(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
08 April 2021 (08.04.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/067134 A1

(51) International Patent Classification:
A61M 5/31 (2006.01) *A61M 3/00* (2006.01)
A61M 5/32 (2006.01) *A61M 5/00* (2006.01)

(21) International Application Number:
PCT/US2020/052760

(22) International Filing Date:
25 September 2020 (25.09.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/908,377 30 September 2019 (30.09.2019) US

(71) Applicant: **BECTON, DICKINSON AND COMPANY** [US/US]; 1 Becton Drive, Franklin Lakes, New Jersey 07417-1880 (US).

(72) Inventors: **YU, Bo Yang**; 62 Irving Street, Winchester, Massachusetts 01890 (US). **WILKINSON, Bradley**; 39 Hillside Drive, North Haledon, New Jersey 07508 (US). **PETERSON, Bart**; 1988 West Silver Spur Way, Farmington, Utah 84025 (US). **NEWBY, Mark**; 1038 W. Abigail Drive, UT, Kamas 84036 (US).

(74) Agent: **METHIPARA, Jomy** et al.; DICKINSON WRIGHT PLLC, 1825 Eye Street, NW, Suite 900, Washington, District of Columbia 20006 (US).

(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, IT, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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,

(54) Title: MEDICAMENT FILLING SYSTEM

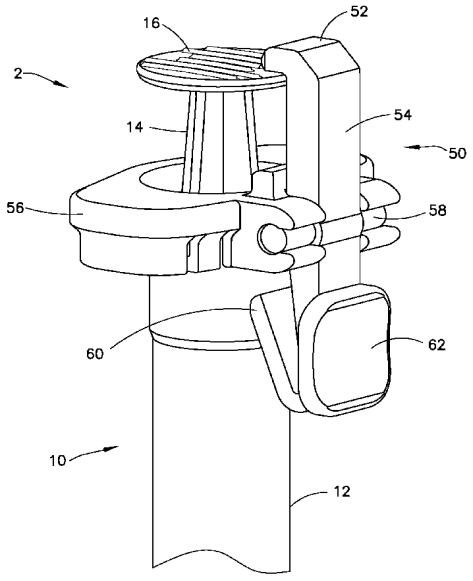


FIG. 1

(57) Abstract: A syringe assembly (2) that locks a syringe (10) to prevent backflow of medicament, the syringe assembly (2) comprising a syringe (10) including a barrel (12) configured to carry the medicament, a plunger (14) that communicates with the barrel (12), and a plunger head (16) disposed on a proximal end of the plunger (14), and a locking assembly (50) disposed around the barrel (12), wherein the locking assembly (50) prevents the plunger (14) from moving away from the barrel (12) to draw the medicament into the barrel (12).

[Continued on next page]

WO 2021/067134 A1

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).

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))*

MEDICAMENT FILLING SYSTEM

RELATED APPLICATION

[0001] This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application Serial 62/908,377, filed on September 30, 2019, which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] Various exemplary embodiments of the invention relate to devices that fill a delivery device with medicament.

BACKGROUND OF THE INVENTION

[0003] Systems such as delivery devices and syringe assemblies are typically used to inject medication, such as insulin, into a patient. However, inefficiencies and inconveniences can arise. These challenges include providing dosage feedback, minimizing air entering into the delivery device, preventing medicament backflow from exiting the delivery device during and after the filling step, and improving safety, handling and stability.

SUMMARY OF THE INVENTION

[0004] It is an aspect of the present invention to provide a syringe assembly that locks a syringe to prevent backflow of medicament. After the delivery device is filled with the medicament, a plunger of the syringe is configured to prevent medicament backflow from the delivery device into the syringe. Such an assembly provides efficient and improved accuracy of the medicament transferred to the delivery device.

[0005] Another aspect of the present invention provides a syringe assembly that provides haptic feedback during dose setting. Such a configuration gives a user confirmation of a specified dose setting, prevents unintended locking and minimizes user confusion.

[0006] In another aspect of the present invention, a fluid transfer device engages a syringe to provide different fluid paths for drawing medicament and injecting the medicament. Such a configuration prevents medicament backflow from the delivery device into the syringe, avoids the use of a locking mechanism and provides efficient and improved accuracy of the medicament transferred to the delivery device while not modifying the syringe.

[0007] The foregoing and/or other aspects of the present invention can be achieved by providing a syringe assembly that locks the syringe to prevent backflow of medicament, the syringe assembly comprising a syringe including a barrel configured to carry the medicament, a plunger that communicates with the barrel, and a plunger head disposed on a proximal end of the plunger, and a locking assembly disposed around the barrel, wherein the locking assembly prevents the plunger from moving away from the barrel to draw the medicament into the barrel.

[0008] The foregoing and/or other aspects of the present invention can further be achieved by providing a syringe assembly that provides haptic feedback during dose setting, the syringe assembly comprising a syringe including a barrel configured to carry a medicament, a plunger having a plunger head disposed on a proximal end of the plunger, the plunger communicating with the barrel, the plunger including a plurality of axial ribs extending along a length of the plunger, and a notch disposed in each axial rib, and a dose selector disposed around the barrel, wherein the dose selector passes through one of the notches to set a dose.

[0009] The foregoing and/or other aspects of the present invention can also be achieved by providing a fluid transfer device that prevents backflow of medicament, the fluid transfer device comprising a barrel configured to carry the medicament, a plunger connected to the barrel, and a vial adapter comprising a first needle cannula that allows the medicament to exit the fluid transfer device, a second needle cannula that allows the medicament to enter the fluid transfer device, the second needle cannula being shorter in length than the first needle cannula, a first one-way valve connected to the first needle cannula, and a second one-way valve connected to the second needle cannula.

[0010] The foregoing and/or other aspects of the present invention can additionally be achieved by providing a fluid transfer device that prevents backflow of medicament, the fluid transfer device comprising a first needle cannula that allows the medicament to exit the fluid transfer device, a second needle cannula that allows the medicament to enter the fluid transfer device, the second needle cannula being shorter in length than the first needle cannula, the second needle cannula being disposed within the first needle cannula, and a two-way valve connected to the first needle cannula and the second needle cannula, wherein the second needle cannula is configured to draw the medicament from a vial, and when the fluid transfer

device is engaged to a delivery device, the first needle cannula transfers medicament to the delivery device.

[0011] Additional and/or other aspects and advantages of the present invention will be set forth in the description that follows, or will be apparent from the description, or may be learned by practice of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The above aspects and features of the present invention will be more apparent from the description for the exemplary embodiments of the present invention taken with reference to the accompanying drawings, in which:

[0013] Figure 1 illustrates a first exemplary embodiment of a left perspective view of a syringe assembly;

[0014] Figure 2 illustrates a second exemplary embodiment of a right perspective view of a syringe assembly with a plunger head platform;

[0015] Figure 3 illustrates a third exemplary embodiment of a side elevation view of a syringe assembly with a dial dose and a position indicator;

[0016] Figure 4 is a perspective view of the syringe assembly of Figure 3 in an unlocked position;

[0017] Figure 5 is a perspective view of the syringe assembly of Figure 3 in a locked position;

[0018] Figure 6 illustrates a fourth exemplary embodiment of a right perspective view of a syringe assembly providing haptic feedback;

[0019] Figure 7 is a cross-sectional view of the syringe assembly along line A-A of Figure 6;

[0020] Figure 8 illustrates a fifth exemplary embodiment of a side elevation view of a syringe assembly engaging the plunger head platform;

[0021] Figure 9 illustrates a sixth exemplary embodiment of a cross-sectional view of a fluid transfer device engaged to a syringe;

[0022] Figure 10 is a cross-sectional view of the fluid transfer device of Figure 9 engaged to a vial;

[0023] Figure 11 is a cross-sectional view of the fluid transfer device of Figure 9 engaged to an insulin delivery device;

[0024] Figure 12 illustrates a seventh exemplary embodiment of a cross-sectional view of a fluid transfer device drawing medicament;

[0025] Figure 13 is a cross-sectional view of the fluid transfer device of Figure 12 shown expelling the medicament;

[0026] Figure 14 is a cross-sectional view of the fluid transfer device of Figure 12 shown drawing the medicament and providing an air vent passage; and

[0027] Figure 15 is a cross-sectional view of the fluid transfer device of Figure 12 shown expelling the medicament and providing an air vent passage.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0028] Figure 1 illustrates a syringe assembly 2 according to one embodiment. The syringe assembly 2 includes a syringe 10 having a barrel 12, a plunger 14, a plunger head 16 and a needle (not shown) as conventionally understood by one skilled in the art. Specifically, the barrel 12 carries medicament and the plunger 14 is disposed in the barrel 12 to move the medicament into and out of the barrel 12. The plunger head 16 is connected to a proximal end of the plunger 14 and allows a user to move the plunger 14 to perform the medicament filling and dispensing operations. The needle receives the medicament from a vial and dispenses the medicament to an insulin delivery device.

[0029] The syringe assembly 2 further includes a locking assembly 50 that locks the plunger 14 of the syringe 10 after the medicament is dispensed to advantageously prevent backflow of medicament into the barrel 12. The locking assembly 50 includes a hook 52, an arm 54, a base 56, a pivot shaft 58, a spring member 60 and a button 62.

[0030] The hook 52 is disposed on a proximal end of the arm 54 and includes a cantilevered surface that is configured to engage a top surface of the plunger head 16 when the medicament is dispensed from the barrel 12 of the syringe 10. The base 56 is fixed to the barrel 12 and surrounds the barrel 12. The pivot shaft 58 is disposed on a side surface of the base 56 and is rotatable. The pivot shaft 58 engages a central portion of the arm 54 to allow the hook 52 to rotate.

[0031] A distal end of the arm 54 includes the spring member 60 and the button 62. The spring member 60 contacts the barrel 12 at one side of the arm 54 and the button 62 is disposed on an opposing side of the arm 54 to provide the user with a depressible surface. The hook 52 is configured to rotate about the pivot shaft 58 disposed between the button 62

and the hook 52. The pivot shaft 58 allows the arm 54 to rotate between an engaged and a disengaged position based on user activation of the button 62.

[0032] Specifically, when the medicament from the syringe 10 is dispensed, the plunger 14 is at a distal position. A natural state of the locking assembly 50 positions the hook 52 above the plunger head 16 to lock the plunger 14 from movement. In this state, the button 62 is in a free or released state and the spring member 60 pushes the button 62 (a first compression force) to provide maximum engagement of the hook 52 to the plunger head 16.

