diameter, the smaller diameter is less than 10% of the larger diameter, etc. It is also understood the anchor is not limited to metal only but other materials such as polymeric materials PTFE, PET, Nylon, Polyethylene, PEEK, Polypropylene, Polyimide.

[0263] Figure 75 illustrates a distal end of a capture device system including the anchor 401. The system can be placed within a vessel 408. The vessel can be any target vessel within the body of a patient. In some embodiments, the vessel is in the central nervous system or a coronary or peripheral vessel as described elsewhere herein. The system is placed

near an obstruction 409 or other source of debris or material. In some embodiments, the obstruction is a blood clot. In some embodiments, the obstruction is a neurological blood clot. In some embodiments, the obstruction is an emboli. In some embodiments, the obstruction is a foreign body.

[0264] Figure 75 illustrates the system with the anchor 401 and the ALTC device 201 deployed. In some methods of use, one or more steps of releasing an anchor 401 and axially lengthening can occur in any order. In some methods of use, the anchor 401 is deployed before axial lengthening of the ALTC device 201. In some embodiments, the anchor forms only a single loop. In some embodiments, the single loop functions in a similar manner to the anchor 401. In some methods of use, the anchor 401 is deployed by axial movement of the anchor pusher 240. The anchor pusher 240 can release the anchor 401 from a sheath such as dual lumen sheath 243 described herein. In some methods of use, the anchor 401 is deployed and then the ALTC device 201 is axially lengthened to cover the anchor 401. In some methods of use, the anchor 401 is deployed before the ALTC device 201 is axially lengthened to cover the anchor 401. In some methods of use, the anchor 401 is partially deployed before the ALTC device 201 is axially lengthened to cover the anchor 401. In some methods of use, the anchor 401 is not deployed before the ALTC device 201 is axially lengthened. In some methods of use, the anchor 401 is deployed after the ALTC device 201 is axially lengthened. In some methods of use, the anchor 401 is partially deployed after the ALTC device 201 is partially axially lengthened. In some methods of use, the anchor 401 is deployed and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchor 401 is deployed and the ALTC device 201 is axially lengthened independently. In some methods of use, the anchor 401 is fixed and the ALTC device 201 is axially lengthened. In some methods of use, the ALTC device 201 is fixed and the anchor 401 is deployed or expanded. In some methods of use, the anchor 401 is only deployed if covered by the ALTC device 201. In some methods of use, the anchor 401 is only deployed the ALTC device 201 provides distal protection. The anchors described herein can function in any manner described herein.

[0265] In some methods of use, the ALTC device 201 is positioned distally to the anchor 401. In some methods of use, the ALTC device 201 is positioned downstream in the direction of blood flow. The direction of blood flow is shown in Figure 75 by the red arrow.

In some methods of use, the ALTC device 201 is positioned distal to the obstruction or clot. In some methods of use, the ALTC device 201 is positioned to capture fragments of the obstruction. In some methods of use, the ALTC device 201 provides distal protection during clot removal. In some methods of use, alternatively, the ALTC device 201 is positioned proximally to the anchor 401. In some methods of use, the ALTC device 201 is positioned upstream to the anchor 401. In some methods of use, alternatively, two or more ALTC device 201 are utilized. In some methods of use, one ALTC device 201 is positioned distally and one ALTC device 201 is positioned proximally. In some methods of use, the two ALTC device 201 can move toward each other. In some methods of use, the two ALTC device 201 can meet at an intermediate location. The systems described herein can include one or more ALTC devices 201. The systems described herein can include one or more ALTC devices 201 positioned as described herein. In some embodiment, the anchor 401 can position distal to the ALTC device 201 (not shown).

[0266] In some methods of use, the anchor 401 is positioned distally to the ALTC device 201. In some methods of use, the anchor can function to block emboli. In some methods of use, the anchor 401 is positioned downstream in the direction of blood flow, or upstream in other embodiments. The direction of blood flow is shown in Figure 75 by the arrow. In some methods of use, the anchor 401 is positioned distal to the obstruction or clot. In some methods of use, the anchor 401 is positioned to capture fragments of the obstruction. In some methods of use, the ALTC device 201 is lengthened for clot removal. In some methods of use, alternatively, two or more the anchors 401 are utilized. In some methods of use, one, two, or more anchors 401 are positioned distally and one, two, or more anchors 401 are positioned proximally of the ALTC device 201. In some methods of use, the two anchors 401 can move toward each other. In some methods of use, the two anchors 401 can meet at an intermediate location. The systems described herein can include one, two, or more anchors 401. The systems described herein can include one, two, or more anchors 401 positioned as described herein.

[0267] In some embodiments, the anchor is deployed adjacent to the clot. In some embodiments, the anchor is deployed within the clot. In some embodiments, the anchor is deployed distal to the clot. In some embodiments, the anchor is deployed proximal to the clot. In some methods of use, the anchor 401 deploys within the obstruction or clot. In some

methods of use, the anchor 401 is positioned to entangle the obstruction. In some methods of use, the anchor 401 is positioned distally to the obstruction or downstream in the direction of blood flow. In some methods of use, the anchor 401 can move proximally through the obstruction. In some methods of use, the anchor 401 is positioned proximally to the obstruction or upstream in the direction of blood flow. In some methods of use, the anchor 401 can move distally through the obstruction. In the illustrated embodiment, the obstruction or clot can pass through the anchor 401. In the illustrated embodiment, the obstruction or clot can be caught in the anchor 401. In some methods of use, the anchor 401 moves after deployment. For instance, the anchor 401 can move distally therefore moving the obstruction distally. The anchor 401 can move proximally therefore moving the obstruction proximally. In some embodiments, the anchor 401 can rotate. After deployment of the anchor 401, the obstruction and the anchor 401 can move together as a unit. After deployment of the anchor 401, the obstruction, the anchor 401, and the ALTC device 201 can move together as a unit. In some methods of use, the anchor 401 moves after axially lengthening of the ALTC device 201. In some methods of use, the anchor 401 moves before axially lengthening of the ALTC device 201.

[0268] Figures 76A-76C illustrates the axial lengthening sequence of the ALTC device 201, according to some embodiments. The ALTC device 201 can be lengthened in any manner described herein. In some methods of use, the ALTC device 201 can be lengthened by retraction of a constraining member such as a sheath. As the sheath is retracted, the capture guide 204 is expanded. After the capture guide 204 is expanded, a portion of the ALTC device 201 is expanded. In some methods of use, the sheath dual lumen sheath 243 can be retracted to axially lengthen the ALTC device 201. In some embodiments, for the dual lumen sheath 243 in some cases, there may be no outer sheath required to constrain the device. In some embodiments, the dual lumen sheath 243 constrains the ALTC device 201. In some embodiments, the dual lumen sheath 243 constrains the anchors. In some embodiments, the dual lumen sheath 243 is loaded with the ALTC device 201. In some embodiments, the dual lumen sheath 243 is loaded with the one or more anchor. In some embodiments, the ALTC device 201 and the one or more anchor are loaded in a single lumen of a single lumen sheath. In some embodiments, the ALTC device 201 and the one or more anchor are loaded in a single lumen of a dual lumen sheath. In some embodiments, the ALTC

device 201 and the one or more anchor are loaded in separate lumens of a sheath. In some embodiments, the ALTC device 201 and the one or more anchor are advanced from a single lumen of a single lumen sheath. In some embodiments, the ALTC device 201 and the one or more anchors are advanced from a single lumen of a dual lumen sheath. In some embodiments, the ALTC device 201 and the one or more anchors are advanced from separate lumens of a sheath. In some embodiments, the device would be loaded in a sheath/guide/microcatheter in advance. Effectively, in some cases the guide/microcatheter can be used as a sheath.

[0269] In some embodiments, the ALTC device 201 maintains the diameter of the capture guide 204. In some methods of use, the ALTC device 201 can be lengthened by extension of a member such as a pusher 202 or corewire 242. Alternatively or in combination, in other methods of use, the inner pusher 202 is advanced distally to advance an end of the ALTC device 201. As described herein, an end of the ALTC device 201 is coupled to the inner pusher 202. In the second configuration, the inner pusher 202 is advanced distally to release a portion of ALTC device 201 from a sheath. As the inner pusher 202 is advanced distally, a portion of the collapsed portion 208 becomes the expanded portion of the ALTC device 201. As the inner pusher 202 is advanced distally, the ALTC device 201 is axially lengthened.

[0270] Figure 76A illustrates the system after deployment of the anchor 401. In some methods of use, the anchor 401 is deployed before axial lengthening of the ALTC device 201. The capture guide 204 is expanded and a portion of the ALTC device 201 is expanded. Figure 76A illustrates the axial lengthen device or ALTC device 201 with an expandable anchor 401 positioned near the opening end of the ALTC device 201. In some embodiments, the expandable anchor 401 can be independently movable such that expandable anchor 401 can retract proximally or distally while the ALTC device 201 is stationary. In some embodiments, alternatively, the anchor 401 and the ALTC device 201 can move together as one unit. In some embodiments, the ALTC device 201 and the expandable anchor 401 are collapsed in the delivery configuration. In some embodiments, the ALTC device 201 and the expandable anchor 401 are expanded when deployed within the target vessel.

[0271] Figure 76B illustrates the axial lengthening of the expanded portion of the ALTC device 201. In some methods of use, the ALTC device 201 is lengthening proximally to encapsulate the anchor 401. In some methods of use, the anchor 401 has captured an obstruction or clot. In some methods of use, the ALTC device 201 is lengthening proximally to encapsulate the obstruction or clot. In some methods of use, the ALTC device 201 is lengthening proximally to encapsulate only a portion of the anchor 401. The collapsed portion 208 of the ALTC device 201 is shortened as the ALTC device 201 is axially lengthened. In some methods of use, the ALTC device 201 is not lengthened proximally to encapsulate a portion of the anchor 401. In some methods of use, the ALTC device 201 and the anchor 401 remain in the position shown in Figure 76A during clot removal.

[0272] Figure 76C illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally to capture the clot secured by the anchor 401. In some methods of use, the ALTC device 201 is lengthening proximally to circumscribe the entire anchor 401. The collapsed portion 208 of the ALTC device 201 is shortened as the ALTC device 201 is lengthened. For instance, collapsed portion 208 has a smaller axial length in Figure 76C than in Figure 76B. Figure 76C illustrates the axial lengthening ALTC device 201 is sufficient to completely capture the clot. In some methods of use, the ALTC device 201 and the anchor 401 can retract proximally to remove the clot. In some methods of use, the ALTC device 201 and the anchor 401 can retract proximally while the configuration shown in Figure 76A. In some methods of use, the ALTC device 201 and the anchors 401 can retract proximally while the ALTC device 201 does not circumscribe the entire anchor 401.

[0273] In Figure 76C, the deployed and expanded ALTC device 201 is longer, e.g., in length, than the deployed and expanded ALTC device 201 in Figure 76B. The collapsed portion 208 resides inside the outer sheath 203 or dual lumen shaft 243 and is shorter in Figure 76C than in Figure 76B. The diameter or cross-section of the ALTC device 201 can remain constant or substantially constant during axially lengthening. The diameter or cross-section of the ALTC device 201 can in some cases remain constant between the initial deployed configuration shown in Figure 76A and the expanded configurations shown in 76B and 76C. In some embodiments, two or more steps can occur simultaneously. In some

methods of use, the anchor 401 is partially deployed and the ALTC device 201 is axially lengthened to cover the anchor 401 simultaneously.

[0274] Figures 77A-77C illustrate additional views of the system. The anchor 405, or any of the anchors described herein, can be deployed in a similar manner as anchor 401. In some embodiments, the ALTC device 201 is axially lengthened with the expandable anchor 401 positioned near the opening end of the ALTC device 201. In some embodiments, the ALTC device 201 is extended over the expandable anchor 401. In some embodiments, the ALTC device 201 is positioned distal to the obstruction, clot, emboli, and/or foreign body for distal protection. In some embodiments, the ALTC device 201 is positioned distally or downstream in the direction of blood flow. In some embodiments, the expandable anchor 401 is deployed within the obstruction. In some embodiments, the ALTC device 201 retracts proximally over the expandable anchor 401 and the obstruction. In some embodiments, the obstruction is removed. In some embodiments, the ALTC device 201 is positioned distal to the obstruction for distal protection. In some embodiments, the expandable anchor 401 deploys within the obstruction and retracts to remove the obstruction while the ALTC device 201 remains in position. In some embodiments, the ALTC device 201 retracts subsequently to remove emboli. In some embodiments, the expandable anchor 401 and the ALTC device 201 retract as one unit to remove the obstruction. In some embodiments, the ALTC device 201 is retracted over the expandable anchor and obstruction and the entire device is removed.

[0275] Figure 78 illustrates another embodiment of an anchor 410. The anchor 410 can include any of the features of anchors described herein. In some embodiments, the anchor 410 can include a balloon. Balloon materials can be compliant, semi-compliant, or non-compliant. In some embodiments, the anchor 410 can comprise a spherical balloon. In some embodiments, the anchor 410 can comprise an oblong balloon. In some embodiments, the anchor 410 can include one or more shaped ends, including conical, square, spherical, tapered, etc. In some embodiments, the anchor 410 can includes a dog bone shaped with proximal and distal areas of increased diameter balloon or stepped balloon having two or more different diameters. In some embodiments, the anchor 410 can include an axially or radially offset balloon. In some embodiments, the anchor 410 can comprise any shape including a conical balloon, tapered balloon, stepped balloon, square balloon, polygonal balloon, etc. In some embodiment, the balloons can be in series or in parallel or

circumferentially or radially. Additional balloon shapes are disclosed in U.S. Patent Application No. 11/851,848, filed Sept. 7, 2007 and published July 23, 2013 as U.S. Patent No. 8491623 ("Vogel"), which is incorporated by reference in its entirety. In some embodiments, the anchor 410 has a diameter. In some embodiments, the anchor 410 has two or more diameters. In some embodiments, the smaller diameter is more than 50% of the larger diameter, the smaller diameter is more than 60% of the larger diameter, the smaller diameter is more than 70% of the larger diameter, the smaller diameter is more than 80% of the larger diameter, the smaller diameter is more than 90% of the larger diameter, the smaller diameter is approximately equal to the larger diameter, etc. In some embodiments, two or more anchors 410 have the same shape. For instance, two or more anchors 410 can be spherical. In some embodiments, two or more anchors 410 can be identical. In some embodiments, two or more anchors 410 have a different shape. For instance, the first anchor 410 can be spherical and the second anchor 410 can be oblong. In some embodiments, two or more anchors 410 have a different diameter or cross-section. Figure 78 illustrates the ALTC device 201 with a single balloon. In some embodiments, the balloon is independently movable relative to the ALTC device 201. In some embodiments, the balloon and ALTC device 201 can also retracted as one unit. Figure 79 for example illustrates balloons 410 are positioned in series. In some embodiment, the balloons can position side-by-side, in parallel, circumferentially, and/or radially. Further in some embodiments, the balloons' shape and diameter can be configured so that there are gaps between the balloons to allow potential blood flow.

[0276] In some embodiments, the anchor 410 can be inflated. In some embodiments, an inflation medium such as gas or liquid is supplied to the anchor 410. In some embodiments, the anchor 410 can be inflated to form a rigid body. In some embodiments, the anchor 410 can be inflated to transmit a force to the obstruction, such as force to compress or move the obstruction. In some embodiments, the anchor 410 can be deflated. The inflation medium can be removed from the anchor 410. In some embodiments, the anchor 410 has a rough or textured outer surface. In some methods of use, the anchor 410 becomes entangled with the obstruction or clot described herein. In some embodiments, the anchor 410 has a smooth outer surface. In some embodiments, the anchor 410 can compress the obstruction or clot thereby opening the blood vessel. The anchor 410 can apply a

compressive force on the obstruction during inflation of the anchor 410. In some embodiments, the anchor 410 can be self-deployed. In some embodiments, the anchor 410 can include a shape memory material to deploy the anchor 410.

[0277] Figure 79 illustrates an embodiment including a plurality of anchors, such as a first anchor 410, a second anchor 410, a third anchor 410, and a fourth anchor 410. The system can include one or more of the anchors 410. In the illustrated embodiment, the system includes four anchors 410 but other configurations are contemplated (e.g., two anchors, three anchors, five anchors, six anchors, seven anchors, eight anchors, nine anchors, ten anchors, etc.). In some embodiments, two or more anchors 410 are inflated simultaneously. For instance, the anchors 410 can be coupled such that fluid can flow between the anchors 410. In some embodiments, two or more anchors 410 are inflated independently. For instance, each anchor can be separately supplied fluid for inflation, or include a common inflation lumen. In some embodiments, two or more anchors 410 are inflated in series. In some embodiments, two or more anchors 410 are inflated in parallel. In some embodiments, two or more anchors 410 are deflated simultaneously. In some embodiments, two or more anchors 410 are deflated independently. In some embodiments, two or more anchors 410 are deflated in series. In some embodiments, two or more anchors 410 are deflated in parallel. The two or more anchors 410 can be coupled via an inflation lumen 411. The inflation lumen 411 can allow delivery of the fluid to inflate the anchors.

[0278] Figure 79 illustrates the ALTC device 201 with a series of balloons positioned near the opening end of the ALTC device 201. In some embodiments, the balloons are independently movable relative to the ALTC device 201. In some embodiments, the balloons and the ALTC device 201 can also retracted as one unit. In some embodiments, the balloons function as anchors as described herein to entangle the clot. In some embodiments, the balloons function to compress the clot to open the target vessel. Other functions for the balloons are contemplated. In some embodiments, the balloons have a uniform size and shape, but can be positioned adjacent each other in order of increasing or decreasing diameter, or have different shapes in some embodiments.

[0279] Figure 80 illustrates the system within the vessel 408 with the obstruction 408 after deployment of the anchors 410. In some methods of use, the anchors 410 are inflated before axial lengthening of the ALTC device 201. In some methods of use, one or

more steps of deploying or inflating anchors 410 and axially lengthening can occur in any order. In some methods of use, the anchors 410 are inflated and then the ALTC device 201 is axially lengthened to cover the anchors 410. In some methods of use, two or more anchors 410 can be inflated before the ALTC device 201 is axially lengthened. In some methods of use, the anchors 410 are fixed such that the anchors 410 need not be inflated. In some methods of use, one or more anchors 410 are deflated before the ALTC device 201 is axially lengthened. In some methods of use, one or more anchors 410 are inflated after the ALTC device 201 is axially lengthened. In some methods of use, the anchors 410 are inflated and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchors 410 are inflated and the ALTC device 201 is axially lengthened independently. In some methods of use, the anchors 410 are only inflated if covered by the ALTC device 201.

[0280] Figure 80 illustrates the ALTC device 201 positioned distal to the obstruction. Figure 80 illustrates the balloons expanding within the obstruction. In some embodiments, one or more anchors 410 are positioned distally to the obstruction before inflation. After inflation, the one or more distal anchors 410 can push the obstruction proximally. In some embodiments, one or more anchors 410 are positioned proximally to the obstruction before inflation. After inflation, the one or more distal anchors 410 can push the obstruction distally toward the ALTC device 201.

[0281] In some methods of use, the ALTC device 201 is positioned distally to the anchors 410. In some methods of use, the ALTC device 201 provides distal protection during clot removal, akin to a filter in some cases. In some methods of use, the anchors 410 inflate within the obstruction. In some methods of use, the anchors 410 are positioned to entangle the obstruction. In some methods of use, the anchors 410 move after deployment. In some methods of use, the anchors 410 move simultaneously. In some methods of use, the anchors 410 move independently, or all in concert in some cases. In some methods of use, the anchors 410 move distally therefore moving the obstruction distally. In some methods of use, the anchors 410 move toward the ALTC device 201. After deployment of the anchors 410, the obstruction and the anchors 410 can move together as a unit. In some methods of use, the anchors 410 move after axially lengthening of the ALTC device 201. In some methods of use, the anchors 410 move before axially lengthening of the ALTC device 201.

[0282] Figure 81 illustrates an embodiment of an anchor 415. The anchor 415 can include any of the features of anchors described herein. In some embodiments, the anchor 415 can comprise a disk. In some embodiments, the anchor 415 can be arcuate shaped such as round or circular, or ovoid. In some embodiments, the anchor 415 can have a constant or variable diameter. In some embodiments, the anchor 415 can be any shape, including a polygon, elliptical, etc. In some embodiments, the anchor 415 can be entirely flat or have flat surfaces. In some embodiments, the anchor 415 can be concave, convex, or another curved shaped. For instance, a first surface 416 of the anchor 415 can be concave and a second surface 417, opposite the first surface can be concave. For instance, a first surface 416 of the anchor 415 can be convex and a second surface 417, opposite the first surface can be convex. In some embodiments, the anchor 415 can have a smooth outer surface. In some embodiments, the anchor 415 can include a roughened or porous outer surface. The anchor can conform when contacting a surface such as a vessel wall.

[0283] In some embodiments, the anchor 415 can be deployed similar to anchor 241. In some embodiments, the anchor 415 can self-deploy. In some embodiments, the anchor 415 can include a shape memory material to deploy the anchor 415. In some embodiments, the anchor 415 can be inflated. In some embodiments, an inflation medium such as gas or liquid is supplied to the anchor 415. In some embodiments, the anchor 415 can be deflated. Figure 81 illustrates the ALTC device 201 with a single disk positioned proximal to the ALTC device 201. In some embodiments, the expandable disk is independently movable relative to the ALTC device 201. In some embodiments, the expandable disk and ALTC device 201 can also be retracted as one unit. In some embodiment, the anchor 415 is adjacent, side-by-side or offset to the ALTC device 201. In some embodiment, the anchor 415 is coaxial or in-line to the ALTC device.

[0284] Figure 82 illustrates an embodiment including a first anchor 415, a second anchor 415, a third anchor 415, a fourth anchor 415, a fifth anchor 415, and a sixth anchor 415. The system can include one, two, or more of the anchors 415. In the illustrated embodiment, the system includes six anchors 415 but other configurations are contemplated (e.g., about, at least about, or no more than about two anchors, three anchors, four anchors, five anchors, seven anchors, eight anchors, nine anchors, ten anchors, etc.). In some embodiments, the anchor 415 comprises a helix or helical structure. For instance, the first

anchor 415 can be joined with the second anchor 415 to form a helix. A helical anchor is disclosed, for example, in Figure 6A of PCT/IB2014/066389, filed Nov. 27, 2014 and published June 4, 2015 as WO 2015/079401 ("Yachia"), which is incorporated by reference in its entirety.

[0285] In some embodiments, two or more anchors 415 are deployed simultaneously. In some embodiments, two or more anchors 415 are deployed independently. For instance, the first anchor 415 and the second anchor 415 can be deployed independently. In some embodiments, two or more anchors 415 are deployed in series. For instance, the first anchor 415 can be deployed before the second anchor 415. In some embodiments, two or more anchors 415 are deployed in parallel. Figure 82 illustrates the ALTC device 201 with a series of expandable disks positioned proximal to the ALTC device 201. In some embodiments, the expandable disks are independently movable relative to the ALTC device 201. In some embodiments, the expandable disks and ALTC device 201 can also be retracted as one unit.

[0286] Figure 83 illustrates the system within the vessel 408 with the obstruction 409. In some methods of use, one or more steps of deploying or inflating anchors 415 and axially lengthening can occur in any order. In some methods of use, the anchors 415 are deployed before axial lengthening of the ALTC device 201. In some methods of use, one or more anchors 415 are deployed before the ALTC device 201 is axially lengthened to cover the anchors 410. In some methods of use, one or more anchors 415 are deployed after the ALTC device 201 is axially lengthened. In some methods of use, the anchors 415 are deployed and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchors 415 are only deployed if covered by the ALTC device 201. Figure 83 illustrates the ALTC device 201 positioned distal to the obstruction and the expandable disks deployed within the obstruction. The single disk embodiment shown in Figure 81 can be deployed within the obstruction in a similar manner. In some methods of use, the ALTC device 201 is positioned distally to the anchors 415. In some methods of use, the ALTC device 201 provides distal protection during clot removal. In some methods of use, the anchors 415 deploy within the obstruction or clot. In some methods of use, the anchors 415 move after deployment.

[0287] Figure 84 illustrates an embodiment of an anchor 420. The anchor 420 can include any of the features of anchors described herein. In some embodiments, the anchor 420 can comprise a funnel. In some embodiments, the anchor 420 can include a round or circular opening. In some embodiments, the anchor 420 can taper from a larger diameter or cross-section to a smaller diameter or cross-section. In some embodiments, the anchor 420 can taper along the length of the anchor 420. In some embodiments, the anchor 420 can be any generally conical shape. In some embodiments, the anchor 420 can include an inflection point. In some embodiments, the anchor 420 can include a radially outward flare. In some embodiments, the anchor 420, or a surface thereof, is concave. In some embodiments, the anchor 420, or a surface thereof, is convex. In some embodiments, the anchor 420 can have a smooth outer surface. In some embodiments, the anchor 420 can include a roughened or porous outer surface. In some embodiment, the anchor 420 is adjacent, side-by-side or offset to the ALTC device 201. In some embodiment, the anchor 420 is coaxial or in-line to the ALTC device.

[0288] In some embodiments, the anchor 420 is formed as a mesh or braid, laser cut or stent structure. The funnel shape of the anchor 420 can in some cases assist in retrieving and containing the obstruction or clot. In some embodiments, the anchor 420 comprises structural features to assist in the deployment of the funnel shape, such as to hold the rim 421 of the funnel shape open. In some embodiments, the anchor 420 can include struts comprising a shape memory or self-expanding material such as nitinol, or other stent structure, mesh, and/or webbing. In some embodiments, the anchor 420 can be deployed similar to anchor 241. In some embodiments, the anchor 420 can be self-deployed. In some embodiments, the anchor 420 can include a shape memory material to deploy the anchor 420. The anchor 420 can include a rim 421. The rim 421 can include any of the features of the capture guides described herein.

[0289] In some embodiments, the proximal end opening of the anchor 420 includes the rim 421 that takes the form of, in some embodiments, a radially expandable shape memory partial or full ring-like annular structure. The rim 421 expands once freed or released from a constraining member such as any sheath or tube described herein. In some embodiments, the rim 421 is coupled with a portion of a mesh, interlaced structure, or covering 422. In some other embodiments, the rim 421 and the proximal end of the covering

422 can be sutured in place using silk or polymeric filaments such as Ultra-High Molecular Weight polyethylene, Nylon, PET, PTFE. In some embodiments, the covering 422 comprises with a low durometer polymeric material.

[0290] The rim 421 and/or the covering 422 can be formed, for example, from metallic, shape memory, or other appropriate materials. In some embodiment, the rim 421 can include a loop configuration and be formed from nitinol shape memory wire of various geometries such as round, oval, elliptical, flat, and the like. The rim 421 can be formed of different shapes such as a circular loop, oval loop, z-shape, etc. In some embodiment, the rim 421 can be shaped set either into coils, multiple full circles, full circle or partial circles where the ends of the wire formed into two legs. The partial circle can be from, for example, 180 degrees to 359 degrees or 220 degrees to 359 degrees. The legs can be configured to be off-axis to the loop such that it can be right angle, acute or obtuse angle relative to the loop. It can be arcuate and form a partial or full ring as illustrated, and can circumscribe or otherwise form an outer diameter, and define the proximal-most end of the anchor 420. The anchor 420 can in some embodiments include a single loop or multiple loops positioned along the length of the covering 422. The anchor 420 can be configured to be compressed and positioned within a lumen of a shaft during introduction into the vascular system where the anchor 420 is configured to be positioned coaxially within the obstruction or clot. In some methods of use, the anchor 420 is configured to be deployed to entangle with the obstruction or clot.

[0291] Figure 84 illustrates the ALTC device 201 with an expandable funnel like anchor. In some embodiments, the funnel shaped anchor is positioned proximal to the ALTC device 201. In some embodiments, the funnel shaped anchor is independently movable relative to the ALTC device 201. In some embodiments, alternatively, the anchor and ALTC device 201 can move as one unit.

[0292] Figure 85 illustrates an embodiment including a plurality of anchors, such as a first anchor 420, a second anchor 420, a third anchor 420, a fourth anchor 420, and a fifth anchor 420. The system can include one or more of the anchors 420. In the illustrated embodiment, the system includes five anchors 420 but other configurations are contemplated (e.g., two anchors, three anchors, four anchors, six anchors, seven anchors, eight anchors, nine anchors, ten anchors, etc.). In some embodiments, two or more anchors 420 are deployed simultaneously. In some embodiments, two or more anchors 420 are deployed

independently. For instance, the first anchor 420 and the second anchor 420 can be deployed independently. In some embodiments, two or more anchors 420 are deployed in series. For instance, the first anchor 420 can be deployed before the second anchor 420. In some embodiments, two or more anchors 420 are deployed in parallel. Figure 85 illustrates the ALTC device 201 with expandable funnel like anchors. In some embodiments, the funnel shaped anchors are positioned proximal to the ALTC device 201. In some embodiments, the funnel shaped anchors are independently movable relative to the ALTC device 201. In some embodiments, alternatively, the anchors and ALTC device 201 can move as one unit.

[0293] Figure 86 illustrates the system within the blood vessel 408 and the obstruction 409. In some methods of use, one or more steps of deploying one or more anchors 420 and axially lengthening can occur in any order. In some methods of use, one or more anchors 420 are deployed before axial lengthening of the ALTC device 201. In some methods of use, the anchors 420 are deployed before the ALTC device 201 is axially lengthened to cover the anchors 420. In some methods of use, one or more anchors 420 are deployed after the ALTC device 201 is axially lengthened. In some methods of use, the anchors 420 are deployed and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchors 420 are deployed and the ALTC device 201 is axially lengthened independently. In some methods of use, the anchors 420 are only deployed if covered by the ALTC device 201. In some methods of use, the ALTC device 201 is positioned distally to the anchors 420. In some methods of use, the ALTC device 201 provides distal protection during clot removal. In some methods of use, the anchors 420 deploy within the obstruction or clot. In some methods of use, the anchors 420 move after deployment.

[0294] Figure 86 illustrates an embodiment in which the anchors 420 face forward. The anchors 420 can taper inward from a distal end 423 to a proximal end 424. The rim 421 of each anchor 420 can be located at the distal end 423 of each anchor 420. Figure 87 illustrates a system with anchors 420 deployed within a vessel 408 comprising an obstruction 409. Figure 87 illustrates an embodiment in which the anchors 420 face backward. The anchors 420 can taper inward from the proximal end 424 to a distal end 423. The rim 421 of each anchor 420 can be located at the proximal end 424 of each anchor 420. In some embodiments, the anchors 420 have a single configuration, e.g., all anchors 420 face

forward as shown in Figure 86, all anchors 420 face backward as shown in Figure 87. In some embodiments, two or more anchors 420 have a different configuration, e.g., the first anchor 420 faces forward and the second anchor 420 faces backward. In some embodiments, the anchor 420 can switch between facing forward and facing backward. In some embodiments, the anchors 420 can be configured to roll out, invert, evert, and/or variably lengthen proximally or distally between facing forward and facing backward. In some embodiments, one or more anchors 420 can be configured to switch between facing forward and facing backward. In some embodiments, one or more anchors 420 can be fixed as either facing forward or facing backward. Figures 86 and 87 illustrate the ALTC device 201 positioned distal to the obstruction. Figures 86 and 87 illustrate the expandable funnel shape anchors deployed within the obstruction.

[0295] The anchors described herein can have any shape. Other expandable shapes and/or geometric anchors are contemplated. In some embodiments, the anchor can be shaped as a coil. In some embodiments, the anchor can be shaped as a loop. In some embodiments, the anchor can be shaped as a clover. In some embodiments, one or more anchors are offset to the ALTC device 201. In some embodiments, the anchor can be coaxial to the ALTC device 201 wherein the anchors can be attached to the shaft of the ALTC device 201. In some embodiments, this configuration allows the anchor and the axial lengthen device move as one unit.

[0296] U.S. Patent Application No. 14/602,014, filed Jan. 21, 2015 and published Aug. 9, 2016 as U.S. Patent No. 9408620 ("Rosenbluth"); U.S. Patent Application No. 08/723,619, filed Oct. 20, 1996 and published Apr. 20, 1999 as U.S. Patent No. 5895398 ("Wensel"); U.S. Patent Application No. 08/968146, filed Nov. 12, 1997 and published Sept. 7, 1999 as U.S. Patent No. 5947985 ("Imran"); U.S. Patent Application No. 09/756476, filed Jan. 8, 2001 and published Dec. 16, 2003 as U.S. Patent No. 6663650 ("Sepetka"); U.S. Patent Application No. 09/789332, filed Feb. 20, 2001 and published Jan. 11, 2005 as U.S. Patent No. 6840950 ("Sanford"); U.S. Patent Application No. 12/581,960, filed Oct. 20, 2009 and published Jan. 10, 2012 as U.S. Patent No. 8092486 ("Berrada"); U.S. Patent Application No. 11/580,546, filed Oct. 13, 2006 and published Aug. 28, 2012 as U.S. Patent No. 8252017 ("Paul"); U.S. Patent Application No. 12/564892, filed Sept. 22, 2009 and

published Oct. 30, 2012 as U.S. Patent No. 8298252 ("Krolik") are all incorporated by reference herein in their entireties.

[0297] In some embodiments, the clot treatment device described by Rosenbluth et al. can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88A-88H, embodiments of an anchor 425 are disclosed. Referring to FIG. 88A, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rounded triangular cross-section. Referring to FIG. 88B, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rounded triangular cross-section wherein the diameter of the disk increases along the length of the anchor 425 thus forming a conical exterior extent. Referring to FIG. 88C, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rectangular cross-section. Referring to FIG. 88D, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a linear (non-rounded) triangular cross-section. Referring to FIG. 88E, some of the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rounded cross-section and others have a rectangular cross section. Referring to FIG. 88F, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 alternate between cylindrical disk shape with a T-shaped cross-section and a flare-shaped cross-section. Referring to FIG. 88G, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a partial cylindrical disk shapes. Referring to FIG. 88H, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by tabs and bumps or protuberances arising from the cylindrical surface of the anchor 425. In some embodiments, the anchors described herein provide greater surface area along the anchor than an anchor that is uniformly cylindrical. In some methods of use, the increased surface area facilitates the treatment and/or retrieval of the obstruction or clot.

[0298] In some embodiments, the anchor 425 can have a generally cylindrical shape that, during use, provides a flow lumen for blood across a clot. The anchor 425 is not, however, limited to a generally cylindrical shape. For example, the shape can be generally

conical, generally concave or generally convex along its axis, so long as such shapes provide the aforesaid lumen for blood flow. In some embodiments, the anchor 425 also has a series of radially extending portions 426 which are separated by generally cylindrical portions 427. In some embodiments, the clot treatment device 425 can be porous so as to allow the flow of blood therethrough. In some embodiments, the anchor 425 is made from a mesh or braided material. The material can be a superelastic material such as nitinol or an alternative material such as cobalt chrome alloy. In some embodiments, the anchor 425 can be made from a wire lattice, wire braid or stent. In some embodiments, the anchor 425 can be self expanding.

[0299] In some embodiments, the anchor radially expands into the clot. In some methods of use, at least a portion of the anchor expands distal of the clot. As shown in some figures herein, at least one of the anchors of a plurality of anchors can be located distal to the clot upon expansion of the anchors. In some methods of use, upon expansion of the anchor, blood flowthrough the clot is restored. More specifically, the blood is now free to move through the mesh of the anchor and exit the anchor distal to the clot. As a result, the acute condition of blockage is corrected thus immediately improving the circulation of oxygenated blood in the patient. The expansion, inflation, or deployment of the anchors described herein can impinge or cut into the clot material. This entanglement can enhance the subsequent removal of the clot since portions of the clot collect between the radially extending portions 426; through the pores of the mesh forming the radially extending portions 426; along the longitudinal cylindrical sections 427 between the radially extending portions 426 of the anchor 425; and/or within the anchor 425 itself.

[0300] In some methods of use, the deployment of the anchor 425 results in an outwardly expanding generally cylindrical force being urged against an inner surface of the clot. In some methods of use, this force pushes the clot material outwardly and creates a lumen through which blood flow is restored. In some methods of use, the outwardly expanding generally cylindrical force can vary in magnitude along the axis of the anchor, due in part to the shape of the anchor. In some embodiments, the deployment of the anchor changes the angular orientation of the anchor with respect to the axis of the system. In some methods of use, this angular change or twisting can improve or enhances adherence of clot material to the anchor 425.

[0301] The clot treatment devices disclosed in Rosenbluth may be included in a system with the ALTC device 201 described herein. The ALTC device 201 can surround the clot treatment devices similar to the anchors described herein. After the clot treatment device has been expanded, the ALTC device 201 can be axially lengthened to capture the clot. In one embodiment, the clot treatment device and the ALTC device 201 are pulled back simultaneously in a proximal direction. This is followed by the entire system being withdrawn.

[0302] The clot and foreign body removal device of Wensel can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88I-88J, embodiments of the anchor 428 are disclosed. The anchor 428 can be a clot capture coil. In some embodiments, the coil is made from a flexible solid elastic or superelastic material which has shape memory, e.g., it can deform to a straight position and then return to a resting coil configuration. In some embodiments, the coil is made out of a solid nitinol wire with a diameter of, e.g., about 0.0005 inches to about 0.038 inches. Nitinol is preferred in some cases because of its superelasticity and its shape memory. However, other solid materials that are also elastic or superelastic and have shape memory could also be used such as some synthetic plastics, metallic alloys, and the like. The diameter of the coils can vary depending on the size of the vessel occluded. The diameter can range from about 1 mm for small vessels to about 30 mm for large vessels such as the pulmonary arteries or inferior vena cava. The length of the coil can also vary but typically ranges from about 3 to about 300 mm in the proximal to distal direction. Because the nitinol coil is superelastic, the coil can be extended to a completely straight configuration with the use of minimal force and then reform to its natural resting configuration when the force is removed. In some embodiments, the coil is made out of a solid biphasic material which changes shape upon heating or the passage of electric current. In some embodiments, the coil is cone-shaped.

[0303] In some embodiments, the anchors described herein can comprise a shape memory body. The anchor can comprise a single wire or multiple wires. The anchor can comprise one or more loops. The anchor can comprise one or more helices. In some embodiments, the loops and/or helices can have an increasing diameter from proximal to distal end of the anchor. In some embodiments, the loops and/or helices can have a

decreasing diameter from proximal to distal end of the anchor. In some embodiments, the loops and/or helices can have a variable diameter from proximal to distal end of the anchor.

[0304] The apparatus of Imran can be used in place of, or in combination with, the anchors described herein. Referring now to Figure 88K, an embodiment of the anchor 429 is disclosed. The anchor 429 can include a brush. The brush is formed on the distal extremity of the flexible elongate tubular member. The brush is comprised of a plurality of radially extending bristles formed of a suitable soft material such as Nylon with the brush having an outer diameter corresponding generally to the inner diameter of the lumen defined by the wall. The distal extremity is provided with a plurality of randomly disposed ports interposed between the bristles for supplying irrigation liquid to the brush. With irrigation liquid being supplied through the ports and aspiration taking place through the aspiration port, the brush can be rotated by rotating the proximal extremity of the therapeutic catheter. By moving the catheter back and forth, the bristles can come into engagement with the wall throughout the entire length of the chamber to remove the plaque in small particles. As the small particles are removed they can be aspirated from the chamber through the aspiration port.

[0305] The obstruction removal device of Sepetka can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88L-88M, the obstruction removing device 430 has an engaging element 431 extending from an insertion element 432. The engaging element 431 is movable from a collapsed position to an expanded position. When the engaging element 431 is contained within a sheath or other member, the engaging element 431 is in a relatively straight configuration. The engaging element 431 has a distal portion, which forms a relatively closed structure, which can catch or trap the obstruction, or any part thereof, to prevent migration of the obstruction or part thereof. The engaging element has a proximal portion which is formed with smaller coils than the distal portion. The proximal portion engages the obstruction as described below. The engaging element 431 preferably has a number of markers which provide an indication as to how much of the engaging element extends from the sheath. For example, markers may indicate when the engaging element 431 is ½, ¾ or fully exposed. In this manner, the user may quickly advance the engaging element 431 through the sheath without inadvertently exposing and advancing the engaging element 431 out of the sheath. The markers can also be used to

provide a controlled diameter of the engaging element 431 since the diameter of the engaging element is known for the various positions corresponding to the markers. The markers may also be used to size the vessel in which the engaging element 431 is positioned by observing when the engaging element 431 engages the vessel walls and determining the size of the engaging element 431 using the markers.

[0306] The engaging element 431 is preferably made of a superelastic material, such as nitinol, and has a diameter of, in some cases, about 0.005-0.018 inch, about 0.005-0.010 inch or about 0.008 inch. The engaging element 431 can have a rounded, atraumatic tip to prevent damage to the vessel and facilitate advancement through the vessel and/or sheath. A radiopaque wire, such as platinum ribbon having a width of 0.004 inch and a thickness of 0.002 inch, is preferably wrapped around the engaging element 431 to improve radiopacity. The device is preferably self-expanding but may also be expanded with an actuator. The actuator is preferably a thin filament which is tensioned to move the device to the expanded position. An advantage is that the filament extends through the same lumen as the device thereby minimizing the overall size of the device. It is understood that throughout discussion of the devices and methods herein that any of the anchors described herein may be expanded using the actuator rather than being self-expanding. The obstruction removal device shown in Figure 88M has a first section with larger diameter coils than a second section. A third section also has larger coils than the second section with the second section positioned between the first and third sections. The obstruction removal device may have a number of alternating small and large sections which can enhance the ability of the obstruction removal device to engage various obstructions. The obstruction removal device can have four large sections with relatively large coils and three sections having smaller coils, but other configurations are contemplated with different numbers of sections.

[0307] The expansion elements of Sanford can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88N, an anchor 433 is shown. The anchor 433 can include a helical expansion ring connected to the inlet of the anchor. Expansion ring has a proximal end and a distal end. The distal end can be fixed to guidewire. Alternately, the anchor could have resilient, expansion material embedded in its inlet. The anchor can include inclined "sail" at its inlet. The sail acts as an expansion mechanism to expand the anchor when exposed to blood flow. In some embodiments, the

anchor has its inlet coated with a hydrogel coating which swells upon contact with blood and acting to expand the inlet of filter.

[0308] The filter devices of Berrada can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88O, the anchor 434 can be an everting filter. Everting filter includes a flexible, mesh, filter body. The filter body may be formed of a plurality of wires or strands which can be used to form the mesh filter body through a variety of methods, for example, braiding, knitting, weaving, helically winding, and counterwinding. The mesh can be fused at some or all of the fiber or strand intersection points. The mesh can also be electrospun, and formed of sheet or film having holes formed by laser drilling, punching, dissolving components selectively, and the like. The strands can be formed of material such as wire, which can be metallic wire or polymeric wire. The wire may be substantially circular in cross section or may have any number of square, rectangular or irregular cross sectional profiles. The mesh is preferably self-expanding. The self-expanding mesh can be formed totally or in part from self-expanding Nitinol, Elgiloy, titanium, or stainless steel wires and the like, and combinations thereof. The self-expanding mesh can also be formed of engineering polymers, for example, liquid crystal polymer, PEEK, polyimide, polyester, and the like. A preferred mesh is formed of Nitinol wires, which can be heat set to the desired expanded shape. The mesh can preferably be heat set to a desired bias shape. Another mesh is highly elastic, and preformed by mechanical overstress to the desired expanded shape. The mesh is preferably made radiopaque by means of plating, core wires, tracer wires, or fillers that have good X-ray absorption characteristics compared to the human body. The mesh may be either partly or totally radiopaque.

[0309] The filter body may be seen to have a plurality of pores or openings between the filter body strands or wires. The pores have an average pore size over the filter body, where the individual pore sizes may vary depending upon the location over the filter body. The filter body also has a proximal opening formed in filter body proximal region. The filter body may also be considered to have an interior within the filter body and an exterior defined outside of the filter body. The everted shape of filter defines an everted cavity or concave region bounded by filter body everted surface region or cavity side walls and the filter body distal-most extent. It may be seen from inspection of Figure 88O that axially translating proximal ring relative to distal ring while holding the filter body diameter

consistent may change the degree of eversion of filter body. The filter material occupying distal-most region may therefore change with the degree of eversion of filter, with different locations of filter body being distal-most varying as a function of the degree of eversion. The length of a distal cavity will increase with increasing eversion.

[0310] The filter devices of Paul can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88P-88Q, the anchor 435 and anchor 436 are everted. The anchor 435 is everted to form a proximally facing concave geometry. The filter portion may be everted by moving the control wires proximally, thereby pulling the first end of the filter portion back over the rest of the filter portion. Further, the filter portion may also be made of a shape memory material such that the filter portion has two defined geometries. For example, the mesh material may be made of a shape memory alloy so that the mesh material is biased into a straight tubular geometry in a non-everting state at a first temperature. The first temperature being controlled, for example, by fluid flowing through the guiding member across the medical device. At a second temperature, such as the ambient temperature inside the vessel, the filter portion is biased into a proximally facing concave geometry. When the filter portion is biased into the proximally facing concave geometry, the filter portion everts causing the filter portion 1to expand against the inner wall of the vessel. While the medical device is expanded against the inner wall of the vessel, the filter portion serves to collect emboli that may break free from the stenosed area preventing such emboli from blocking smaller vessels downstream of the medical device. When everted, the first end of the filter portion is biased against the inner wall of the vessel forcing the fluid to flow through the proximally facing concave geometry formed by the filter portion. Therefore, emboli are trapped in the distal region of the proximally facing concave geometry. The medical device remains in this expanded state during the interventional procedure to capture any emboli that break free from the stenosis. After the interventional procedure is completed, the medical device may be removed. To trap the emboli in the filter portion, the control wires may be pulled further proximally drawing the filter portion against the guiding member.

[0311] For anchor 436, the control wires extend through the tubular geometry of the filter portion. Accordingly, the control wires form a frame structure along the length of the filter portion. The control wires may be made of a synthetic material, a stainless steel, or a shape memory alloy, such as Nitinol. The shape memory characteristics of the control wire

may be used to support the first end of the filter portion against the inner wall of the vessel. Supporting the filter portion against the wall of the vessel ensures that the fluid will flow through the proximally facing concave geometry formed by the everted filter portion, thereby causing emboli to be trapped by the medical device.

[0312] The cages of Krolik can be used in place of, or in combination with, the anchors described herein. Referring now to Figure 88R, the anchor 437 can include a macerator cage. Generally, the macerator cage includes a closed proximal or first end and an open distal or second end. The cage may include a plurality of struts extending between the first and second ends and/or around a periphery of the cage, thereby defining a cylindrical or other tubular outer wall including a plurality of apertures.

[0313] The open distal end of the cage may include a plurality of distally protruding elements or distal tips 438. The cage includes at least two different types of struts. For example, the cage may include a plurality of relatively thick struts that extend substantially continuously along a length of the cage e.g., in a first helical configuration between the first and second ends. In addition, the cage may include a plurality of relatively thin struts, which may connect adjacent thick struts together. As shown, the thin struts are not substantially continuous as are the thick struts, but may extend in a discontinuous pattern helically and/or circumferentially around the cage. Optionally, the thin struts may also have bends or other features, e.g., relatively thinned or perforated portions, that allow the struts to bend relatively easily compared to the thick struts. The apertures may be defined by the spaces between the thick struts and the thin struts, thereby defining a desired pore size for the cage.

[0314] The distal tips 438 on the open end may provide a substantially atraumatic distal end for the cage, e.g., to prevent puncture or other damage to a wall of a body lumen within which the cage is deployed. In addition or alternatively, the distal tips 438 may be sufficiently flexible to allow the distal tips to twist helically and/or interlock with one another during use. The distal tips 438 may facilitate engaging and/or removing obstructive material within a body lumen. Alternatively, the distal tip 438 can include a series of slots or indentations spaced apart along a length of the distal tip e.g., that may allow the distal tips to entangle with each other and/or with the obstructive material captured or otherwise engaged by the distal tips to facilitate removal. For example, when the cage is rotated, the distal tips

438 and obstructive material may be wound together, e.g., such that portions of other distal tips and/or obstructive material may enter the slots and the distal tips 438 become interlocked with one another.

[0315] During distal advancement, the cage may be concurrently advanced and rotated, e.g., manually or using a driveshaft. This may cause the distal tips 438 of the cage to track along the inside wall of the body lumen, e.g., in a helical manner as the cage is advanced. When thrombus or other obstructive material is encountered, the distal tips 438 may pass between the material and the wall of the body lumen, thereby positioning the material inside the cage. In some methods of use, the anchors described herein are rotated. In some methods of use, the anchors described herein are translated.

[0316] The distal tips 438 of the cage may facilitate separation and/or capture of material within the cage. For example, the edges of the distal tips may provide distal leading edges of the cage that are not a substantially smooth cylinder but define an undulating surface. Consequently, the distal tips 438 of the cage may act as a saw by repeatedly making contact with the material as the cage is rotated, which may increase the chance of material being dislodged from the wall of the body lumen and/or captured within the cage. To further ensure that the leading edge of the cage passes between the unwanted material and the wall of the body lumen, the distal tips 438 and/or edges of the struts may also act as blades shearing along the wall of the body lumen to draw adherent material into the cage. Thus, the struts may cut or otherwise separate the interface between the body lumen and the obstructive material.

[0317] The distal tips 438 may be formed such that they conform substantially to the cylindrical shape of the cage, e.g., defining a diameter similar to the rest of the expanded cage, although alternatively the distal tips 438 may be biased radially outwardly, e.g., to ensure that the distal tips 438 pass between the wall of the body lumen and the obstructive material and/or enhance engagement of the distal tips against the wall of the body lumen. Alternatively, the distal tips 438 may by biased to extend radially inwardly, e.g., laterally inwardly, relative to a central longitudinal axis of the apparatus, e.g., to prevent substantial risk of damage to the wall of the body lumen.

[0318] The systems described herein are intended for use in any size vessel. The systems can be deployed in vessels with a diameter about 10 μm, 20 μm, 30 μm, 40 μm, 50

μm, 60 μm, 70 μm, 80 μm, 90 μm, 100 μm, 200 μm, 300 μm, 400 μm, 500 μm, 600 μm, 700 μm, 800 μm, 900 μm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, 20 mm, 21 mm, 22 mm, 23 mm, 24 mm, 25 mm, between 1 mm and 8 mm, between 10 μm, and 1 mm, between 100 μm and 1 mm, between 100 μm and 10 mm etc. The anchors can have a diameter or cross-section about 10 μm, 20 μm, 30 μm, 40 μm, 50 μm, 60 μm, 70 μm, 80 μm, 90 μm, 100 μm, 200 μm, 300 μm, 400 μm, 500 μm, 600 μm, 700 μm, 800 μm, 900 μm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, 20 mm, 21 mm, 22 mm, 23 mm, 24 mm, 25 mm, less than 10 mm, less than 1 mm, less than 100 μm, less than 10 μm, etc. The ALTC device 201 can have a diameter or cross-section about 10 μm, 20 μm, 30 μm, 40 μm, 50 μm, 60 μm, 70 μm, 80 μm, 90 μm, 100 μm, 200 μm, 300 μm, 400 μm, 500 μm, 600 μm, 700 μm, 800 μm, 900 μm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, 20 mm, 21 mm, 22 mm, 23 mm, 24 mm, 25 mm, less than 10 mm, less than 1 mm, less than 100 μm, less than 10 μm, etc., or ranges incorporating any two of the aforementioned values. It is contemplated that different sizes of the systems will be available for selection by the user based on the obstruction and the target vessel.

[0319] A perspective view of another embodiment of a capture system is shown in Figure 89. Figure 89 also illustrates non-limiting examples of various possible elements that can be included in a material capture system, according to some embodiments described herein. As illustrated in Figure 89, included in some embodiments are any number of, such as one, two, or more of the following components: a thrombus capturing device or ALTC device 201 having any of the features described herein, e.g., a pusher wire or inner pusher 202, a first tubular member such as an outer sheath (not shown), and an anchor such as any of the anchors described herein. Figure 89 illustrates an anchor 450. In some embodiments, the ALTC device 201 can attach to the anchor 450. In some embodiments, the anchor 450 functions as the capture guide 204 described herein. In some embodiments, the anchor 450 comprises a metallic material, such as Nitinol. The anchor 450 can be in the form of, for example, a loop, as shown, or any closed shape including an oval, ellipse, or polygon. The anchor 450 can be in the form of an open shape such as any linear or non-linear segment. The

ALTC device 201 and the anchor 450 can be coupled such as being sutured together. The ALTC device 201 and the anchor 450 can be encapsulated in a low durometer polymeric material. The anchor 450 can be coupled to the outer sheath 203. The proximal end of the ALTC device 201 can be coupled to an inner pusher 202 as described herein. The anchor 450 can have any of the features of anchors described herein, including anchor 401.

[0320] The anchor 450 can be connected to an anchor pusher 451. The anchor pusher 451 can, in some embodiments, be an elongate tubular member with a central lumen therethrough, and have a proximal end and a distal end, both shown in Figure 89. The distal end of the anchor pusher 451 can be operably connected to the anchor 450 (e.g., tubular mesh as described herein). In some embodiments, anchor 450 can be fixed or stationary with respect to the anchor pusher 451. In some embodiments, anchor 450 can be move axially with respect to the anchor pusher 451. The proximal end can include any number of, such as one, two, or more of the following components: a hemostasis assembly 206, a flush port 207, and a collapsed segment 208. The anchor pusher 451 extends proximally and can be coupled to the hemostasis assembly 206. The anchor pusher 451 extends proximally and can be coupled to a luer. In some embodiments, the anchor pusher 451 can have a lumen to allow passage of a guidewire. In some embodiments, the anchor pusher 451 is a solid shaft.

[0321] Figure 89 also shows the distal end of the ALTC device 201 in a deployed configuration. In some methods of use, a portion of the ALTC device 201 is axially extended while the remaining length of the ALTC device 201 is collapsed and contained within a sheath as previously described. In some methods of use, the ALTC device 201 can be collapsed and tracked through a sheath or guide catheter (not shown) to the intended treatment area. In some embodiments, the guide catheter can be retracted proximally to initially deploy the ALTC device 201 and the self expandable anchor 450. For instance, the retraction of the guide catheter can cause the anchor 450 to expand. The anchor 450 can include a compressed or constrained configuration while within the guide catheter. During the initial deployment, the anchor 450 is released from a constrained position to a neutral position. In the neutral position, the anchor 450 creates a perimeter for the ALTC device 201. In the case of a loop or other circular configuration, the anchor 450 can create a constant diameter. In the case of other shapes or configurations, the anchor 450 can create a constant

cross-section. Alternatively or in combination, in other methods of use, the ALTC device 201 can be advanced distally from the guide catheter to deploy the ALTC device 201.

[0322] In some cases, only a small fractional portion of the ALTC device 201, such as less than about 50%, 45%, 40%, 35%, 30%, 25%, 20%, 15%, 10%, 5%, or less of the axial length of the device can be initially deployed. The small portion can correspond to an amount of the ALTC device 201 which allows the anchor 450 to assume the neutral position. During the deployment of the anchor 450, a length of the ALTC device 201 can be retained within the outer sheath 203. The ALTC device 201 can follow a curve from the anchor 450 to the outer sheath 203. Retracting the outer sheath 203 can lengthen the ALTC device 201 while maintaining a constant diameter or cross-section provided by the anchor 450. In some embodiments, the proximal end of the ALTC device 201 is fixed relative to the anchor 450. In some embodiments, the ALTC device 201 can axially lengthen by releasing the compressed portion 208 as described herein. In some methods of use, the ALTC device 201 is axially lengthened. In some methods of use, the ALTC device 201 is not axially lengthened. The ALTC device 201 can serve as distal protection without further axially lengthening. In some embodiments, the ALTC device 201 is deployed before the anchor 450. In some embodiments, the ALTC device 201 is deployed after the anchor 450.

[0323] Figure 89 illustrates a system including a dual ALTC device 201 and anchor 450. The anchor functions to replace the nitinol. In some methods of use, the ALTC device 201 and the anchor 450 retract together. In some methods of use, the ALTC device 201 and the anchor 450 move as a unit. In some embodiments, the distal end consists of axial lengthen device wherein the opening end attaches to an expandable anchor. The ALTC device 201 comprises a proximal opening. In some embodiments, the capture guide 204 is replaced with an anchor, such as anchor 450. The proximal opening of the ALTC device 201 is coupled to the anchor 450 such that the ALTC device 201 and the anchor move together. In some embodiments, the distal end of the axial lengthen device is fixed to the pusher 202 that extends proximally. The ALTC device 201 can be coupled to the pusher 202. The pusher 202 can push the compressed portion 208 from the sheath 451 to cause axially lengthening of the ALTC device 201. The pusher 202 can extend to the proximal end of the system to be controlled by the user. In some embodiments, the proximal end of the expandable anchor attaches a pusher tube 451 extending proximally and attaches to a hemostasis housing. In

some embodiments, the proximal end of the anchor 450 is coupled to the anchor pusher 451. The anchor pusher 451 can extend proximally and attach to the hemostasis housing as described herein. The system can be designed for thrombectomy. The system can include a distal basket or ALTC device 201 and anchor 450. The anchor 450 can be made of wireform, laser cut or stent-like structure. The materials can be such as shape memory, stainless steel, Cobalt Chromium.

[0324] Figure 90 illustrates the distal end of the system of Figure 89. The system includes the ALTC device 201 and the expandable anchor 450. In some embodiments, the ALTC device 201 and the anchor 450 are fixed and move as one unit. In some embodiments, the distal end of the expandable anchor 450 attaches to the opening end of the ALTC device 201. In some embodiments, the proximal end of the anchor 450 attaches to the catheter shaft 451. In some embodiments, the distal end of the ALTC device 201 extends through the anchor 450. In some embodiments, the distal end of the ALTC device 201 extends through the anchor 450 centrally or along a longitudinal axis. In some embodiments, the distal end of the ALTC device 201 extends through the anchor 450 along an axis offset from the longitudinal axis of the anchor 450. The distal end of the ALTC device 201 can be the compressed portion 208 as described herein. In some embodiments, the distal end of the ALTC device 201 is coupled to a pusher wire 202. In some embodiments, the distal end of the ALTC device 201 is coupled to the pusher wire 202 or other device described herein.

[0325] In some embodiments, alternatively, the distal end of the expandable anchor 450 is separated from the opening end of the ALTC device 201. In some embodiments, the proximal end of the expandable anchor 450 attaches to distal end of catheter shaft. In some embodiments, the body of the ALTC device 201 extends through the anchor 450 centrally and attaches to the pusher 202. The pusher 202 can be contained within the pusher tube 451, sheath 203, dual lumen sheath 243 or other constraining member described herein. The anchor 450 can be designed to collapse within the pusher tube 451. The ALTC device 201 can be designed to collapse within the pusher tube 451. In some methods of use, the ALTC device 201 can be released from the pusher tube 451 by proximal movement of the pusher tube 451. In some methods of use, the anchor 450 can be released by proximal movement of the pusher tube 451. In some methods of use, the ALTC device 201

can be released from the pusher tube 451 by distal movement of the pusher 202. In some methods of use, the anchor 450 can be released by distal movement of the pusher 202.

[0326] Figure 91 illustrates another embodiment of a capture system, which can have any of the features described herein. The capture system includes an anchor 452. The anchor 452 can have any of the features of anchors described herein, including anchor 405. A portion of the anchor 452 can be contained within the pusher tube 451. In some embodiments, the ALTC device 201 can attach to the anchor 452 as described herein.

[0327] Figure 92 illustrates another embodiment of a capture system, which can have any of the features described herein. The capture system includes an anchor 453. In some embodiments, the ALTC device 201 can attach to the anchor 453 as described herein. In some embodiments, the anchor 453 is formed as a stent structure. The anchor 453 can includes a plurality of struts. Each strut can be connected to the ALTC device 201 at one or more locations. In the illustrated embodiment, each strut is connected to the ALTC device 201 at two locations but other configurations are contemplated (e.g., one location, three locations, four locations, five locations, a plurality of locations, etc.). In some embodiments, the struts can be equally spaced. In some embodiments, the struts are not equally spaced. In some embodiments, the struts can include a zig-zag pattern or bends 454. In some embodiments, the bends 454 can improve flexibility of the capture system. In some embodiments, the bends 454 can allow the capture system to turn. In some embodiments, the bends 454 can be located near a proximal end of the anchor 453. In some embodiments, the bends 454 can be located near a distal end of the anchor 453. In some embodiments, the struts of the anchor 453 assist in retrieving and containing the obstruction or clot. In some embodiments, the struts comprise a shape memory or self-expanding material such as nitinol. In some embodiments, the anchor 453 can be self-expanded.

[0328] Figures 93-94 illustrate another embodiment of a capture system, which can have any of the features described herein. The capture system includes anchor 455. In some embodiments, the struts 456 of the anchor 455 can be straight. In some embodiments, the struts 456 can include a straight portion. In some embodiments, the straight portion in near a proximal end of the anchor. Figures 93-94 illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally. The compressed or constrained segment of the ALTC device 201 is shortened within the

pusher tube 241. In some embodiments, the pusher tube 241 can be retracted to axially lengthen the ALTC device 201, as described herein. The ALTC device 201 and the anchor 455 can be retracted as a unit. Figure 93 illustrates the axial lengthening device and the expandable anchor in the initial configuration. Figure 94 illustrates the axial lengthening device and the expandable anchor wherein the axial lengthening device is lengthened.

[0329] Figure 95 illustrates another embodiment of a capture system, which can have any of the features described herein. The capture system includes an anchor 457. In some embodiments, a portion of the anchor 457 is connected to the ALTC device 201. The anchor 457 can include one or more distal tips 458. In some embodiments, one or more distal tips 458 are not connected to the ALTC device 201. The distal tips 458 can function as distal tips described herein.

[0330] The distal tips 458 may provide a substantially atraumatic distal end, e.g., to prevent puncture or other damage to a wall of a body lumen within which the anchor 457 is deployed. The distal tips 458 may facilitate engaging and/or removing obstructive material within a body lumen. Alternatively, the distal tips 458 can entangle with each other and/or with the obstructive material captured or otherwise engaged by the distal tips 458 to facilitate removal. The distal tips 458 may facilitate separation and/or capture of material. The distal tips 458of the anchor 457 may act as a saw by repeatedly making contact with the material, which may increase the chance of material being dislodged from the wall of the body lumen and/or captured within the anchor 457. To further ensure that the leading edge of the anchor 457 passes between the unwanted material and the wall of the body lumen, the distal tips 458 and/or edges may also act as blades shearing along the wall of the body lumen to draw adherent material into the anchor 457. Thus, the distal tips 458 may cut or otherwise separate the interface between the body lumen and the obstructive material. The distal tips 458 may be formed such that they conform substantially to the cylindrical shape of the ALTC device 201, e.g., defining a diameter similar to the rest of the ALTC device 201. In some embodiments, the distal tips 458 may be biased radially outwardly or biased to extend radially inwardly. Other configurations of the distal tips 458 are contemplated.

[0331] In some embodiments, the systems described herein comprise a fixed ALTC device 201. In some embodiments, the ALTC device 201 is inserted into the patient in the initial configuration. For instance, the capture guide 204 described herein can be fixed

such that the ALTC device 201 assumes the initial configuration. In some embodiments, the ALTC device 201 does not lengthen. In some embodiments, the axial length of the ALTC device 201 is fixed. In some embodiments, the anchor is fixed. In some embodiments, the anchor is inserted into the patient in the expanded or inflated configuration. In some embodiments, the anchor does not expand or inflate within the body of the patient. In some embodiments, the anchor has a fixed shape or configuration. In some embodiments, the system includes a clot buster or debulking at the front end. In some embodiments, the clot buster moves distally to break apart the clot. In some embodiments, the clot buster is a portion of the anchor. In some embodiments, the clot buster is separate device.

[0332] Figure 96A-96B illustrate an expandable guide catheter 460. The guide catheter 460 includes an expandable distal end, configured to be positioned away from a user, within a body of a patient. The guide catheter 460, or at least the distal end, can feature at least a dual braid layer including an outer layer and an inner layer. In some embodiments, the expandable guide catheter 460 can include a dual layer structure. In some embodiments, the expandable guide catheter 460 can include an outer braid layer 461. In some embodiments, the outer braid layer 461 is coated with a material such as one or more polymeric materials. In some embodiments, the expandable guide catheter 460 can include an inner braid layer 462. In some embodiments, the inner braid layer 462 is not coated with a polymeric material. In some embodiments, a portion of the inner braid layer 462 is not coated. In some embodiments, a distal portion of the inner braid layer 462 is not coated. In some embodiments, a length of the inner braid layer 462 is not coated. In some embodiments, the entire length of the inner braid layer 462 is not coated. In some embodiments, a portion of the outer braid layer 461 is coated. In some embodiments, a distal portion of the outer braid layer 461 is coated. In some embodiments, a length of the outer braid layer 461 is coated. In some embodiments, the entire length of the outer braid layer 461 is coated. In some embodiments, the outer braid layer 461 remains coated or encased with the polymer during the procedure.

[0333] In some embodiments, the outer braid layer 461 is coated with a polymer. The polymer can be any material including Pellethane, Silicone, Tecoflex, Tecothane, Latex, Pebax. The polymer can function akin to a slip layer. The polymer can facilitate the sliding of the catheter against a target vessel. In some embodiments, the inner braid layer 462 is not coated with a polymer, instead, retains the mesh-like structure as shown. The inner braid

layer 462 advantageously provides decreased surface area, decreased surface contact, and/or decreased friction relative to an object within the lumen of the catheter. For instance, the mesh-like structure of the inner braid layer 462 has less surface area to contact the object within the lumen than a solid, inner wall. The inner braid layer 462 allows for a retrieval catheter, one or more anchors, the obstruction, or the ALTC device 201 to more easily slide axially when withdrawn proximally through the lumen. In some methods of use described herein, the ALTC device 201 can be axially lengthened over one or more anchors before retraction into the guide catheter 406. In some methods of use described herein, the ALTC device 201 can be axially lengthened over an obstruction such as a clot before retraction into the guide catheter 406. In some methods of use described herein, the ALTC device 201 can provide distal protection as the ALTC device 201 is retracted into the guide catheter 460.

[0334] In some embodiments, the guide catheter 460 has a funnel shape at the distal end. In some embodiments, distal refers to the portion of the guide catheter 460, or component thereof, which is furthest from the user during use, while proximal refers to the portion of the guide catheter 460 or component thereof which is closest to the user. In some embodiments, the distal end of the guide catheter 460 is positioned within the body of the patient and the proximal end is outside the body of the patient.

[0335] In some embodiments, the expandable guide catheter 460 can include any of the features of the ALTC device 201 described herein. In some embodiments, the mesh can be made from metallic materials such as individual non-elastic wires. In some embodiments, the mesh can be made from elastic elements. In some embodiments, the mesh can be made from a combination of elastic and non-elastic wires. In some embodiments, the dual braid can be made of either polymeric or metallic materials. In some embodiments, the metallic materials can be Nitinol, stainless steel, steel, shape memory alloy, elastic alloy, Nickel Titanium alloy, etc. In some embodiments, the braid wire diameter can range from .0005" to .030", e.g., .0005", .001", .0015", .002", .0025", or .003", between .0005"-.0015", between .001"-.002", between .0015"-.0025", between .002"-.003" etc. Other configurations of braid wire diameter are contemplated. The braid wire can be woven in any pattern. In some embodiments, the guide catheter 460 can include at least one polymer layer. The at least one polymer layer can applied to any surface of the braid wire. The braid wire can include one or more woven patterns, for instance a first wave pattern in a first portion of the

guide catheter 460 and a second wave pattern in a second portion of the guide catheter 460. The woven pattern can be a typical over under pattern, e.g., two over, two under; one over, one under, etc. The woven paten can from a tubular braid. In some embodiments, the guide catheter 460 can include multiple layers of braid wire.

[0336] The braid wire can form a mesh. In some embodiments, the cross-section of the wire can be any shape including round, polygonal, elliptical, etc. The shape of the wire can be flat, square, ribbon, round, etc. In some embodiments, the total braid angle can range from 10 degrees to 170 degrees. In some embodiments, the total braid angle is 0 degrees, 10 degrees, 20 degrees, 30 degrees, 40 degrees, 50 degrees, 60 degrees, 70 degrees, 80 degrees, 90 degrees, 100 degrees, 110 degrees, 120 degrees, 130 degrees, 140 degrees, 150 degrees, 160 degrees, 170 degrees, 180 degrees, between 0-45 degrees, between 45-90 degrees, between 90-135 degrees, between 135-180 degrees, etc. In some embodiments, the braid density can range from 5 PPI to 60 PPI. In some embodiments, the braid density is less than 5 PPI, 5 PPI, 10 PPI, 15 PPI, 20 PPI, 25 PPI, 30 PPI, 35 PPI, 40 PPI, 45 PPI, 50 PPI, 55 PPI, 60 PPI, 65 PPI, 70 PPI, 75 PPI, 80 PPI, between 0-20 PPI, between 20-40 PPI, between 40-60 PPI, between 60-80 PPI, etc. In some embodiments, the inner diameter can range from 1F to 30F. In some embodiments, the inner diameter is less than 1F, 1F, 2F, 3F, 4F, 5F, 6F, 7F, 8F, 9F, 10F, 11F, 12F, 13F, 14F, 15F, 16F, 17F, 18F, 19F, 20F, 21F, 22F, 23F, 24F, 25F, 26F, 27F, 28F, 29F, 30F, 31F, 32F, 33F, 34F, 35F, between 0F-5F, between 5F-10F, between 15F-20F, between 20F-25F, between 25F-30F, between 30F-35F, etc. In some embodiments, the outer diameter can range from 2F up to 33F. In some embodiments, the outer diameter is less than 1F, 1F, 2F, 3F, 4F, 5F, 6F, 7F, 8F, 9F, 10F, 11F, 12F, 13F, 14F, 15F, 16F, 17F, 18F, 19F, 20F, 21F, 22F, 23F, 24F, 25F, 26F, 27F, 28F, 29F, 30F, 31F, 32F, 33F, 34F, 35F, between 0F-5F, between 5F-10F, between 15F-20F, between 20F-25F, between 25F-30F, between 30F-35F, etc.

[0337] In some embodiments, the expandable guide catheter 460 can include a shaft. In some embodiments, the expandable guide catheter 460 can include a shaft that expands under compression. In some embodiments, the expandable guide catheter 460 can include a shaft that lengthens under compression. In some embodiments, the expandable guide catheter 460 can include a shaft that expands upon release of a constraint. In some embodiments, the expandable guide catheter 460 can include a shaft that expands due to

temperature. In some embodiments, the expandable guide catheter 460 can include a shaft that expands to assume a neutral configuration.

[0338] In some embodiments, the expandable guide catheter 460 can include an inverted structure. In some embodiments, one end of the braid begins at the proximal end and extends to the distal end where it folds inward and extends back to the proximal end. In some embodiments, the dual braid extends from the proximal end to the distal end. In some embodiments, the braid at the distal end can be continuous. In some embodiments, the braid at the distal end can be discontinuous. In some embodiments, one end of the braid begins at the proximal end and extends to the distal end wherein it folds inward and extends back to the proximal region. In some embodiments, one end of the braid begins at the proximal end and extends to the distal end wherein it folds outward and extends back to the proximal region. The outer braid layer 461 and the inner braid layer 462 are concentric.

[0339] In some embodiments, the outer layer braid 461 is encapsulated with polymeric materials. In some embodiments, the polymer layer can have uniform wall thickness. In some embodiments, the polymer layer can have uniform density. In some embodiments, the polymer layer can have uniform wall thickness throughout the entire catheter length. In some embodiments, the polymer layer can have non-uniform wall thickness. In some embodiments, the proximal end of the catheter wall thickness is thicker than the wall thickness at the distal end. In some embodiments, the polymeric material can have the same softness (durometer) through the catheter length. In some embodiments, the polymeric material can have different or a variety of softness (durometer) through the catheter length. In some embodiments, the polymeric material is expandable. In some embodiments, the polymeric material is flexible. In some embodiments, the outer layer composite is expandable. In some embodiments, polymeric materials can be any elastomer materials such as Polyurethane, Pellethane, Silicone, Tecoflex, Tecothane, Latex, Pebax and/or combination thereof. In some embodiments, the polymer can be coupled to the braid material through any methods known in the art. In some embodiments, the polymer can be coated, molded, dipped or thermally fused onto the braid.

[0340] In some embodiments, the guide catheter 460 has a funnel shape at distal end. In some embodiments, the guide catheter outer braid is encapsulated from the proximal end to the distal end near the funnel. In some embodiments, the funnel outer and inner braid

layer is not encapsulated with polymer. In some embodiments, the funnel outer braid is encapsulated with polymer. In some embodiments, the inner braid layer can be encapsulated with polymer and the outer layer is not.

[0341] The guide catheter 460 can function as an access system. In some embodiments, the guide catheter 460 is introduced in a compressed diameter configuration. In some embodiments, after introduction, the guide catheter 460 may be radially expanded to accommodate passage of larger diameter surgical instruments therethrough such as ALTC device 201 and/or the anchors described herein.

[0342] The guide catheter 460 can be useful for forming and enlarging access area in target locations within a patient's body. In some embodiments, the guide catheter 460 is delivered in a small diameter configuration and expanded. In some embodiments, only a distal end or a funnel end is expanded. In some embodiments, the guide catheter 460 can change the size of the lumen that the guide catheter 460 is inserted into, such as enlarging a vessel by pressing against the vessel wall. The guide catheter 460 can include a polymeric coating that facilitates sliding contact with the vessel wall.

[0343] In some embodiments, passage of the ALTC device 201 through the guide catheter 460 can cause expansion of the guide catheter 460. In some embodiments, the collapsed ALTC device 201 can be sized to fit within the guide catheter 460. In some embodiments, the expanded ALTC device 201 can be sized to fit within the guide catheter 460. In some embodiments, the expanded ALTC device 201 can be retracted through the guide catheter 460. In some embodiments, the one or more expanded anchors can be retracted through the guide catheter 460. In some embodiments, the one or more expanded anchors can be sized to fit within the guide catheter 460. The uncoated inner braid layer 462 reduces sliding contact between the guide catheter 460 and any components passed therethrough.

[0344] In some embodiments, the guide catheter 460 can function as a variable sized cannula. In some embodiments, the guide catheter 460 can function as a tissue dilator. In some embodiments, the guide catheter 460 can change shape during axial compression of the braid. In some embodiments, axial shortening can cause radial expansion of the guide catheter 460. In some embodiments, the guide catheter 460 can be variably expanded based on the amount of compressive force. In some embodiments, the guide catheter 460 is self-

expanding. In some embodiments, the guide catheter 460 is expanded by a mechanism e.g., pull strings, release from a constraint, application of compressive force, application of tension, etc. In some embodiments, the guide catheter 460 is a shape memory material.

[0345] In some embodiments, the guide catheter 460 can facilitate the removal of a blockage within the vasculature of a patient. In some embodiments, the guide catheter 460 can surround the one or more anchors that are entangled in the clot. In some embodiments, the surface of the clot can slide easily within the guide catheter, due in part, to the inner surface of the guide catheter 460. In some embodiments, the guide catheter 460 can slide easily within the target vessel, due in part, to the outer surface of the guide catheter 460. In some embodiments, the guide catheter 460 can be collapsed after receiving the one or more anchors. In some embodiments, the guide catheter 460 can surround the ALTC device 201 which itself encapsulates the obstruction. In some embodiments, the outer surface of the ALTC device 201 can slide easily within the guide catheter, due in part, to the inner surface of the guide catheter 460. In some embodiments, the guide catheter 460 can be collapsed after receiving the ALTC device 201.

[0346] Systems and methods can be utilized or modified for use in connection with those described herein can be found, for example, in U.S. Patent Application No. 11/101,224, filed Apr. 7, 2005 and published July 2, 2013 as U.S. Patent No. 8475487 ("Bonnette"); U.S. Patent Application No. 12/738,702, filed Oct. 27, 2008 and published Oct. 21, 2010 as U.S. Patent Pub. No. 20100268264 ("Bonnette '264") are all incorporated by reference herein in their entireties.

[0347] In some methods of use, the ALTC device 201 is used in combination with a thrombectomy catheter, such as an AngioJet® thrombectomy device or potentially an aspiration catheter may be used to remove the embolic debris. In some methods of use, one or more anchors described herein is used in combination with a thrombectomy catheter or an aspiration catheter, such as an AngioJet® thrombectomy device. The use of the AngioJet®, a rheolytic cross stream thrombectomy catheter, can include an inherent ability to remove thrombus of larger diameter than the catheter's diameter. However, the disruptive strength of the device falls off with the radial distance from the catheter. Hence, at some radial distance the clot can be stronger than the disruptive force generated by the AngioJet® cross stream

flow patterns. In the case of organized thrombus, this radial distance from the catheter can be smaller than for softer thrombus.

[0348] Water jet thrombectomy procedures in general can be limited in ability in some cases. However, adding mechanical disruption such as by use of the anchors described herein can unexpectedly and synergistically improve water jet ablation. By combining mechanical agitation, e.g.,, abrasive intimate contact of thrombus by a flexible and expandable anchor component and an ALTC device 201, with a rheolytic thrombectomy catheter (AngioJet®), a variety of thrombus can be cleared than can be cleared by mechanical agitators or rheolytic cross stream thrombectomy catheters individually.

[0349] Another aspect and feature of some embodiments of the devices of the present disclosure is a device having the ability to capture large and small embolic debris. Another aspect and feature of the devices of the present disclosure is a device having the ability to temporarily capture debris which may later be removed by manual aspiration or by the use of an AngioJet® thrombectomy device and catheter or which may be treated by thrombolytics. Another aspect and feature of the devices of the present disclosure is a device having the ability to macerate debris to a clinically insignificant size (depending on the area of the body) or to a size which can be pharmacologically treated or removed by another device, such as an AngioJet® thrombectomy device and catheter. Another aspect and feature of the devices of the present disclosure is a device having the ability to macerate non-embolic debris, such as a stationary thrombus, by pulling the device through such an obstruction.

[0350] Systems and methods can be utilized or modified for use in connection with those described herein can be found, for example, in U.S. Patent Application No. 14/774,735, filed Mar. 17, 2014 and published Jan. 28, 2016 as U.S. Pub No. 20160022290 ("Johnson"); U.S. Patent Application No. 13/741,845, filed Jan. 15, 2013 and published Jan. 2, 2014 as U.S. Patent Pub. No. 20140005712 ("Martin") are all incorporated by reference herein in their entireties.

[0351] An intravascular ultrasound (IVUS) transducer disclosed in Johnson can be incorporated into the systems described herein. In some embodiments, an intravascular ultrasound (IVUS) transducer can be added to or incorporated into the delivery system and method. A pressure sensor can be used to measure the pressure at various positions within the vasculature, which can be used to determine blood flow, while the intravascular ultrasound

(IVUS) transducer can be used to measure fluid flow and/or provide imaging within the vessel. In some embodiments, the pressure sensor and/or IVUS transducer can be incorporated into the guidewire at one or more locations, such as the distal end or distal portion of a guidewire, as well as being incorporated into intermediate and proximal portions of the guidewire. The guidewire with the pressure sensor and/or the IVUS transducer can be used much like a normal guidewire to help navigate the delivery device through the vasculature, with the added benefit of providing pressure measurements and ultrasound imaging to help in the navigation, to visualize the device placement site, and to monitor and ensure proper device deployment. In some embodiments, the IVUS transducer generates image slices as it is advanced and retracted which can then be assembled together to form a three dimensional reconstruction of the vasculature and/or the device within the vasculature. In some embodiments, the guidewire with the pressure sensor and/or IVUS transducer can be fastened to a catheter in a similar manner to that described below for a catheter having a pressure sensor and/or IVUS transducer that is fastened to another catheter.

[0352] Use of the ultrasound imaging system can allow the operator to deliver the device without fluoroscopy or using less fluoroscopy, thereby reducing the radiation exposure to the patient, while allowing more accurate evaluation of the vasculature, aiding placement of the device and allowing confirmation that device placement was proper. The imaging can be used to aid in the deployment of the filters or other devices. The imaging can also be used to aid in the retrieval of the deployed devices by providing visualization of, for example, the retrieval features on the deployed device and of the retrieval features, such as loops on a snare, of the retrieval device. The vasculature and implant location can be imaged prior to deployment, after deployment and/or during deployment. The imaging can be used during the retrieval process. The imaging can be used to aid in positioning of the filter or device within the vasculature. The imaging can be used to image the deployment location and determine the appropriate sizing of the filter or other device. The imaging can be used to help estimate treatment duration.

[0353] Although imaging systems described above have been primarily described as ultrasound based, other imaging systems can be used instead or in addition. For example, the imaging system can be based on intravascular ultrasound (IVUS), Forward-Looking

IVUS (FLIVUS), optical coherence tomography (OCT), piezoelectric micro-machined ultrasound traducer (PMUT), and/or FACT.

[0354] Other components described by Martin can also be incorporated into the systems described herein. All or some of the device can be designed to increase their ability to adhere to the obstruction. For example, the wires may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to "weld" to the obstruction. Application of energy to the device can allow the surrounding portion to deform into the obstruction and "embed" within the obstruction. Alternatively, the device can impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. In another variation, a negative charge could be applied to further build thrombus and nest the device for better pulling force. The wires can be made stickier by use of a hydrophilic substance(s), or by chemicals that would generate a chemical bond to the surface of the obstruction. Alternatively, the filaments may reduce the temperature of the obstruction to congeal or adhere to the obstruction.

[0355] Another aspect applicable to variations of the devices can be to configure the devices (whether the traversing filament or the surrounding portion) for better adherence to the obstruction. One such mode includes the use of coatings that bond to certain clots (or other materials causing the obstruction.) For example, the wires may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the device secures about a clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction. Coatings may also be combined with the capturing portions or catheter to improve the ability of the device to encapsulate and remove the obstruction (e.g., a hydrophilic coating).

[0356] Such improvements may also be mechanical or structural. Any portion of the capturing portion can have hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. The hooks, fibers, or barbs can be incorporated into any portion of the device. However, it will be important in some embodiments that such features do not hinder the ability of the practitioner to remove the device from the body.

[0357] In addition to additives, the device can be coupled to an RF, microwave, magnetic, thermal, cryo, or other power source, to allow electrical, current, ultrasound or RF

energy to transmit through the device and induce clotting or cause additional coagulation of a clot or other obstruction.

[0358] The methods described herein may also include treating the obstruction prior to attempting to remove the obstruction. Such a treatment can include applying a chemical or pharmaceutical agent with the goal of making the occlusion shrink or to make it more rigid for easier removal. Such agents include, but are not limited to chemotherapy drugs, or solutions, lytic agents such as tPA, urokinase, or streptokinase for example, an anticoagulant, a mild formalin, or aldehyde solution.

[0359] Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that the inventions may be practiced otherwise than as specifically described herein. It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments disclosed above may be made and still fall within one or more of the inventions. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with an embodiment can be used in all other embodiments set forth herein. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. Moreover, while the inventions are susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the inventions are not to be limited to the particular forms or methods disclosed, but to the contrary, the inventions are to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they can also include any third-party instruction of those actions, either expressly or by implication. For example, actions such as "inserting a catheter transfemorally" includes "instructing the insertion of a catheter transfemorally." The ranges disclosed herein also encompass any and all overlap, sub-ranges, and combinations thereof. Language such as "up to," "at least,"

"greater than," "less than," "between," and the like includes the number recited. Numbers preceded by a term such as "approximately", "about", and "substantially" as used herein include the recited numbers (e.g., about 10% = 10%), and also represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

WHAT IS CLAIMED IS:

1. A clot capture system, comprising:

an anchor,

a tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening,

wherein the tubular body and the anchor are compressed in a delivery configuration,

wherein the tubular body and the anchor are transformable to a deployed configuration in which the anchor and the shape memory tubular body first end are expanded but the shape memory tubular body second end and a majority of the shape memory tubular body remains compressed and the tubular body has a first expanded axial length,

wherein the shape memory tubular body is transformable to a capture configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor, or a portion thereof, in the capture configuration.

2. The clot capture system of Claim 1, further comprising two or more anchors.

3. The clot capture system of Claim 2, wherein the two anchors have a central longitudinal axis that is coaxial.

4. The clot capture system of Claim 1, wherein the anchor is a stent like structure.

5. The clot capture system of Claim 1, wherein the anchor is a balloon.

6. The clot capture system of Claim 1, wherein the anchor is a disk.

7. The clot capture system of Claim 1, wherein the anchor comprises nitinol.

8. The clot capture system of Claim 1, wherein the anchor comprises a spherical balloon.

9. The clot capture system of Claim 1, wherein the anchor is configured to entangle a clot.

10. The clot capture system of Claim 1, wherein the anchor is coupled to the shape memory tubular body.

11. The clot capture system of Claim 1, wherein the anchor is a funnel.

12. The clot capture system of Claim 1, wherein the anchor is tapered from the distal end to the proximal end of the anchor.

13. The clot capture system of Claim 1, wherein the shape memory tubular body comprises a central longitudinal axis and wherein the anchor is offset from the central longitudinal axis.

14. The clot capture system of Claim 1, wherein the second end of the shape memory tubular body is coupled to an inner pusher.

15. A clot capture system, comprising:

an anchor;

a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening,

wherein the shape memory tubular body and the anchor are configured to be compressed during delivery,

wherein the first end of the shape memory tubular body and the anchor are configured to be expanded while the second end and a majority of the shape memory tubular body remains compressed, wherein the shape memory tubular body has a first expanded axial length with a first cross-section,

wherein the shape memory tubular body is configured to be axially lengthened.

16. The clot capture system of Claim 15, further comprising a pusher, wherein the second end of the shape memory tubular body is coupled to the pusher.

17. The clot capture system of Claim 15, wherein the anchor and the shape memory tubular body are fixed together.

18. A method of using a clot capture system, comprising:

positioning the system of Claim 15 near a blood clot;

expanding the shape memory tubular body and the anchor; and

axially lengthening the shape memory tubular body to encapsulate the clot.

19. The method of Claim 18, wherein the blood clot is within the central nervous system.

20. A method of using a clot capture system, comprising:

positioning the system of Claim 1 near a blood clot;

transforming the shape memory tubular body and the anchor to the deployed configuration;

transforming the shape memory tubular body and the anchor to the capture configuration to encapsulate the anchor.

21. A clot capture system, comprising:

an outer sheath comprising a central lumen;

a dual lumen shaft configured to be positioned within the central lumen of the outer sheath;

an inner pusher configured to be positioned within a first lumen of the dual lumen shaft;

an anchor pusher configured to be positioned within a second lumen of the dual lumen shaft,

an anchor coupled to the anchor pusher,

a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to a portion of the opening,

wherein the shape memory tubular body and the anchor are compressed in a first configuration,

wherein the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed within the lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide,

wherein the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor in the third configuration.

22. The clot capture system of Claim 21, further comprising two anchors.

23. The clot capture system of Claim 22, wherein the two anchors have a central longitudinal axis that is coaxial.

24. The clot capture system of Claim 21, further comprising three anchors.

25. The clot capture system of Claim 21, wherein the cross-section is round.

26. The clot capture system of Claim 21, wherein the anchor comprises nitinol.

27. The clot capture system of Claim 21, wherein the anchor forms an angle with the anchor pusher, wherein the angle is approximately 90 degrees.

28. The clot capture system of Claim 21, wherein the anchor forms an angle with the anchor pusher, wherein the angle is approximately 45 degrees.

29. The clot capture system of Claim 21, wherein the anchor forms an angle with the anchor pusher, wherein the angle is between 5 degrees and 135 degrees.

30. The clot capture system of Claim 21, wherein the diameter of the anchor is less than the diameter of the shape memory tubular body when radially expanded.

31. The clot capture system of Claim 21, wherein a portion of the anchor pusher is crescent shaped.

32. The clot capture system of Claim 21, wherein the capture guide comprises nitinol.

33. The clot capture system of Claim 21, wherein the capture guide comprises a central longitudinal axis and wherein the dual lumen shaft is offset from the central longitudinal axis.

34. The clot capture system of Claim 21, wherein the second end of the shape memory tubular body is coupled to the inner pusher.

35. A clot capture system, comprising:

an inner pusher element;

a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to at least a portion of the opening, the second end coupled to the inner pusher element,

wherein the shape memory tubular body and the capture guide are compressed in a first configuration,

wherein the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed and the shape memory tubular body has a first expanded axial length

with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide,

wherein the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length.

36. The clot capture system of Claim 35, wherein the capture guide forms a continuous loop.

37. The clot capture system of Claim 35, wherein the capture guide forms a non-continuous loop.

38. A method of using a clot capture system, comprising:

positioning the system of Claim 35 near a blood clot in the first configuration;

transforming the shape memory tubular body to the second configuration; and

transforming the shape memory tubular body to the third configuration to encapsulate the clot.

39. The method of Claim 38, wherein the blood clot is within the CNS.

40. A method of using a clot capture system, comprising:

positioning the system of Claim 21 near a blood clot;

transforming the shape memory tubular body to the second configuration;

expanding the anchor; and

transforming the shape memory tubular body to the third configuration to encapsulate the anchor.

41. The method of Claim 40, wherein deploying the anchor comprises securing the anchor within the clot.

42. The method of Claim 40, wherein transforming the shape memory tubular body to the third configuration to encapsulate the anchor further comprises encapsulating the clot.

43. The method of Claim 40, wherein the blood clot is a neurological blood clot.

44. A clot capture system, comprising:

a first tubular member comprising a central lumen;

a second tubular member;

a plurality of axially spaced-apart anchors extending radially outwardly from the first tubular member or the second tubular member; and

a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to the second tubular member,

wherein at least part of the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration,

wherein the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains radially compressed within the central lumen of the first tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length,