[0033] To unlock the syringe 10 from the locking assembly 50, the user depresses the button 62 against the springe force of the spring member 60 (a second compression force). This causes the arm 54 to rotate about the pivot shaft 58 and disengage the hook 52 from the plunger head 16. The second compression force is greater than the first compression force.

[0034] When a syringe conventionally fills an insulin delivery device, the user must simultaneously hold down the plunger head and remove the syringe from the insulin delivery device to avoid backflow of medicament into the syringe 10. The locking assembly 50 disclosed herein advantageously locks the plunger head 16 after the medication is dispensed into the insulin delivery device. In this manner, no medicament will backflow into the syringe 10 and the user can comfortably remove the syringe 10 from the insulin delivery device. The locking assembly 50 also advantageously allows the user to unlock the syringe 10 for use if the syringe 10 was accidentally locked.

[0035] Figure 2 illustrates a syringe assembly 4 according to a second embodiment. This embodiment discloses the syringe 10 and the locking assembly 50 as similarly described above with the following modifications. The plunger head 16 of the syringe 10 includes a plunger head platform 20. The platform 20 is disposed below the plunger head 16 such that a gap is present between the two features. The platform 20 is preferably molded as part of the plunger 14 but alternately can be a separate part attached to the plunger 14. The hook 52 of the locking assembly 50 is advantageously configured to engage the gap to lock the plunger 14 after the medicament is dispensed from the barrel 12 of the syringe 10.

[0036] Additionally, the hook 52 includes a plurality of protrusions 66 that provide a depressible surface. Accordingly, the user can advantageously apply a force to the hook 52 where the plurality of protrusions 66 are located or apply a force to the button 62 to move the hook 52 from an engaged, locked position to a disengaged, unlocked position. The configuration in this embodiment advantageously provides a complete surface at the plunger

head 16 available for the user to manipulate when engaging and disengaging the locking assembly 50.

[0037] Figures 3-5 illustrate a syringe assembly 6 according to a third embodiment. This embodiment discloses the syringe 10 and the locking assembly 50 as similarly described above with the following modifications. The plunger head 16 includes a dial dose 18. The dial dose 18 indicates a dosage unit amount. Specifically, the plunger head 16 is rotated to set a desired dose identified by the dial dose 18.

[0038] In addition, the locking assembly 50 includes a position indicator 64 shaped as an arrowhead. The position indicator 64 advantageously cooperates with the dial dose 18 to identify a dose position of the plunger head 16. As illustrated in Figure 5, the position indicator 64 points to a specific dosage amount expressed by the dial dose 18 that is set by the user via rotation of the plunger head 16. The button 62 on the locking assembly 50 also includes protrusions 66 that provide a friction surface for the user to depress the button 62.

[0039] In operation, Figures 3 and 4 illustrate an unlocked position of the locking assembly 50 whereas Figure 5 illustrates a locked position. In the unlocked position, the plunger 14 is free to move in the barrel. In the locked positon, the plunger 14 is unable to move since the hook 52 engages the platform 20 to prevent movement.

[0040] Figures 6 and 7 illustrate a syringe assembly 8 according to a fourth embodiment. This embodiment discloses the syringe 10 as similarly described above with the following modifications. This embodiment incorporates a dose selector 70 with the syringe 10 to advantageously provide haptic feedback to the user when setting a dose.

[0041] The plunger 14 of the syringe 10 is modified to cooperate with the dose selector 70. Specifically, the plunger 14 includes a plurality of axial ribs 24 extending along a length of the plunger 14. The axial ribs 24 provide stability and stiffness to the plunger 14. A curved indent 28 is disposed between each of the adjacent axial ribs 24.

[0042] Figure 6 illustrates that a vertical portion of the plurality of axial ribs 24 includes a notch 26. A cross section of the plunger 14 at the notch 26 is illustrated in Figure 7. The notch 26 advantageously provides a smooth raised surface around the plunger 14. The notch 26 also advantageously provides a continuous surface between the adjacent curved indents 28.

[0043] Figure 6 further illustrates the dose selector 70 including an arm 72, a position indicator 74, a base 76 and a tab 78. The base 76 is fixed to and surrounds the barrel 12 of

the syringe 10. The arm 72 extends upwardly from the base 76 and includes the position indicator 74 such as an arrowhead, for example, that indicates a set dose. The base 76 and the position indicator 74 are also similarly described above for various embodiments of the locking assembly.

[0044] The tab 78 is an inwardly extending member disposed on an inner surface of the base 76. The tab 78 cooperates with the plunger 14 and the notch 26. Specifically, the plunger 14 can only move vertically when the tab 78 is disposed between the axial ribs 24, in the curved indent 28 and outside of the notch 26 of the plunger 14. The user places the tab 78 at a vertical position of the plunger 14 where the notch 26 is located to rotate the plunger 14 and adjust the dosage.

[0045] When the user rotates the plunger 14 to set the dose, every time the tab 78 encounters the notch 26 of one of the axial ribs 24, a detent or force is advantageously provided. As illustrated in Figure 7, this force or detent occurs because there is contact between the axial rib 24 and the tab 78 in the notch 26. This detent or force is the haptic feedback the user receives to indicate that the dosage is being changed. In this position, the plunger 14 is also locked to prevent vertical movement.

[0046] When the tab 78 is disposed between two of the axial ribs 24 as illustrated in Figure 7, no detent or force is provided because there is no contact. That is, the tab 78 does not contact the curved indent 28. Accordingly, the user advantageously experiences alternate pressures (haptic feedback) when rotating between dose setting positions.

[0047] Figure 8 illustrates a syringe assembly 9 according to a fifth embodiment. This embodiment also discloses the syringe 10 and the locking assembly 50 as similarly described above with the following modifications. Specifically, the plunger head platform 20 includes a rounded circumferential surface that the hook 52 engages. More specifically, the hook 52 includes a hook indent 53 that is contoured to engage and receive the rounded circumferential surface of the plunger head platform 20. Such a configuration advantageously provides a more secure and smooth engagement of the hook 52 to the platform 20 when the locking assembly 50 is in the locked position.

[0048] Figures 9-11 illustrate a cross-sectional view of a fluid transfer device 120 attached to a syringe 121 according to a fifth embodiment. Figure 10 illustrates the fluid transfer device 120 engaged to a vial 100 to receive medicament. Figure 11 illustrates the

fluid transfer device 120 engaged to an insulin delivery device (IDD) 110 to transfer medicament. Further details of the fluid transfer device 120 are provided below.

[0049] The syringe 121 is commonly understood by one skilled in the art and includes, for example, a barrel 122 that carries the medicament and a plunger 124 disposed in the barrel 122 to draw and dispense the medicament. The syringe 121 is configured to engage a vial adapter 130 of the fluid transfer device 120 to establish fluid communication. In an alternate embodiment, the fluid transfer device 120 includes the barrel 122 and the plunger 124 that are in fluid communication with the vial adapter 130.

[0050] The vial adapter 130 includes a first needle cannula 132, a second needle cannula 134, a first one-way valve 136 and a second one-way valve 138. The first needle cannula 132 is used for transferring the medicament from the barrel 122 into the insulin delivery device 110 as illustrated in Figure 11. The second needle cannula 134 is used to receive the medicament from the vial 100 as illustrated in Figure 10.

[0051] The first needle cannula 132 is advantageously longer than the second needle cannula 134 so that only the first needle cannula 132 engages the insulin delivery device 110. As illustrated in Figure 11, the second needle cannula 132 is too short to engage the insulin delivery device 110.

[0052] On the other hand, the second needle cannula 134 is advantageously shorter than the first needle cannula 132 to receive more of the medicament from the vial 100. Figure 10 illustrates that both the first and second needle cannulas 132, 134 are disposed in the vial 100. However, a distal end of the second needle cannula 134 is closer to a bottom portion of the vial 100. As the medicament exits the vial 100, the associated fluid level decreases in the vial 100. Having a short needle cannula 134 advantageously optimizes the amount of medicament that can be removed from the vial 100.

[0053] The first one-way valve 136 controls medicament flow through the first needle cannula 132 such that the medicament in the barrel 122 can only exit through the first needle cannula 132. That is, the first one-way valve 136 does not allow the first needle cannula 132 to receive the medicament into the barrel 122.

[0054] On the other hand, the second one-way valve 138 controls medicament flow through the second needle cannula 134 such that the medicament can only enter through the second needle cannula 134 to fill the barrel 122. Conversely, the second one-way valve 138

does not allow the second needle cannula 134 to dispense the medicament from the barrel 122.

[0055] The fluid transfer device 120 of this embodiment provides an alternate means to prevent backflow of the medicament from the insulin delivery device 110 into the syringe 121. To achieve this benefit, the fluid transfer device 120 advantageously provides separate fluid paths without the use of a plunger locking mechanism and without the need to manually hold down a syringe plunger after fluid delivery.

[0056] Figures 12-15 illustrate a cross-sectional view of a fluid transfer device 220 according to a sixth embodiment. The fluid transfer device 220 includes a vial adapter 230, a first needle cannula 232, a second needle cannula 234, a two-way valve 236, a vent membrane 239 and a syringe adapter 242. Figure 14 illustrates that the vial adapter 230 is engaged to a vial 200, preferably via a snap lock engagement, although other means are contemplated herein. The syringe adapter 242 is configured to engage a syringe (not shown), preferably via a luer lock, although other means are contemplated herein.

[0057] As similarly described above, the first needle cannula 232 is used for transferring the medicament from the syringe into the insulin delivery device 210 as illustrated in Figure 15. The second needle cannula 234 is used to receive the medicament from the vial 200 as illustrated in Figure 14.

[0058] The first needle cannula 232 is advantageously longer than the second needle cannula 234 so that only the first needle cannula 232 engages the insulin delivery device 210. A bottom surface of the vial adapter 230 advantageously controls the insertion depth of the first needle cannula 232 in the insulin delivery device 210. As illustrated in Figure 15, the second needle cannula 232 is too short to engage the insulin delivery device 210. Specifically, the second needle cannula 232 does not extend beyond the bottom surface of the vial adapter 230 to advantageously ensure that no fluid communication to the insulin delivery device 210 takes place.