wherein the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

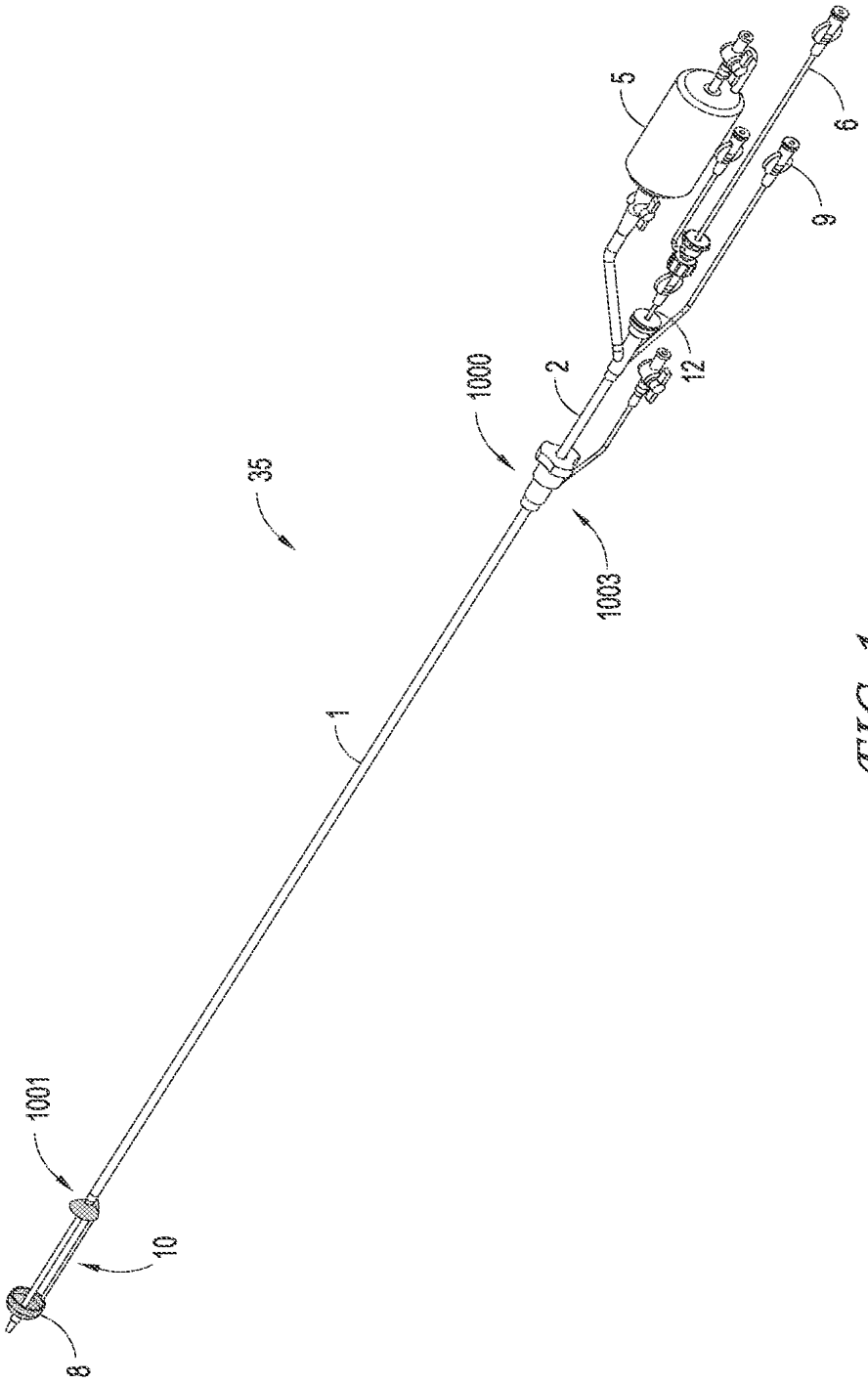

FIG. 1

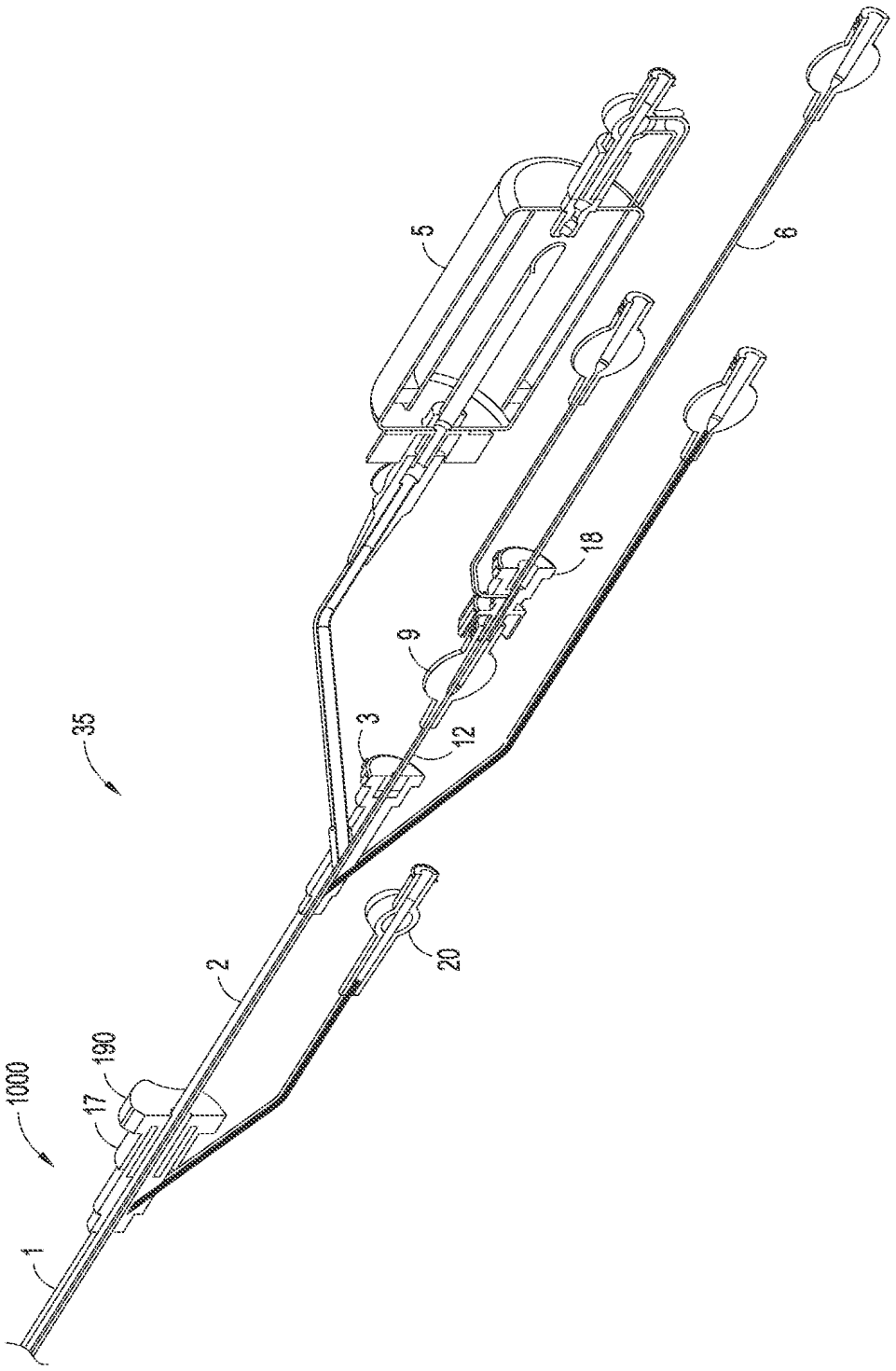

FIG. 2

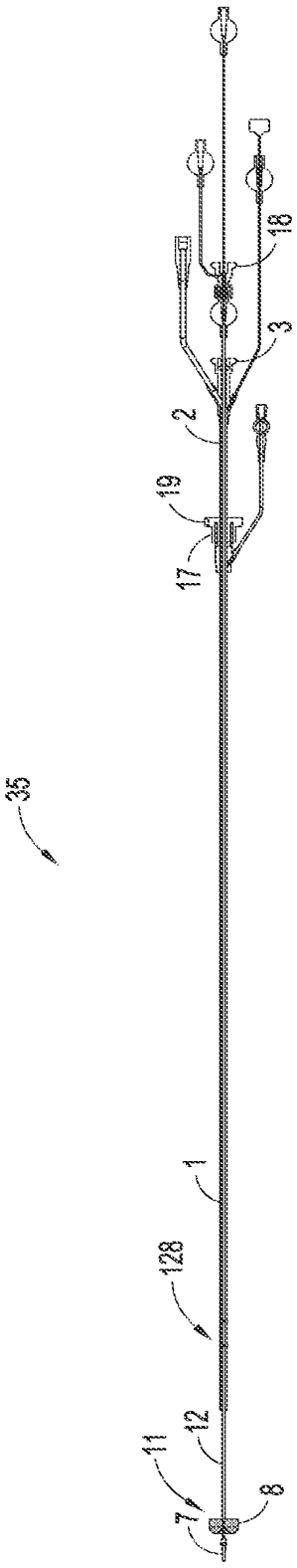

FIG. 3

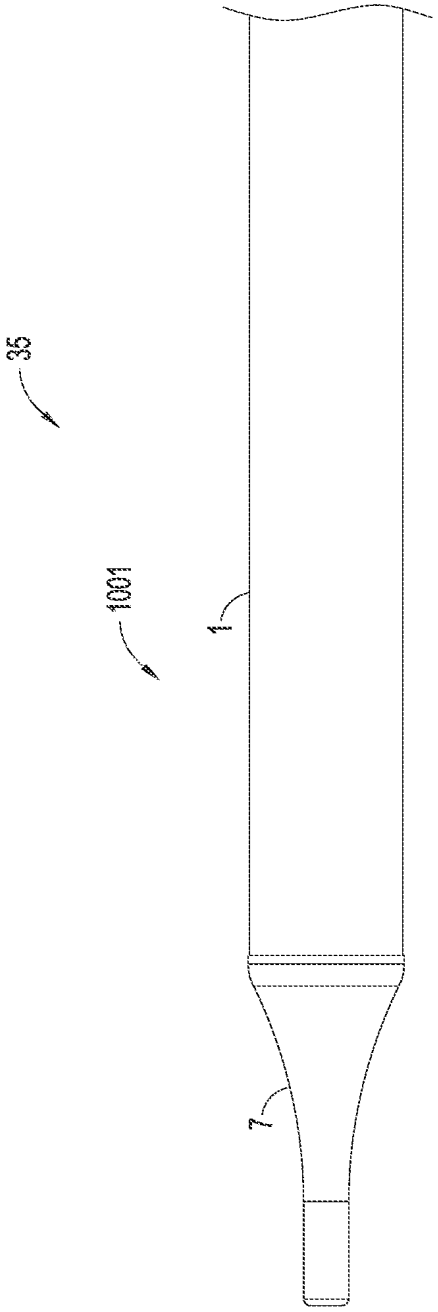

FIG. 4

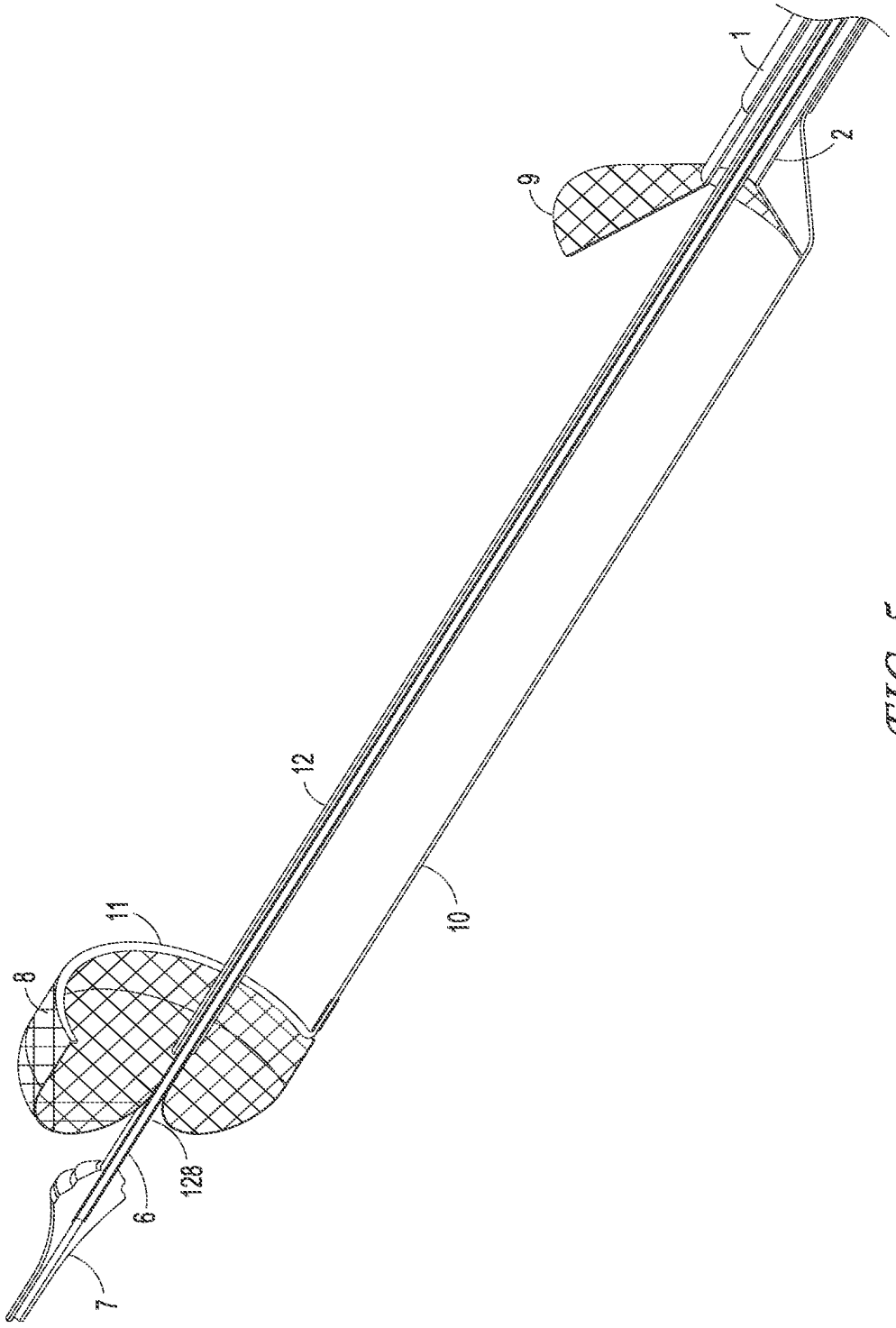

FIG. 5

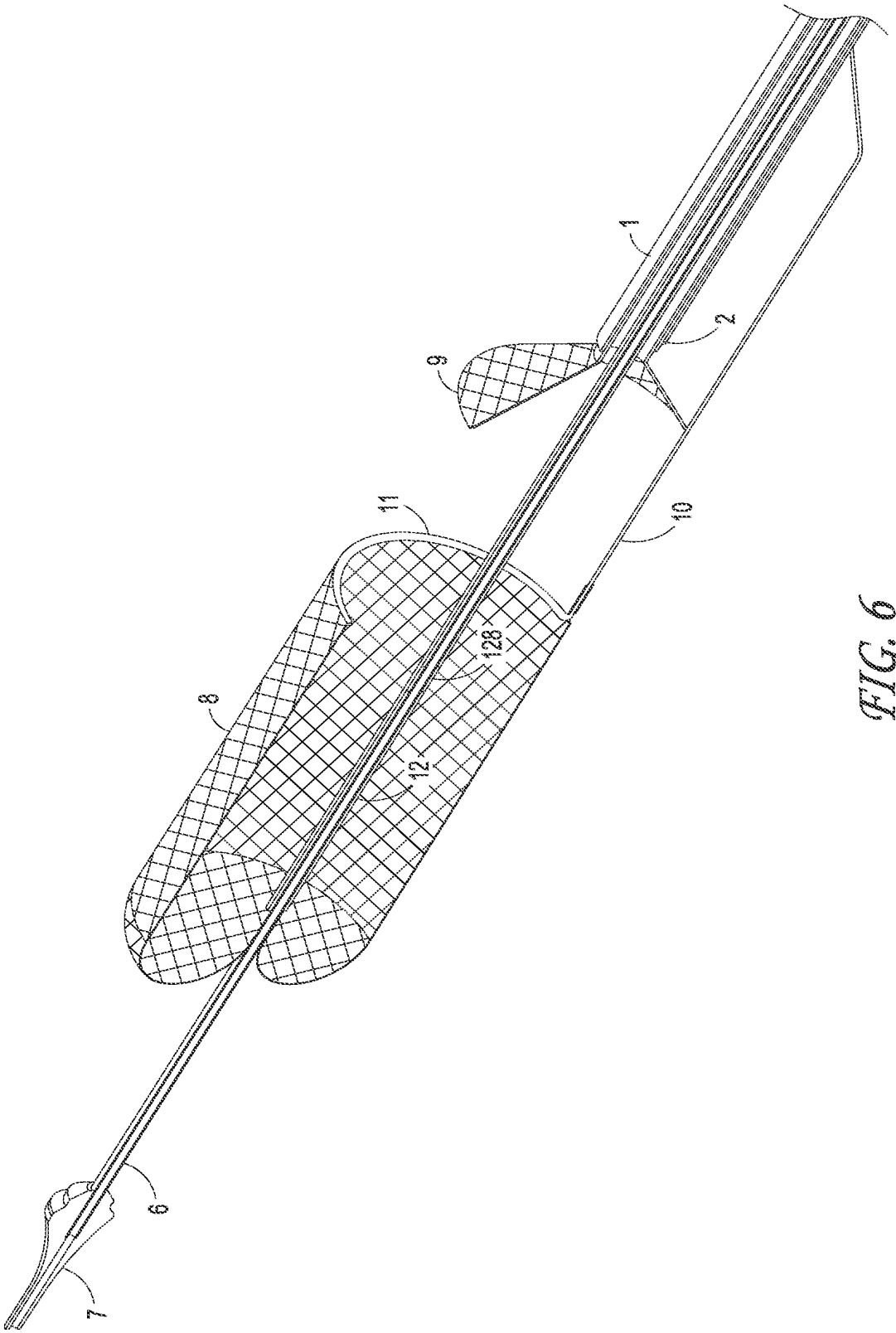

FIG. 6

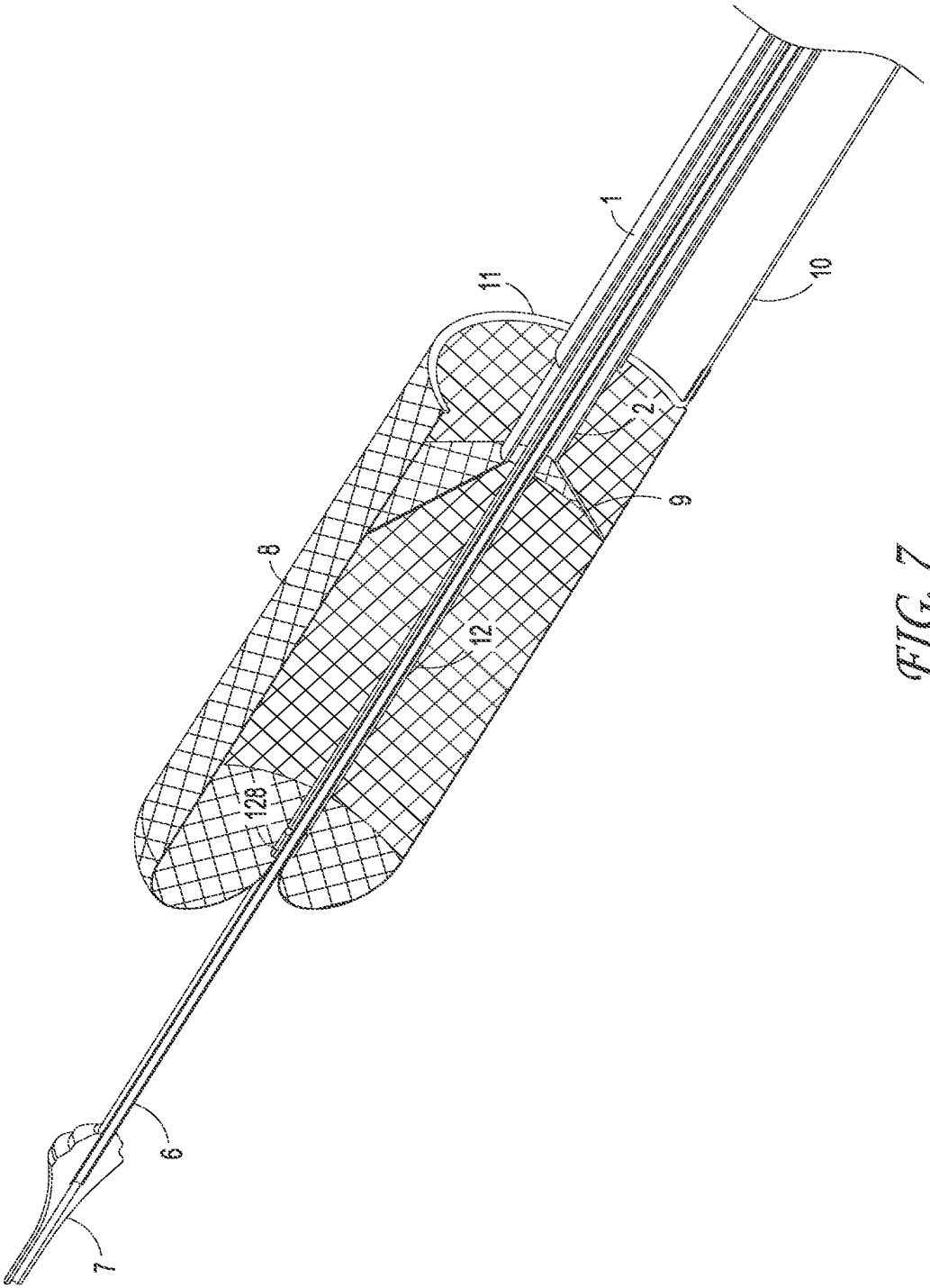

FIG. 7

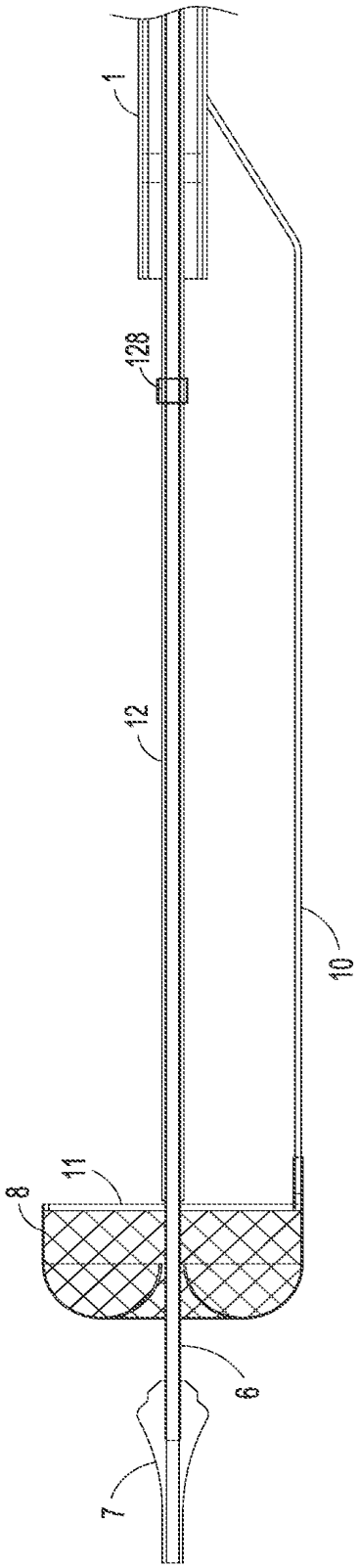

FIG. 8

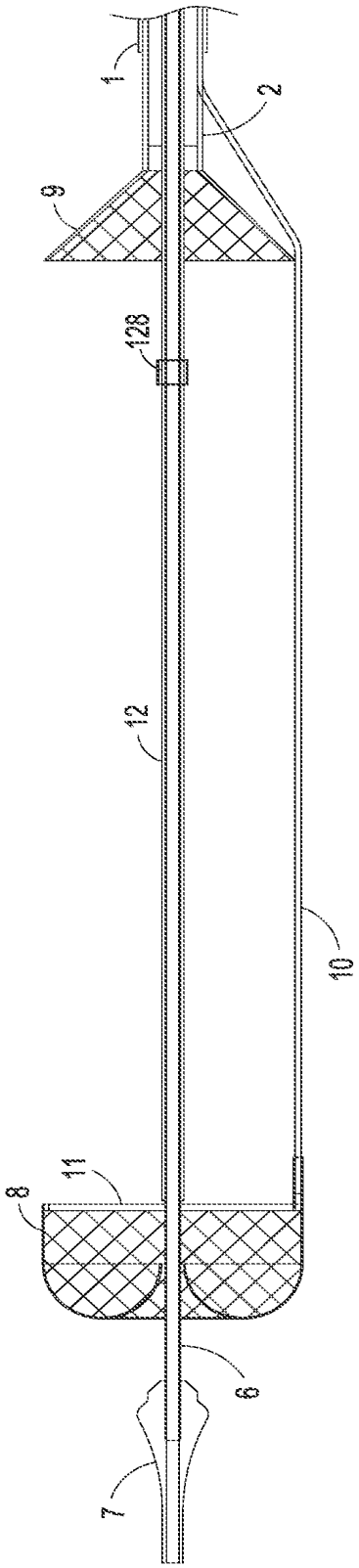

FIG. 9

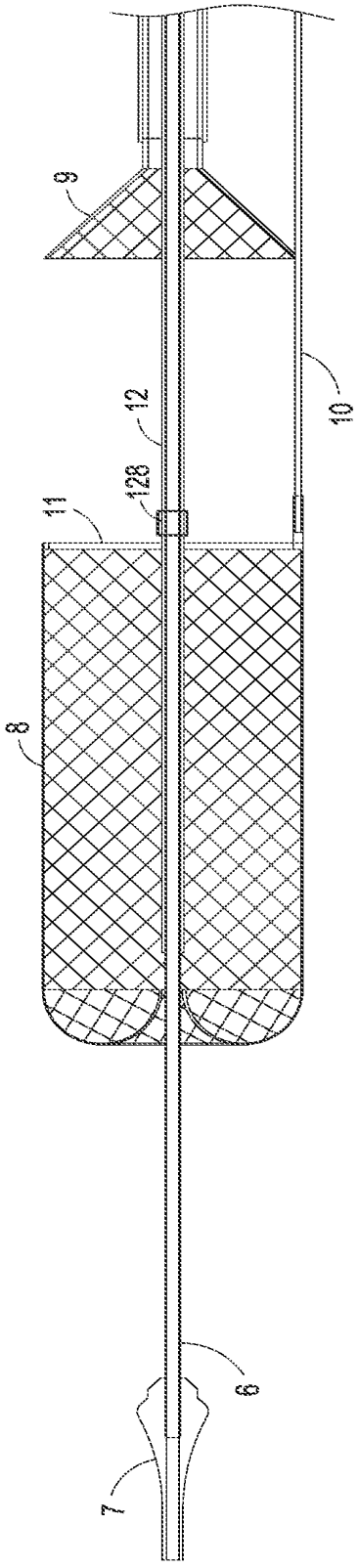

FIG. 10

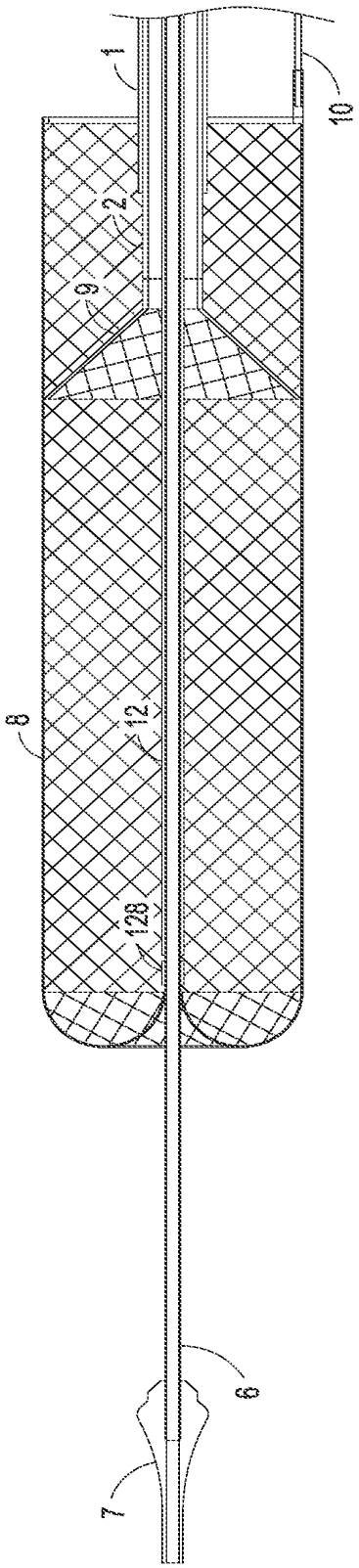

FIG. 11

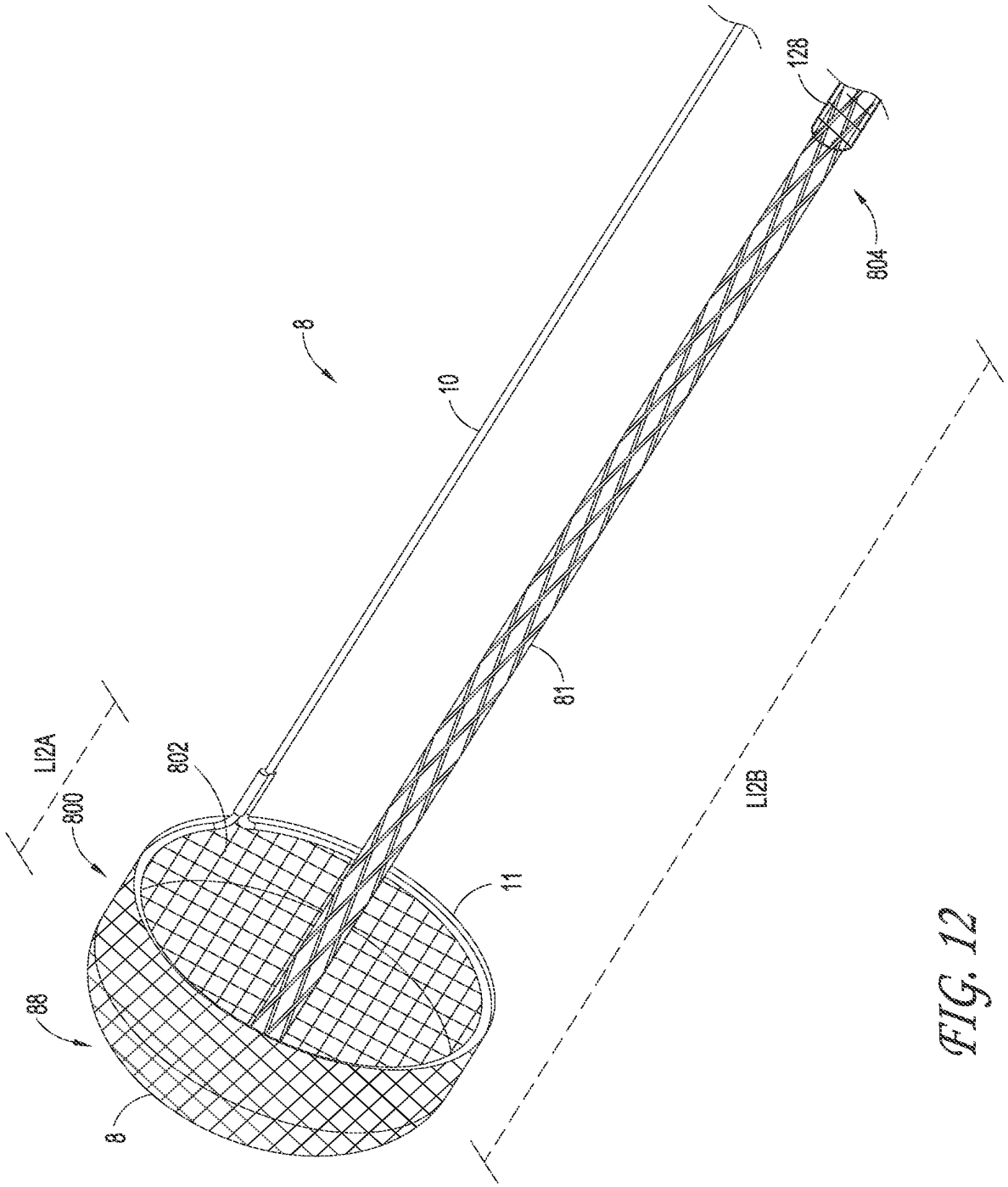

FIG. 12

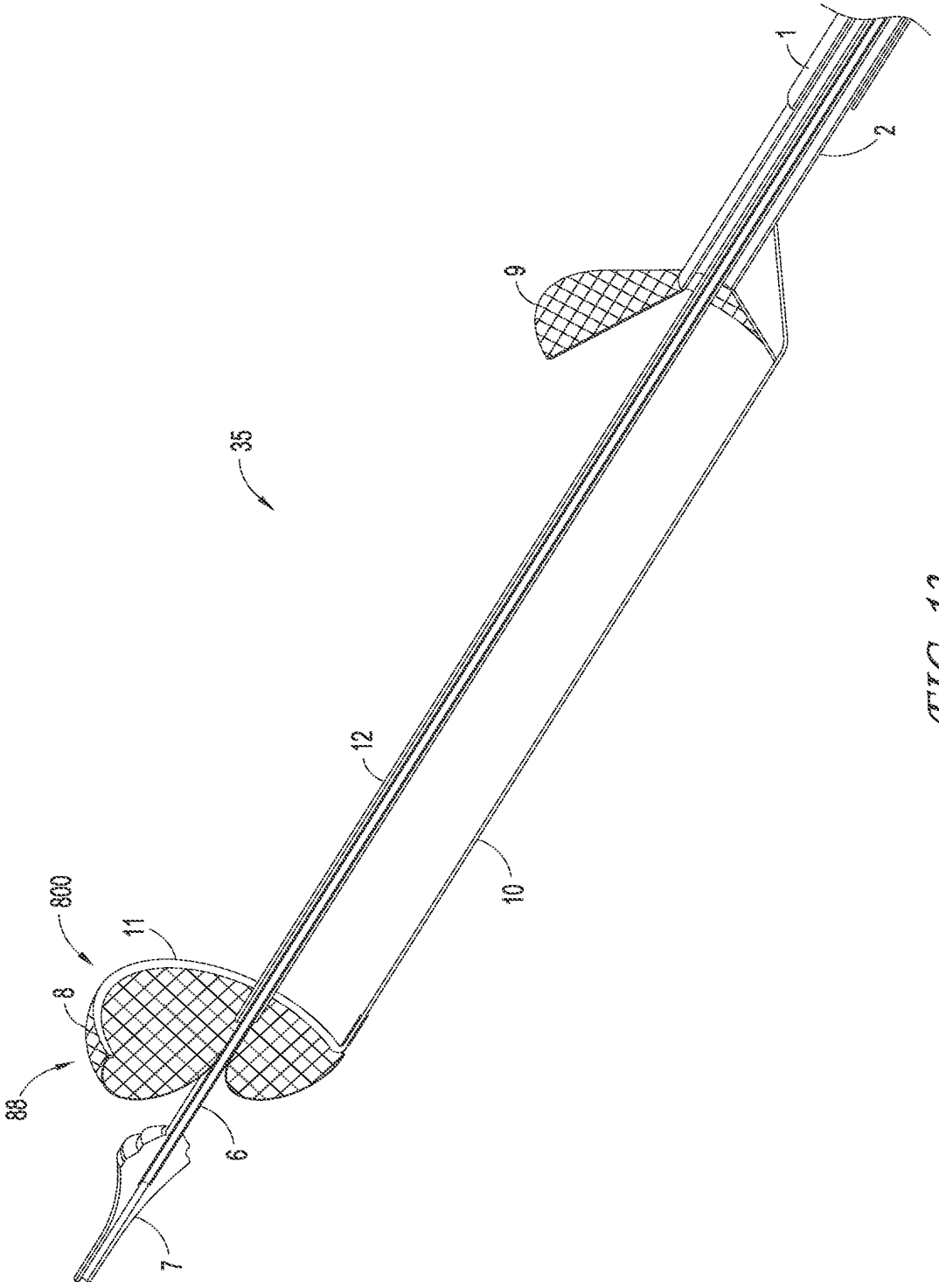

FIG. 13

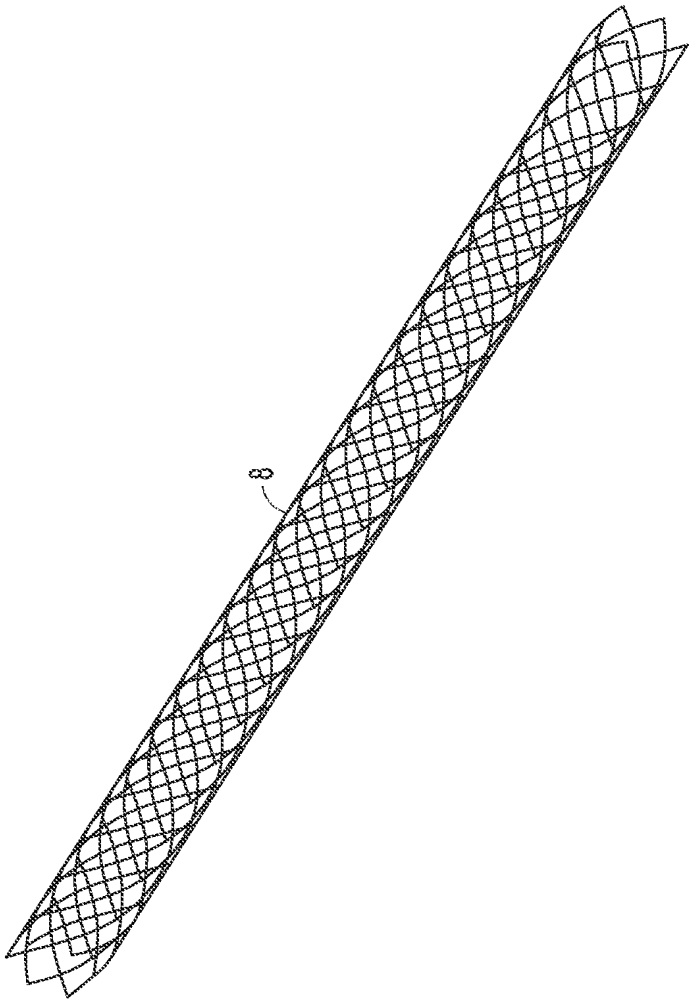

FIG. 14

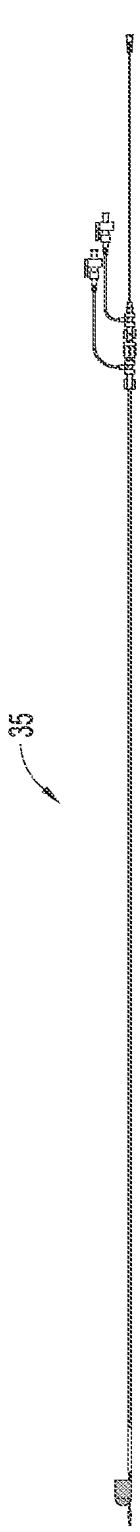

FIG. 15A

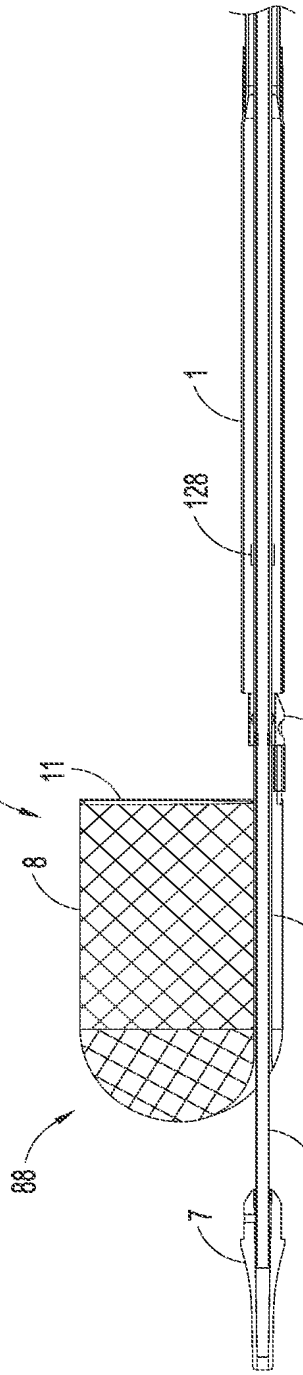

FIG. 15B

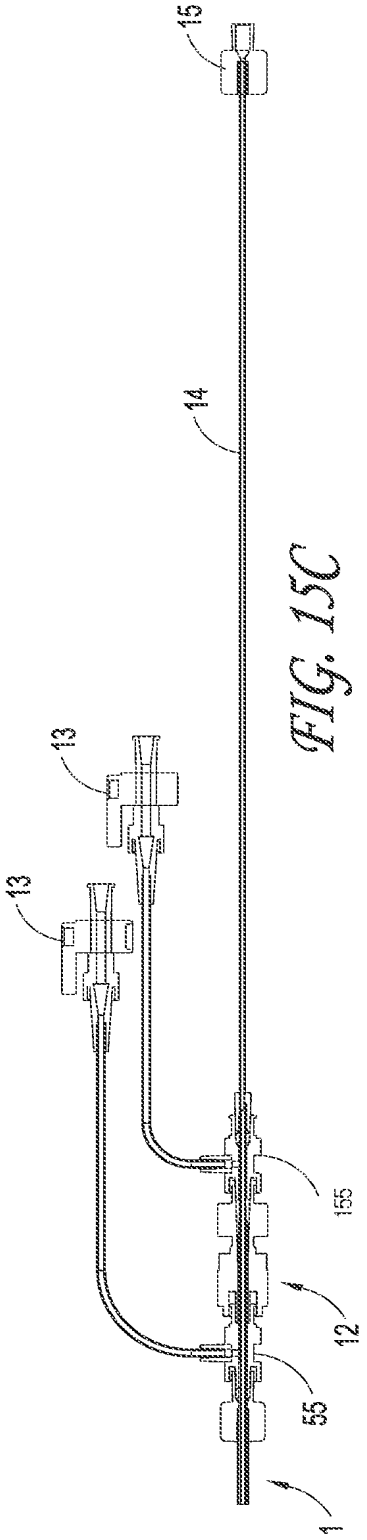

FIG. 15C

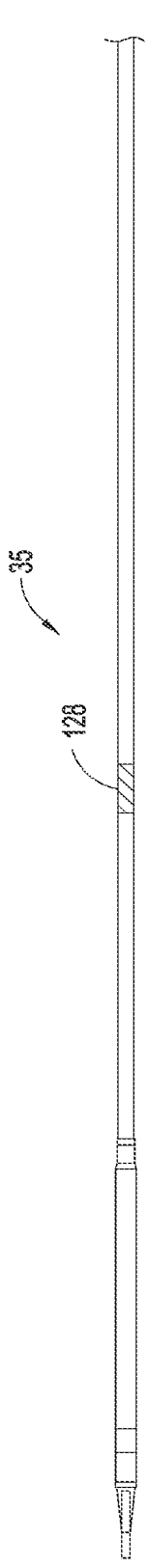

FIG. 16A

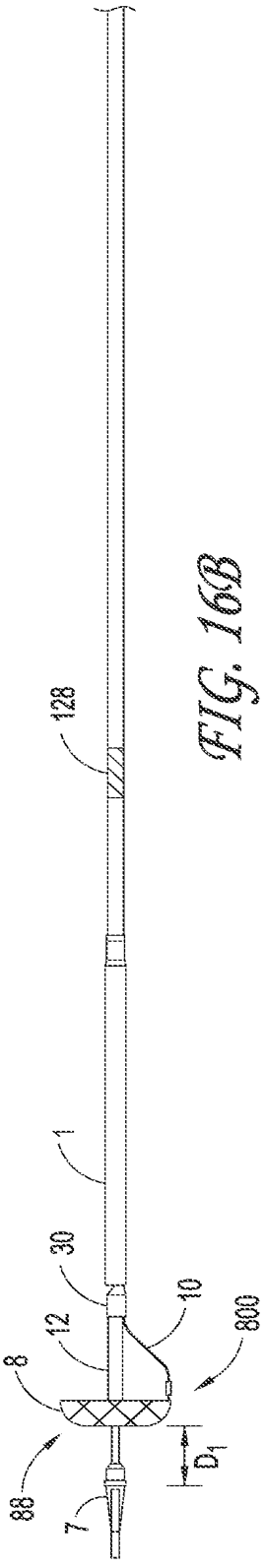

FIG. 16B

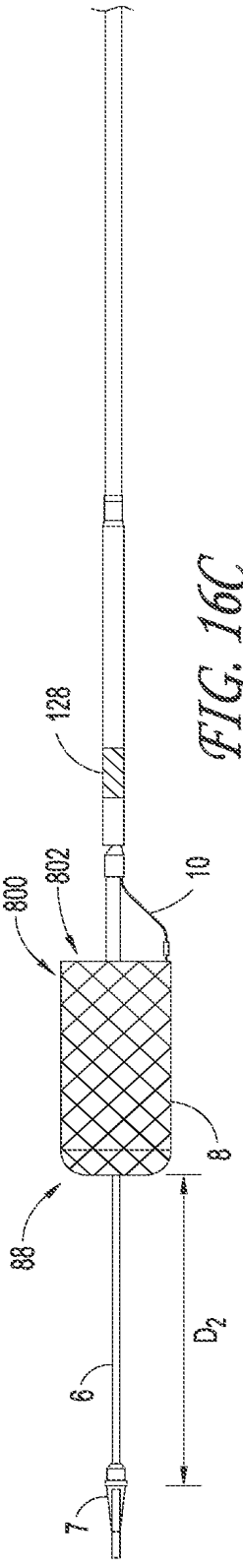

FIG. 16C

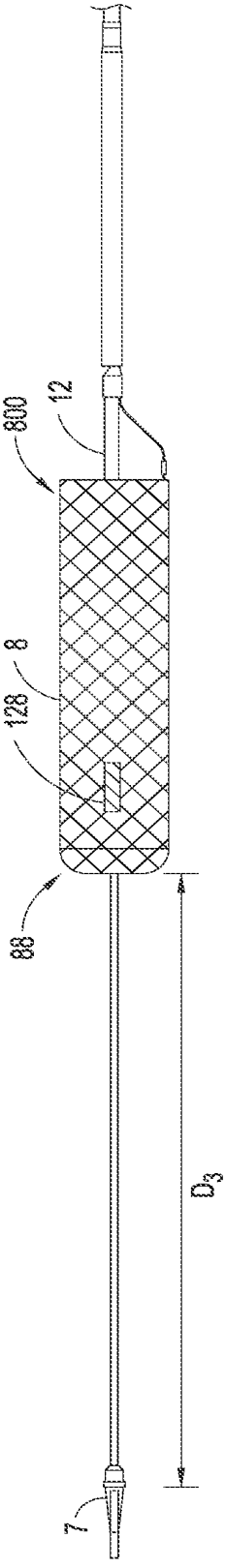

FIG. 16D

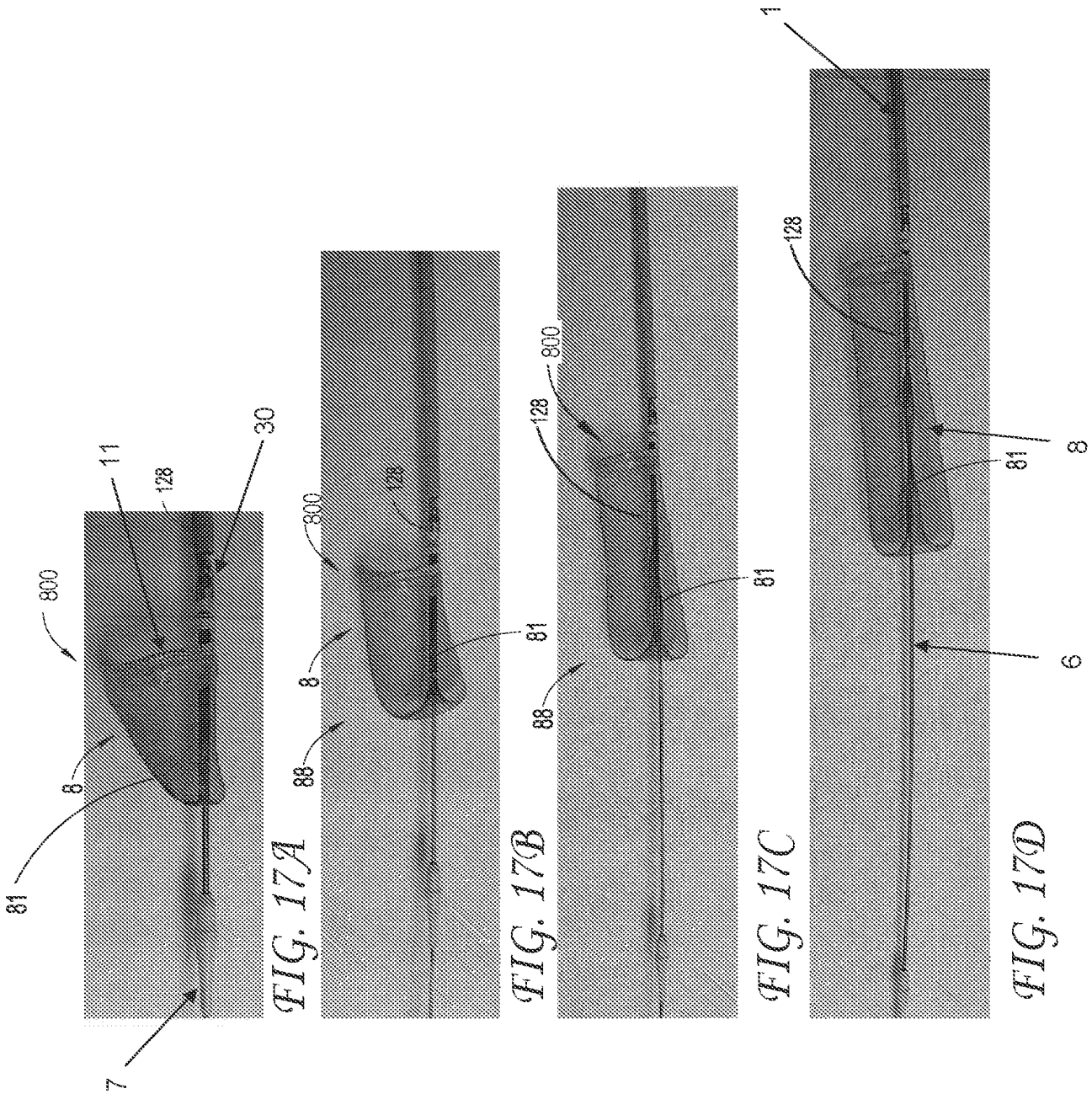
800
11
128
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FIG. 17A
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128
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FIG. 17B
128
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FIG. 17C
1
128
81
8
6
FIG. 17D