[0059] On the other hand, the second needle cannula 234 is advantageously shorter than the first needle cannula 232 to receive more of the medicament from the vial 200. Figure 14 illustrates that a distal end of the second needle cannula 234 is closer to a bottom portion of the vial 200. As the medicament exits the vial 200, the associated fluid level decreases in the vial 200. Having a short second needle cannula 234 optimizes the amount of medicament

that is removed from the vial 200. A depth of a cavity in the vial adapter 230 that engages the vial 200 advantageously controls the insertion depth of the second needle cannula 234.

[0060] Further, the first needle cannula 232 is advantageously disposed within the second needle cannula 234. Such a configuration optimizes space, provides a simple design and continues to provide different fluid paths as described in more detail below.

[0061] The two-way valve 236 is preferably a combination duckbill and umbrella valve. However, other combination of valves can be used to achieve the functional benefits described herein. The two-way valve 236 controls medicament flow through the first needle cannula 232 such that the medicament in the syringe can only exit through the first needle cannula 232. That is, the two-way valve 236 does not allow the first needle cannula 232 to receive the medicament into the syringe.

[0062] The two-way valve 236 also controls medicament flow through the second needle cannula 234 such that the medicament can only enter through the second needle cannula 234 to fill the syringe. Similarly, the two-way valve 236 does not allow the second needle cannula 234 to dispense the medicament from the syringe.

[0063] In view of the above, the two-way valve 236 advantageously controls the transfer of the medicament. However, the two-way valve 236 does not control the exchange of air. Further explanation of an airflow path 254 in the fluid transfer device 220 is described below.

[0064] Figures 12-15 also illustrate a vent membrane 239 connecting to the airflow path 254, as well as a medicament entrance path 250 and a medicament exit path 252. Figure 12 illustrates the syringe being filled with the medicament. Specifically, the medicament entrance path 250 is described in a manner where the medicament enters a distal end of the second needle cannula 234, routed in a path offset from the centerline of the vial adapter 230 to the two-way valve 236 and ultimately enters into the syringe adapter 242 to fill the syringe.

[0065] Figure 14 illustrates the medicament entrance path 250 when the vial adapter 230 is engaged to the vial 200. The vent membrane 239 cooperates with the transfer of the medicament from the vial 200 to the syringe and is located upstream from the two-way valve 236.

[0066] Specifically, when the medicament exits the vial 200, air advantageously enters into the vial 200 via the airflow path 254 and the vent membrane 239. The airflow path 254 includes a path upstream from the two-way valve 236 and through the first needle cannula

232. In this manner, there is no vacuum created in the vial 200 and the pressure in the vial 200 is equalized with the environmental pressure.

[0067] Figures 13 and 15 illustrate the medicament exit path 252 that allows the medicament to exit the syringe and enter the insulin delivery device 210. The medicament exit path 252 travels through the two-way valve 236, through a centerline of the fluid transfer device 220, and through the first needle cannula 232 before ultimately entering into the insulin delivery device 210.

[0068] Meanwhile, the same airflow path 254 through the first needle cannula 232 and the vent membrane 239 as described above is used to remove air from the insulin delivery device 220. Advantageously, there is no vacuum created in the insulin delivery device 220 and the pressure in the insulin delivery device 220 is equalized with the environmental pressure.

[0069] The fluid transfer device 220 of this embodiment provides an alternate means to prevent backflow of the medicament from the insulin delivery device 210 into the syringe. To achieve this benefit, the fluid transfer device 220 advantageously provides separate fluid and air paths without the use of a plunger locking mechanism and without the need to manually hold down a syringe plunger after fluid delivery.

[0070] The foregoing detailed description of the certain exemplary embodiments has been provided for explaining the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications as are suited to the particular use contemplated. This description is not necessarily intended to be exhaustive or to limit the invention to the precise embodiments disclosed. In addition, any of the embodiments, features and/or elements disclosed herein may be combined with one another to form various additional combinations not specifically disclosed, as long as the embodiments, features and/or elements being combined do not contradict each other. Accordingly, additional embodiments are possible and are intended to be encompassed within this specification and the scope of the invention. The specification describes specific examples to accomplish a more general goal that may be accomplished in another way.

[0071] As used in this application, the terms "front," "rear," "upper," "lower," "upwardly," "downwardly," and other orientational descriptors are intended to facilitate the description of the exemplary embodiments of the present invention, and are not intended to

limit the structure of the exemplary embodiments of the present invention to any particular position or orientation. Terms of degree, such as "substantially" or "approximately" are understood by those of ordinary skill to refer to reasonable ranges around and including the given value, for example, general tolerances associated with manufacturing, assembly, and use of the described embodiments.

CLAIMS

1. A syringe assembly that locks a syringe to prevent backflow of medicament, the syringe assembly comprising:

a syringe, including:

a barrel configured to carry the medicament;

a plunger that communicates with the barrel; and

a plunger head disposed on a proximal end of the plunger; and

a locking assembly disposed around the barrel;

wherein the locking assembly prevents the plunger from moving away from the barrel to draw the medicament into the barrel.

2. The syringe assembly of claim 1, wherein the plunger head includes a dial dose to indicate a dose setting.

3. The syringe assembly of claim 1, wherein:

the locking assembly includes:

a hook configured to engage the plunger head; and

a depressible button and spring member connected to the hook,

wherein the depressible button controls engagement and disengagement between the hook and the plunger head.

4. The syringe assembly of claim 3, wherein:

the locking assembly further includes:

a base engaged to the barrel;

an arm that connects the hook to the depressible button and the spring member; and

a shaft that connects the arm to the base.

5. The syringe assembly of claim 4, wherein the shaft allows the arm to rotate to control engagement and disengagement between the hook and the plunger head.

6. The syringe assembly of claim 4, wherein:

the spring member contacts the barrel and is disposed on one side surface of the arm while the button is disposed on an opposing side surface of the arm;

when the button is in a free state, the spring is compressed at a first compression force and the hook is engaged to the plunger head;

when the button is depressed, the spring member is compressed at a second compression force and the hook is disengaged from the plunger head; and

the second compression force is greater than the first compression force.

7. The syringe assembly of claim 3, wherein:

the plunger head further includes a platform disposed distally from a top surface of the plunger head; and

the hook is configured to engage the plunger between the top surface of the plunger head and the platform to lock the plunger.

8. The syringe assembly of claim 7, wherein the hook includes an indent feature that engages and disengages the platform to secure engagement.

9. The syringe assembly of claim 3, wherein the hook includes one of protrusions and a position indicator to aid in handling and dose setting.

10. A syringe assembly that provides haptic feedback during dose setting, the syringe assembly comprising:

a syringe, including:

a barrel configured to carry a medicament; and

a plunger having a plunger head disposed on a proximal end of the plunger, the plunger communicating with the barrel, the plunger includes:

a plurality of axial ribs extending along a length of the plunger; and

a notch disposed in each axial rib; and

a dose selector disposed around the barrel wherein the dose selector passes through one of the notches to set a dose.

11. The syringe assembly of claim 10, wherein:

the plunger includes a curved indent between each of the notches, the curved indents are disposed between adjacent axial ribs of the plurality of axial ribs; and

the dose selector engages and disengages the notches to provide haptic feedback regarding the dose setting.

12. The syringe assembly of claim 11, wherein:

the plunger head includes a dial dose to indicate a dose setting; and

the dose selector includes an arm having a position indicator that cooperates with the dial dose to identify and set a desired dose.

13. The syringe assembly of claim 12, wherein:

the dose selector having a base that is fixed to the barrel;

the arm extends upward from the base; and

a tab is disposed on an inner surface of the base to engage and disengage the notches.

14. A fluid transfer device engagable to a syringe having a barrel configured to carry a medicament and a plunger connected to the barrel, the fluid transfer device preventing backflow of medicament into the syringe, the fluid transfer device comprising:

a vial adapter comprising:

a first needle cannula that allows the medicament to exit the fluid transfer device;

a second needle cannula that allows the medicament to enter the fluid transfer device, the second needle cannula being shorter in length than the first needle cannula; and

a first one-way valve connected to the first needle cannula and a second one-way valve connected to the second needle cannula.

15. The fluid transfer device of claim 14, wherein:

the medicament is drawn from a vial through the second needle cannula; and

when the fluid transfer device is engaged to a delivery device, the first needle cannula is in fluid communication with the delivery device to transfer the medicament.

16. The fluid transfer device of claim 14, wherein the first one-way valve prevents pressure in a delivery device from pushing the medicament back into the fluid transfer device.

17. The fluid transfer device of claim 14, wherein when the fluid transfer device is engaged to a delivery device, the second needle cannula is disengaged from the delivery device.

18. A fluid transfer device that prevents backflow of medicament, the fluid transfer device comprising:

a first needle cannula that allows the medicament to exit the fluid transfer device;

a second needle cannula that allows the medicament to enter the fluid transfer device, the second needle cannula being shorter in length than the first needle cannula, the second needle cannula being disposed within the first needle cannula; and

a two-way valve connected to the first needle cannula and the second needle cannula;

wherein the second needle cannula is configured to draw the medicament from a vial; and

wherein when the fluid transfer device is engaged to a delivery device, the first needle cannula transfers medicament to the delivery device.

19. The fluid transfer device of claim 18, wherein the two-way valve comprises a combination duckbill and umbrella valve.

20. The fluid transfer device of claim 18, further comprising a vent membrane that provides air to the vial when the medicament is drawn and releases air from the delivery device when the medicament is delivered to the delivery device.

21. The fluid transfer device of claim 18, wherein the two-way valve prevents backflow of the medicament when the medicament is delivered to the delivery device.

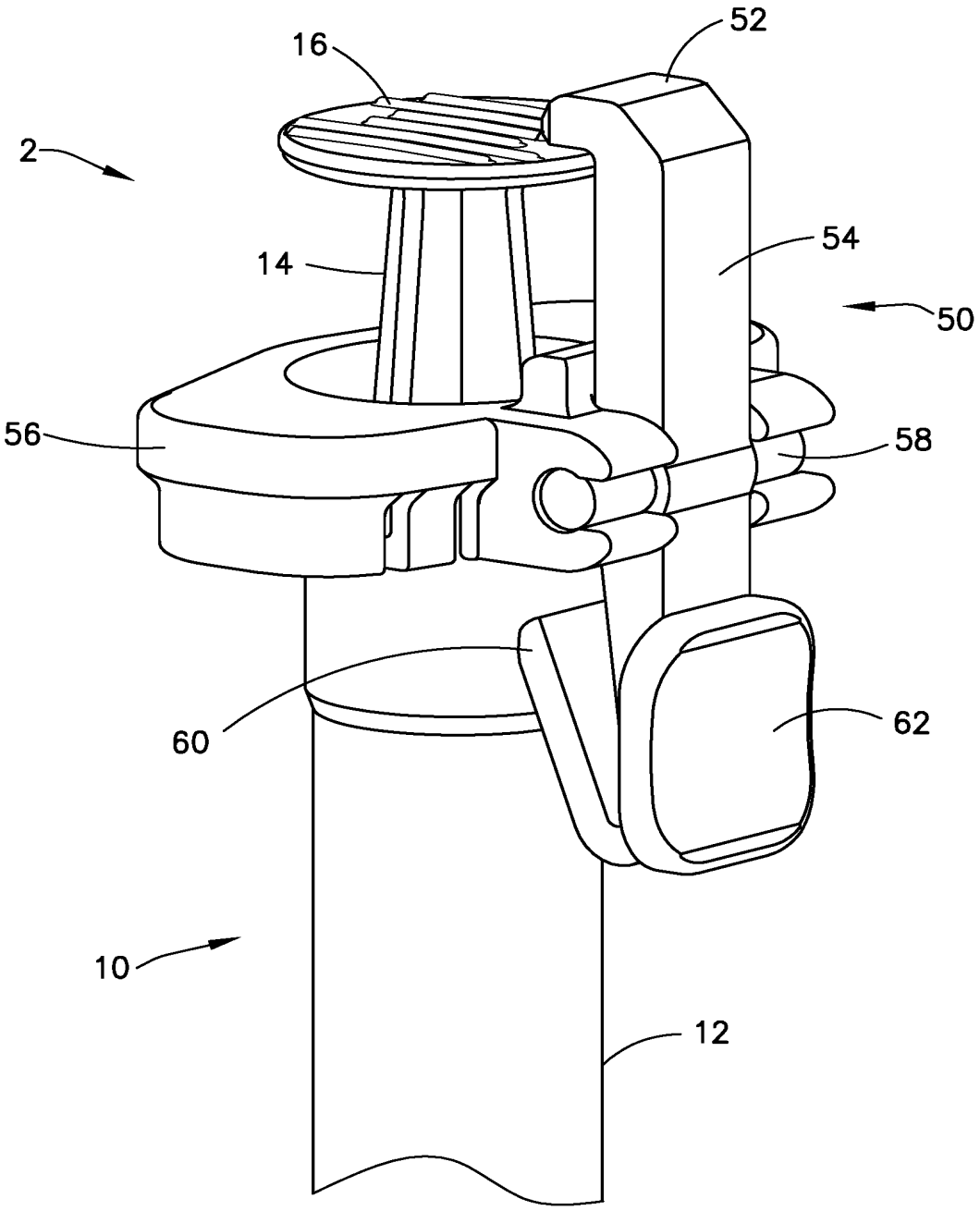


FIG. 1

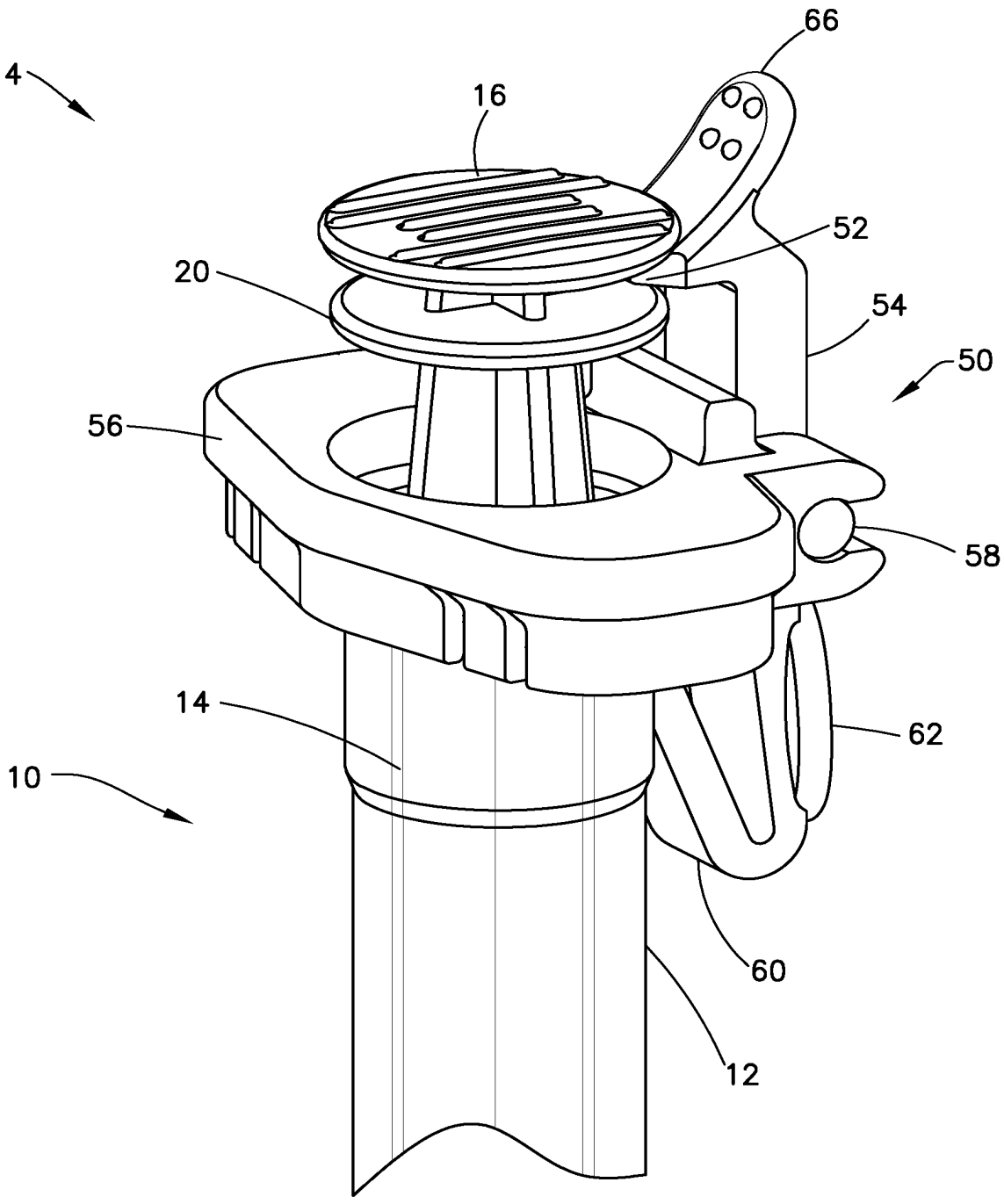


FIG.2

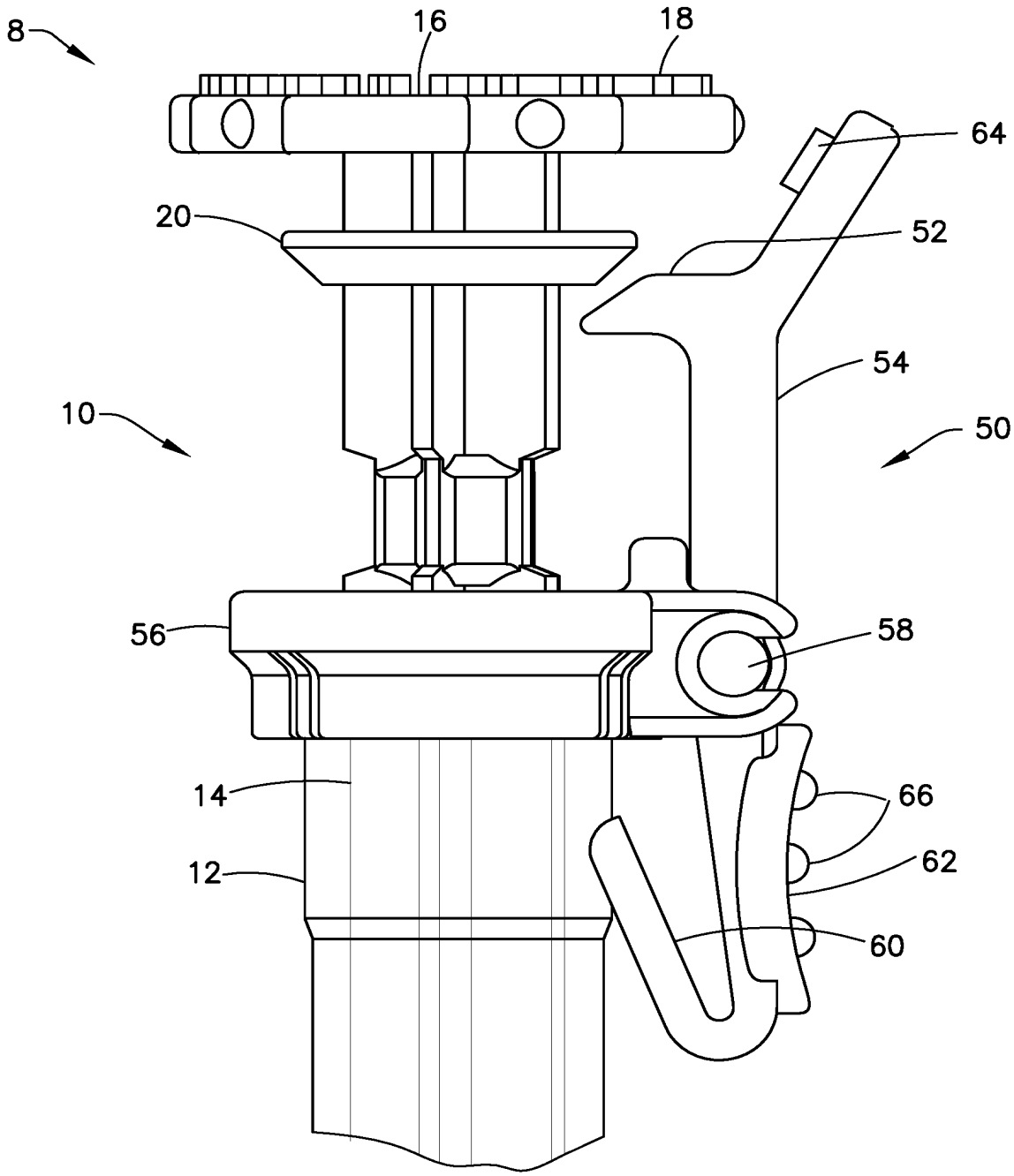