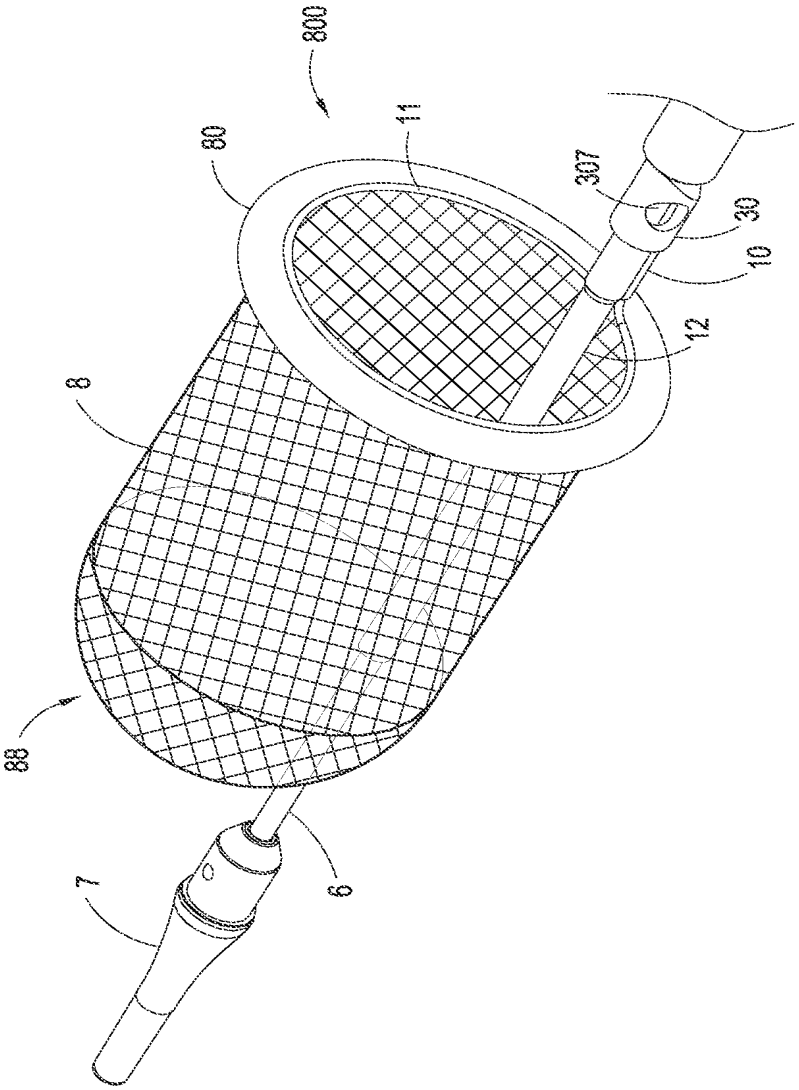

FIG. 18A

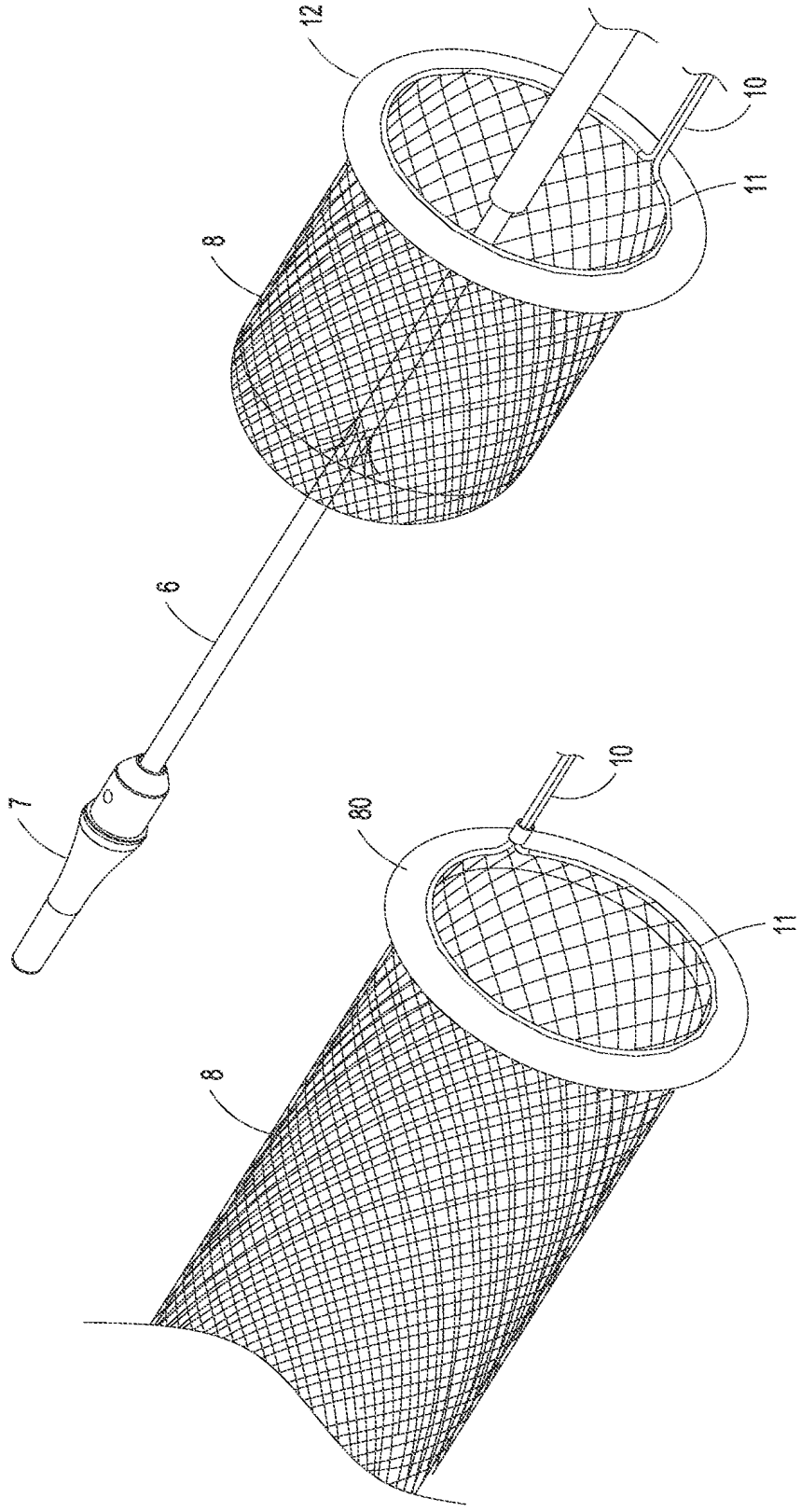

FIG. 18B

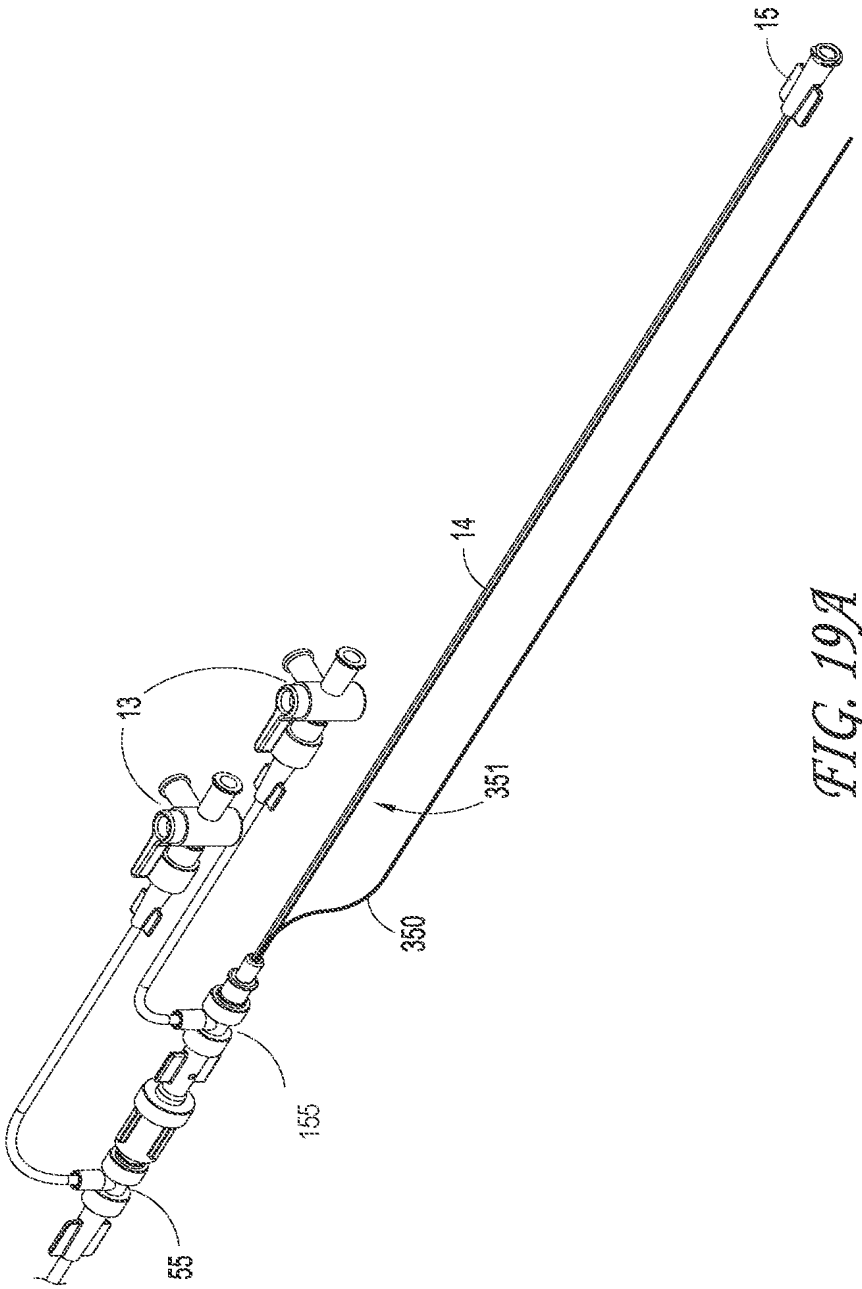

FIG. 19A

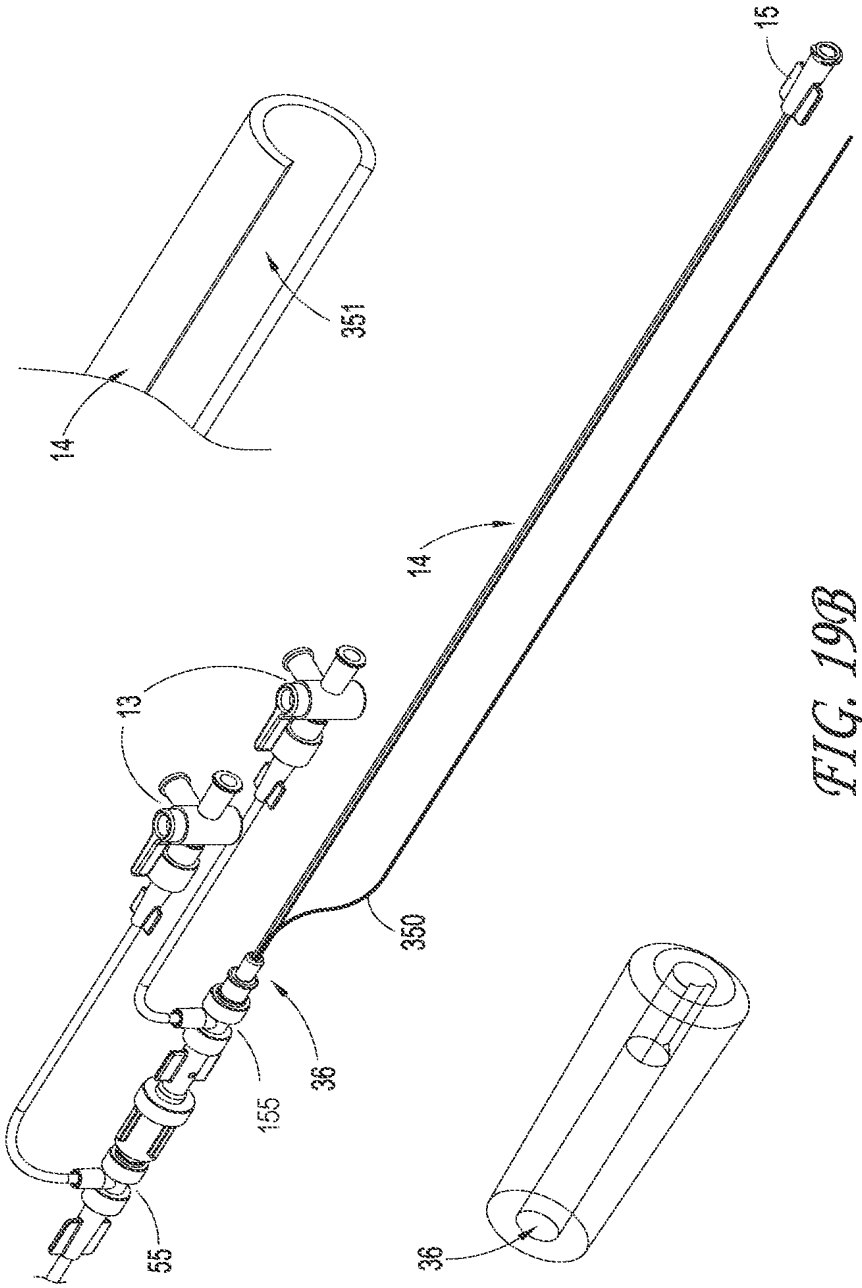

FIG. 19B

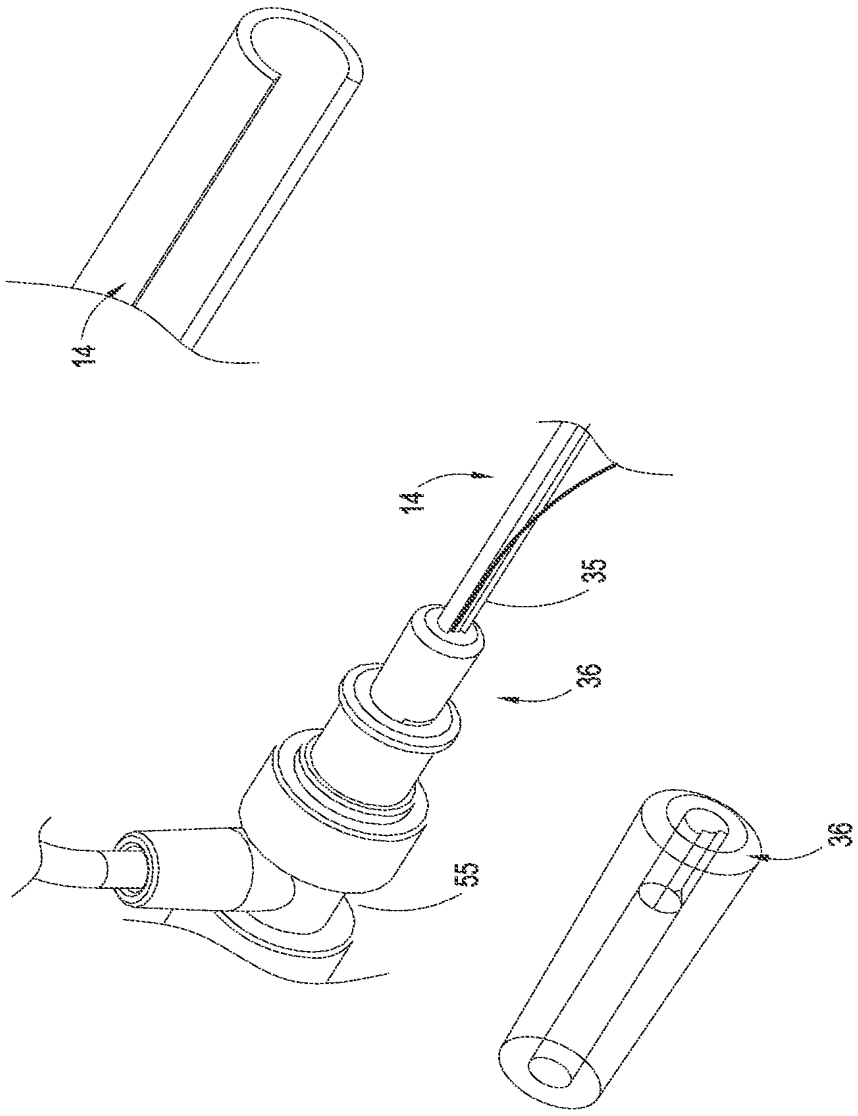

FIG. 19C

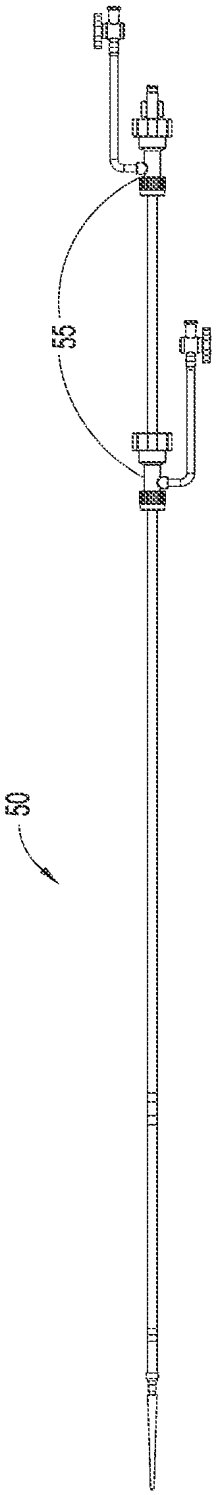

FIG. 20A

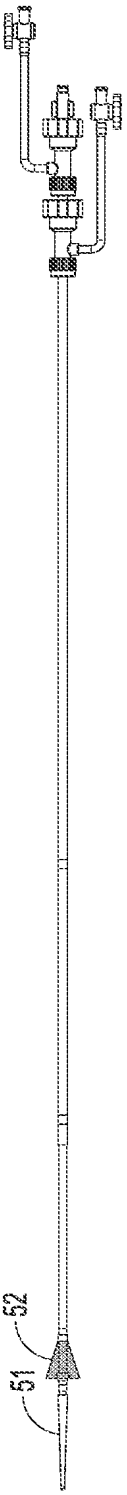

FIG. 20B

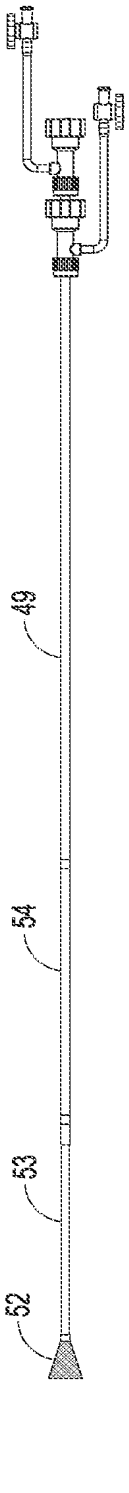

FIG. 20C

FIG. 20D

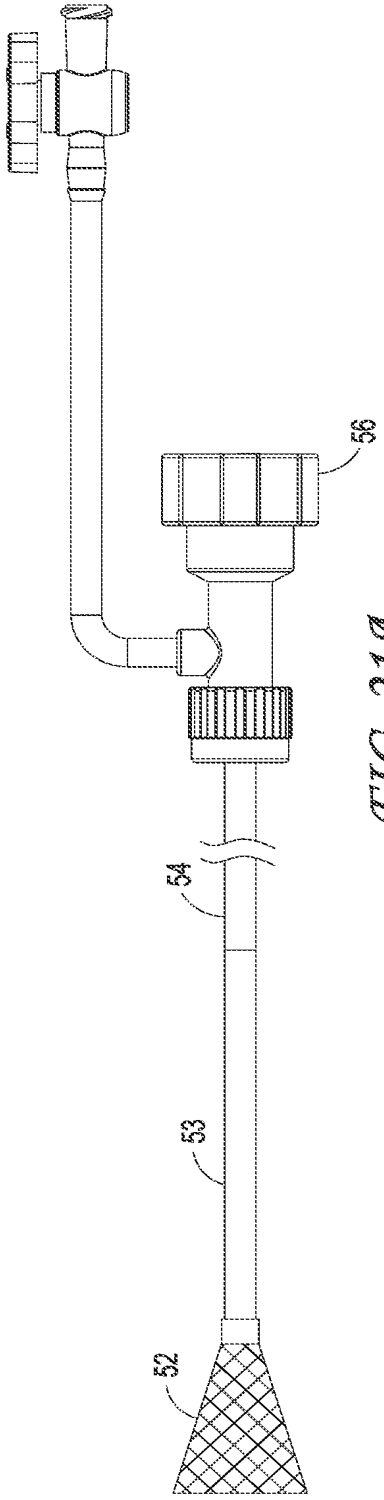

FIG. 21A

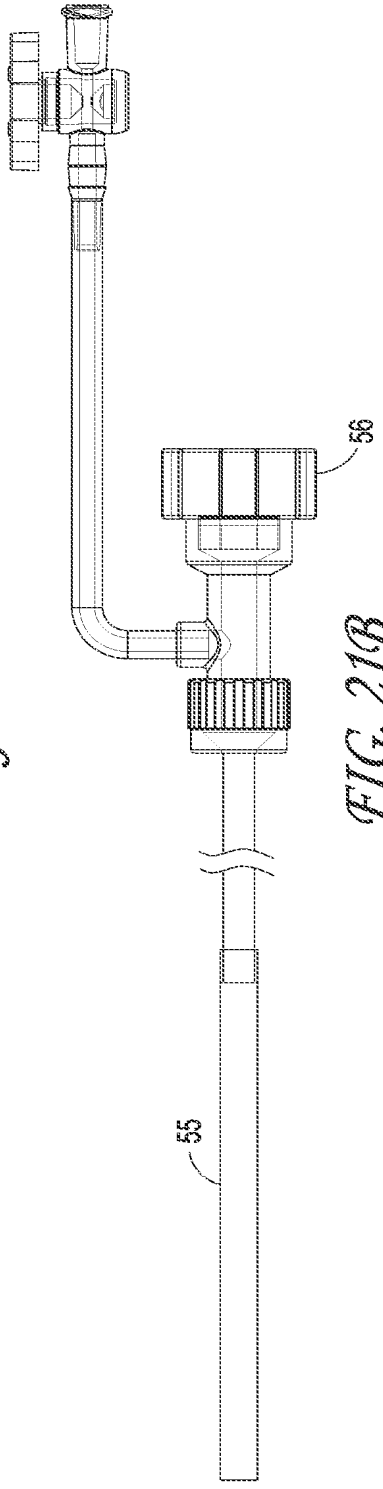

FIG. 21B

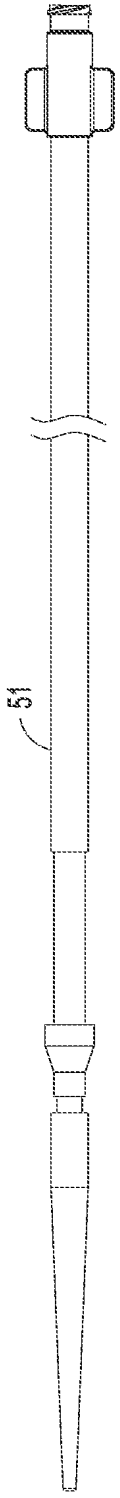

FIG. 21C

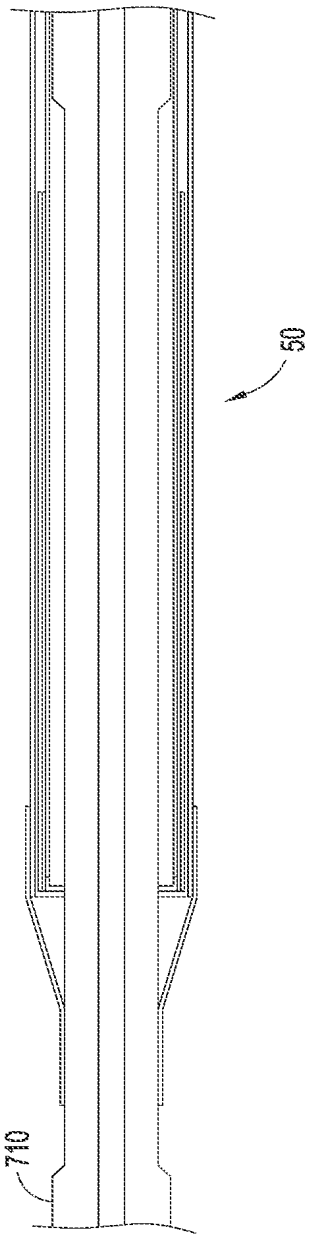

FIG. 21D

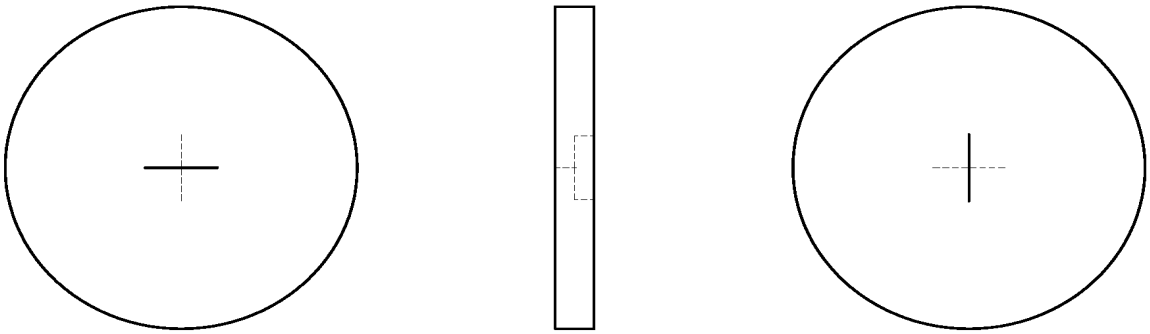

FIG. 21E

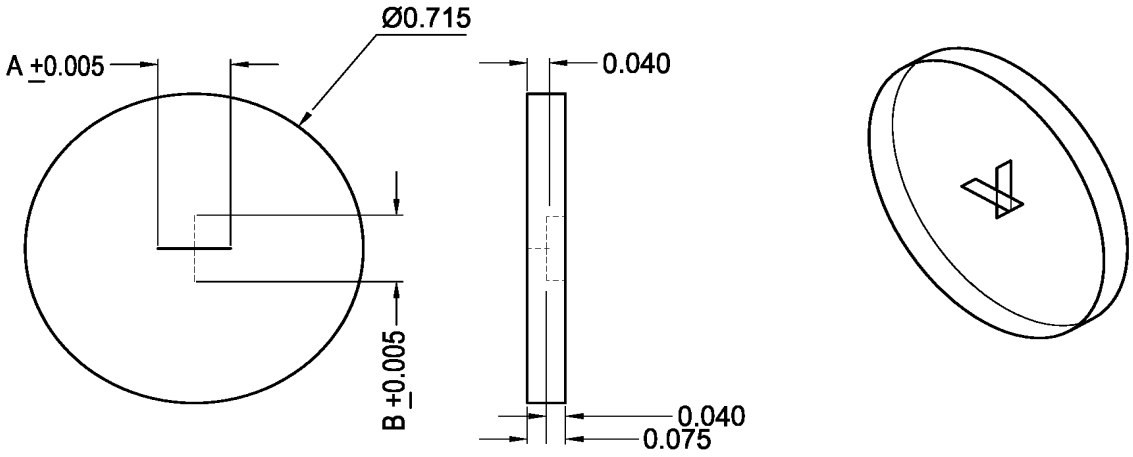

FIG. 21F

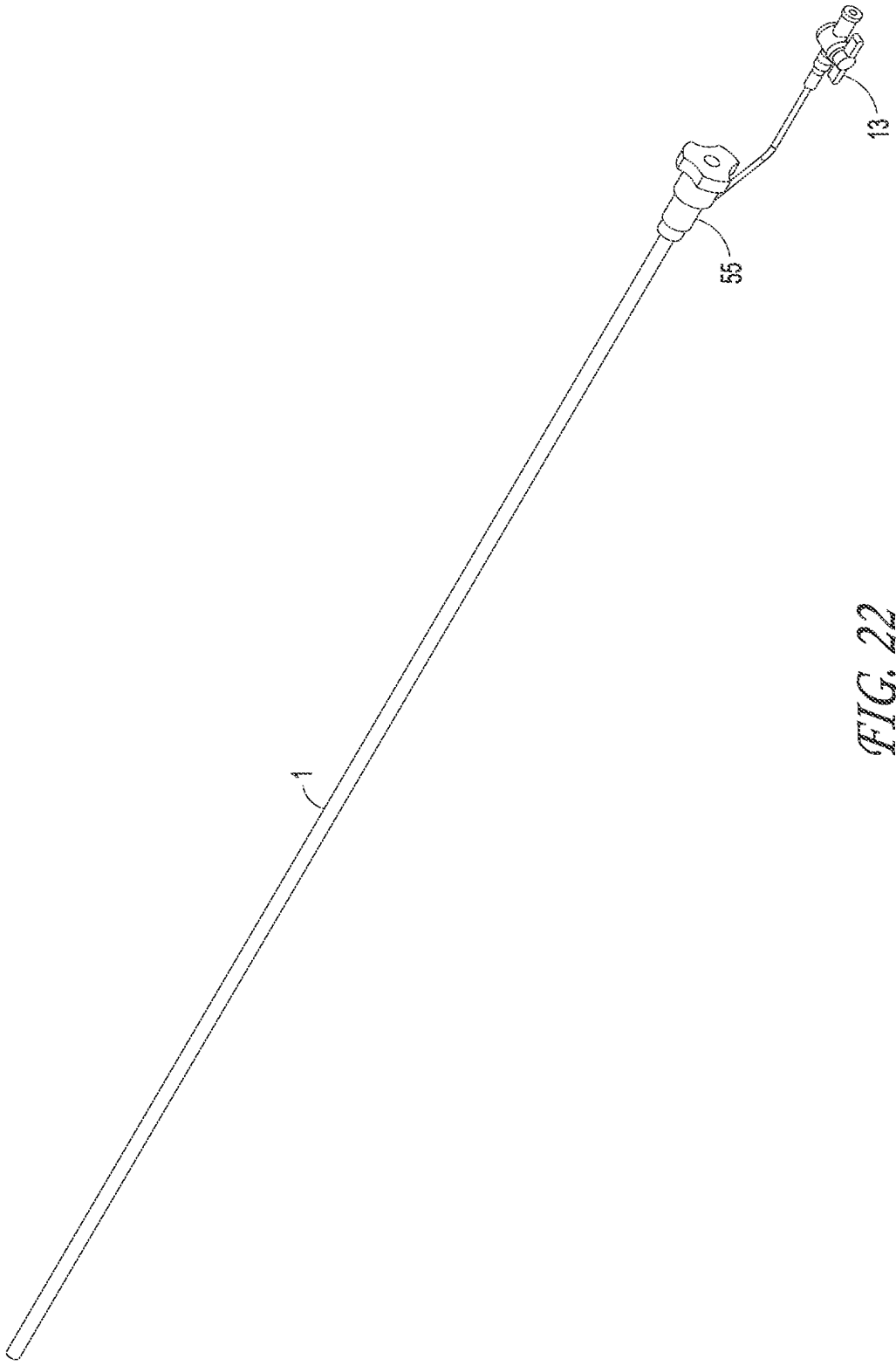

FIG. 22

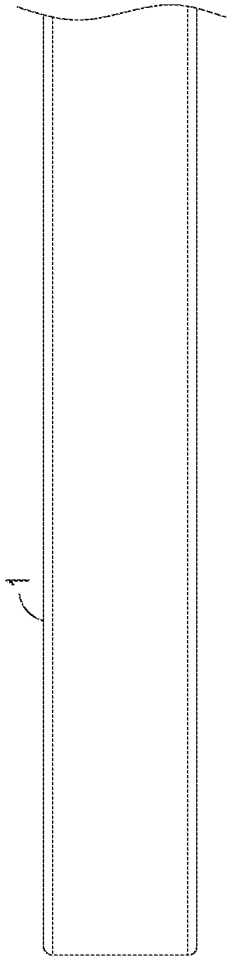

FIG. 23

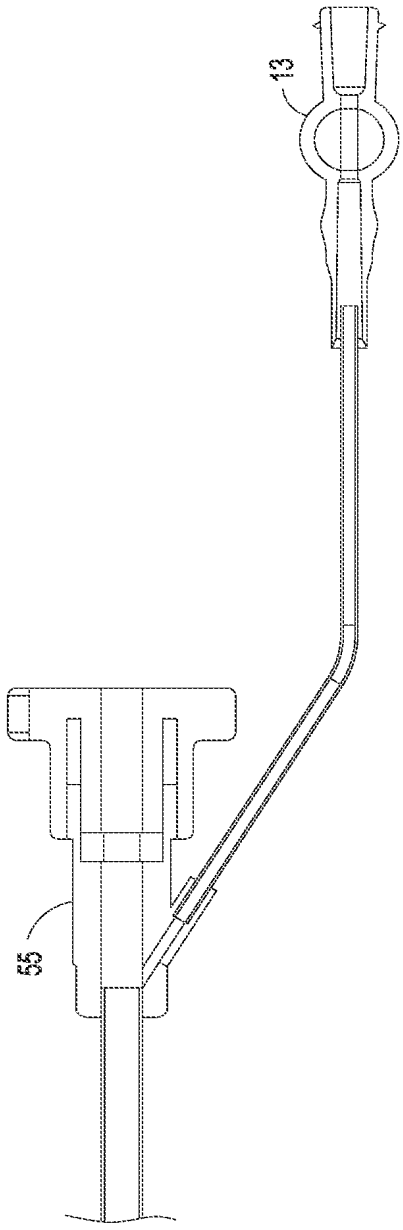

FIG. 24

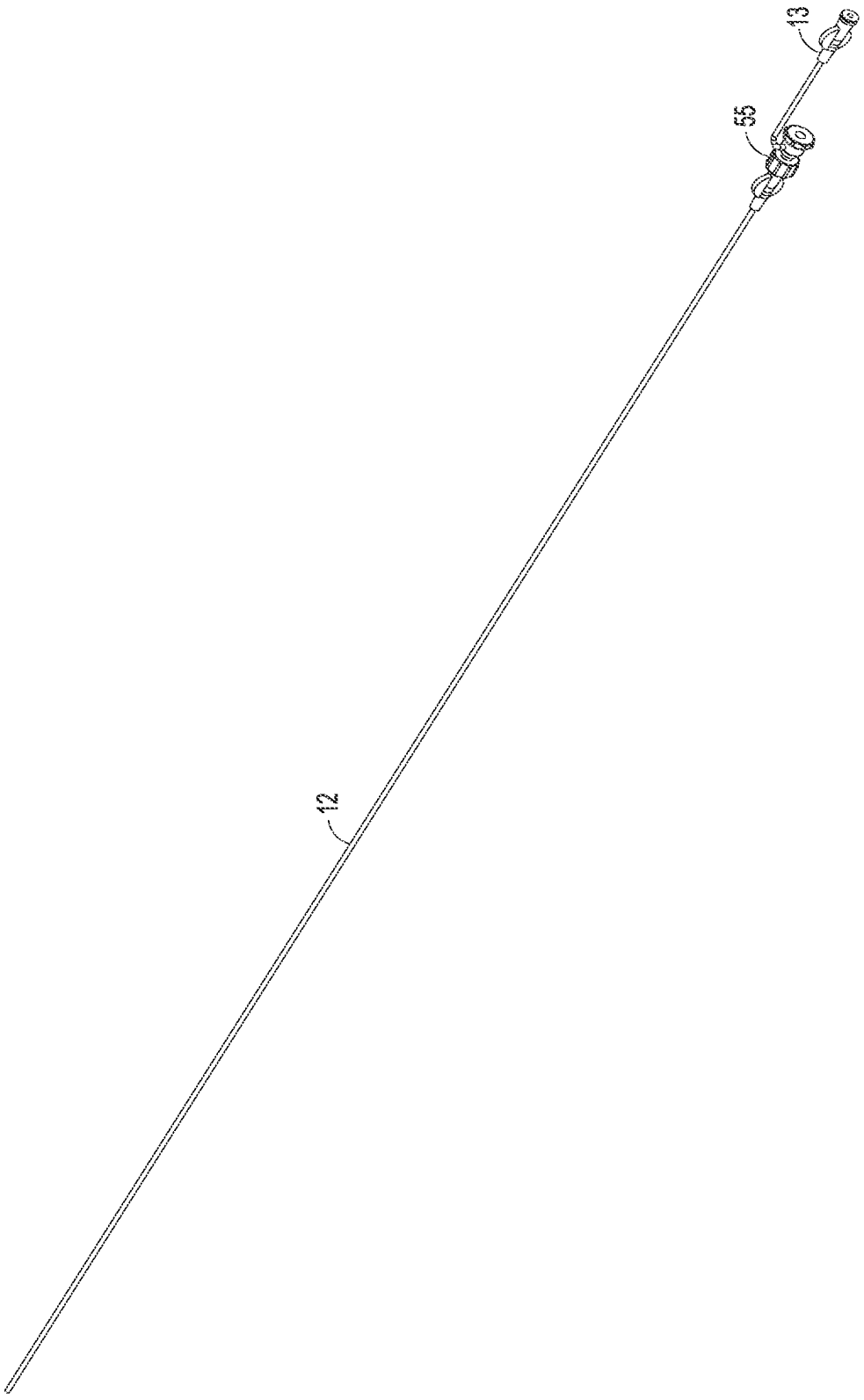

FIG. 25

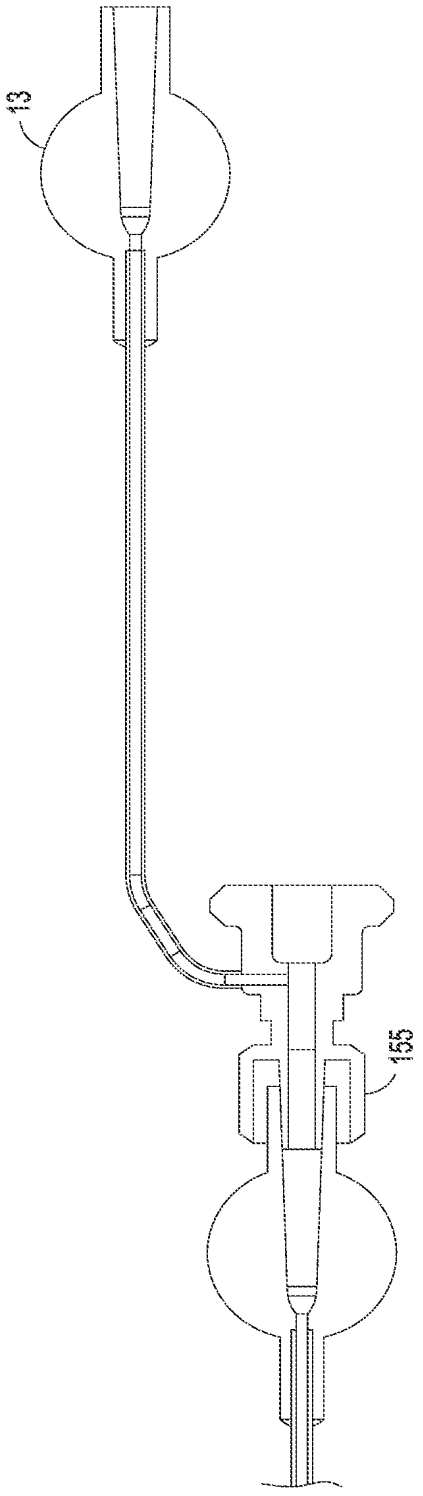

FIG. 26

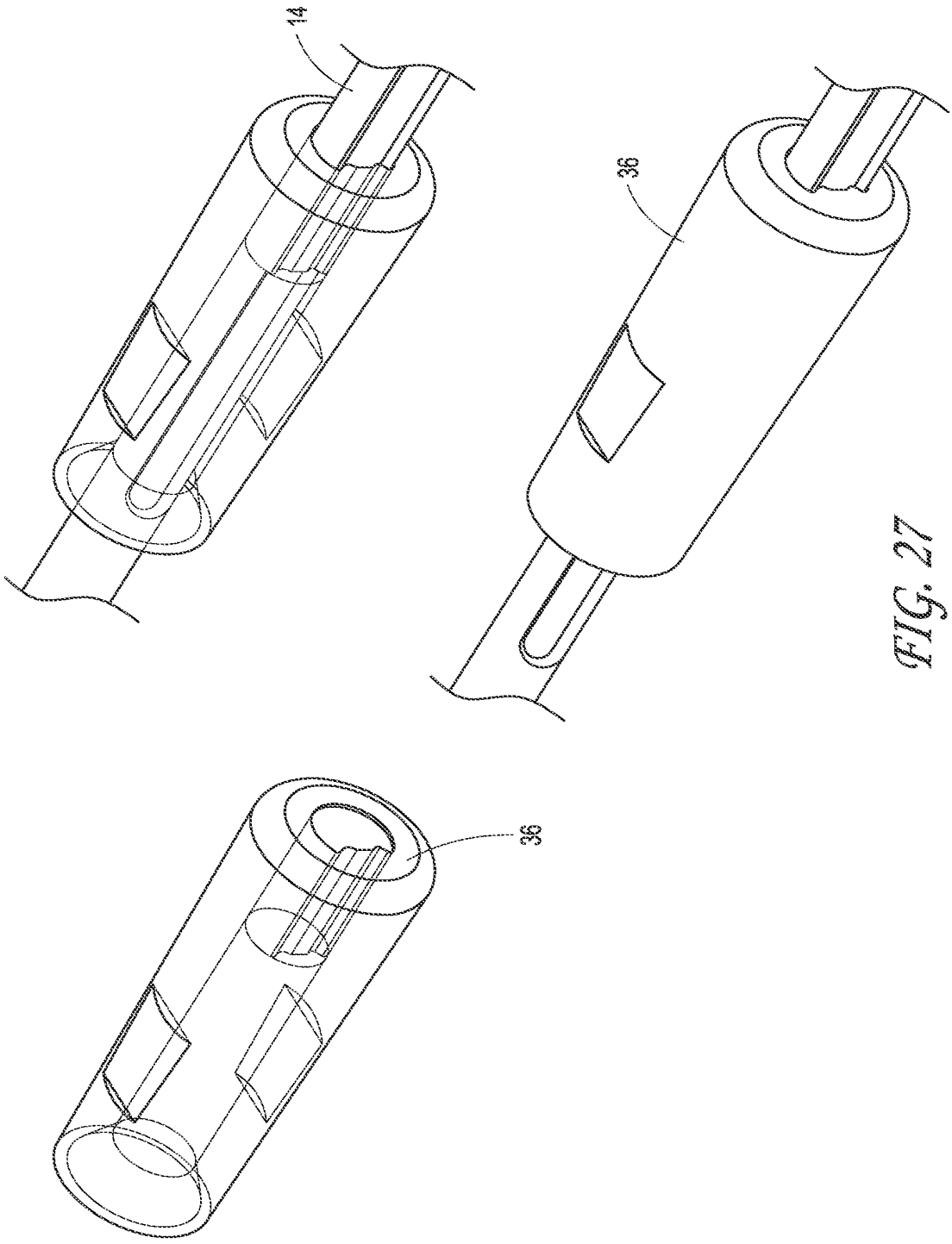

FIG. 27

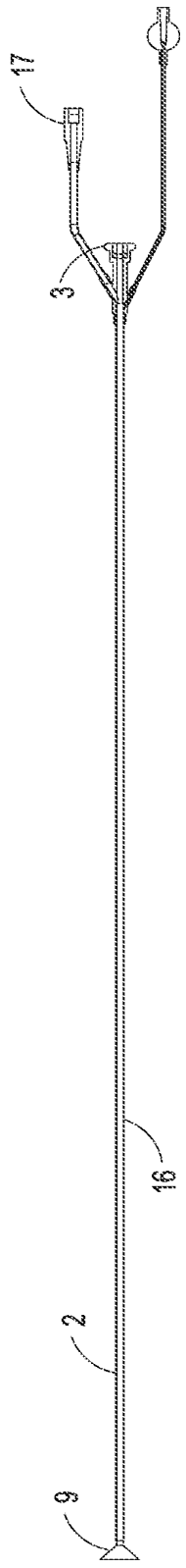

FIG. 28

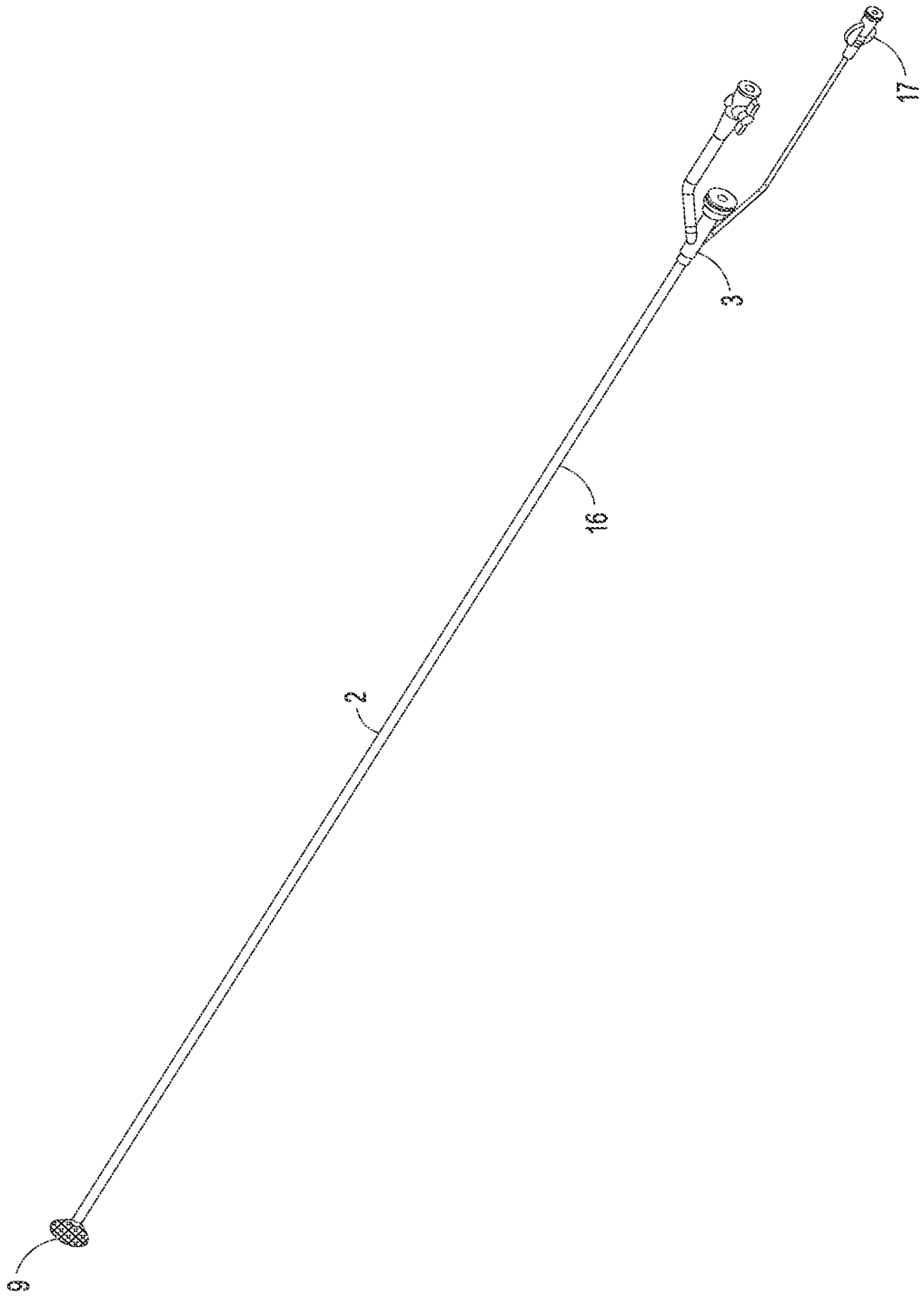

FIG. 29

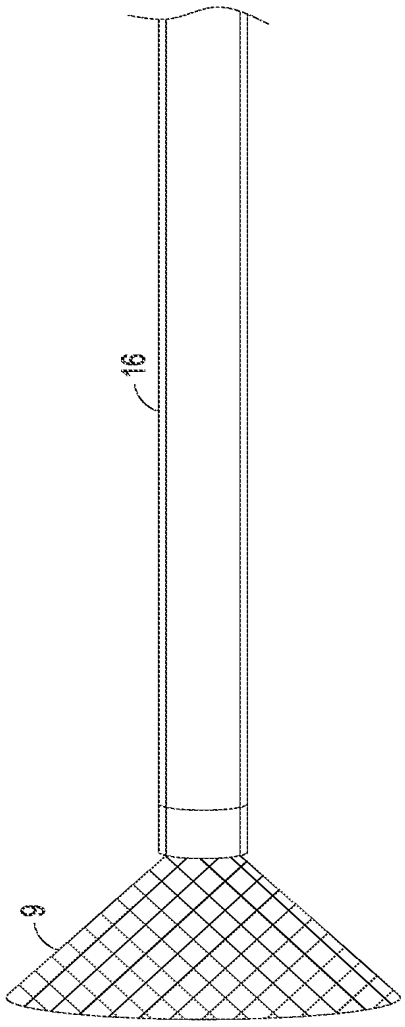

FIG. 30

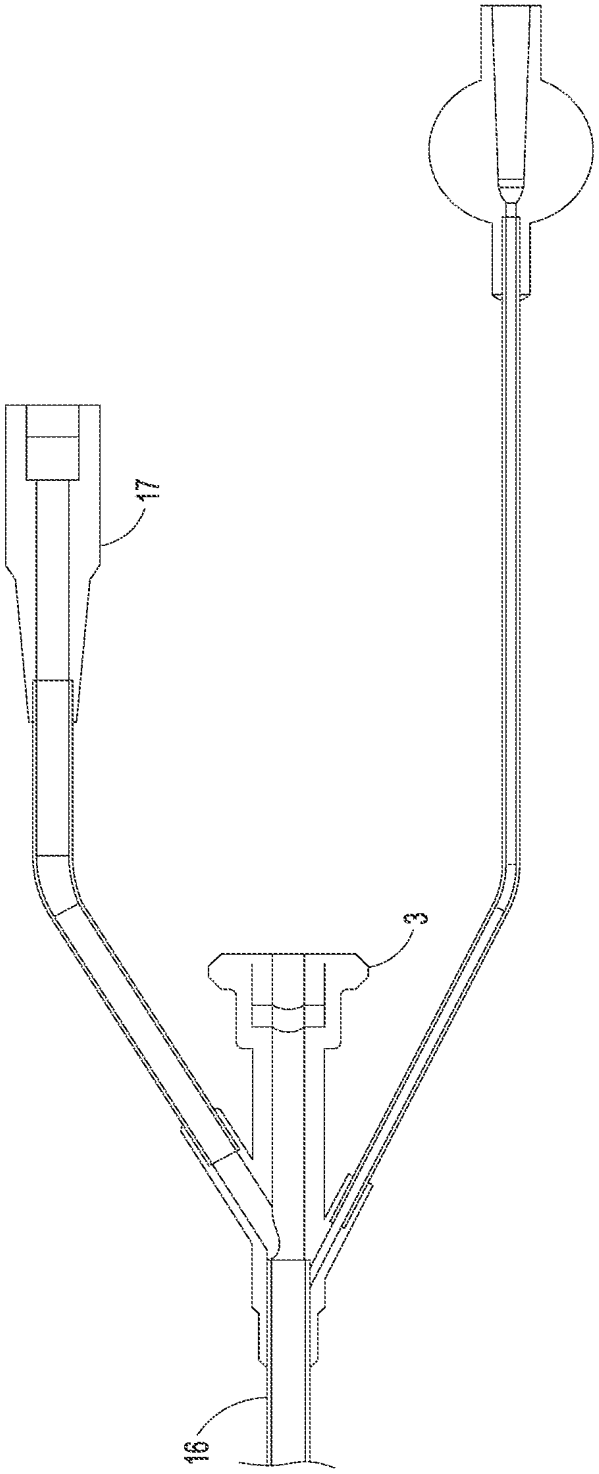

FIG. 31

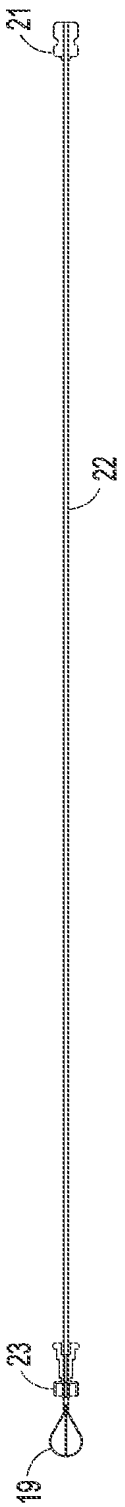

FIG. 32

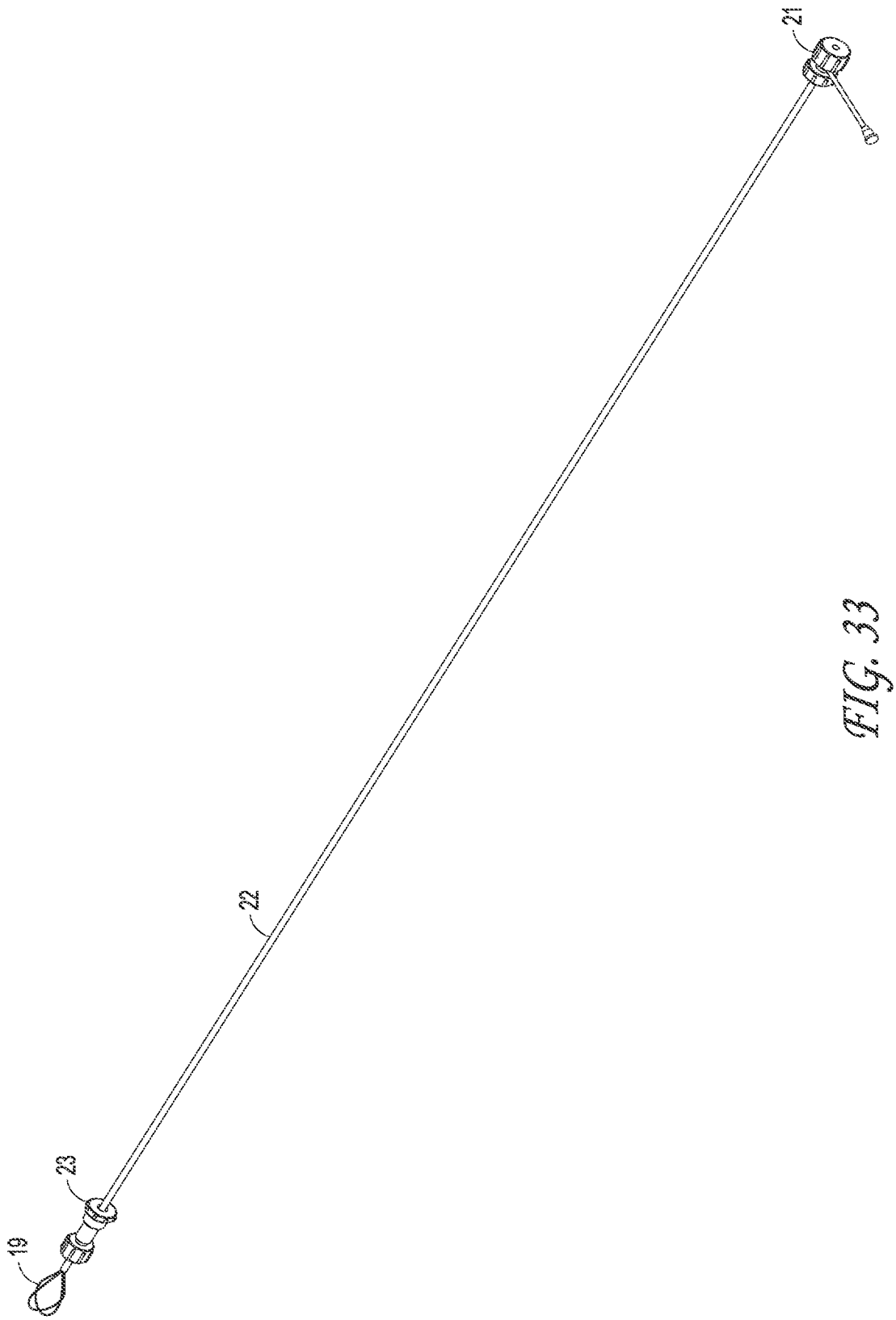

FIG. 33

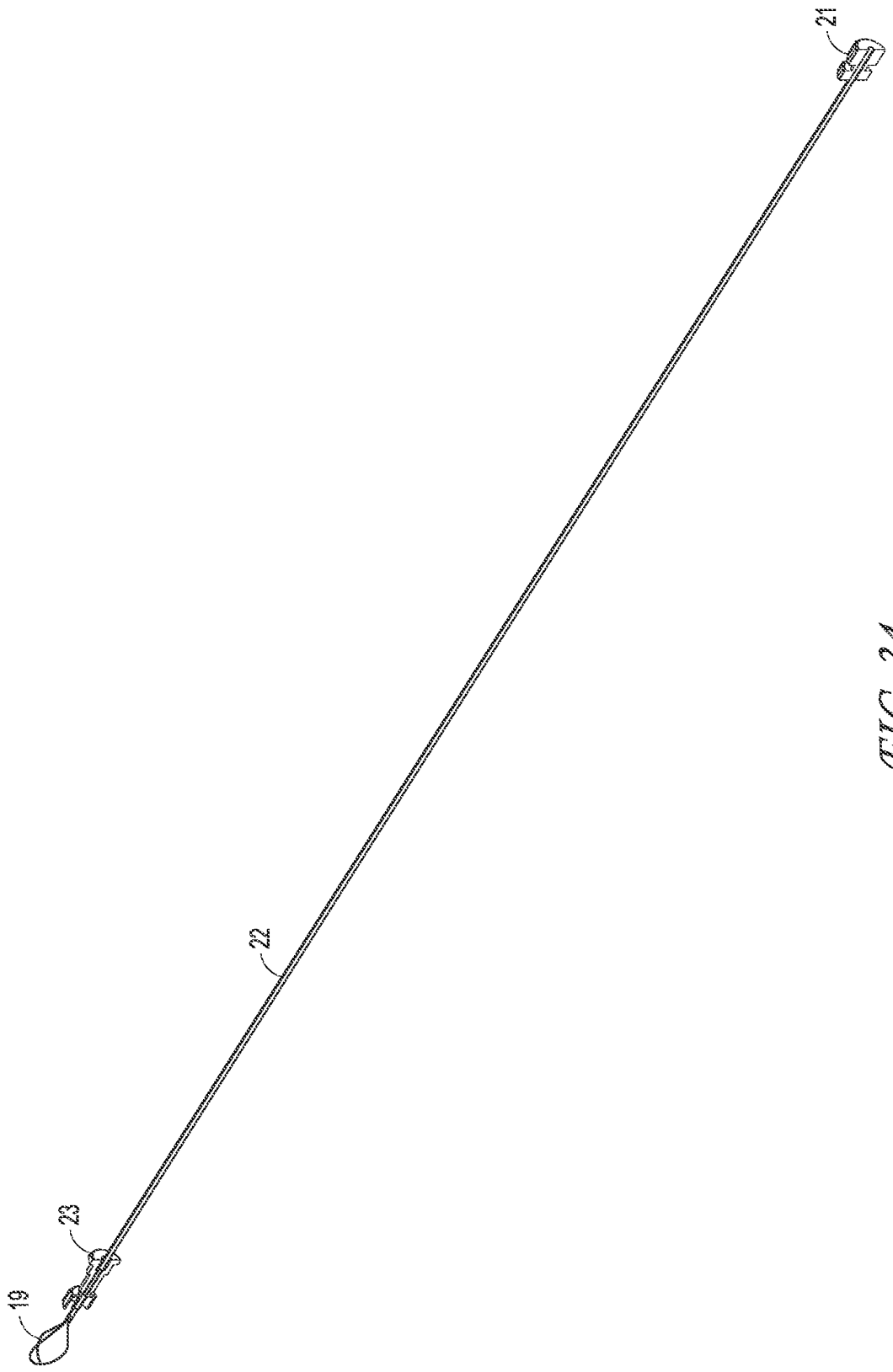

FIG. 34

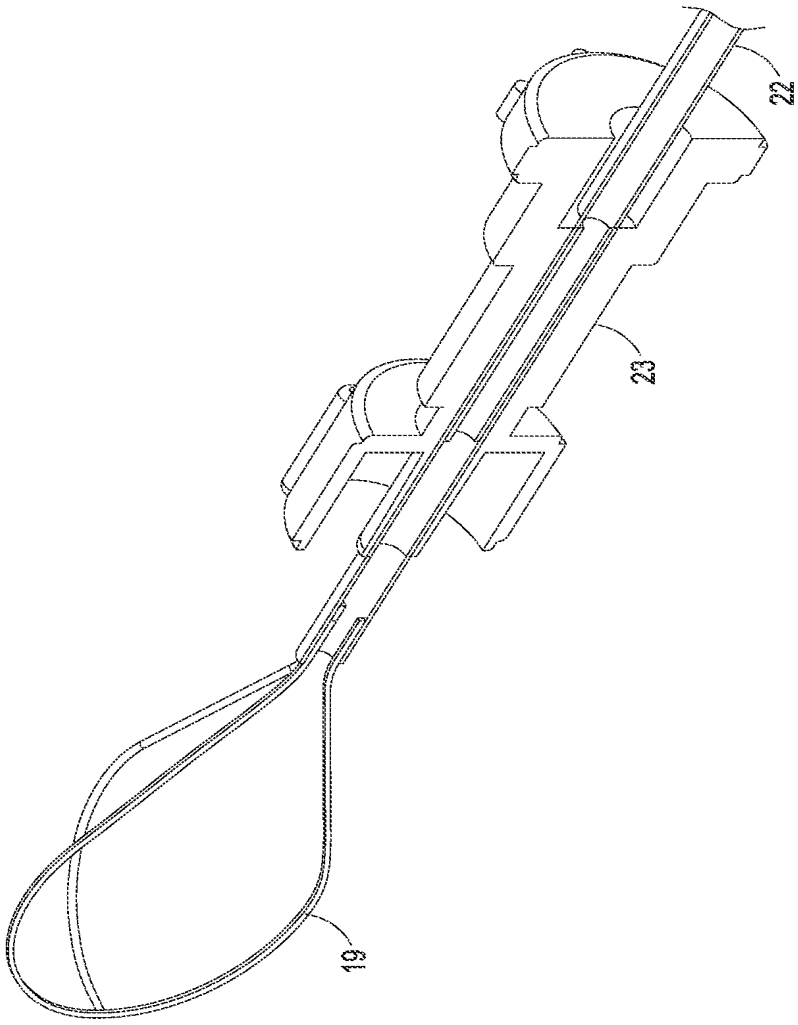

FIG. 35