FIG.3

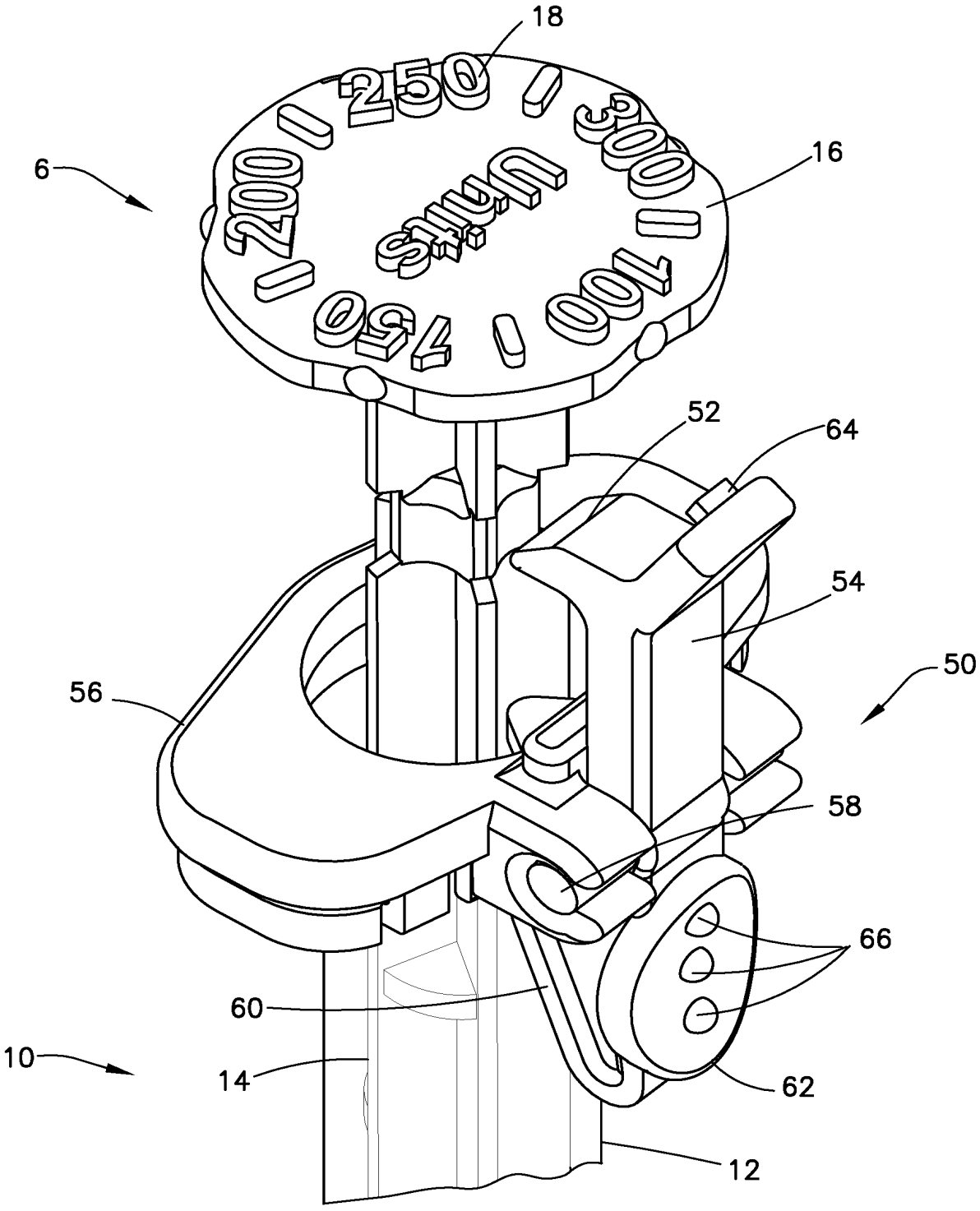


FIG.4

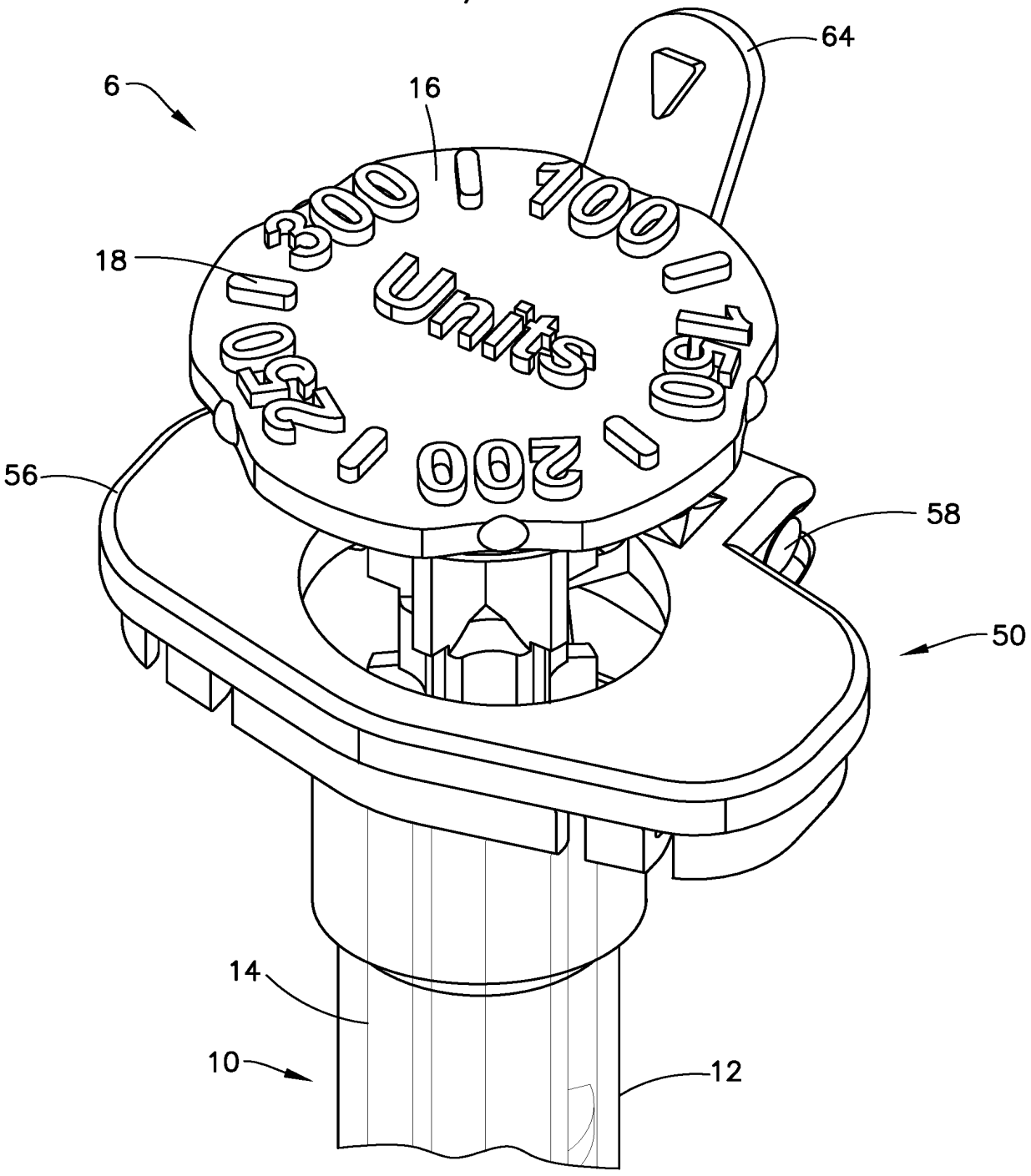


FIG.5

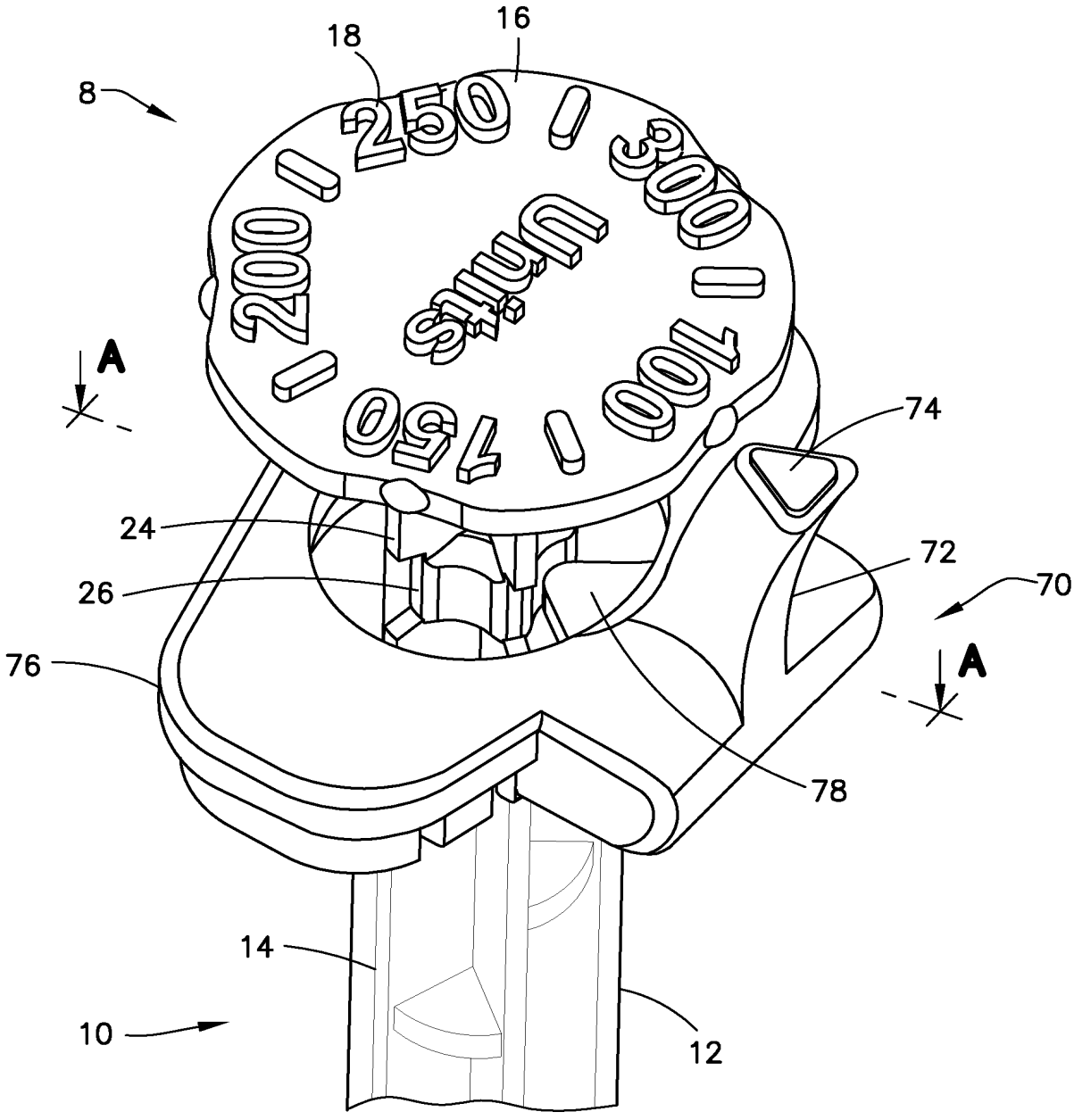