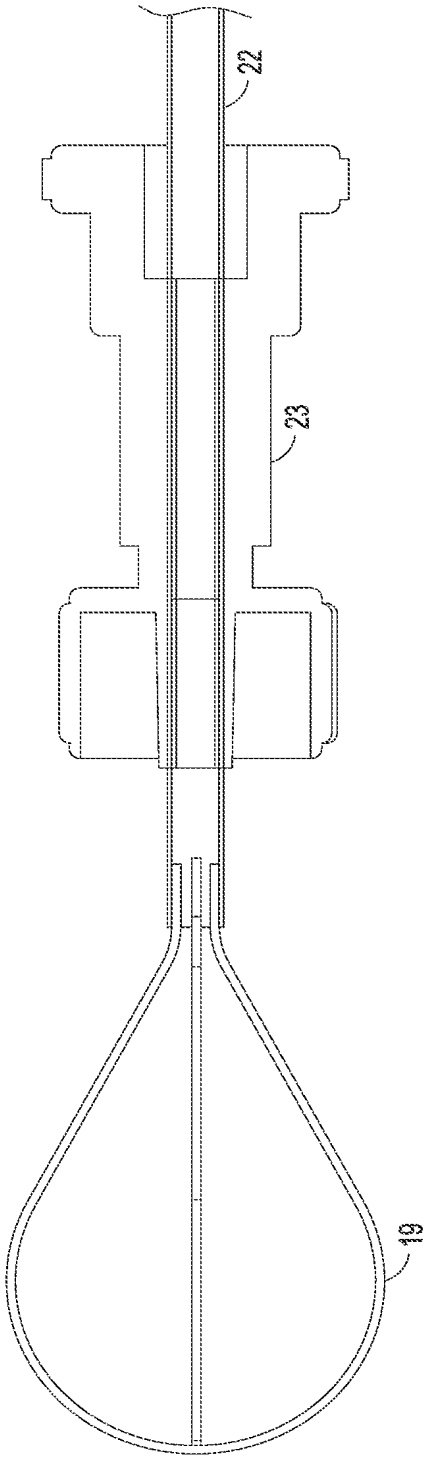

FIG. 36

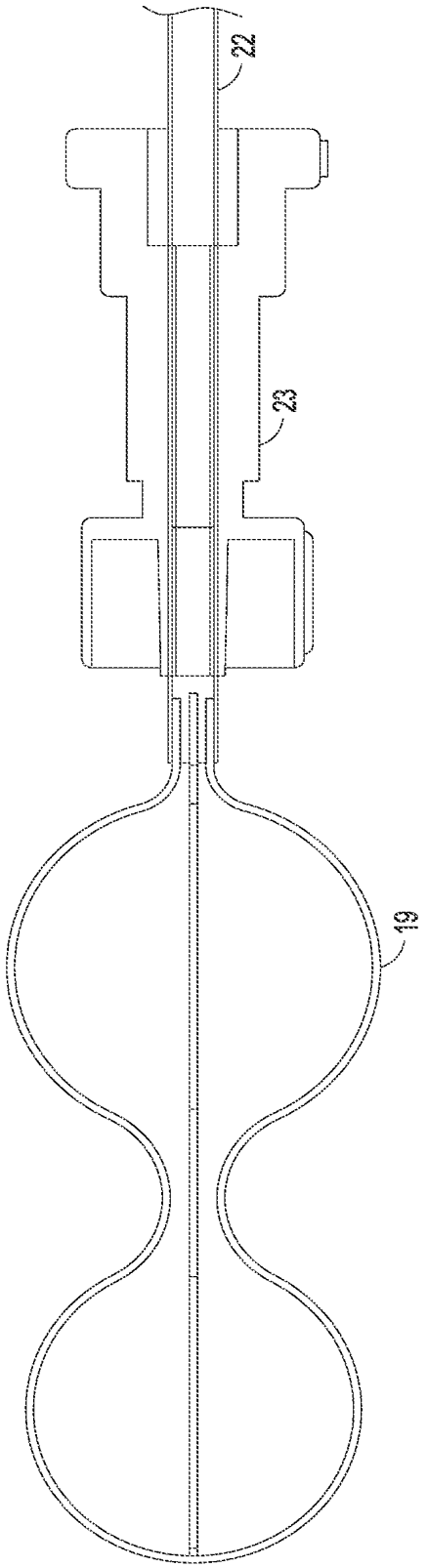

FIG. 37

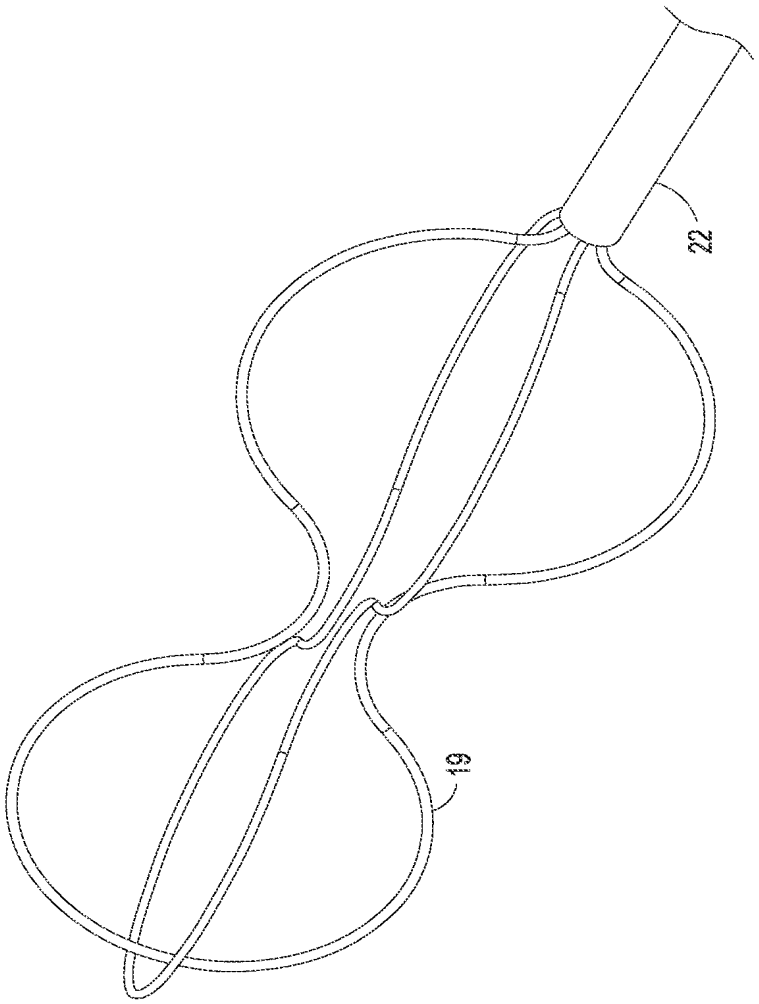

FIG. 38

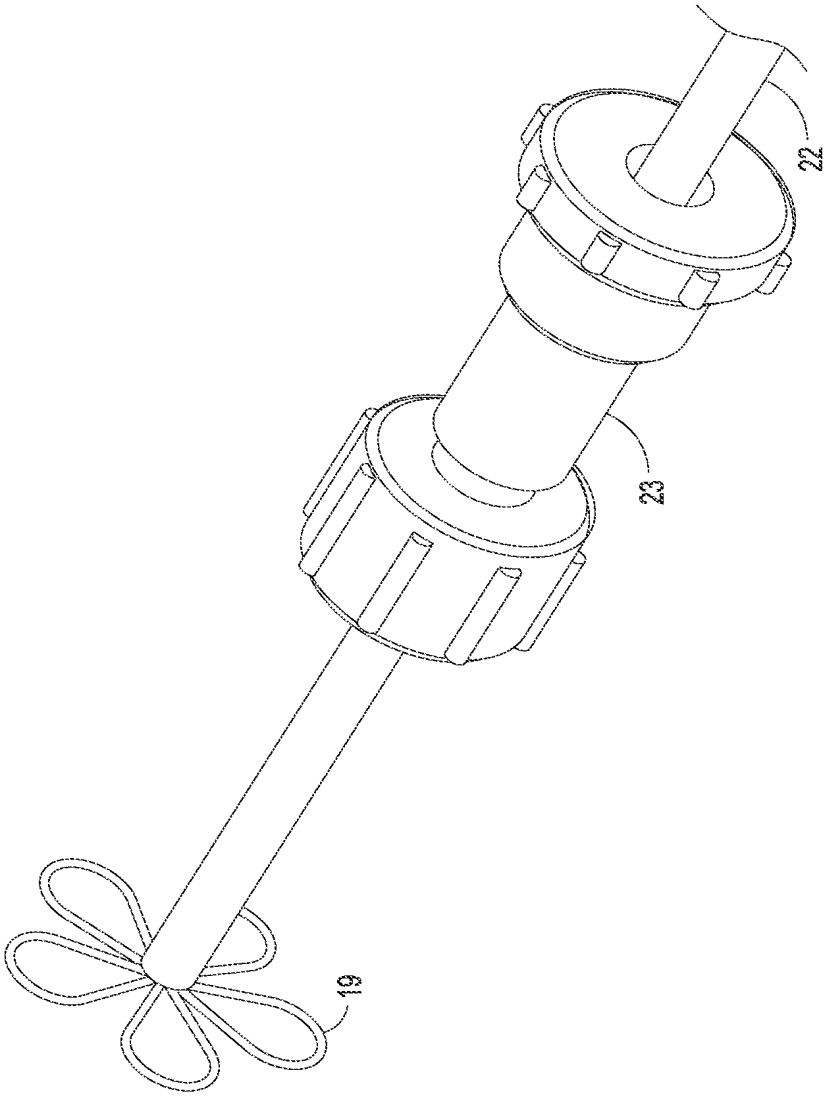

FIG. 39

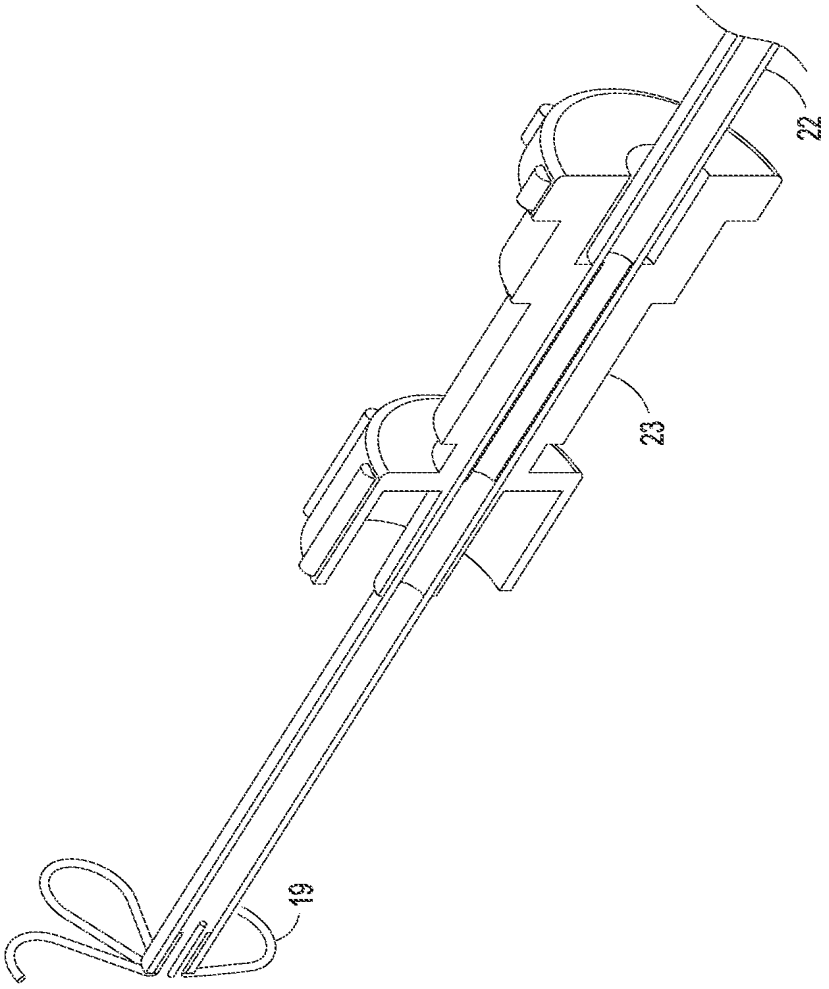

FIG. 40

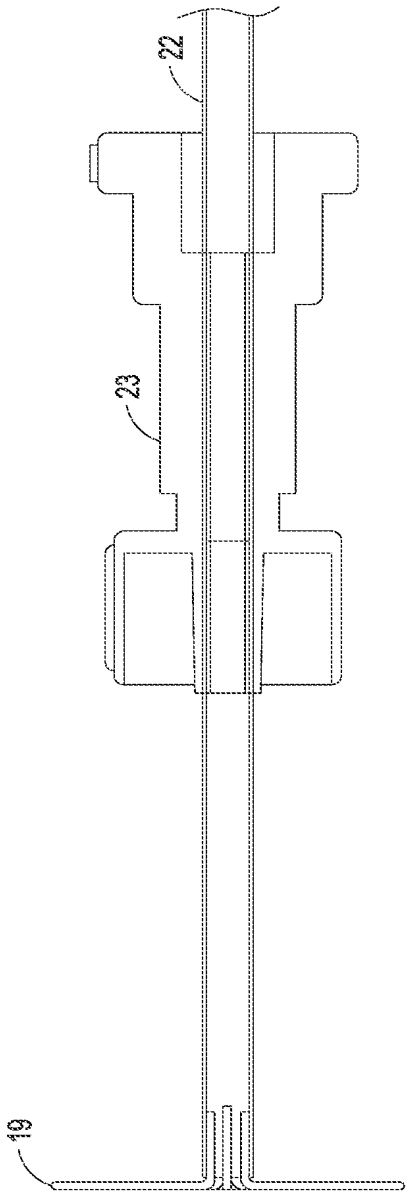

FIG. 41

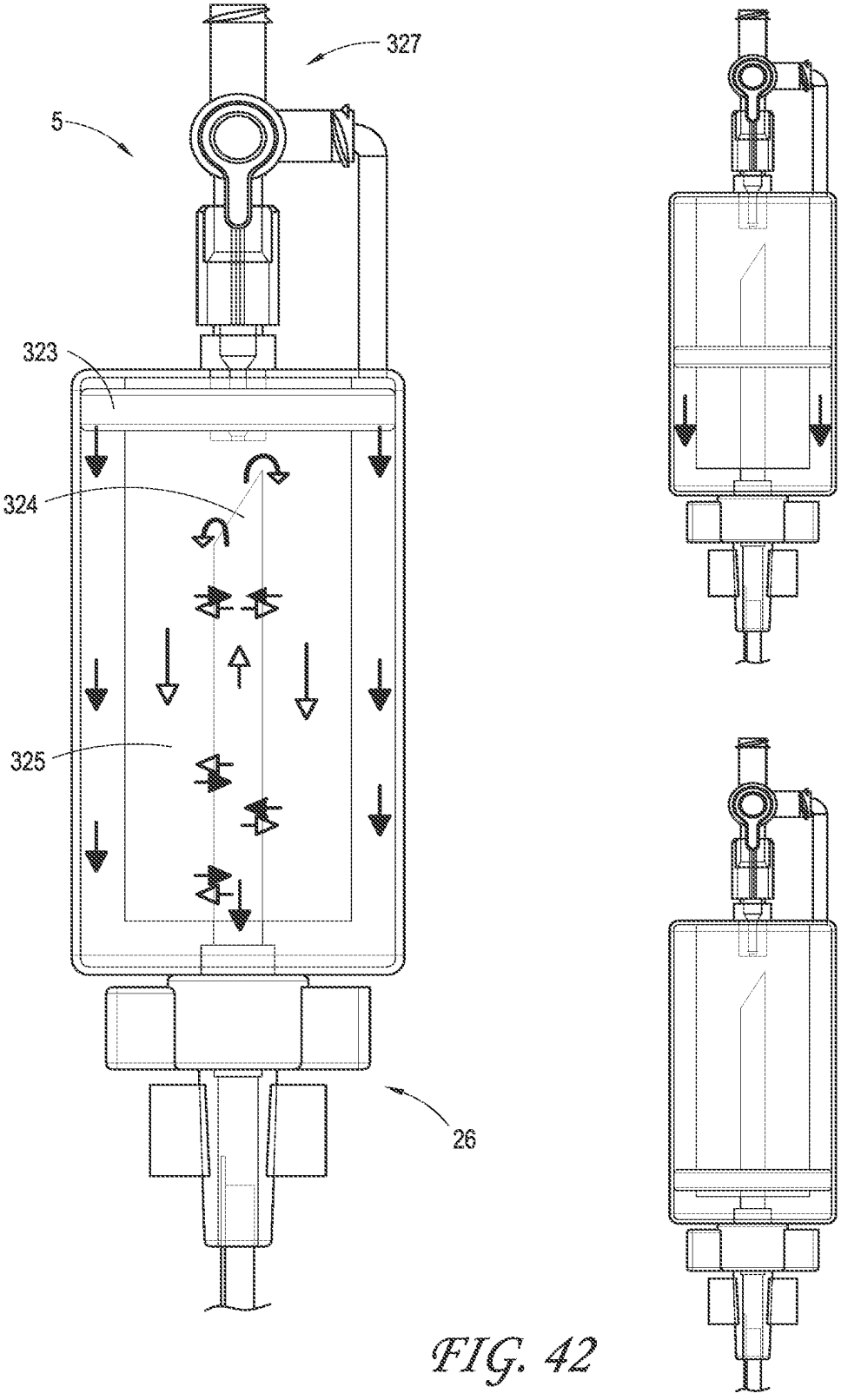

FIG. 42

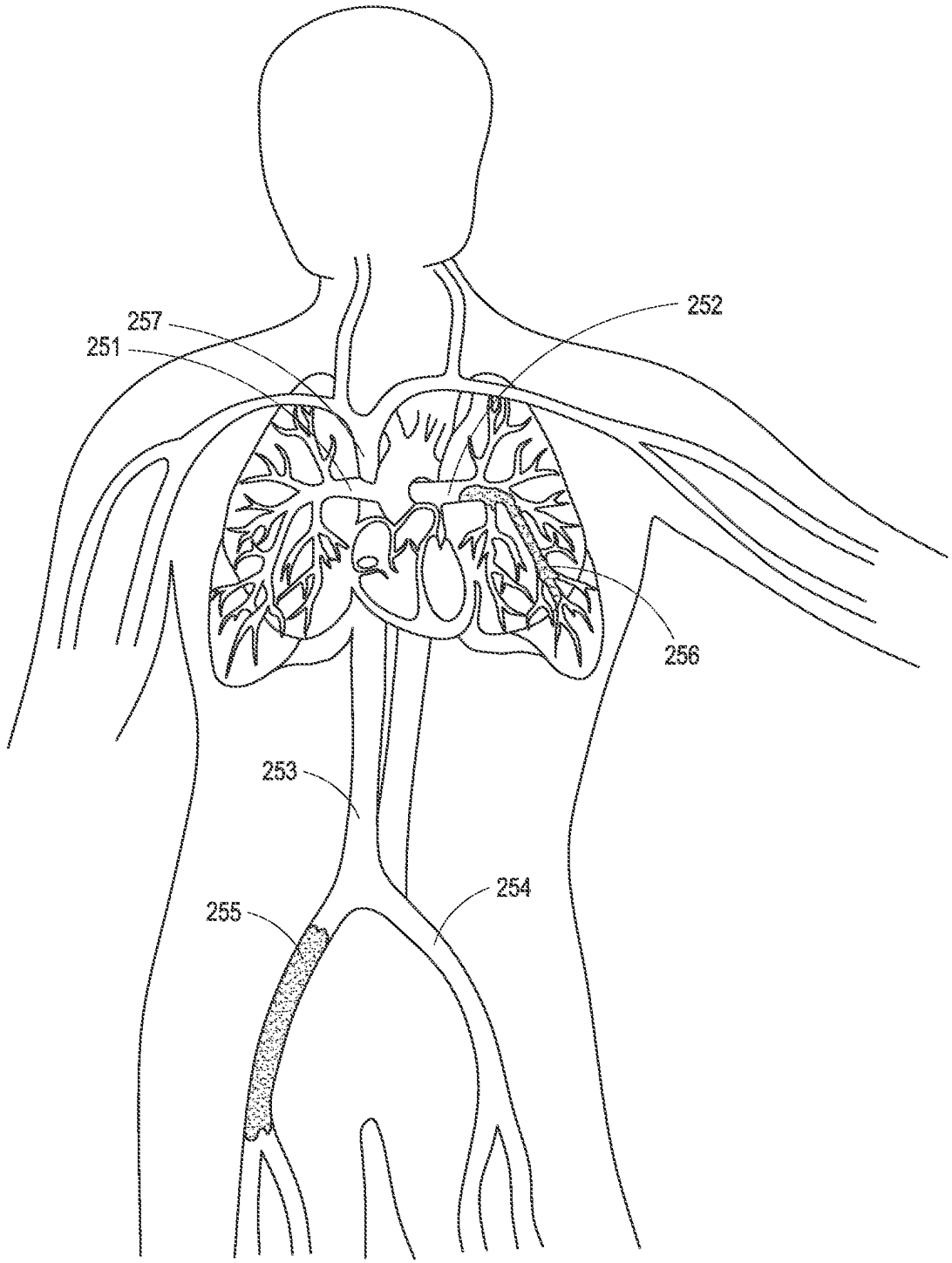

FIG. 43

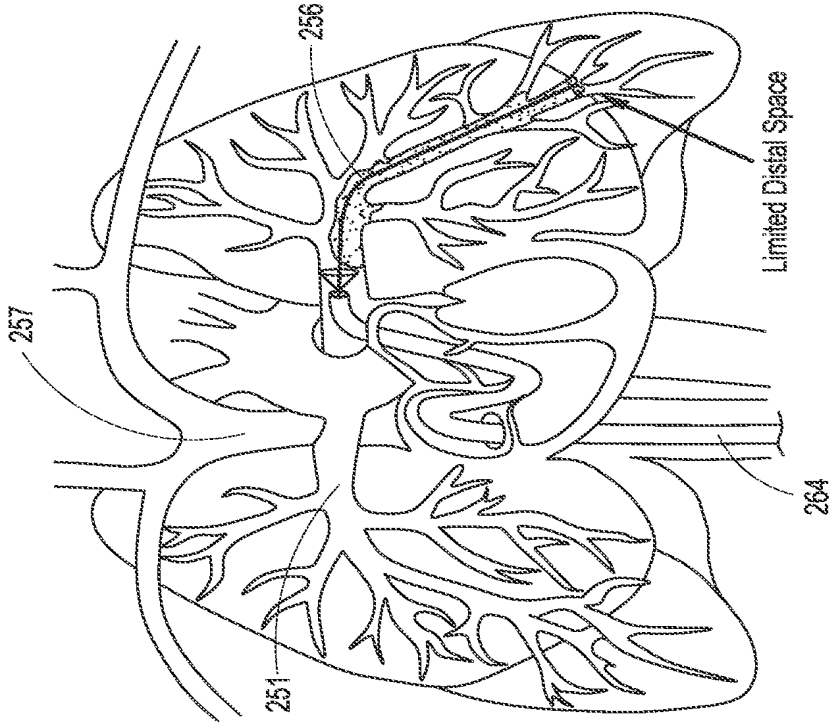

FIG. 44B

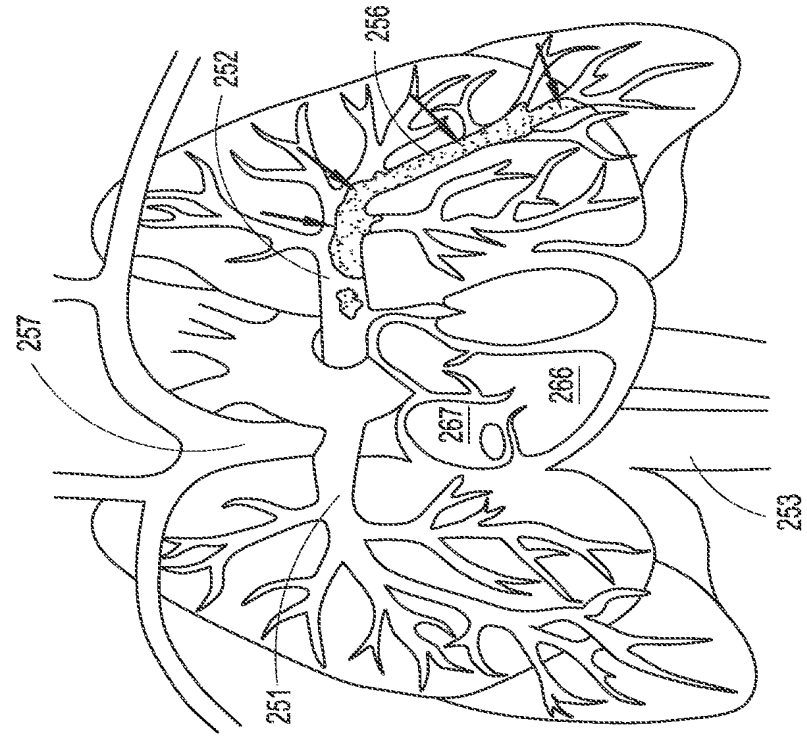

FIG. 44A

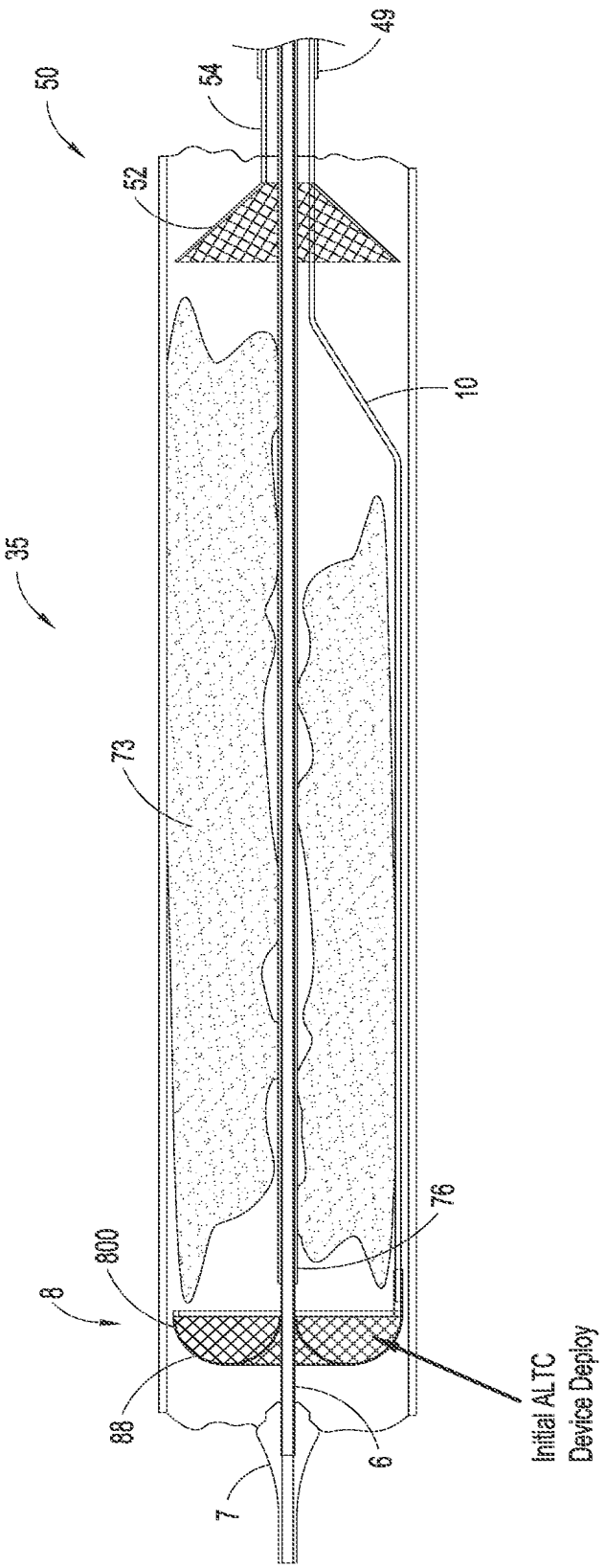

FIG. 45

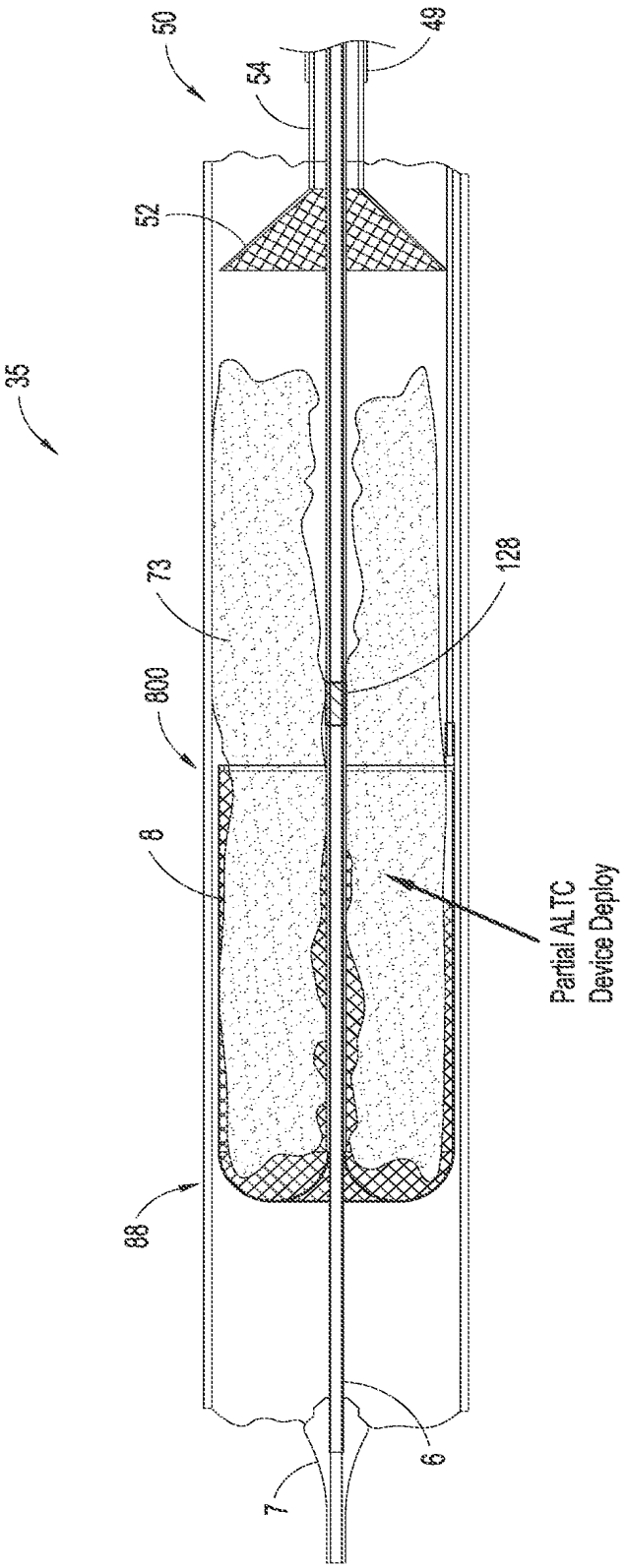

FIG. 46

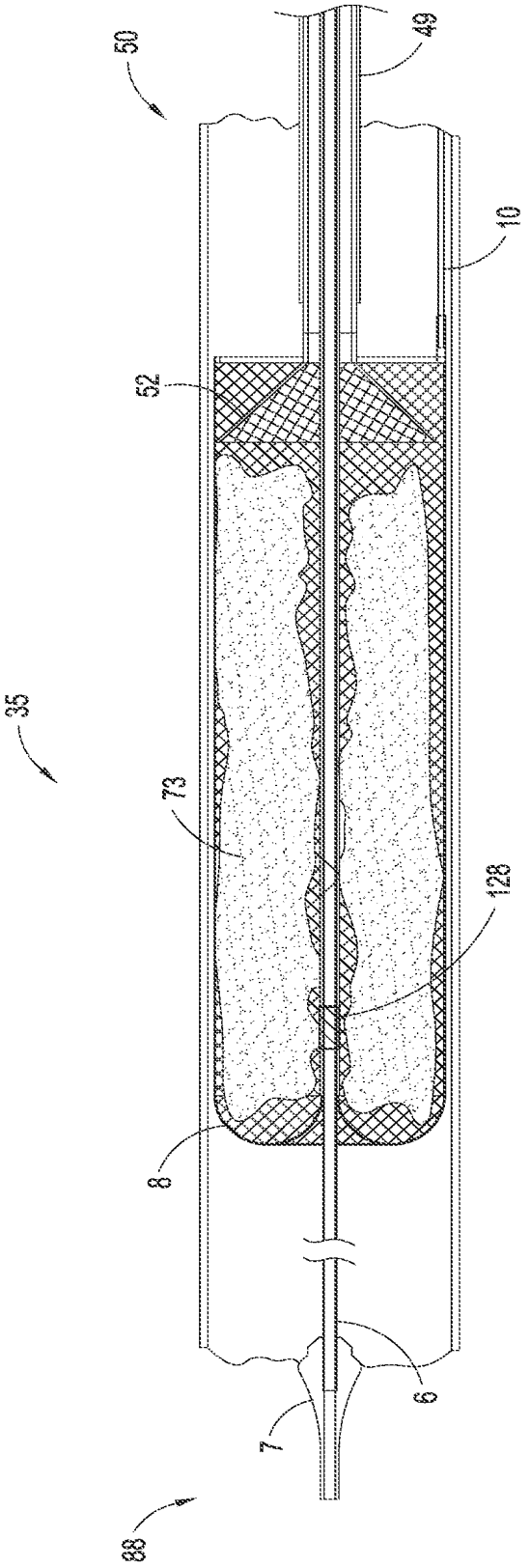

FIG. 47

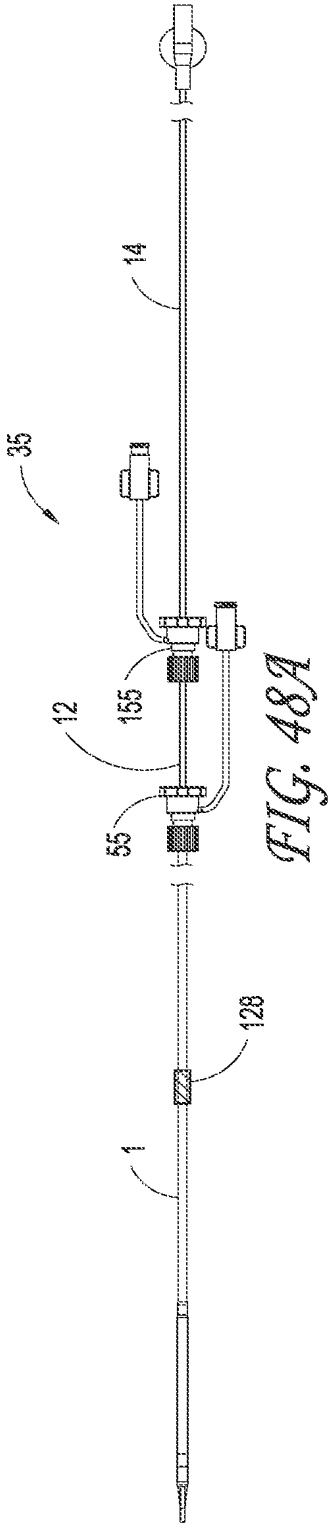

FIG. 48A

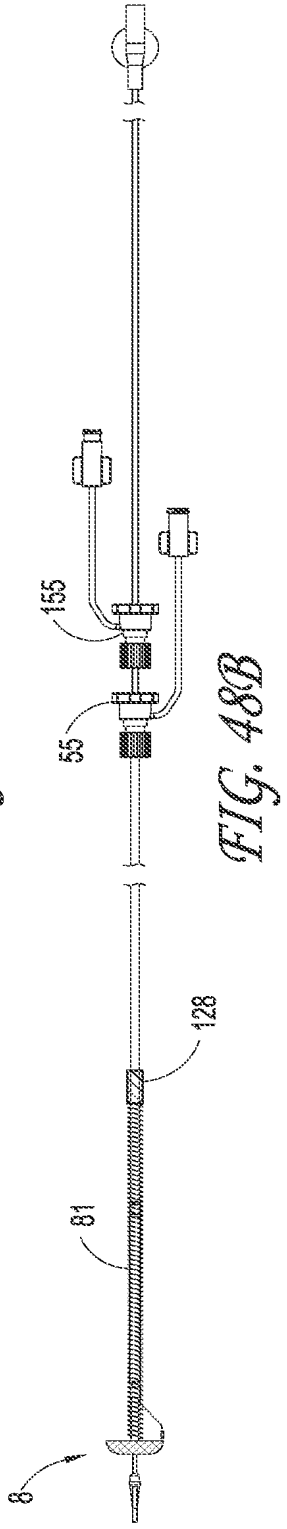

FIG. 48B

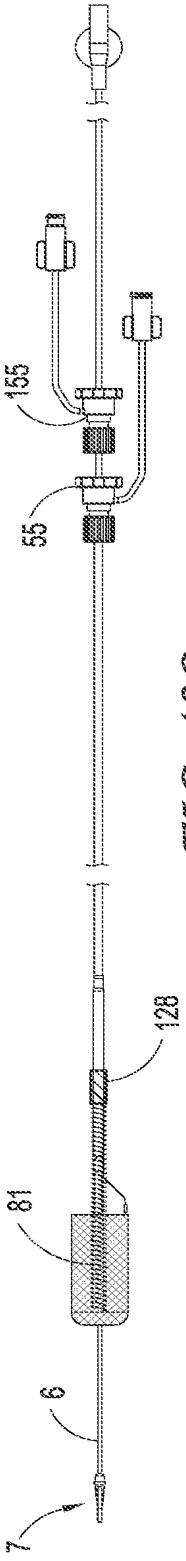

FIG. 48C

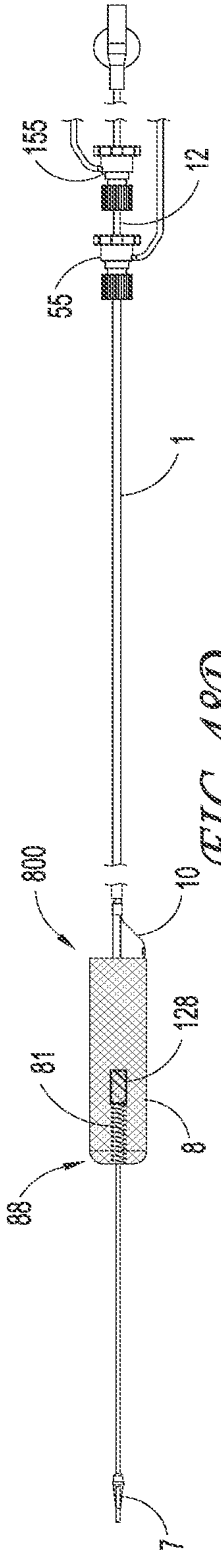

FIG. 48D

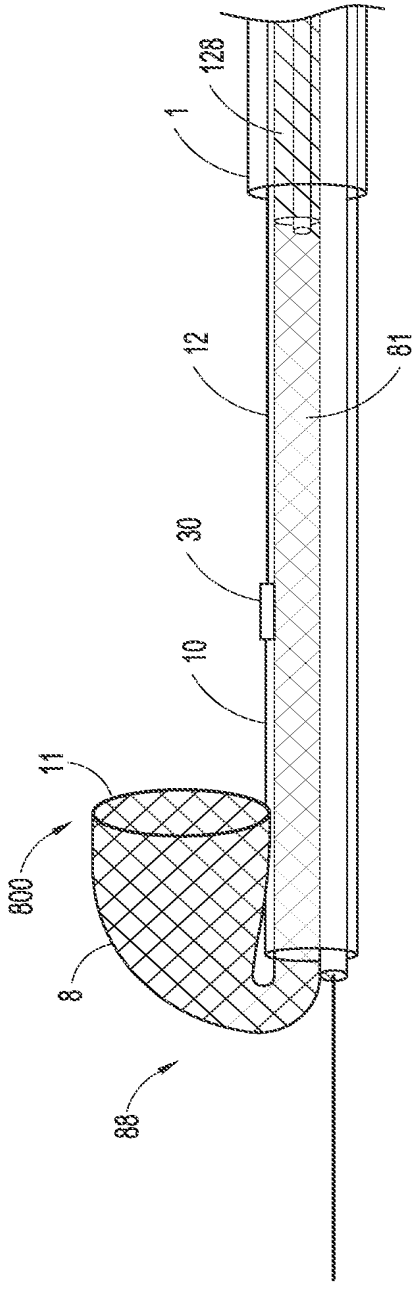

FIG. 49A

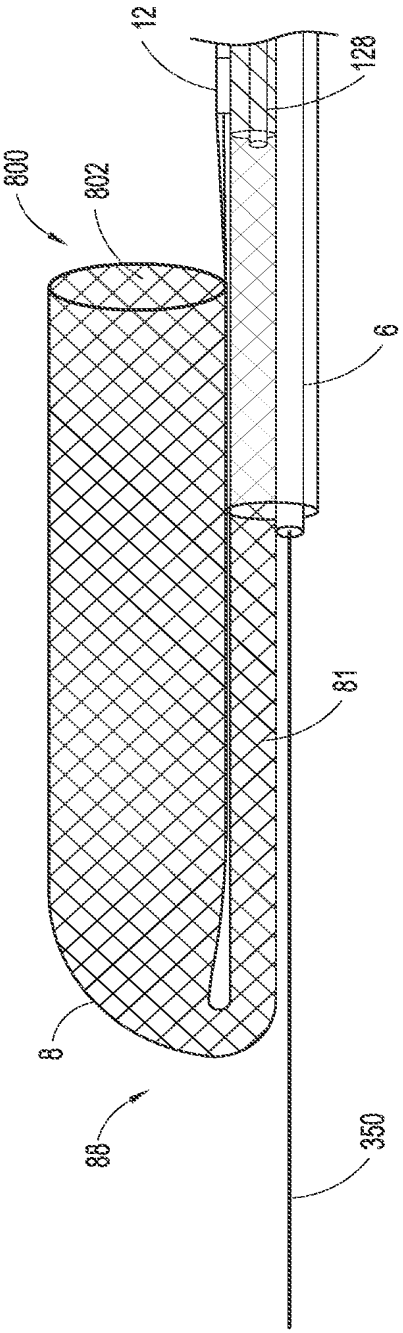

FIG. 49B

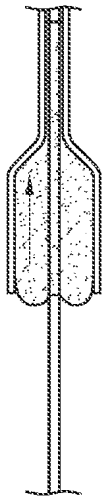

FIG. 50E

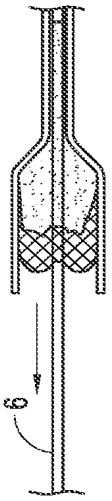

FIG. 50F

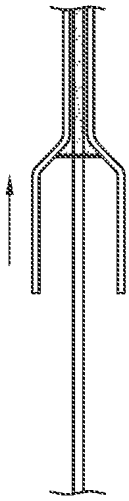

FIG. 50G

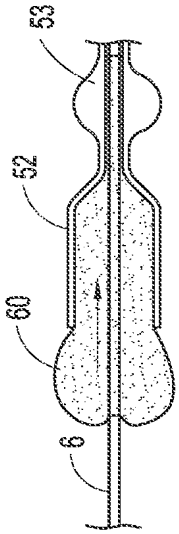

FIG. 50A

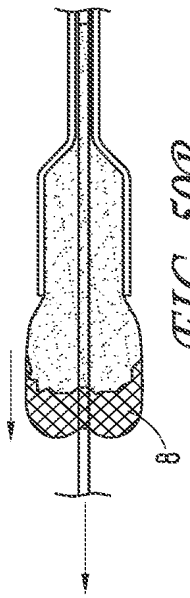

FIG. 50B

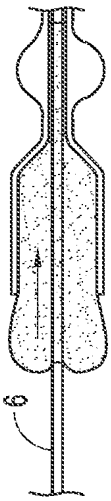

FIG. 50C

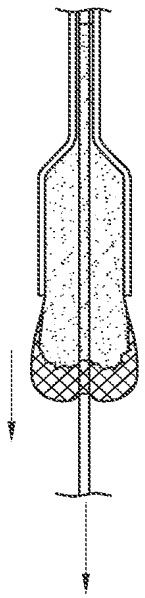

FIG. 50D

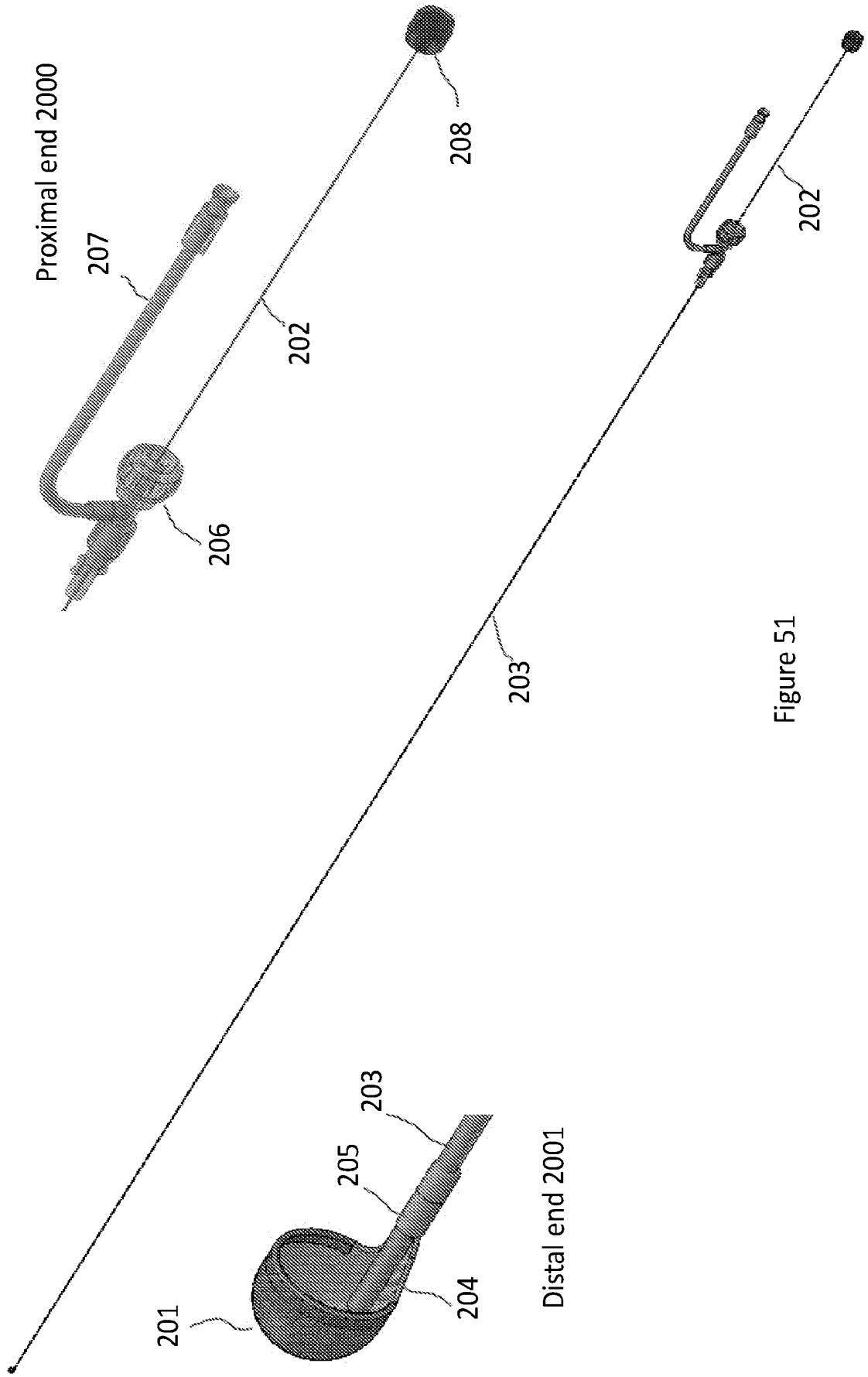
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Figure 51