FIG.6

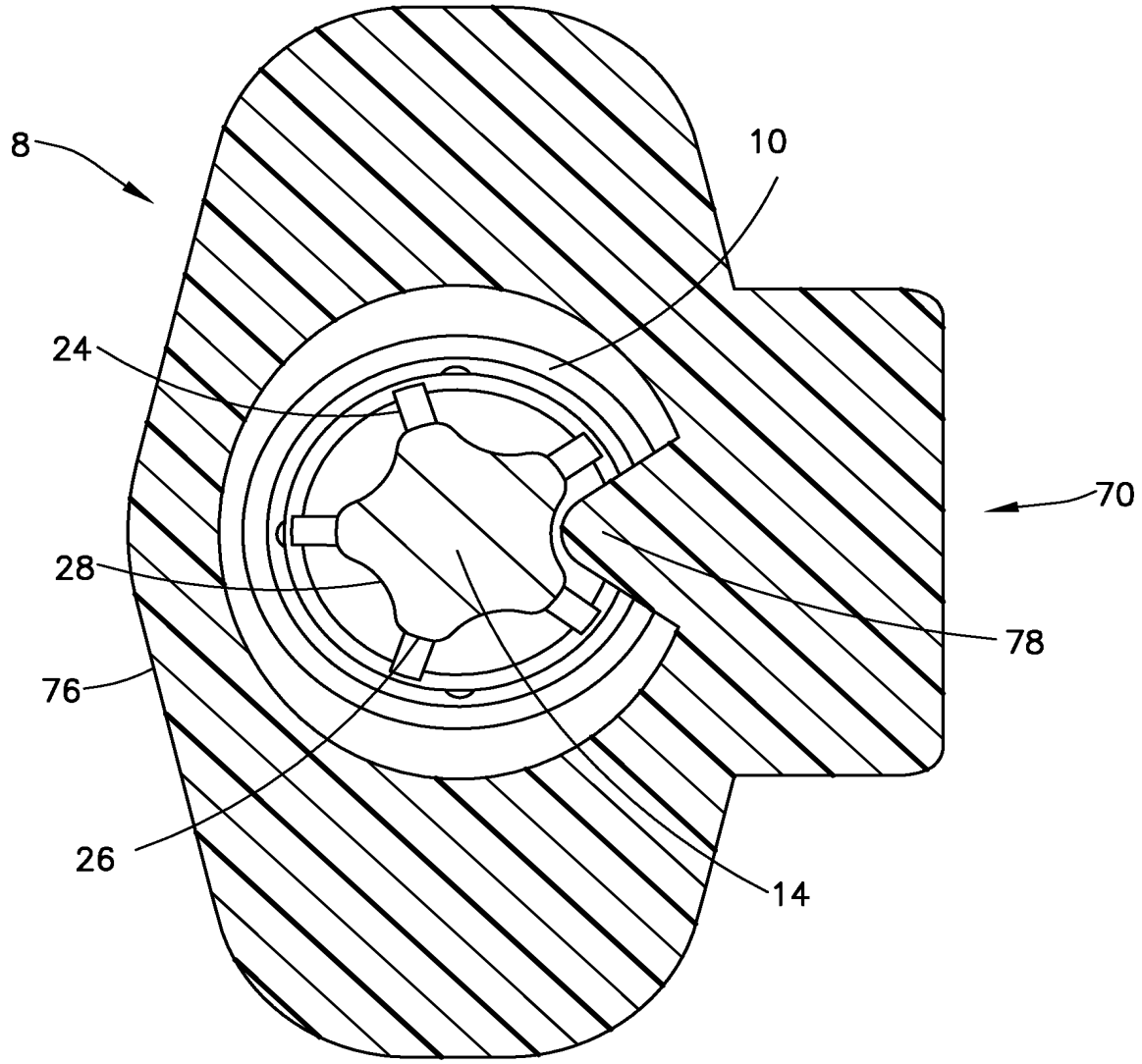


FIG.7

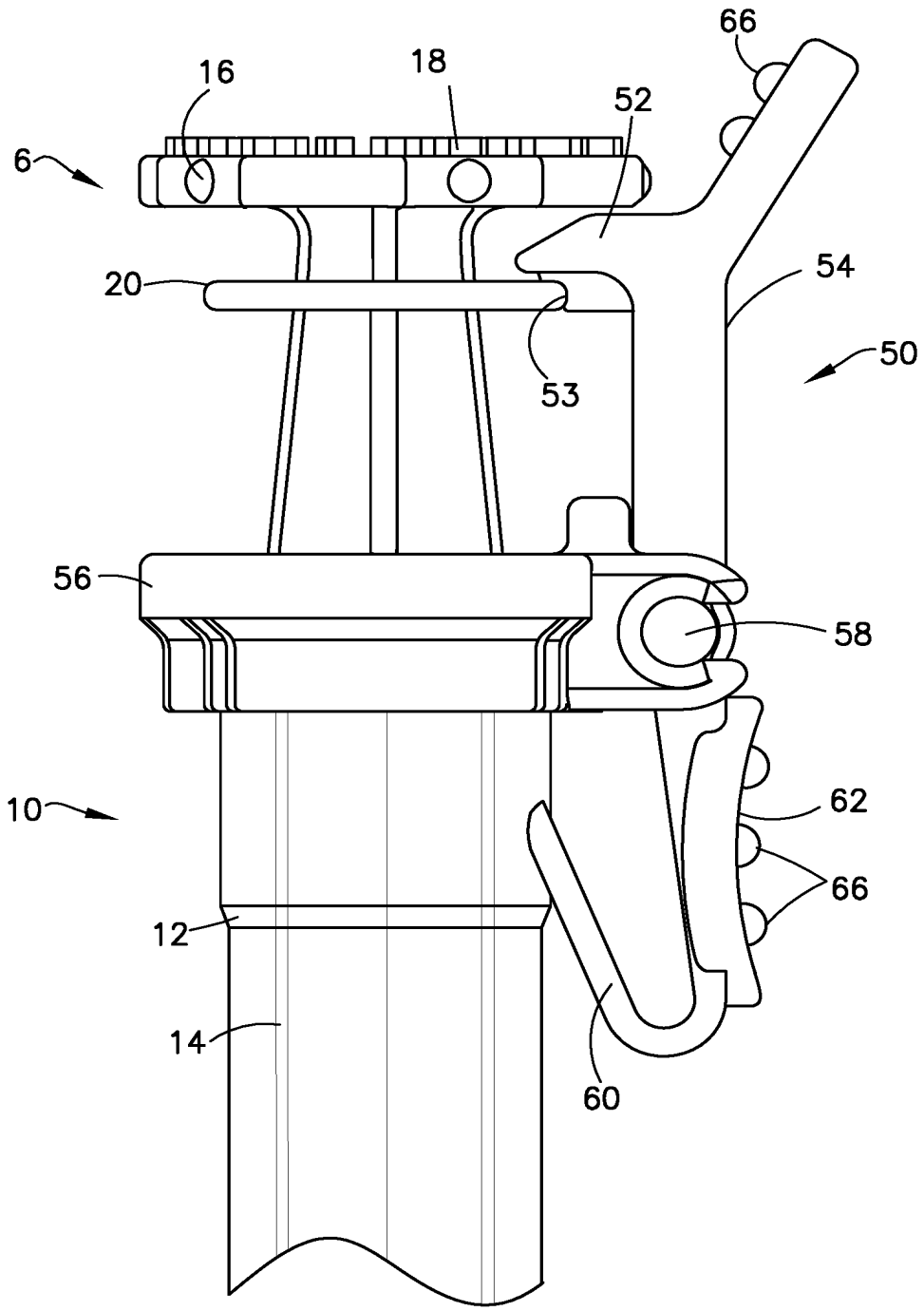


FIG.8

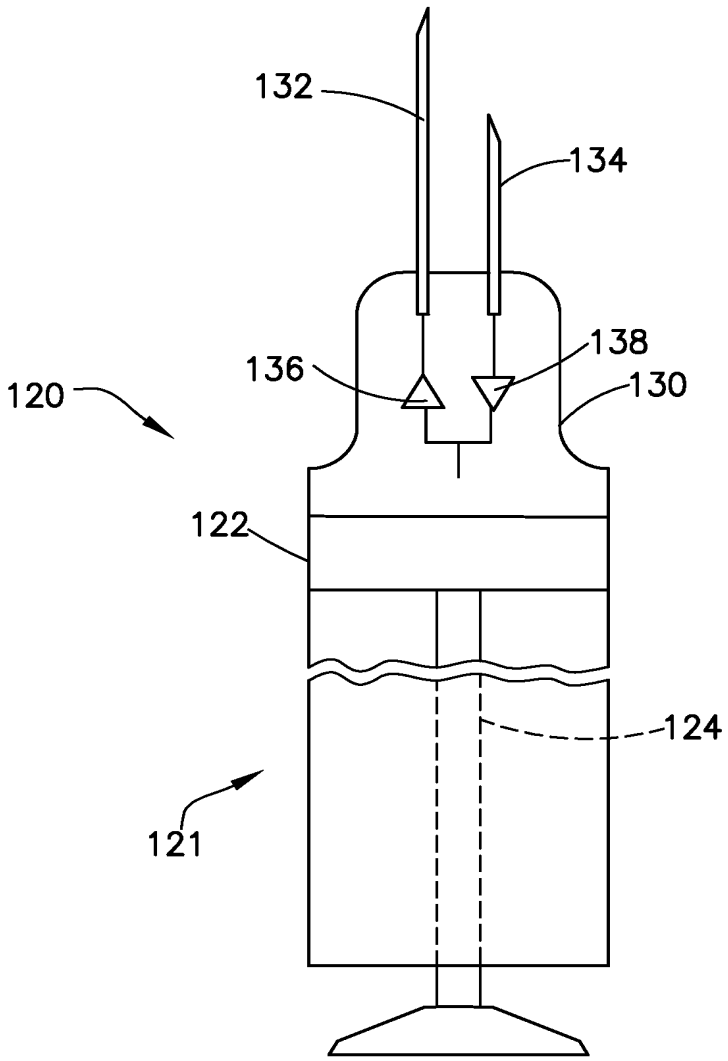