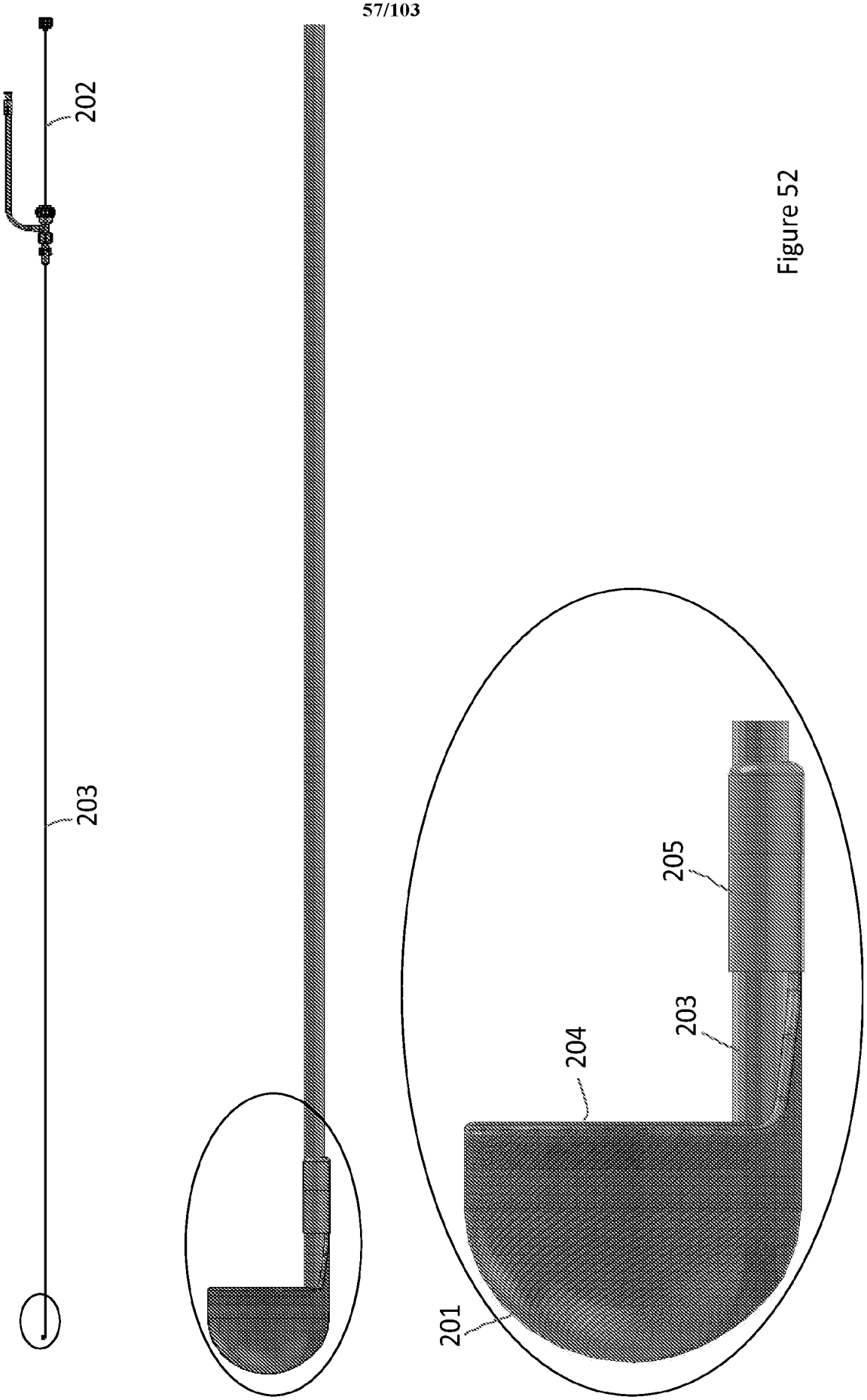

Figure 52

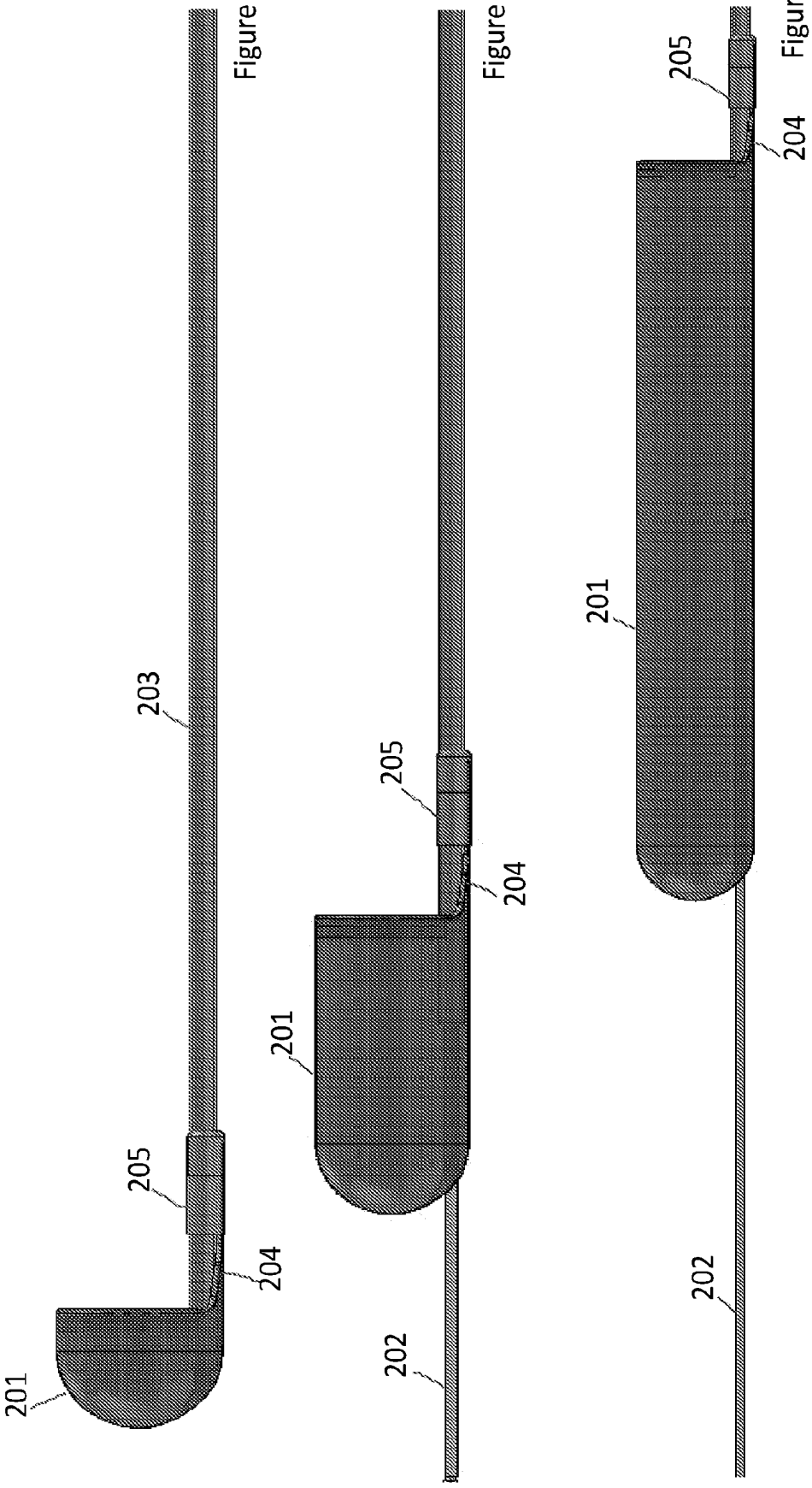
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Figure 54
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Figure 55
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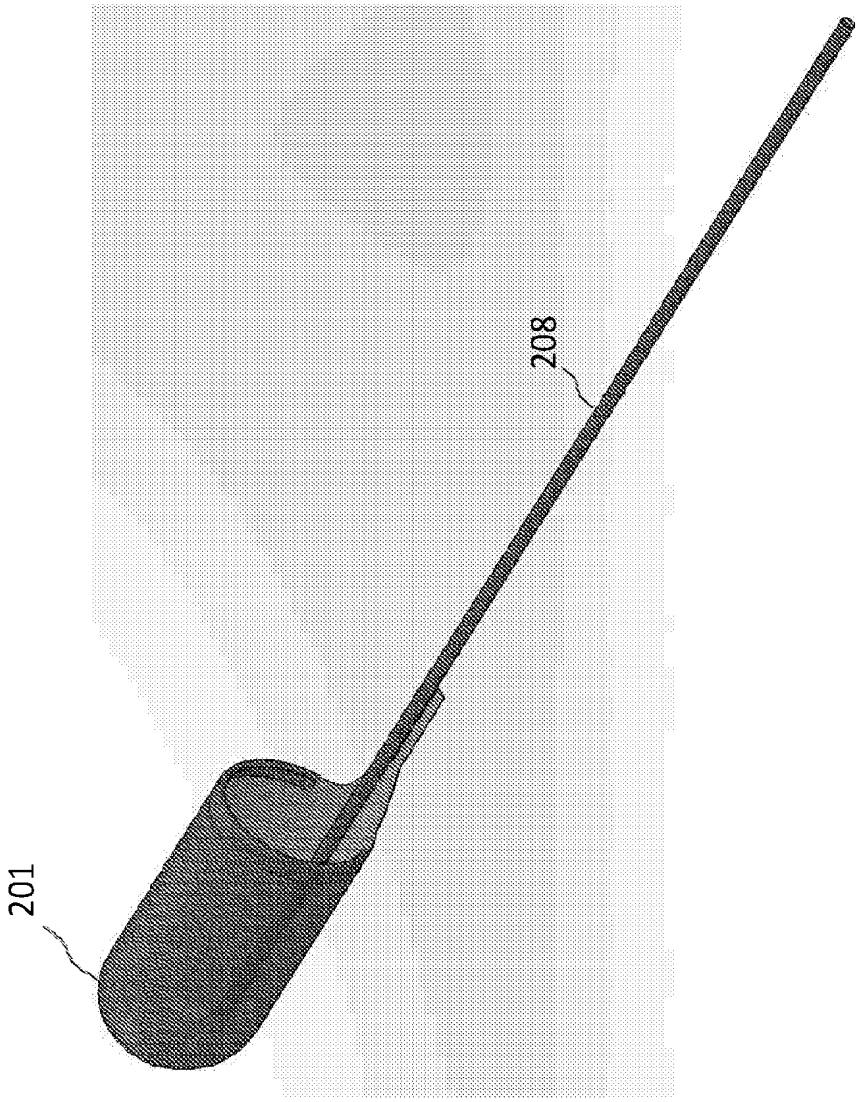

Figure 57

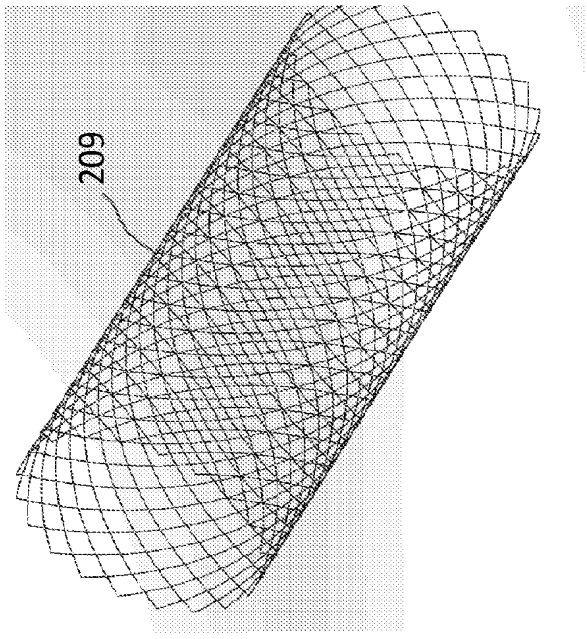

Figure 56

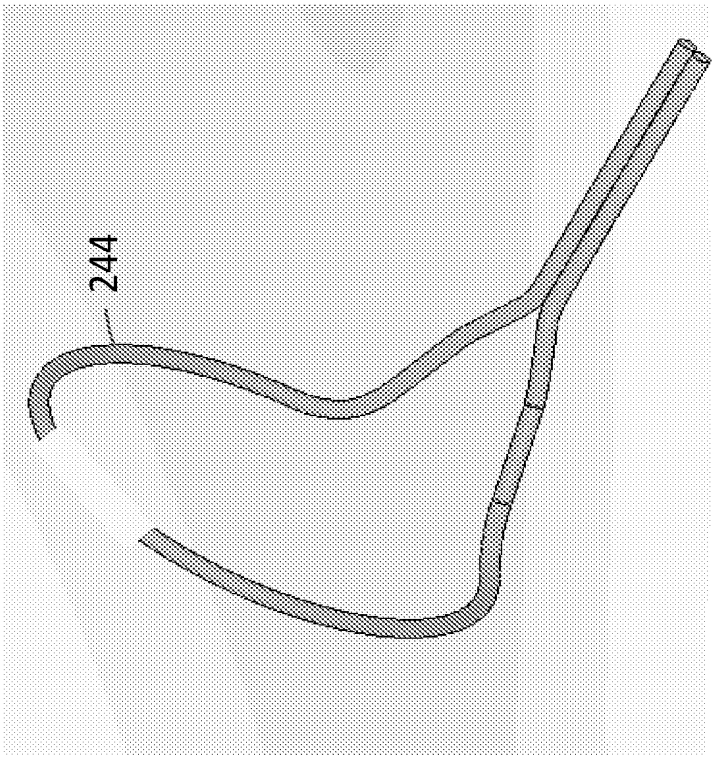

Figure 58B

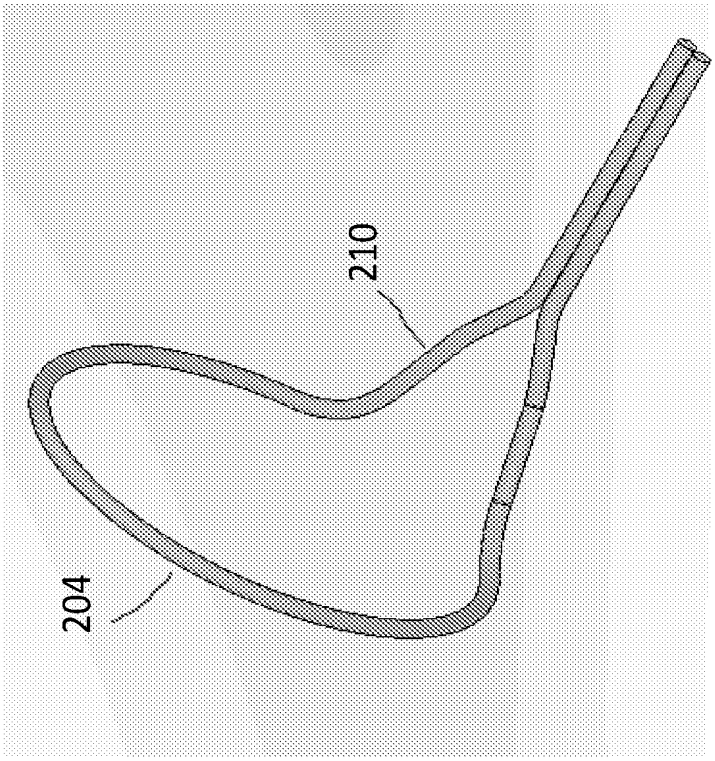

Figure 58A

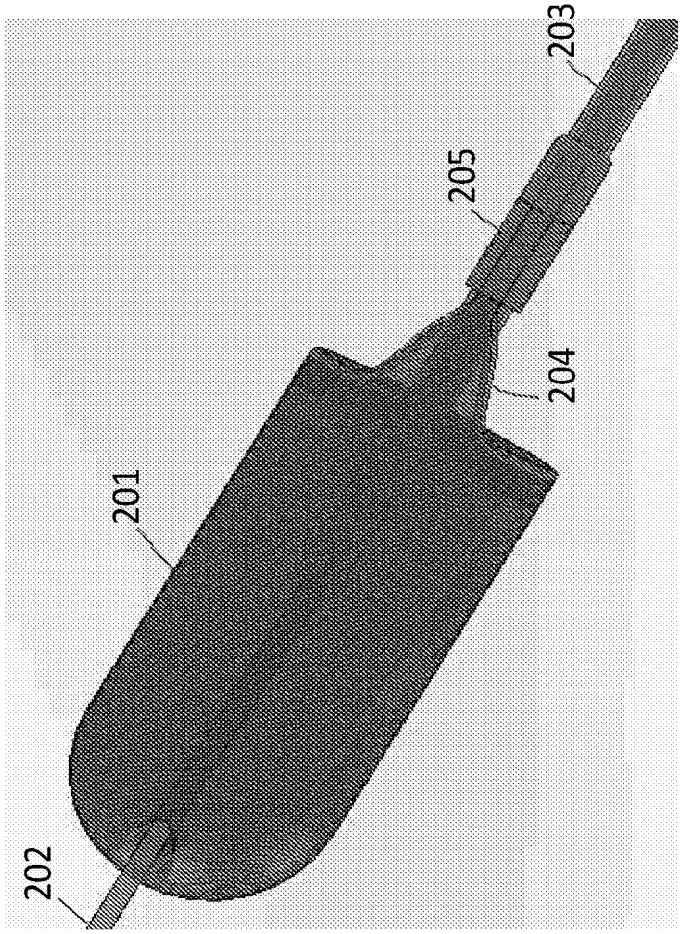

Figure 60

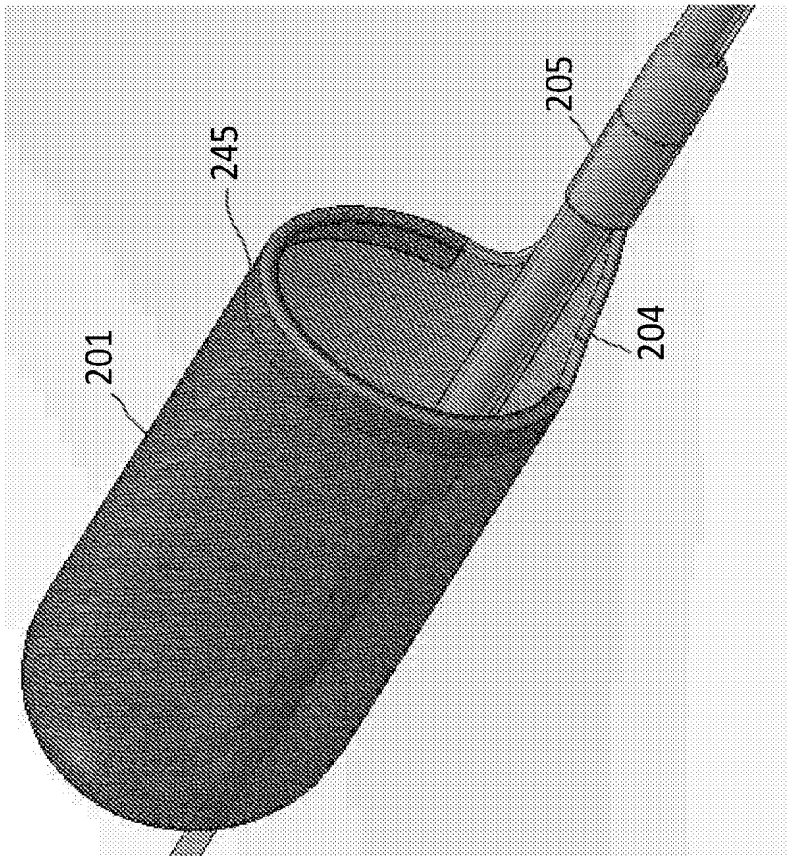

Figure 59

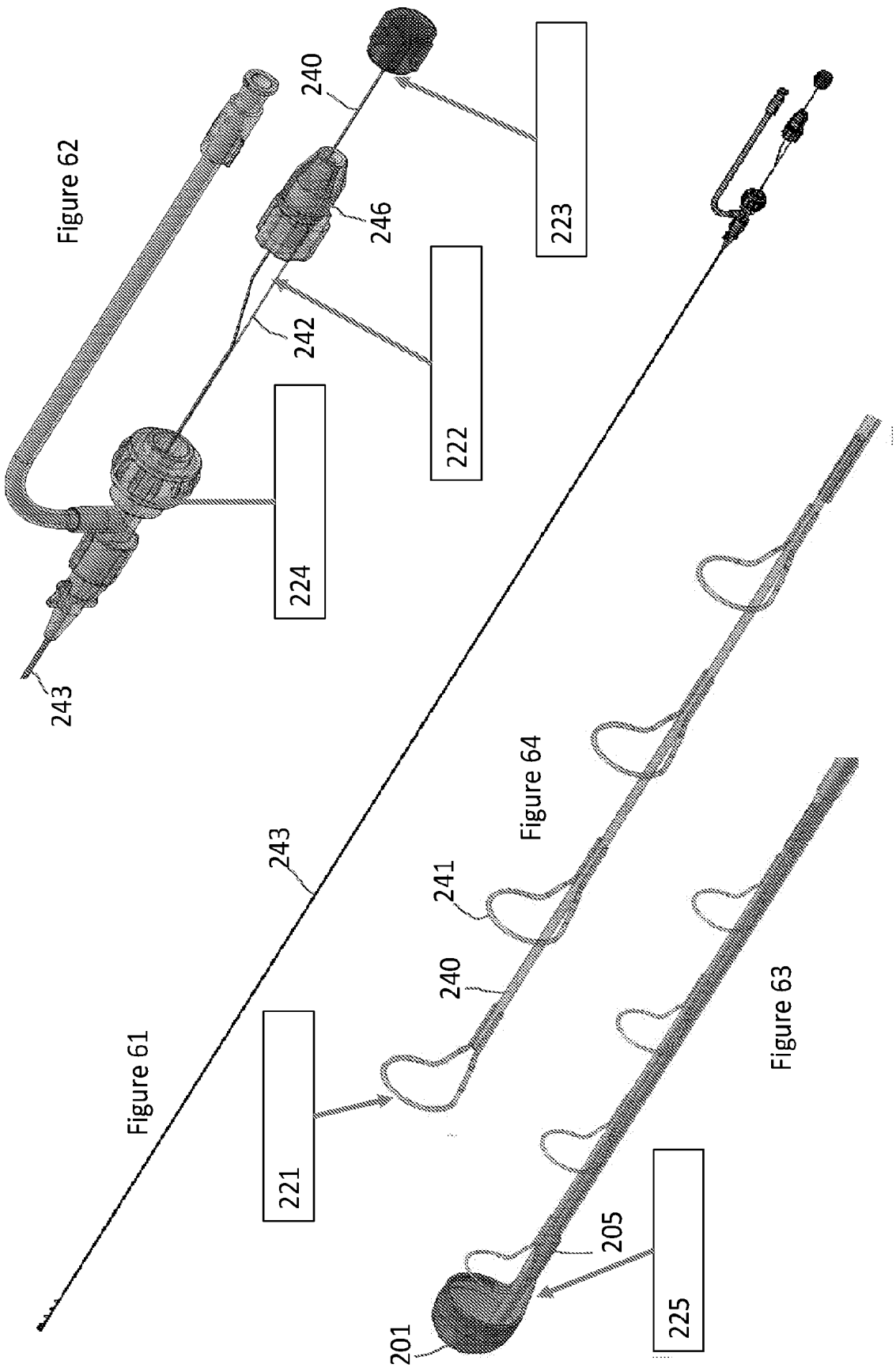
Figure 62
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Figure 61
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Figure 63
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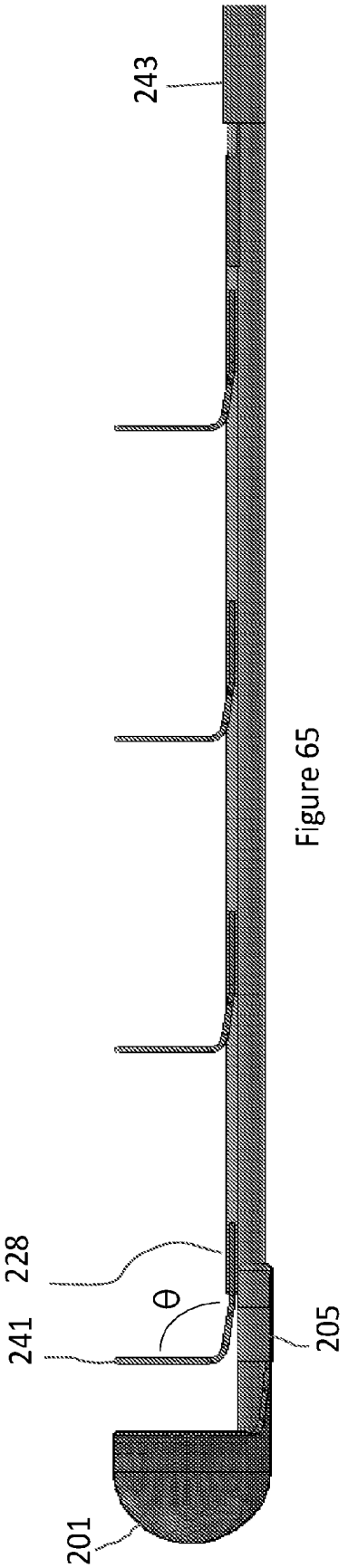

Figure 65

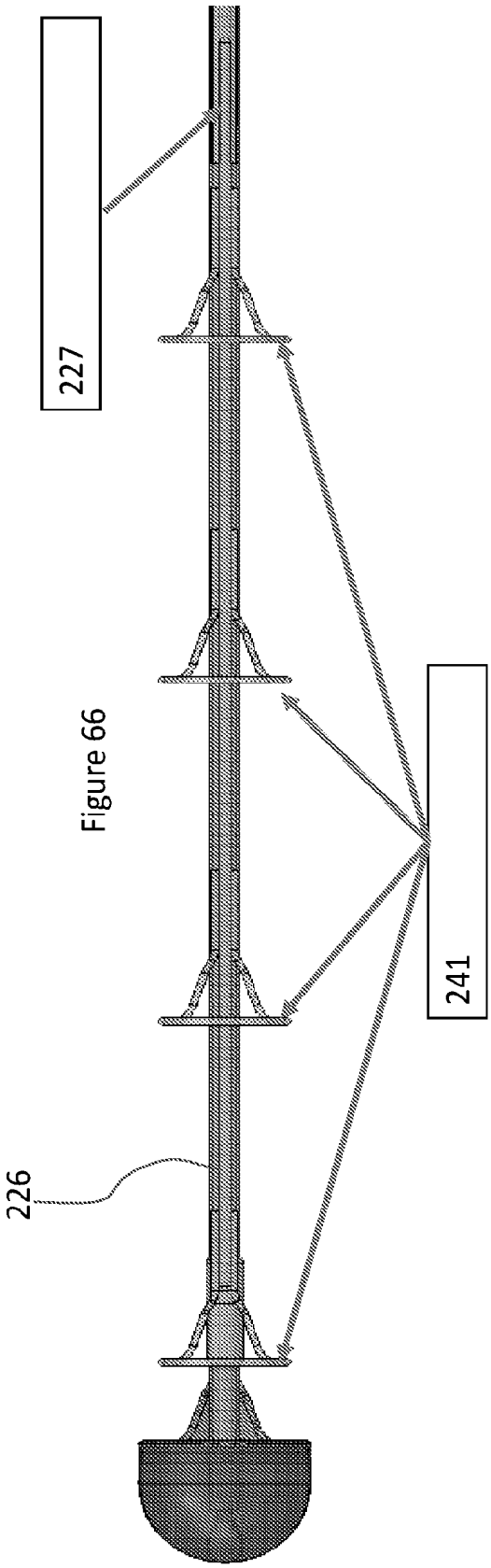

Figure 66

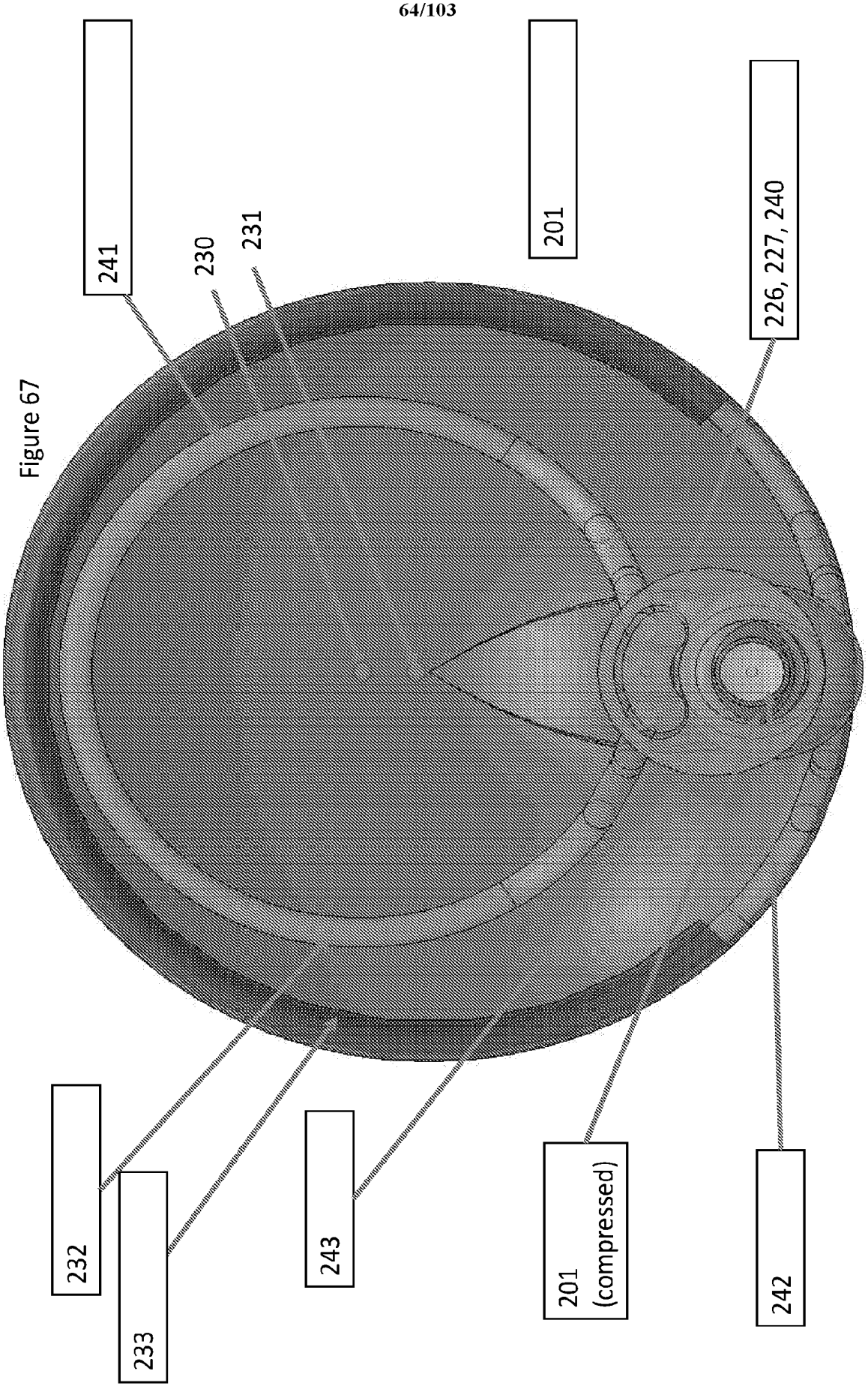

Figure 67

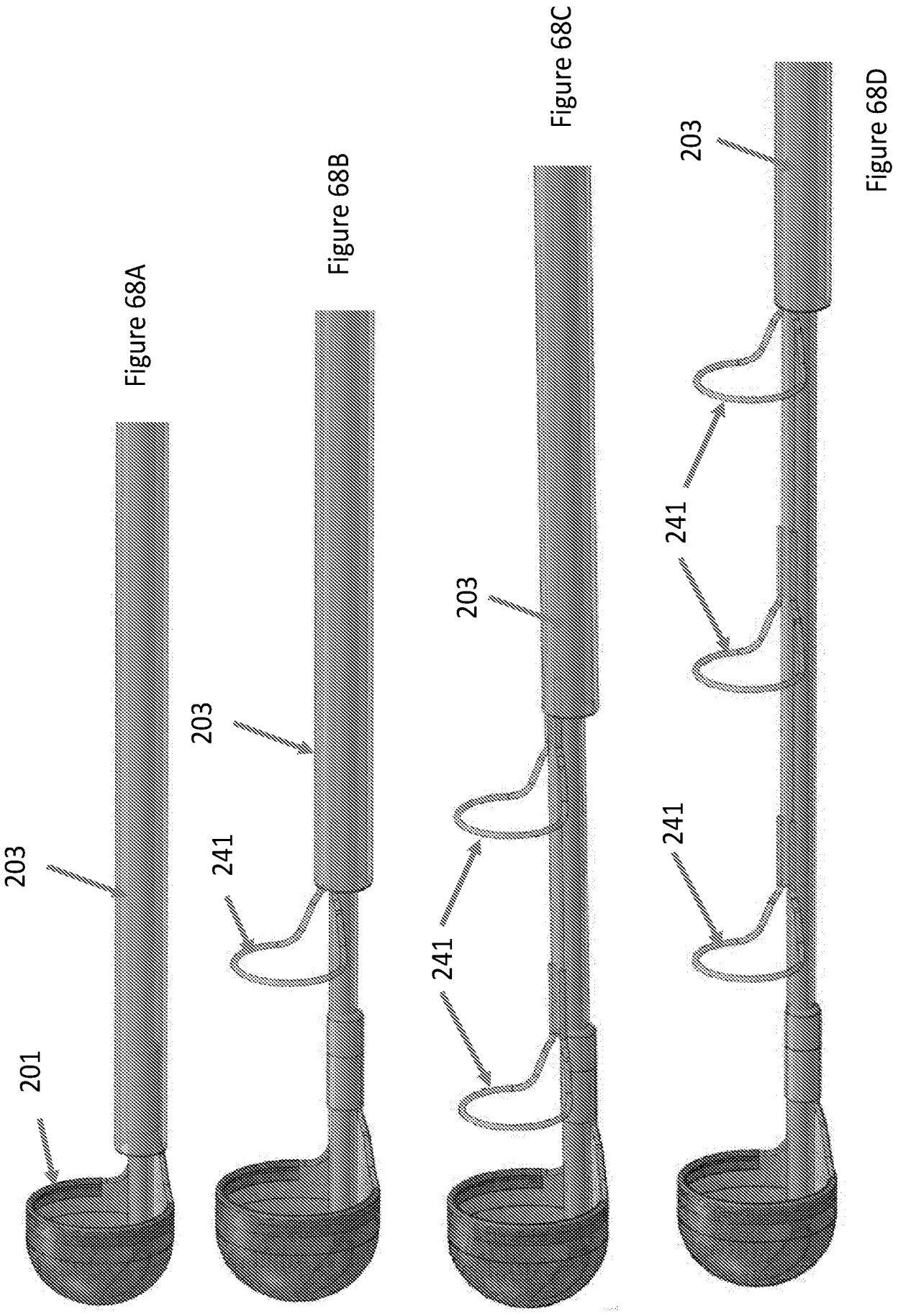
Figure 68A
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Figure 68B
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Figure 68C
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Figure 68D
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241

Figure 69A

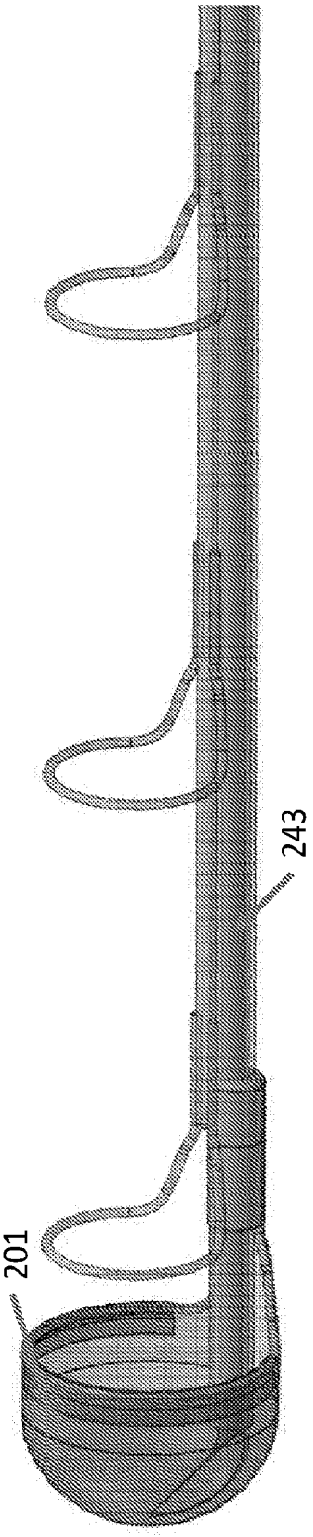


Figure 69B

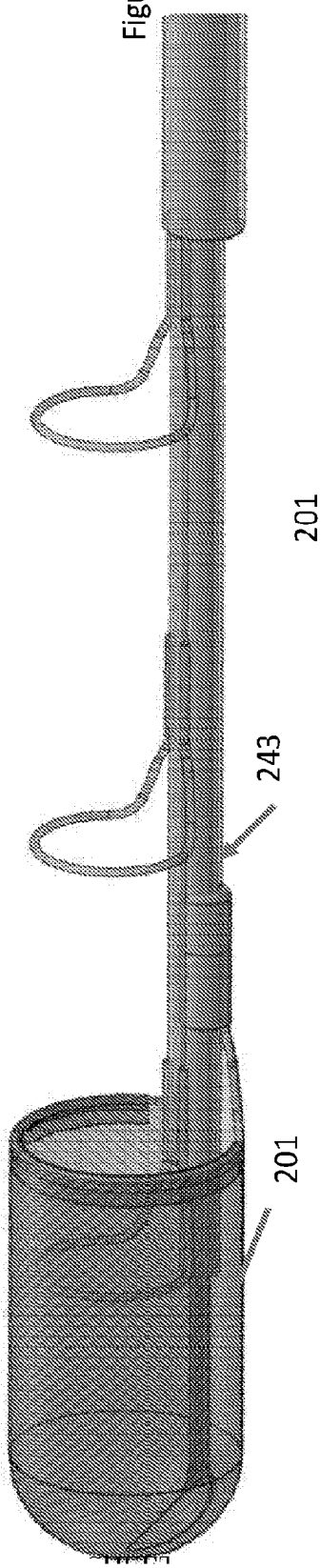
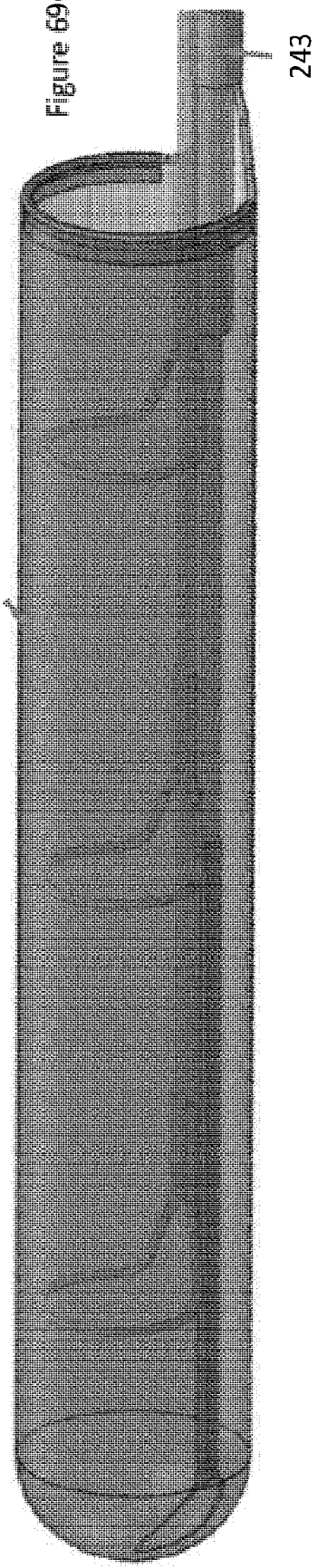