FIG.9

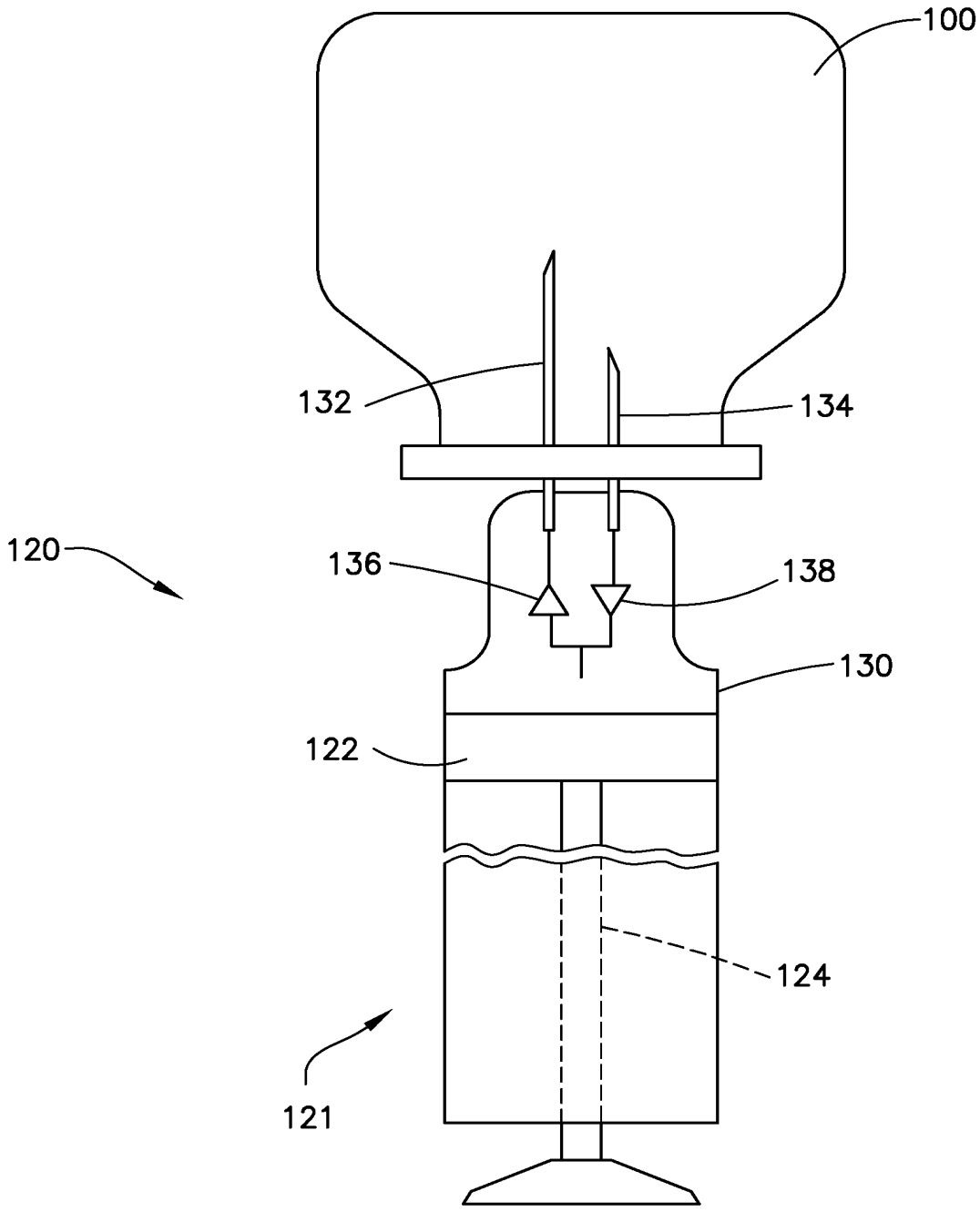


FIG.10

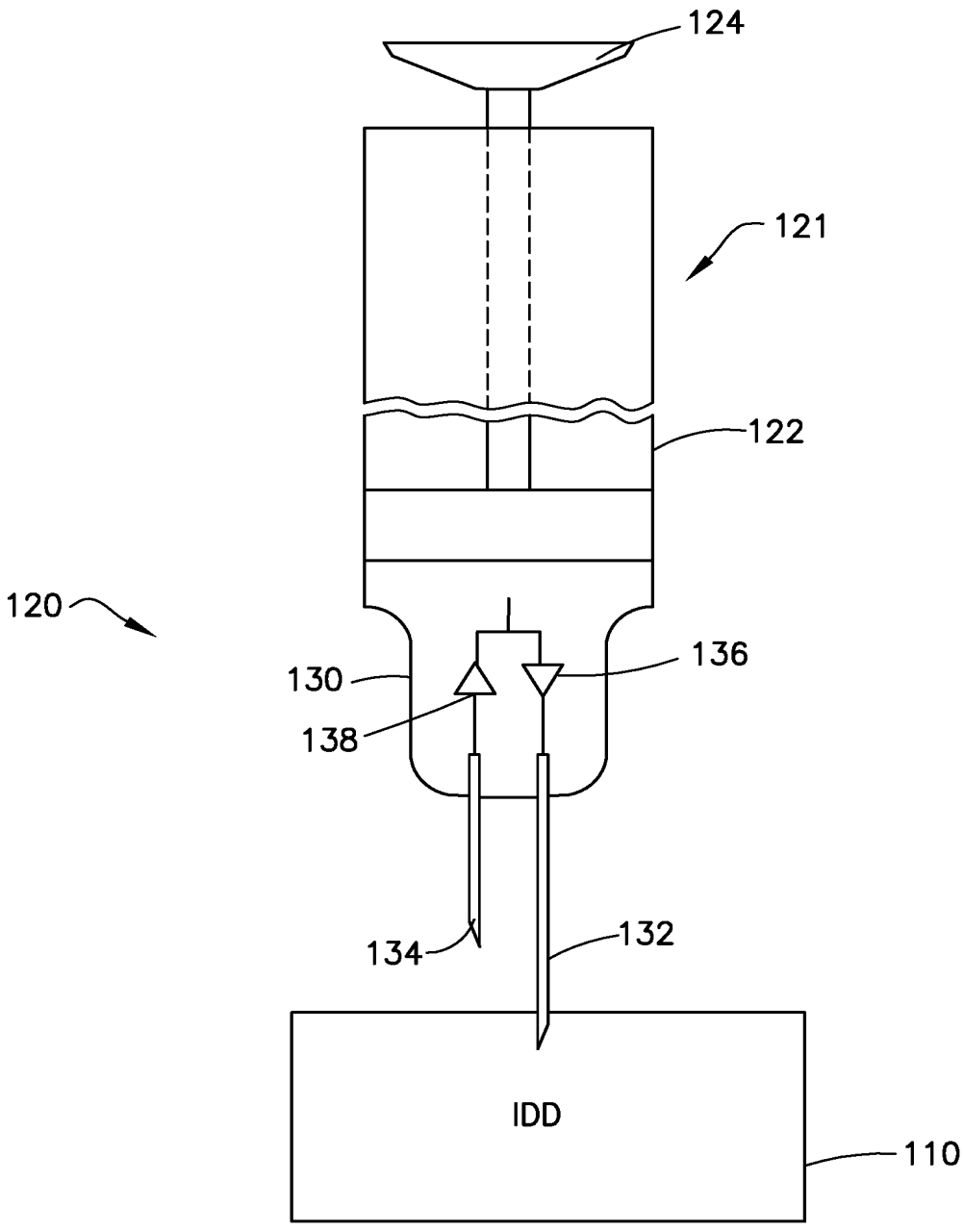


FIG.11