Figure 69C



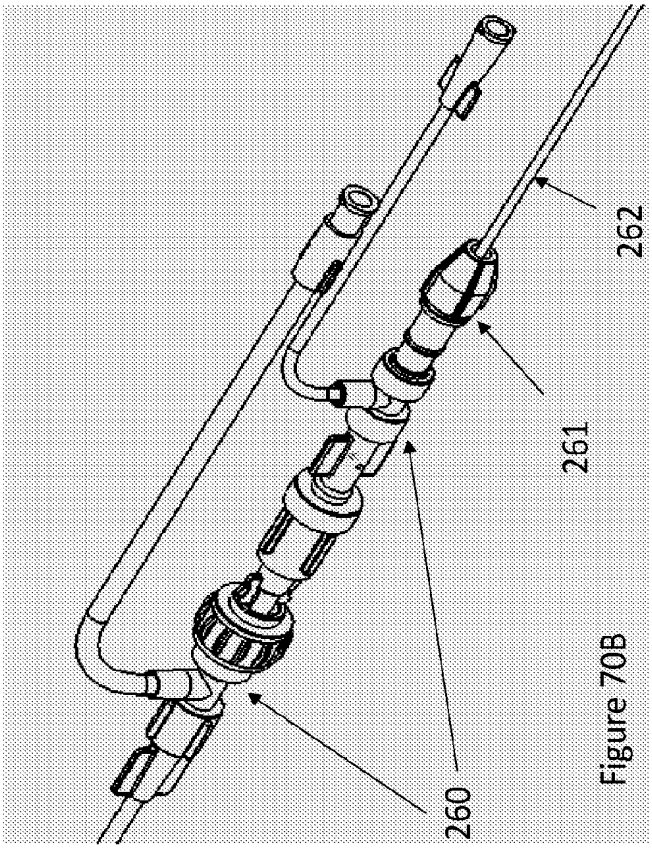


Figure 70B

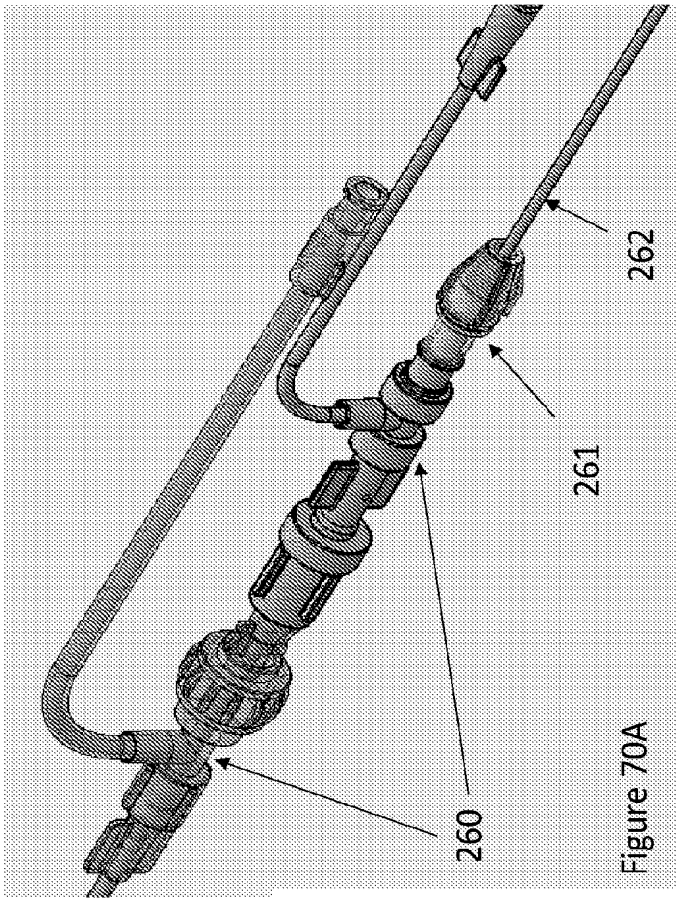


Figure 70A

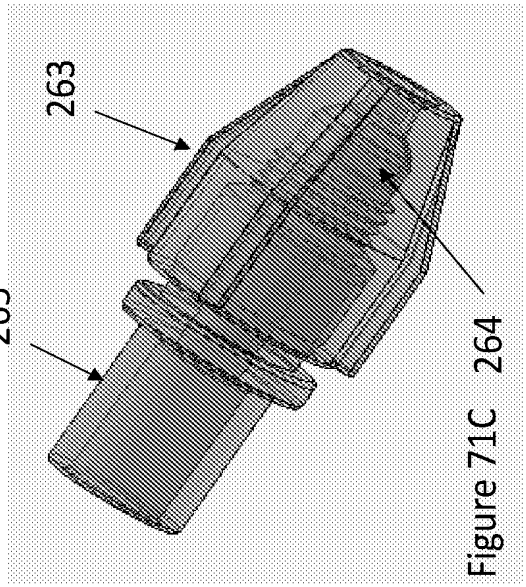


Figure 71C

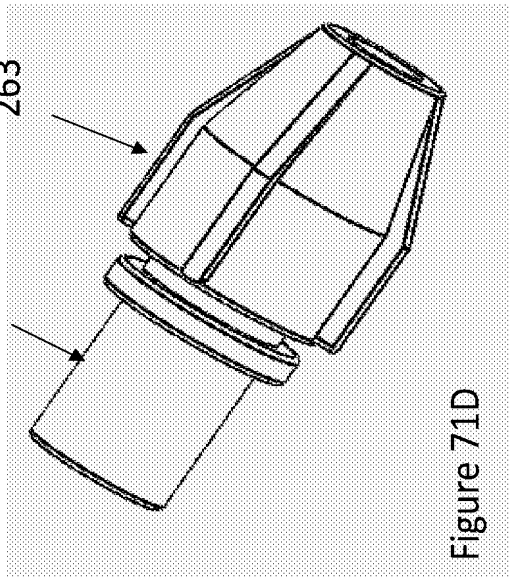


Figure 71D

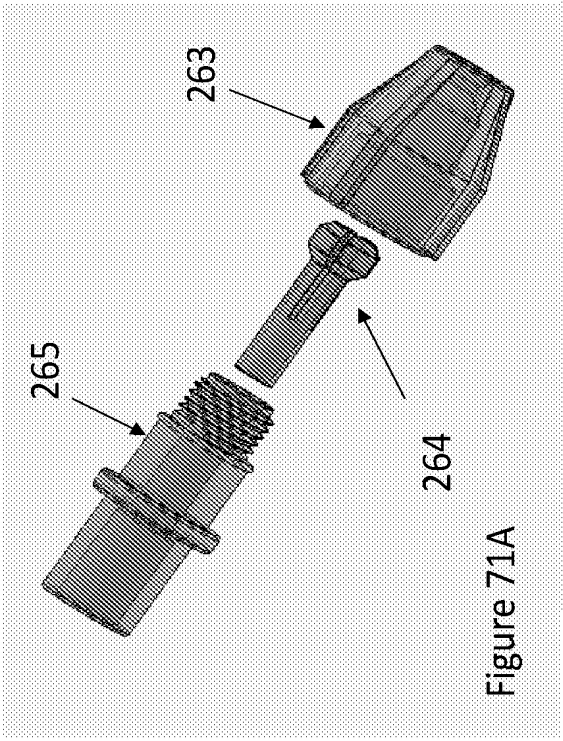


Figure 71A

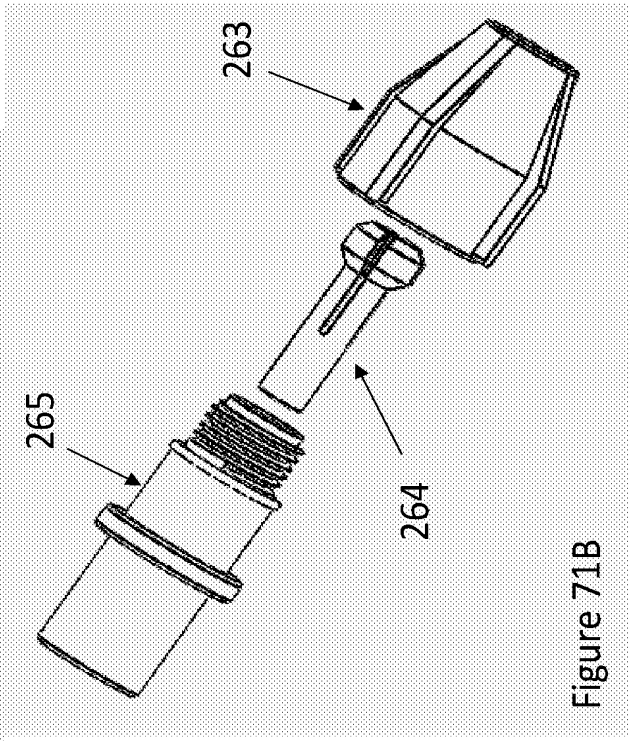


Figure 71B

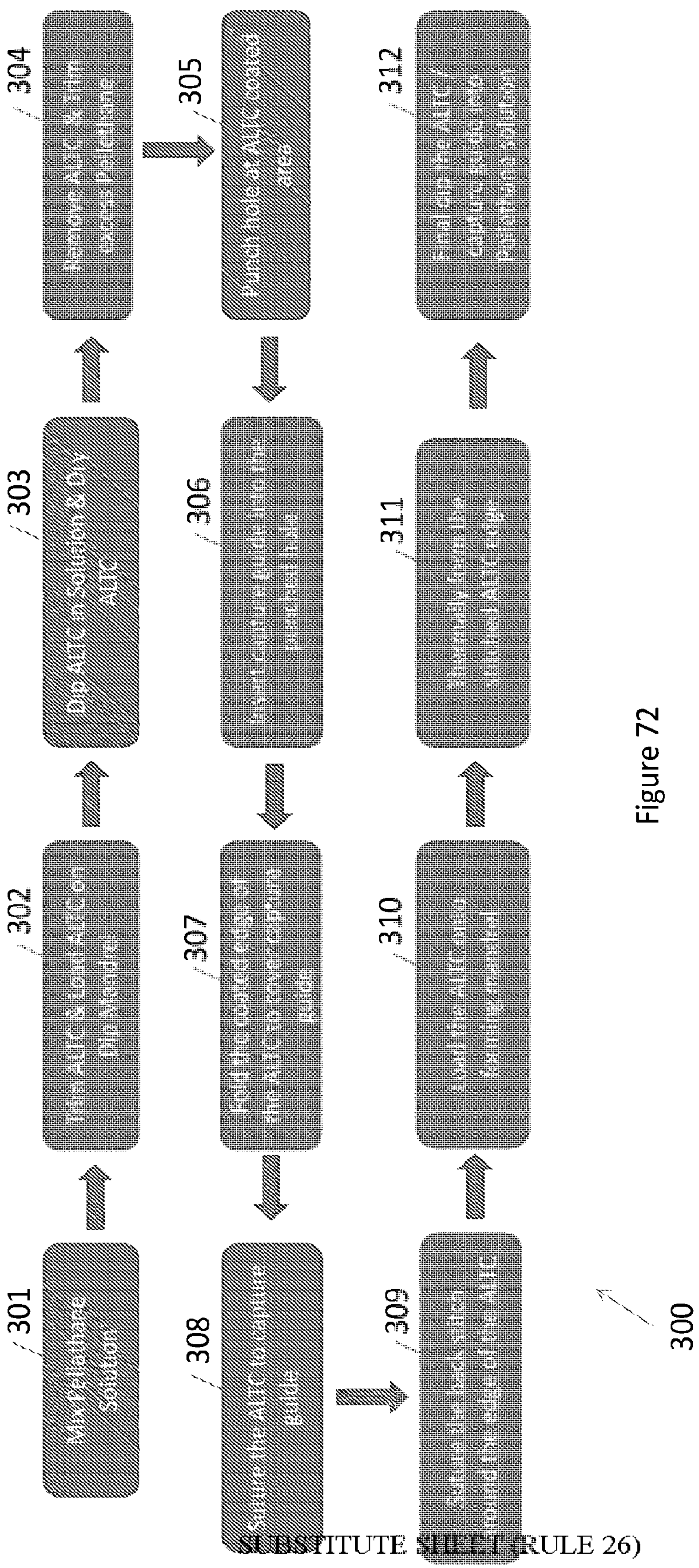


Figure 72

SUBSTITUTE SHEET (RULE 26)

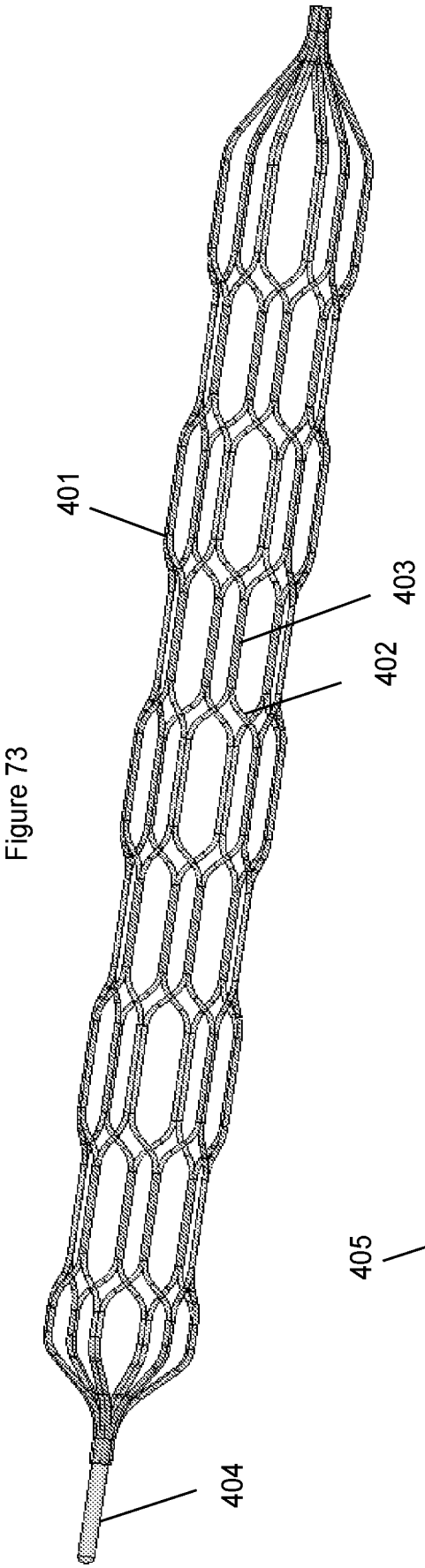


Figure 73

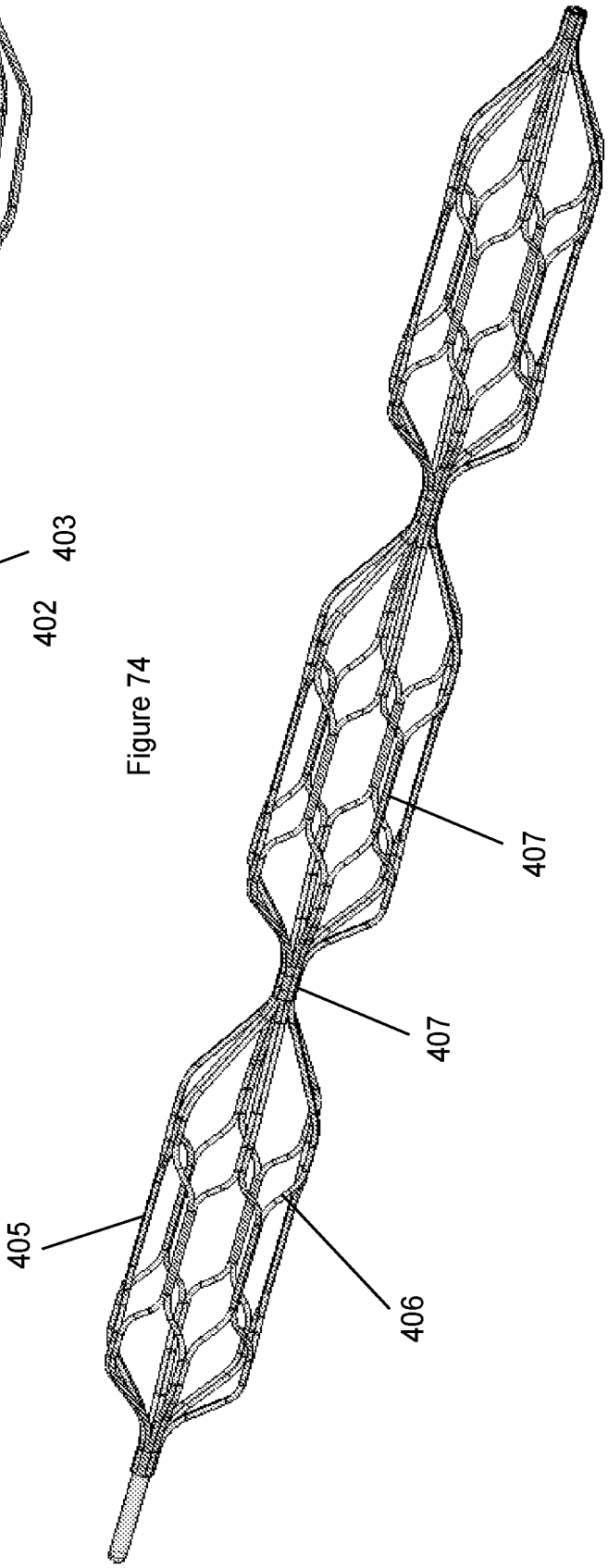


Figure 74

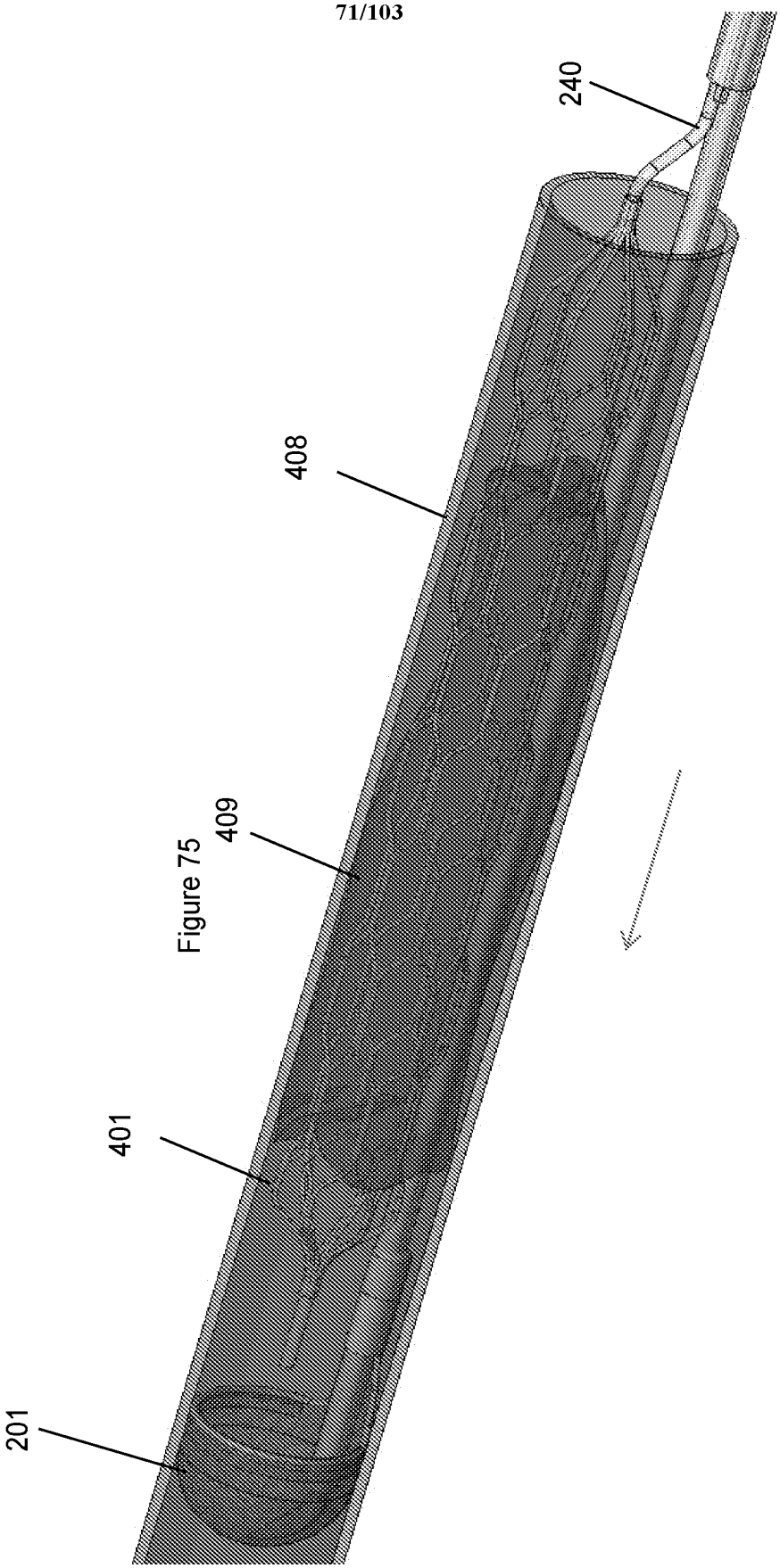
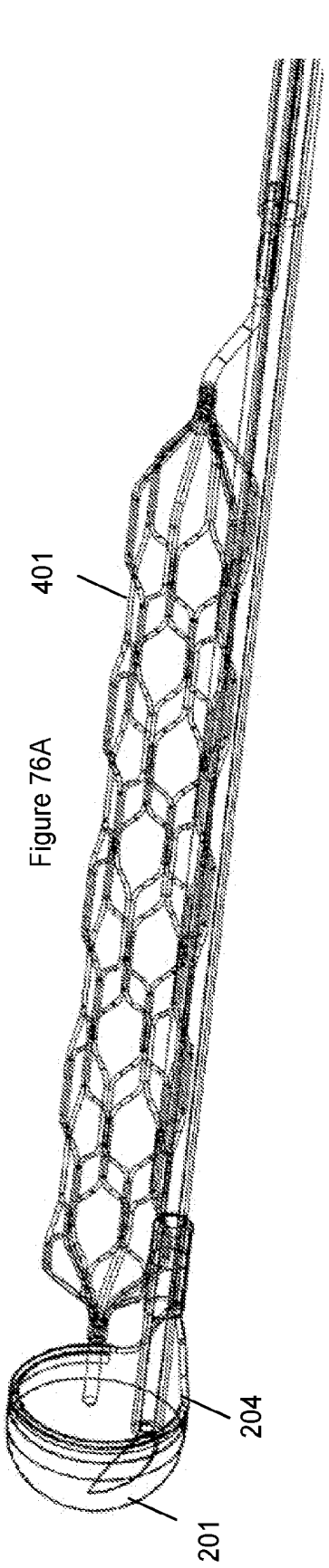


Figure 75



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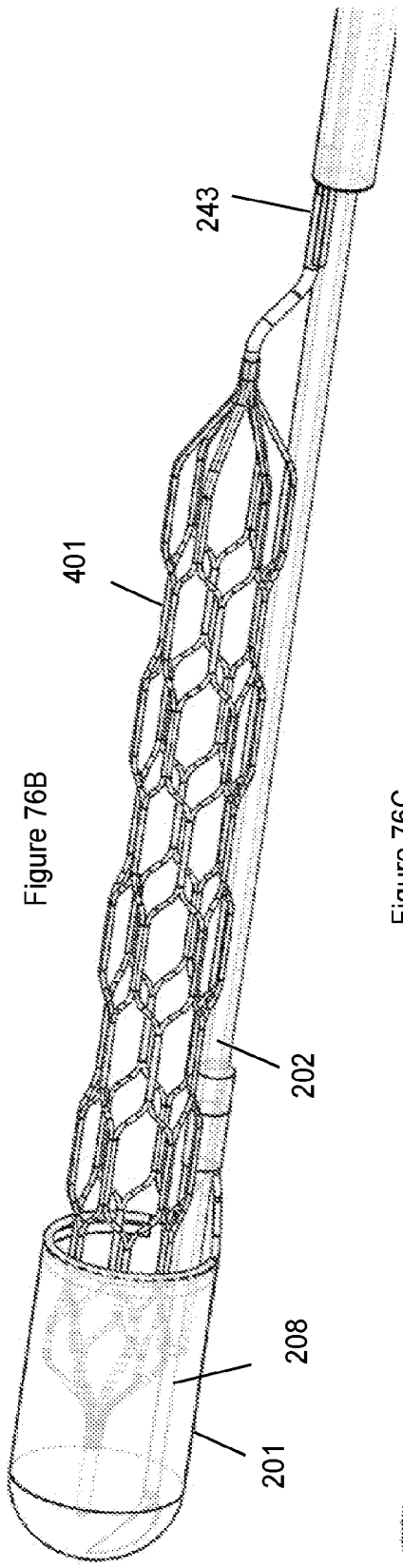

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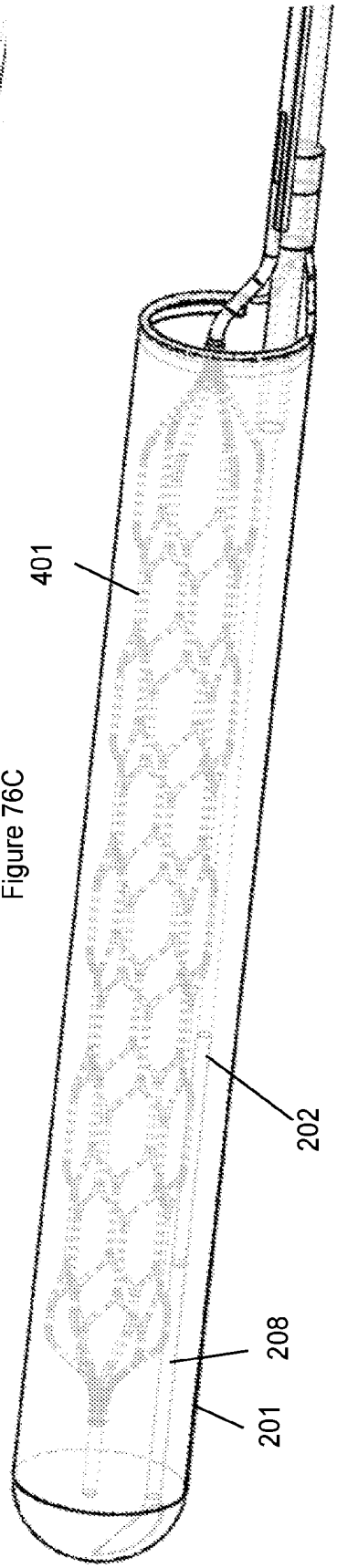

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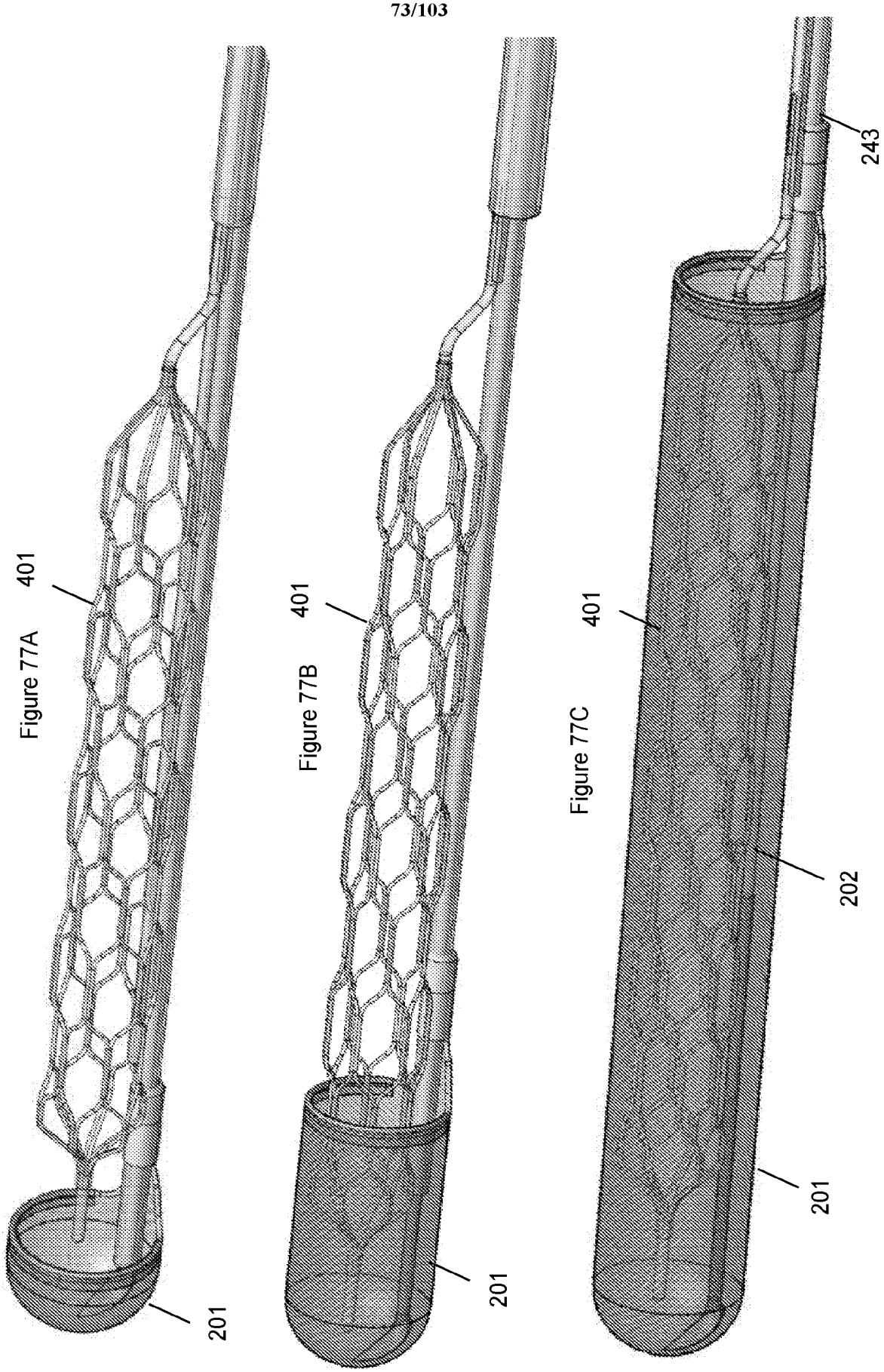
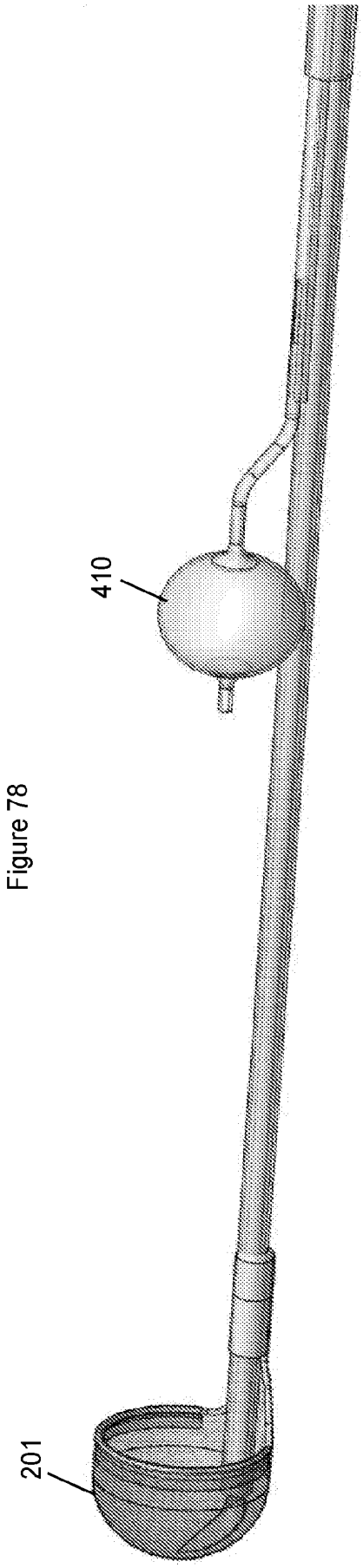


Figure 77A

Figure 77B

Figure 77C



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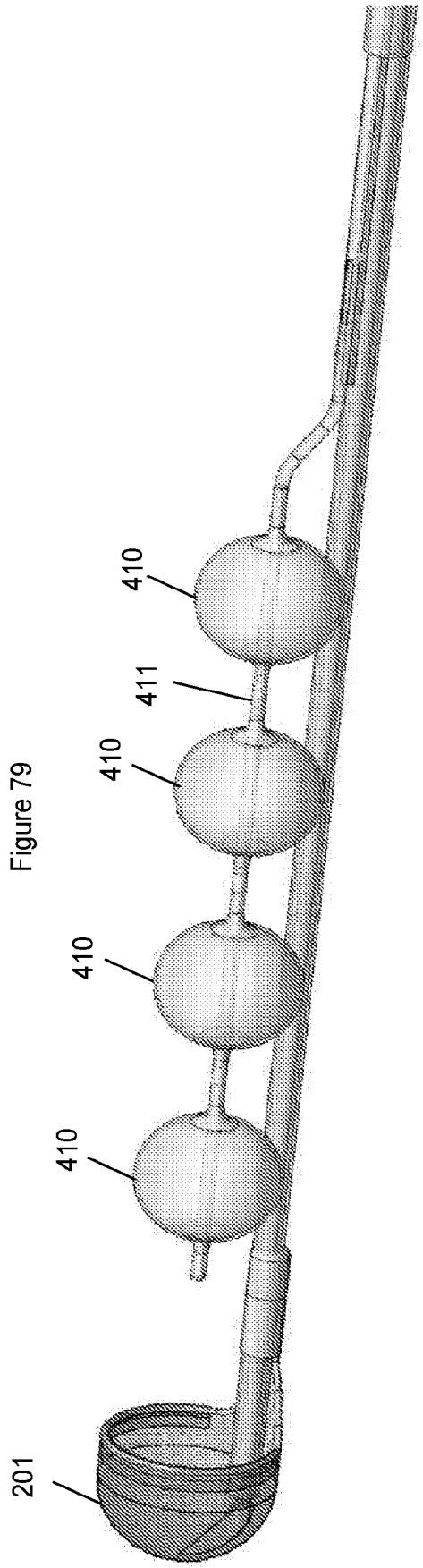

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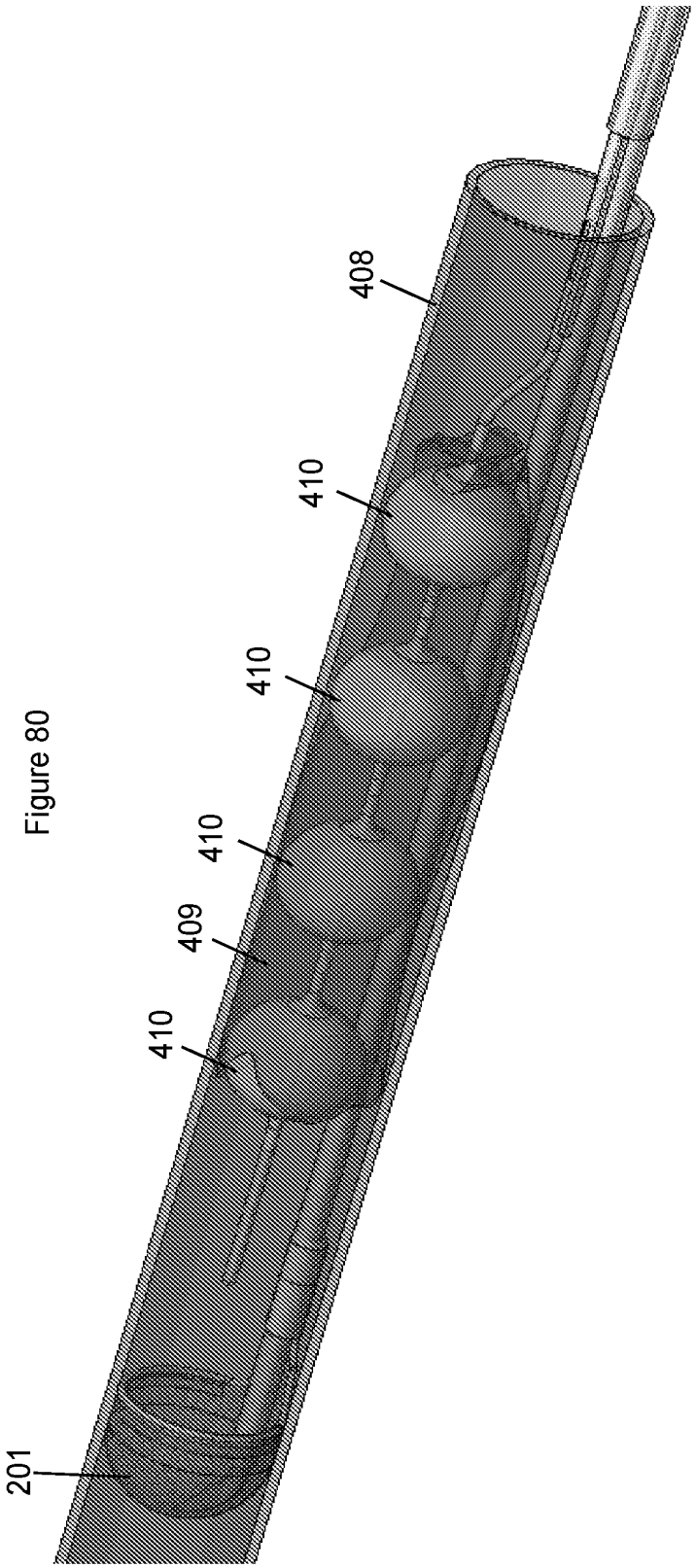

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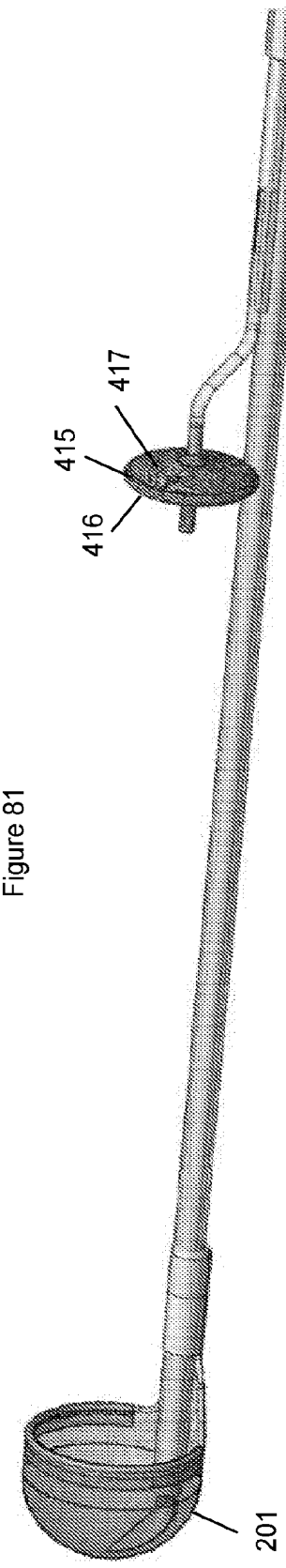

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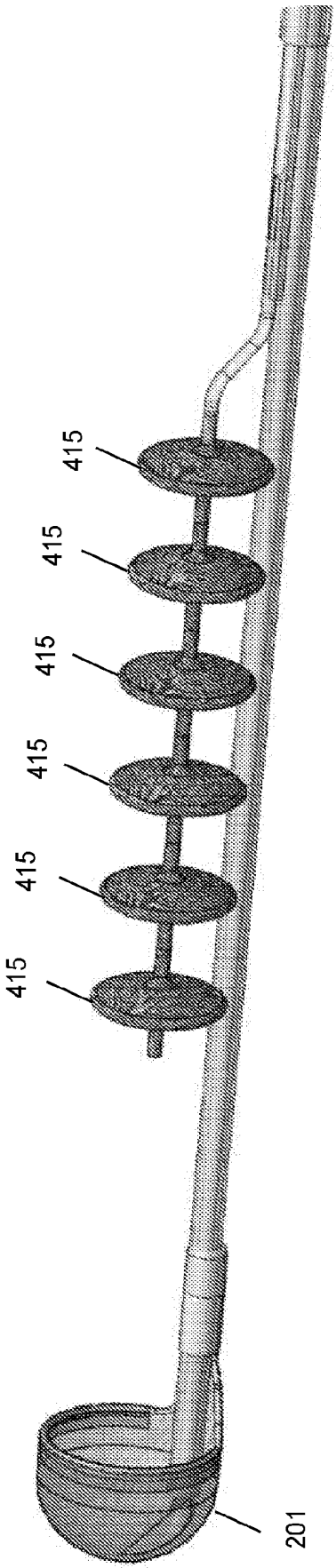

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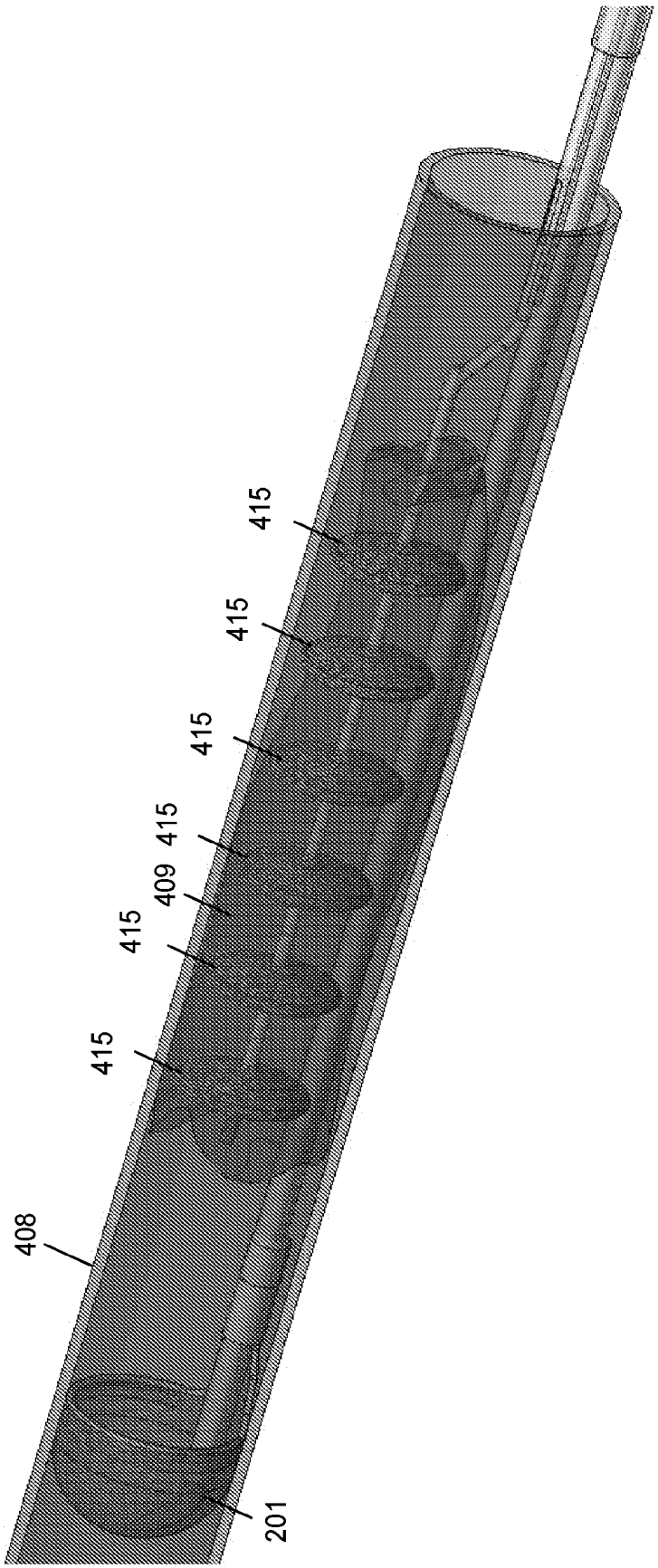

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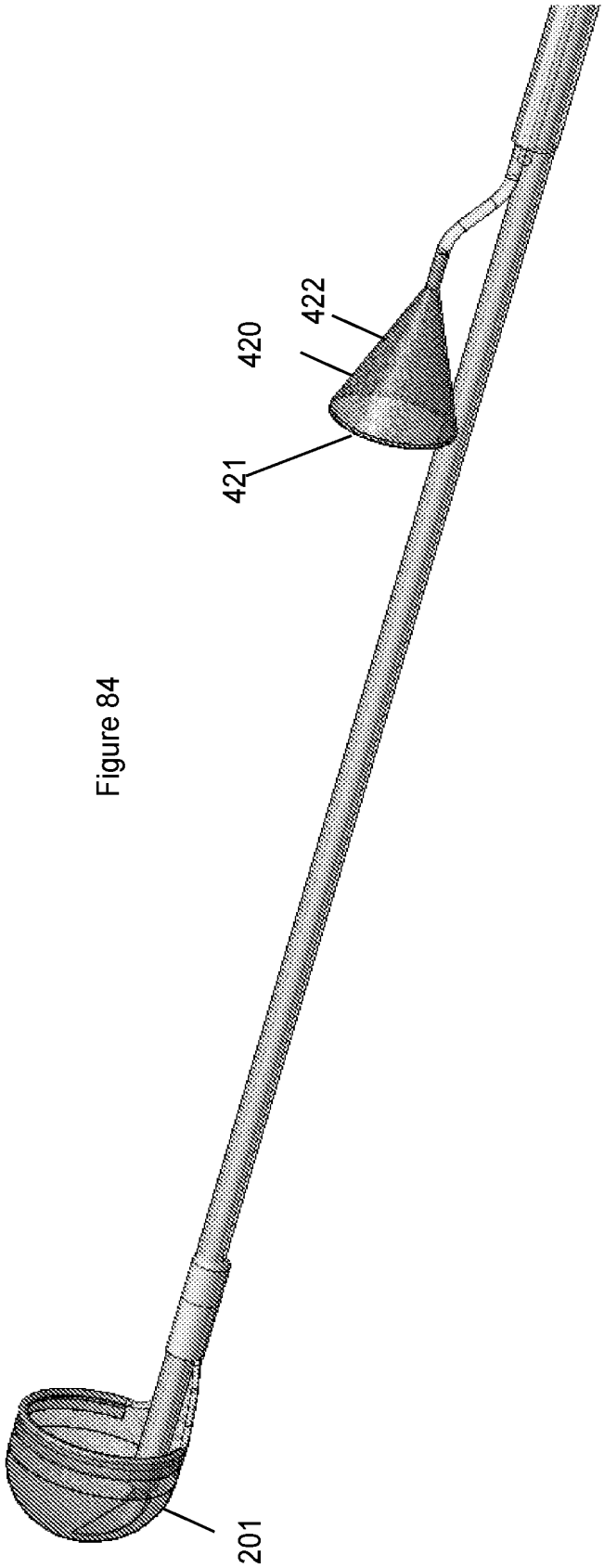

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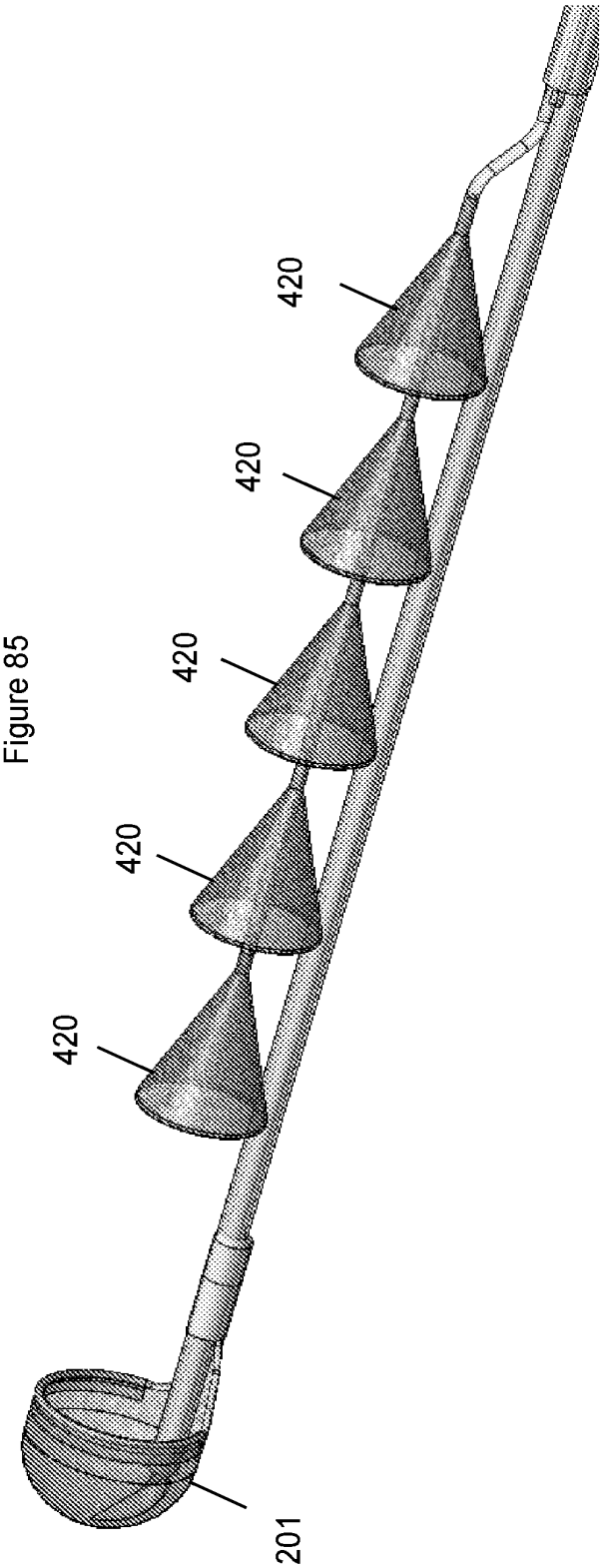

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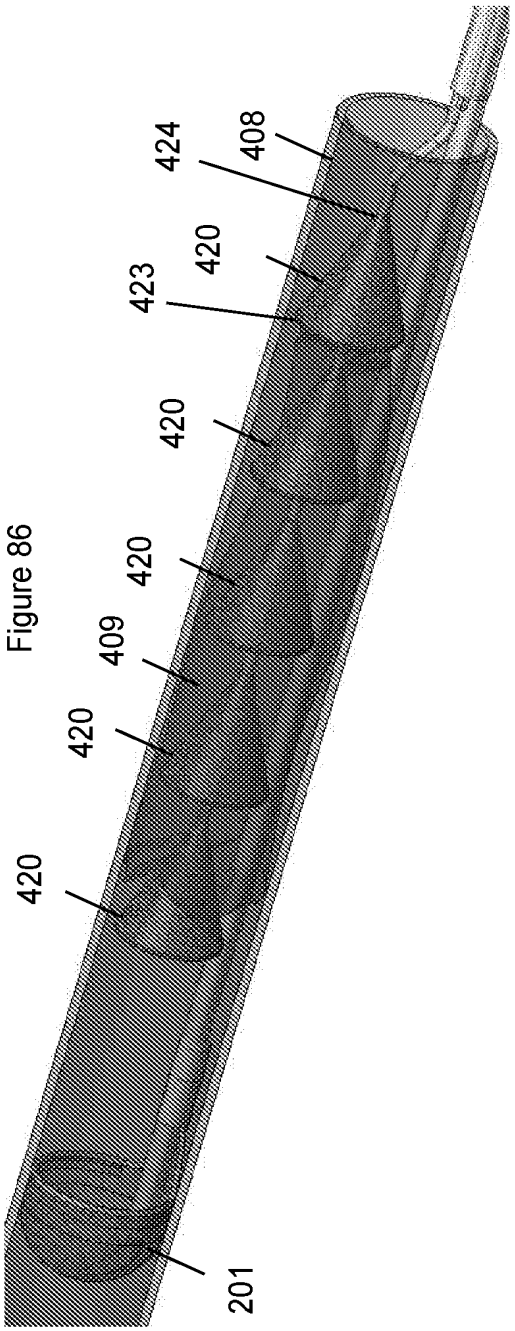

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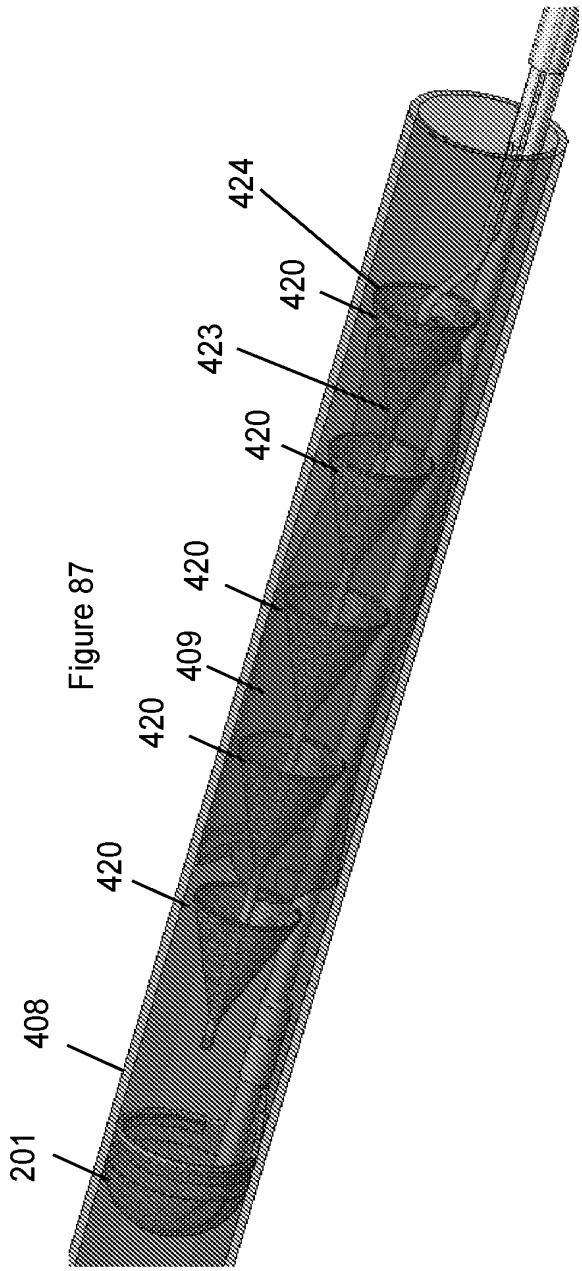


Figure 87

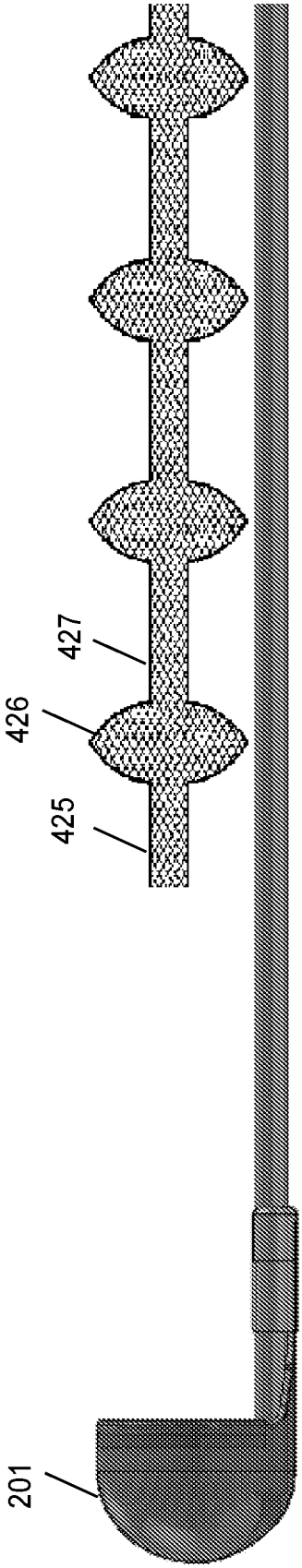
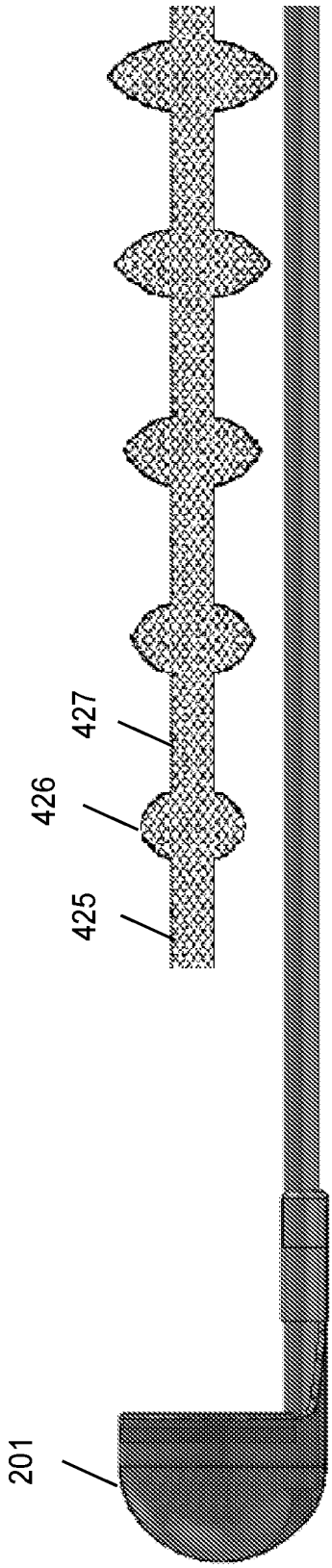


Figure 88A

Figure 88B



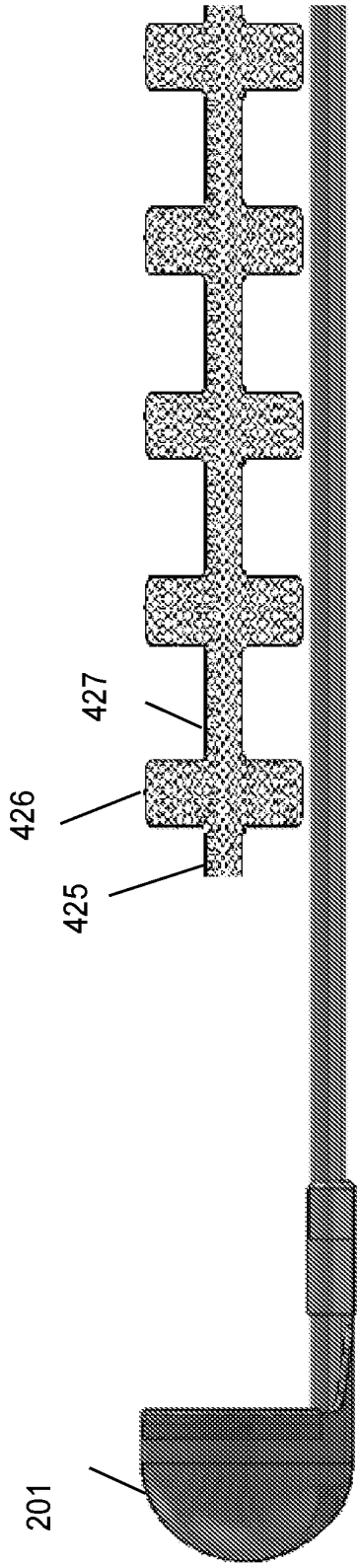
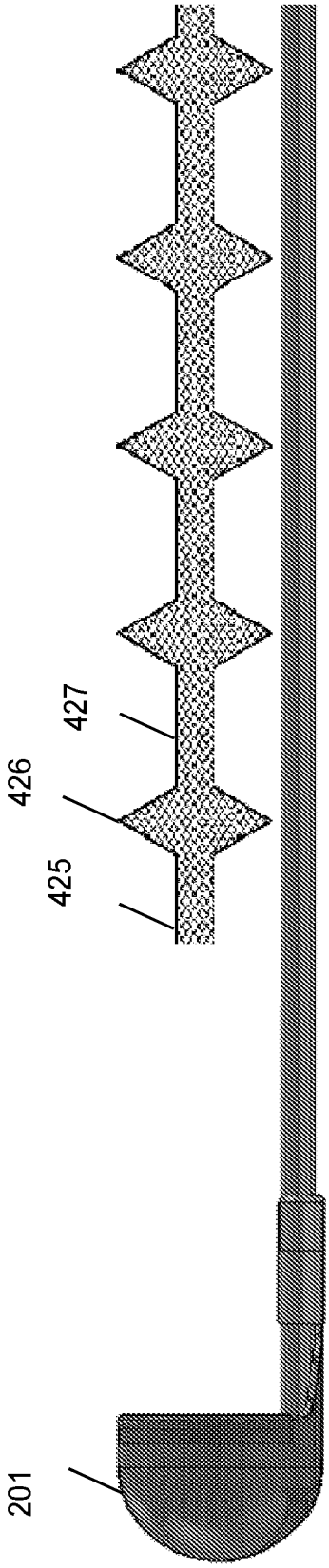


Figure 88C



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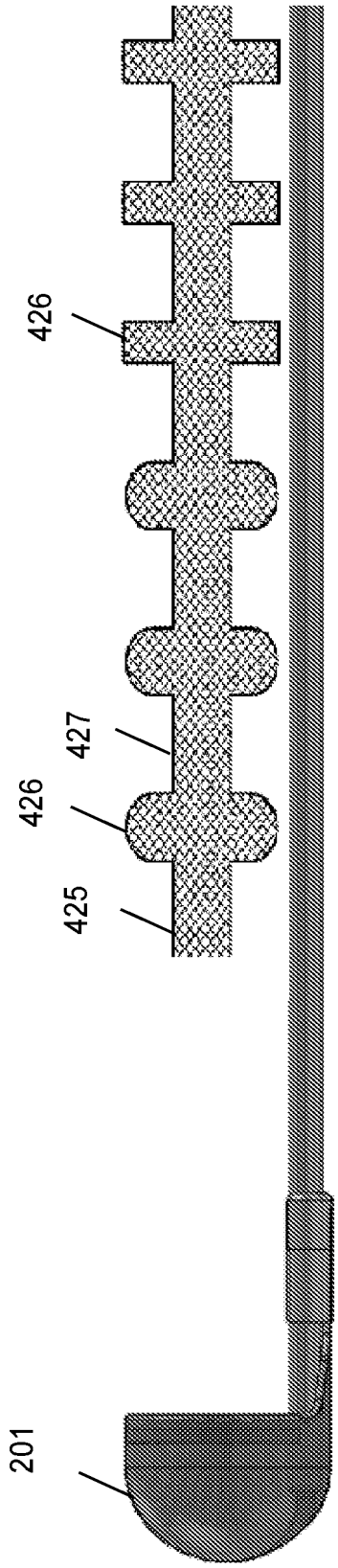

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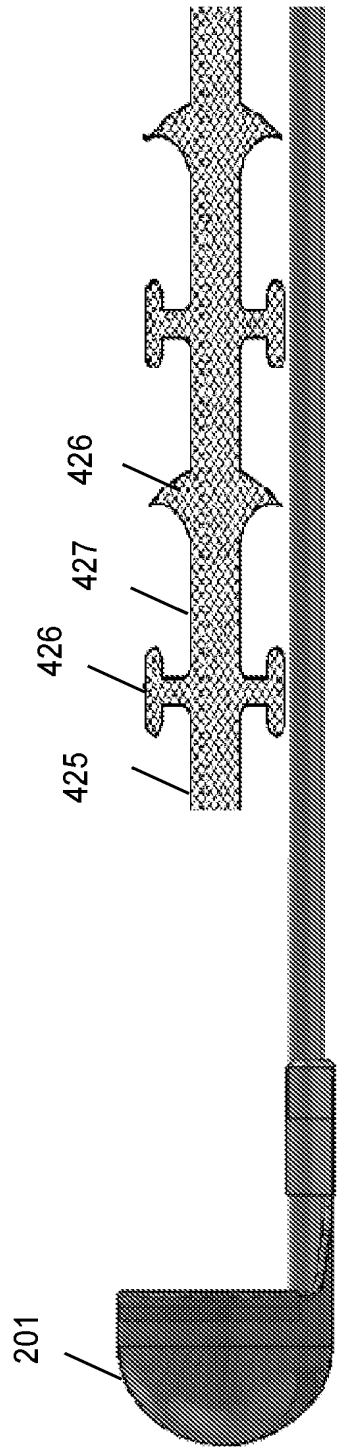


Figure 88F

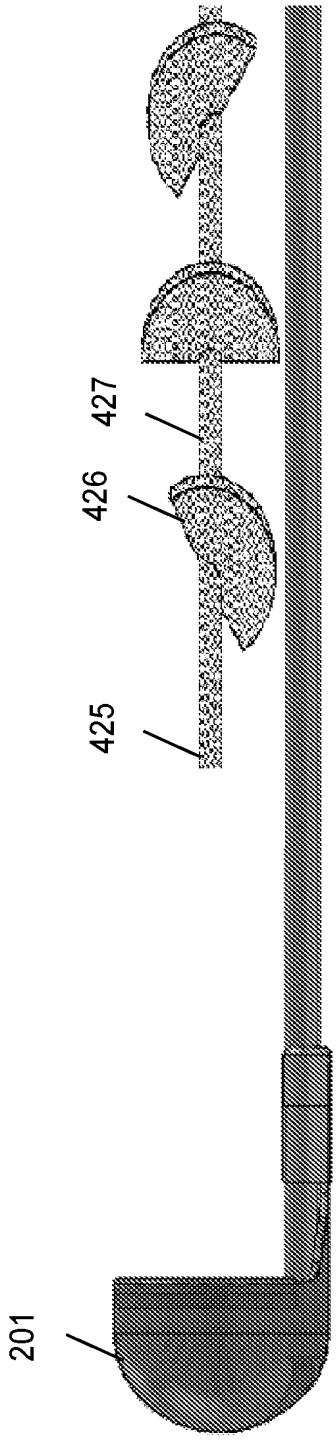


Figure 88G

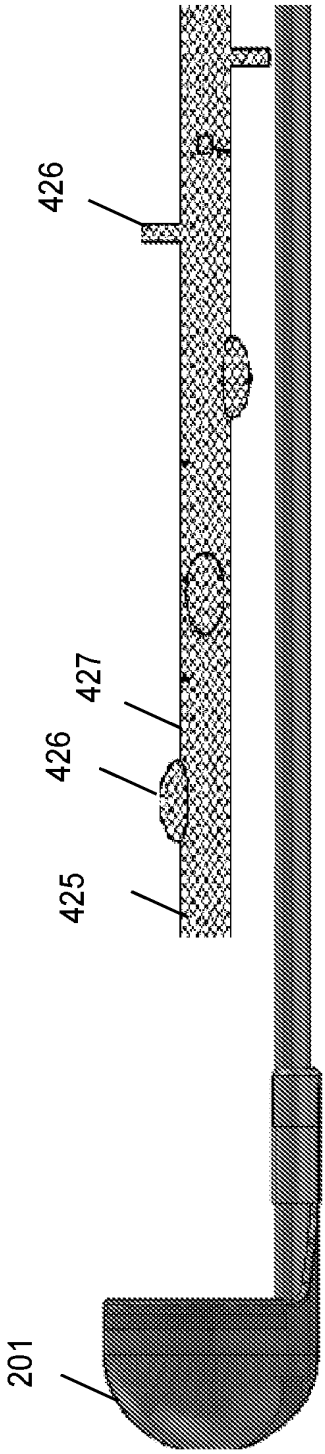


Figure 88H

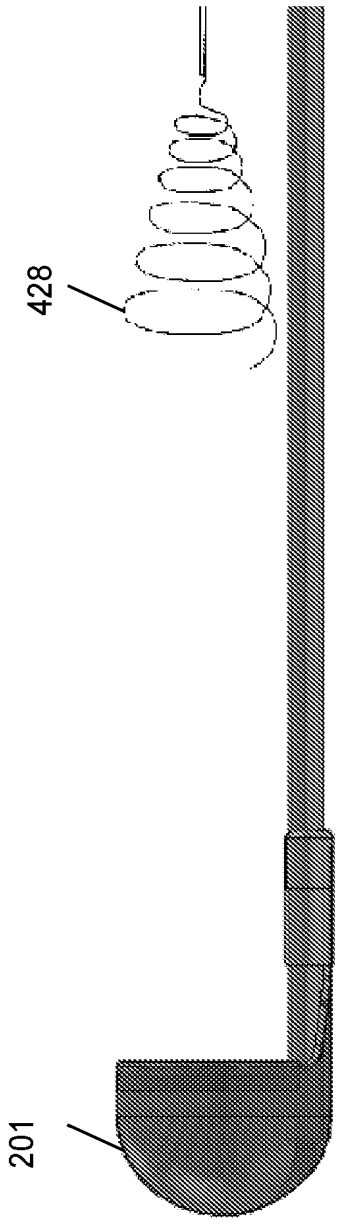


Figure 88I

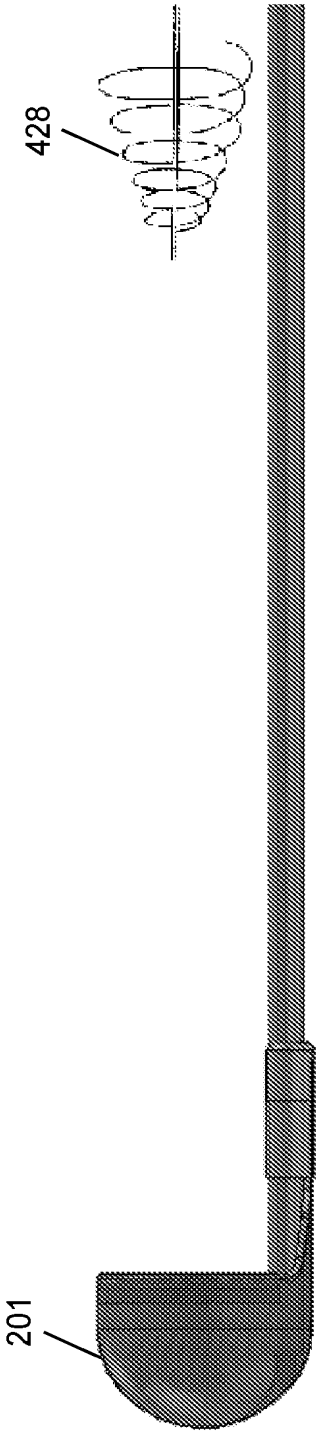
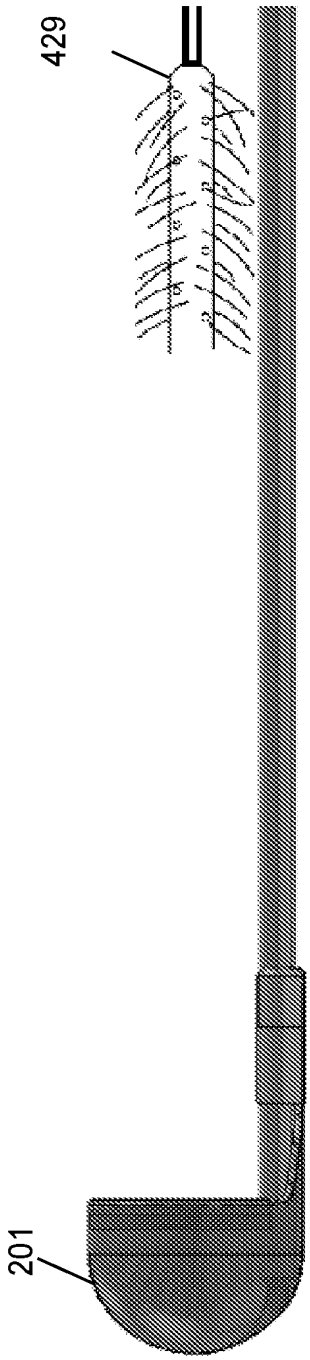


Figure 88J



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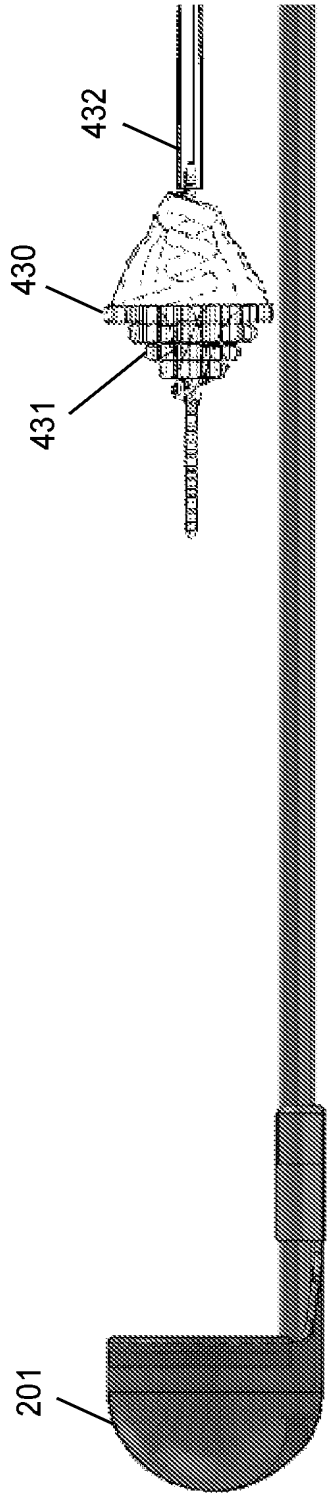

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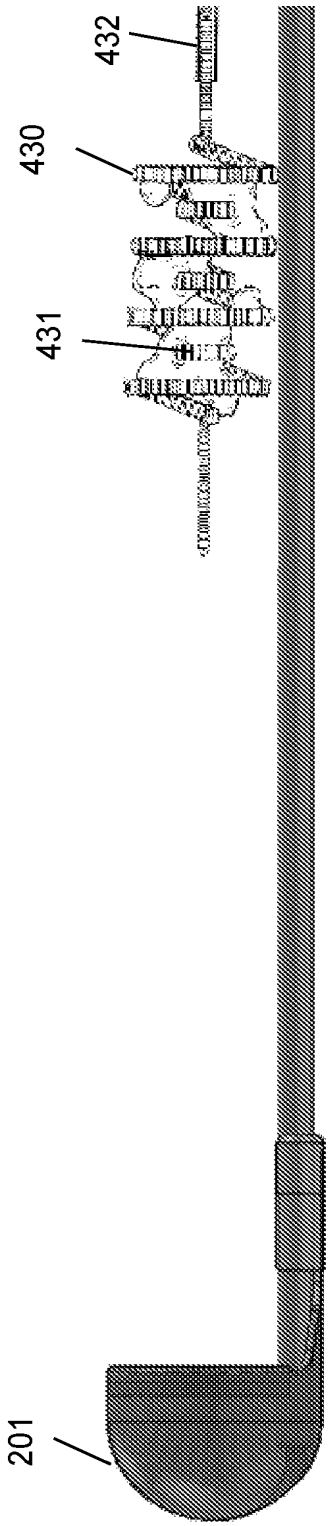

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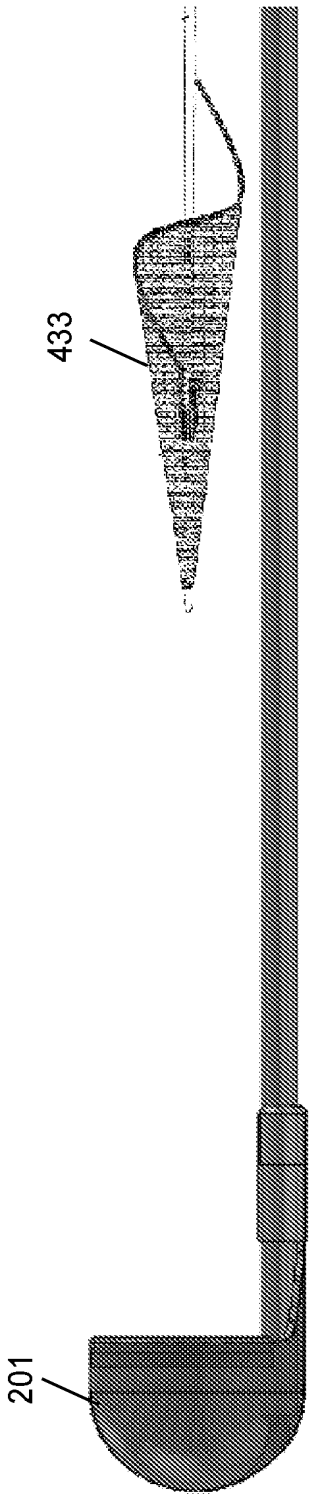
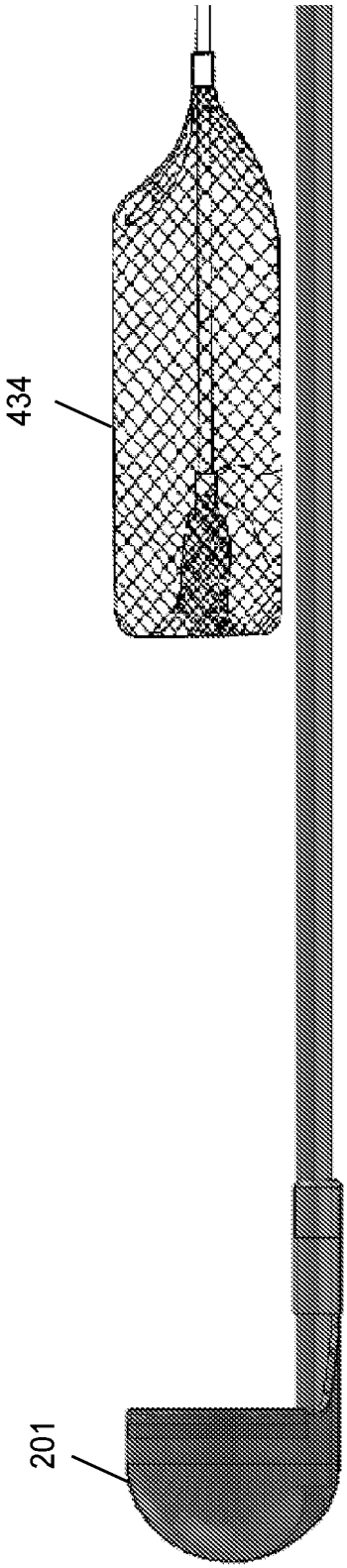


Figure 88N



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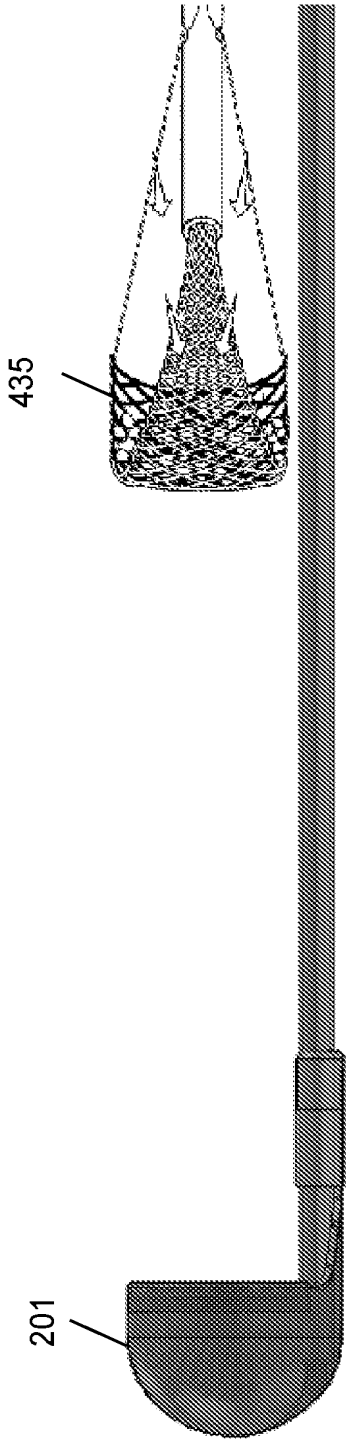

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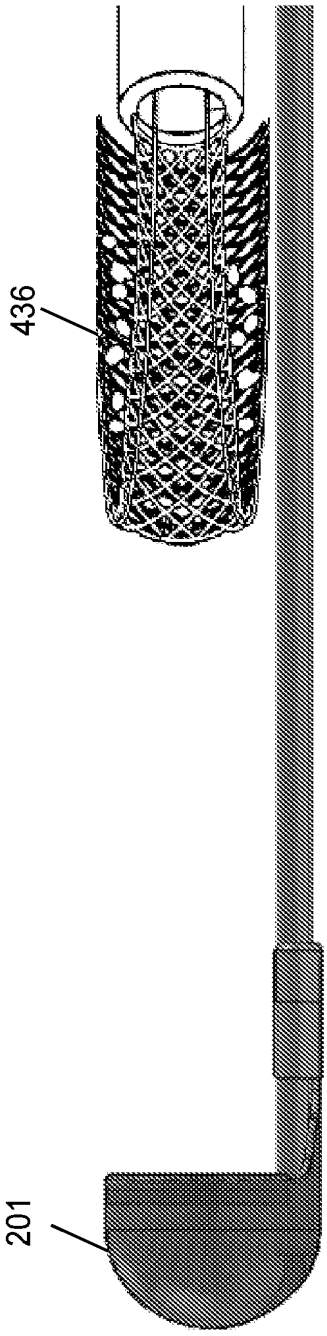

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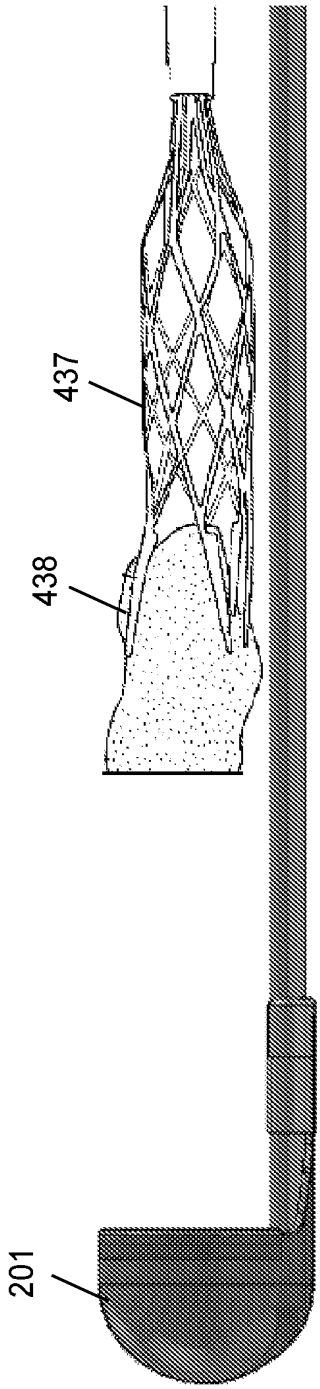

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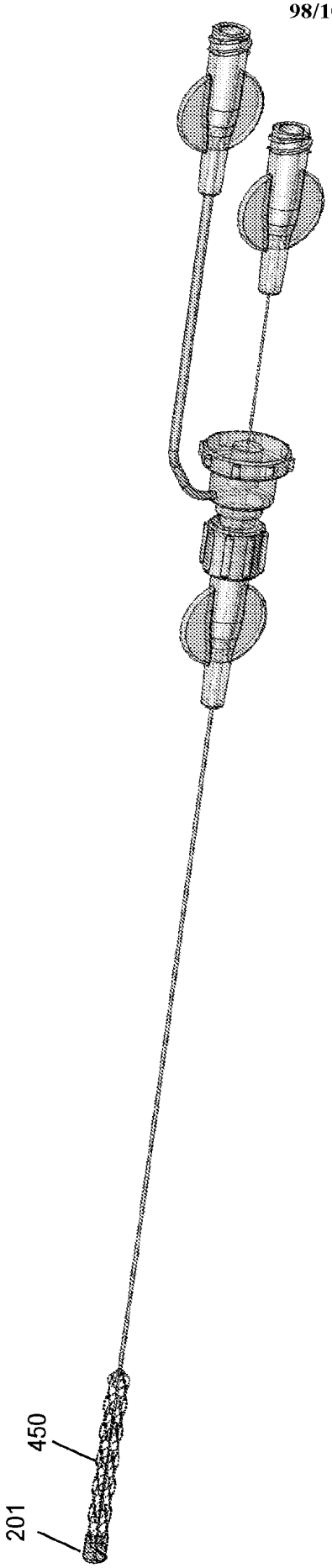

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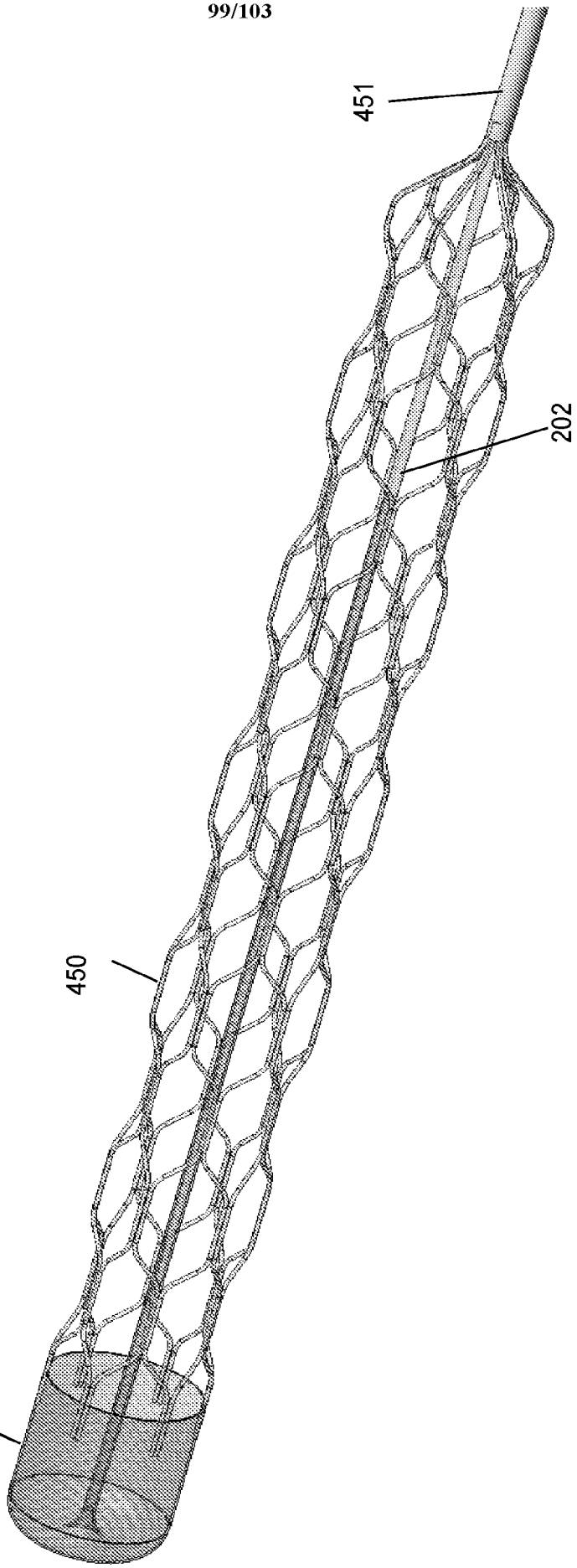

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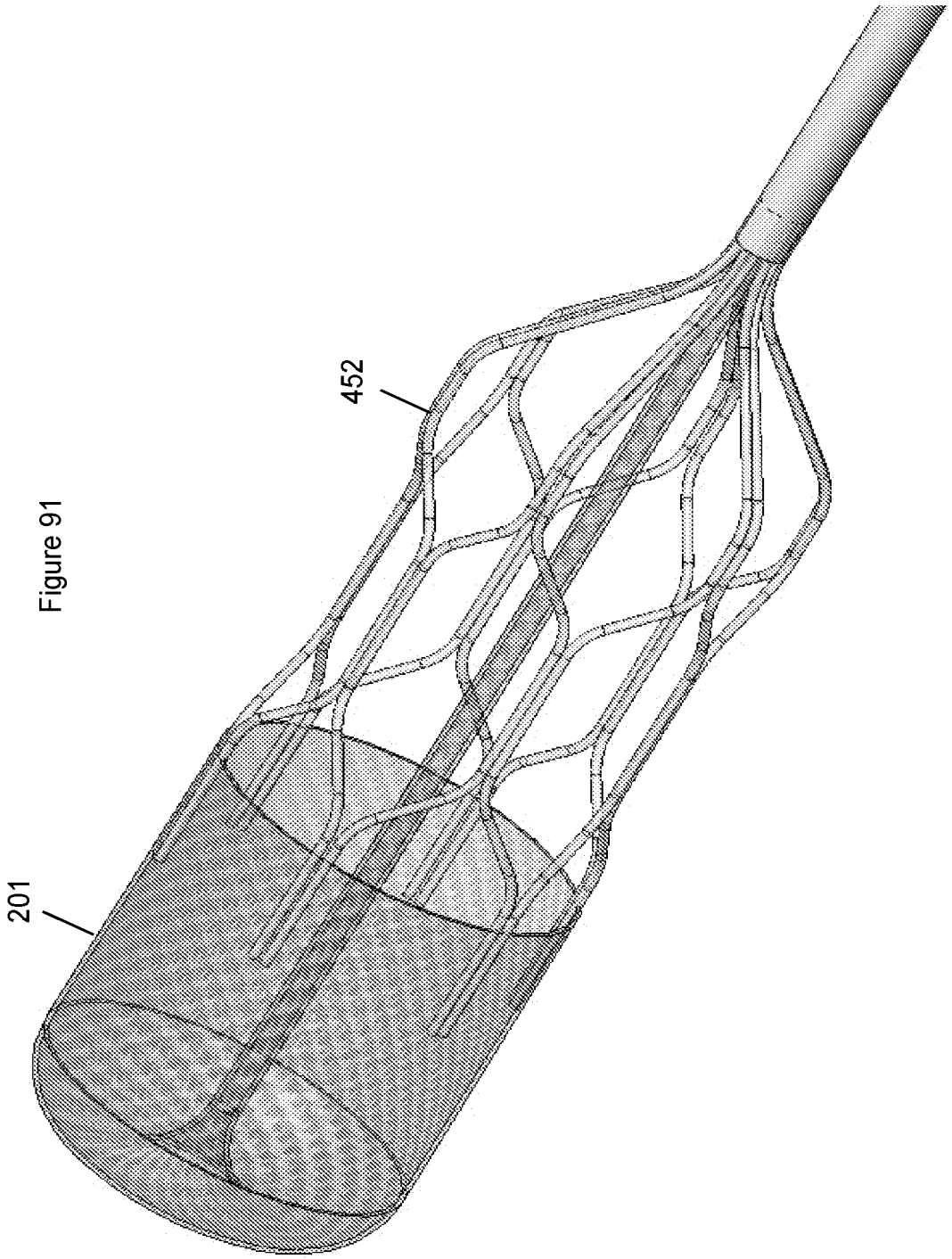

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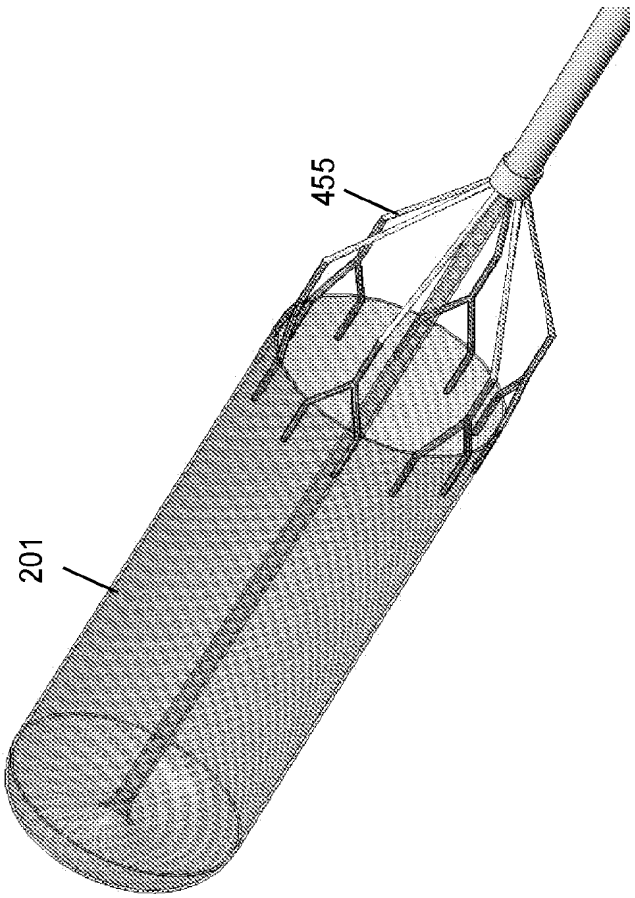

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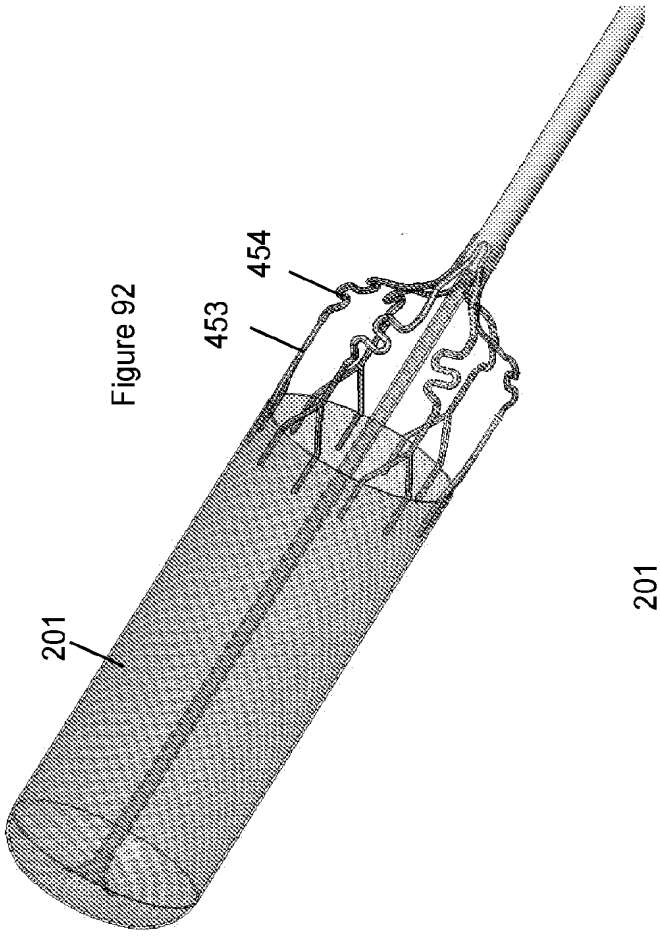

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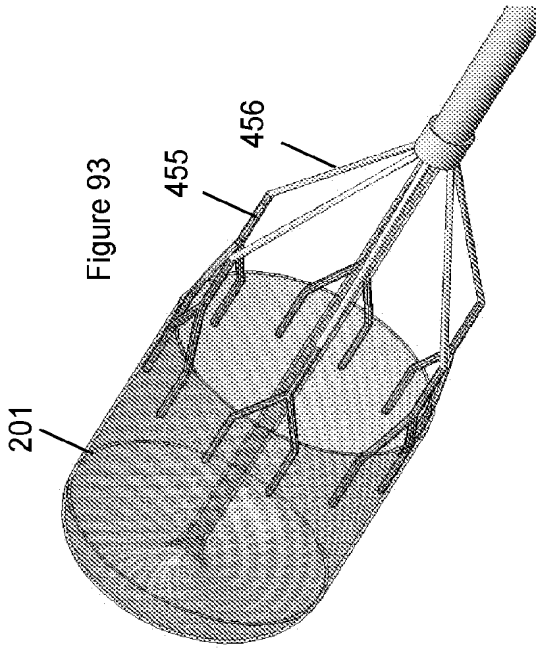

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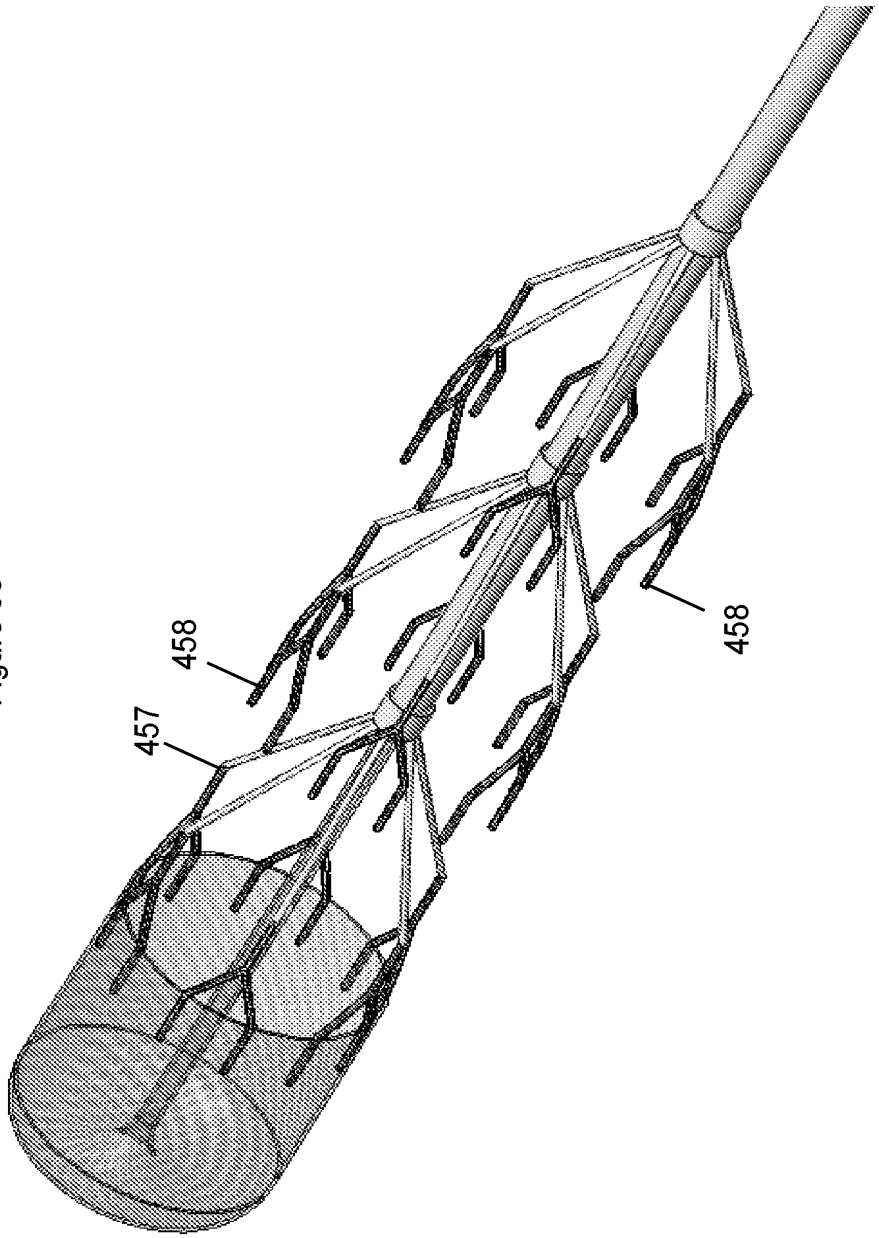

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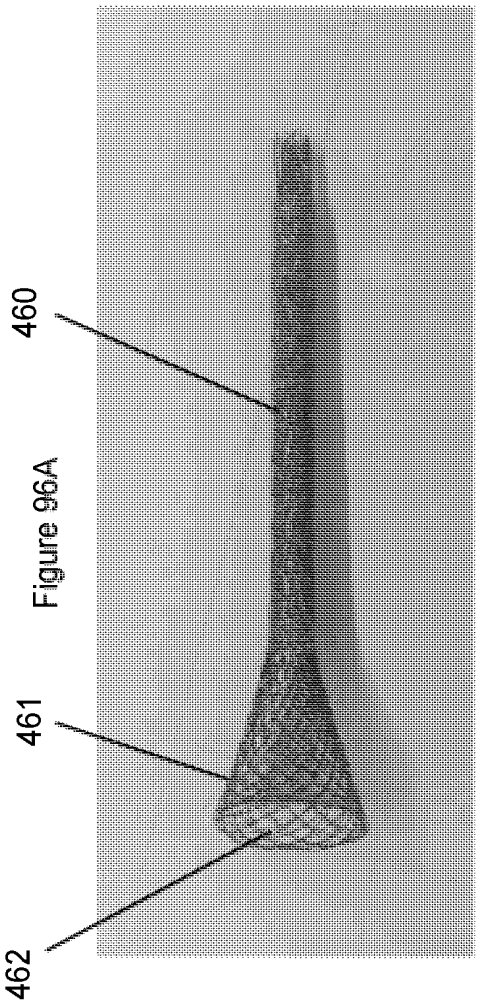

Figure 96A

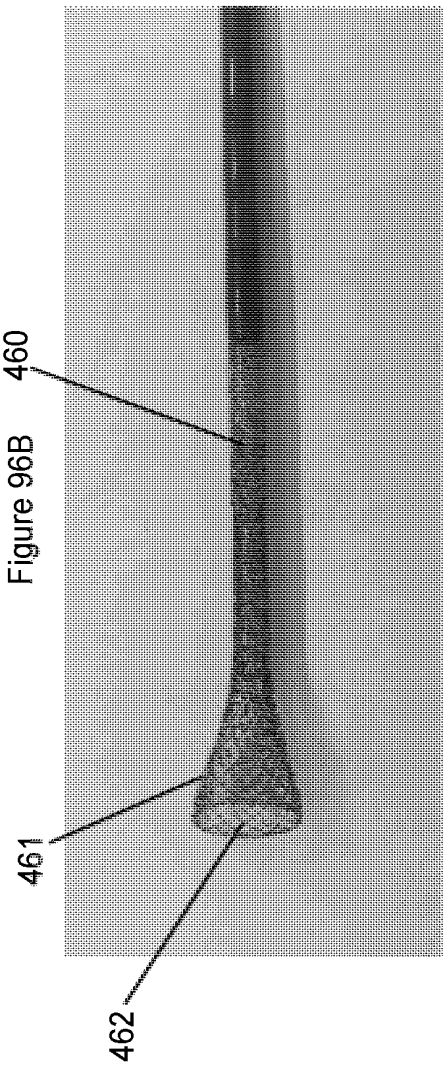

Figure 96B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2018/016976

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/22 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 17/00, 17/22, 17/221, A61F 2/01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSearch (RUPTO internal), Esp@cenet, PAJ, USPTO, Information Retrieval System of FIPS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	US 8968330 B2 (INCEPTUS MEDICAL LLC) 03.03.2015, fig. 6E-7B, 9A-9H, col. 3, line 57 - col. 7, line 39	1-4, 6, 7, 9-18, 20, 44 5, 8, 9 21-43
Y	US 5868708 A (APPLIED MEDICAL RESOURCES CORPORATION) 09.02.1999, fig. 1, 5, 7, 9-11, col. 6, line 10 - col. 9, line 65	5, 8
Y	US 6221006 B1 (ARTEMIS MEDICAL INC.) 24.04.2001, col. 8, lines 32-37, col. 9, lines 19-26	19
A	US 2011/0125181 A1 (EAMON BRADY et al.) 26.05.2011	1-44

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 April 2018 (27.04.2018)	24 May 2018 (24.05.2018)
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Authorized officer Y. Leonova Telephone No. (495)531-64-81

Form PCT/ISA/210 (second sheet) (January 2015)