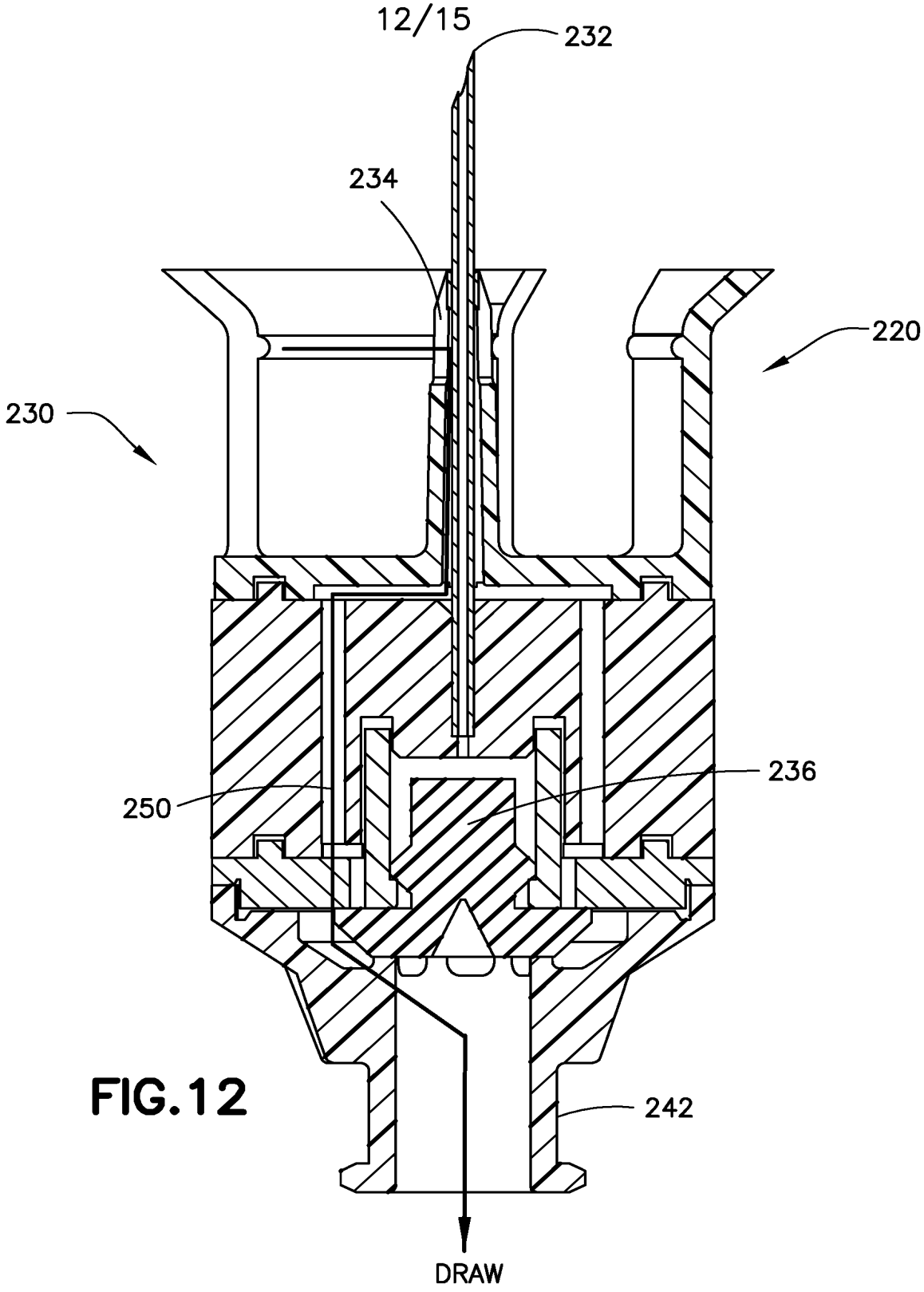


FIG.12

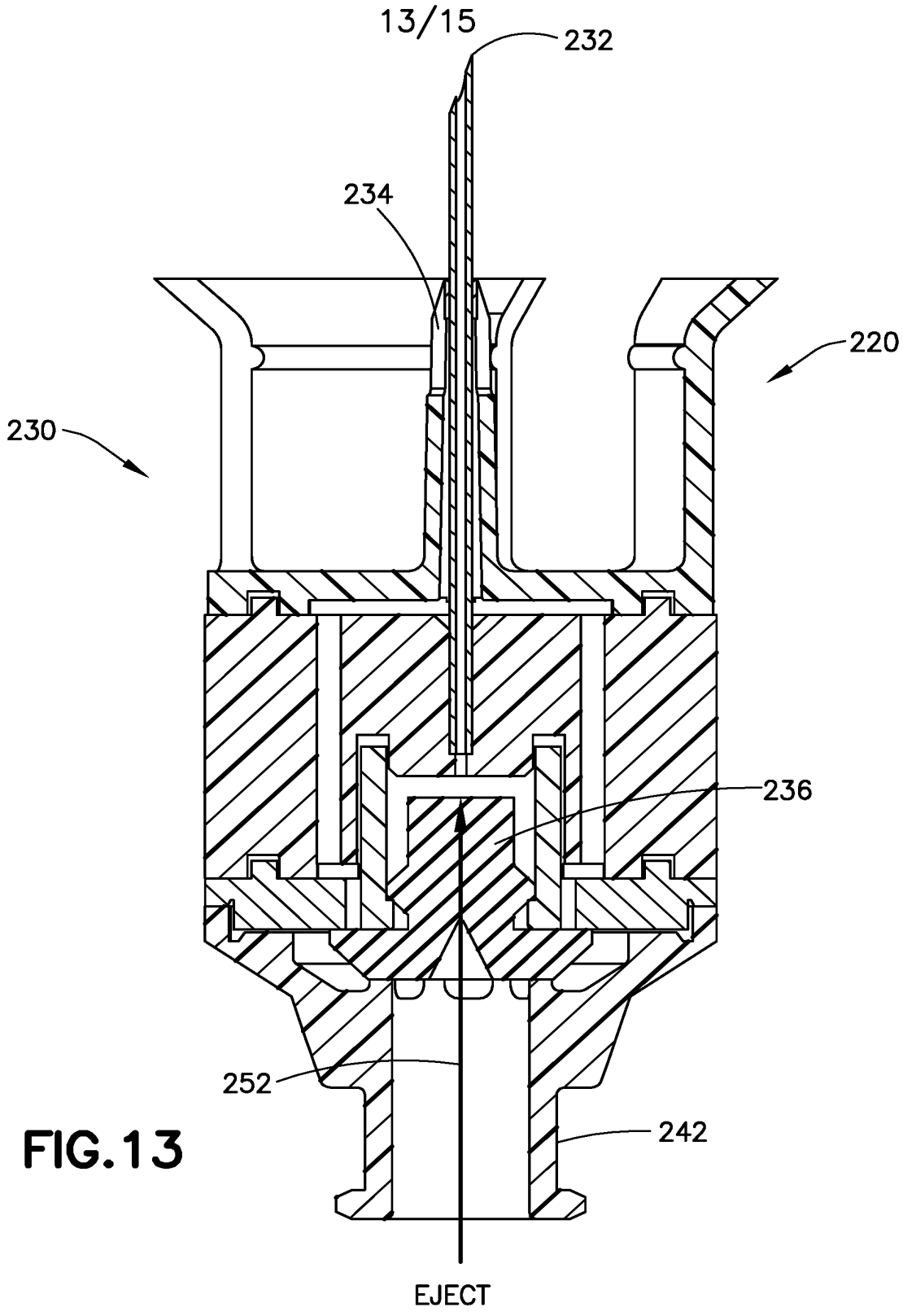


FIG.13

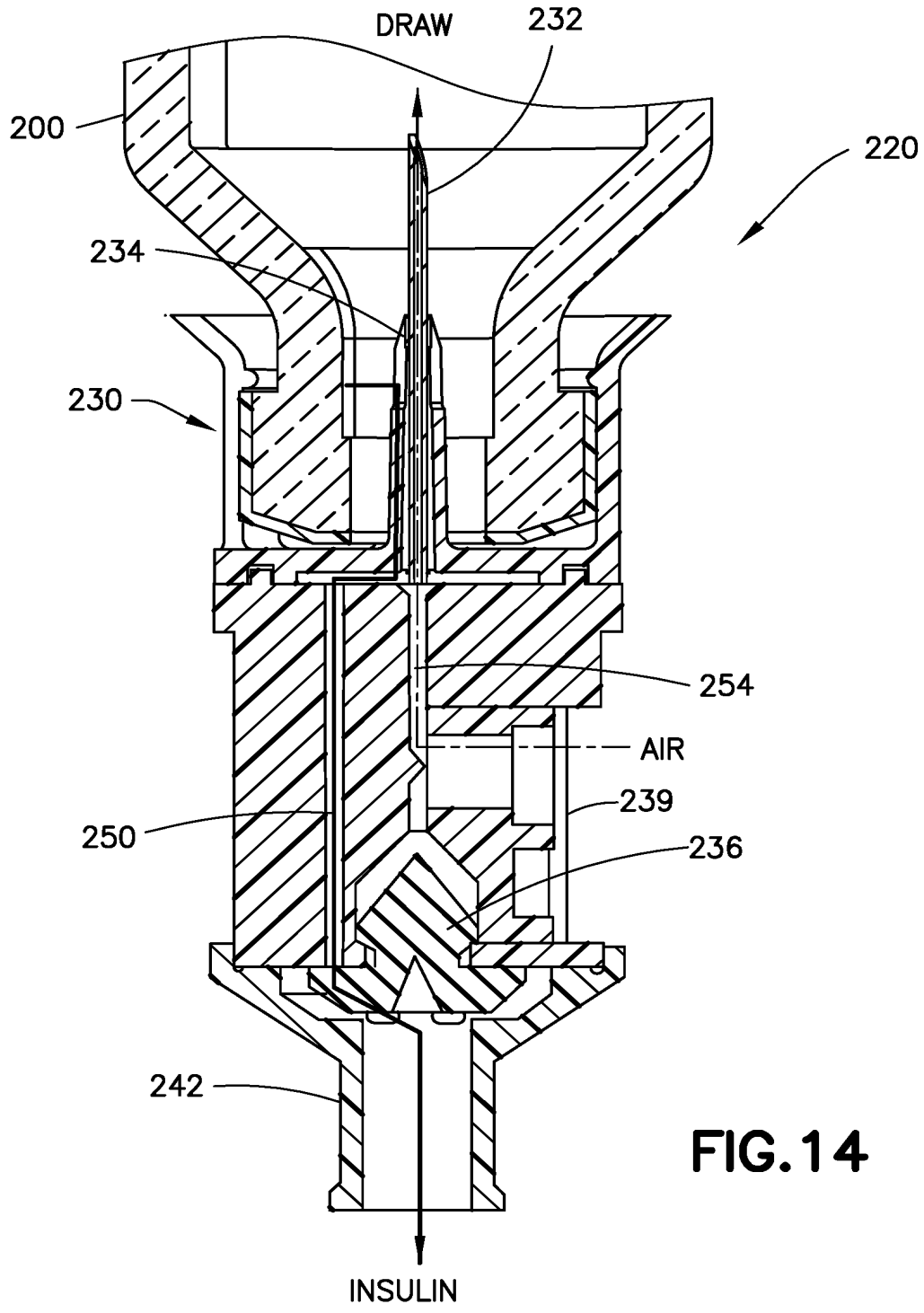


FIG.14

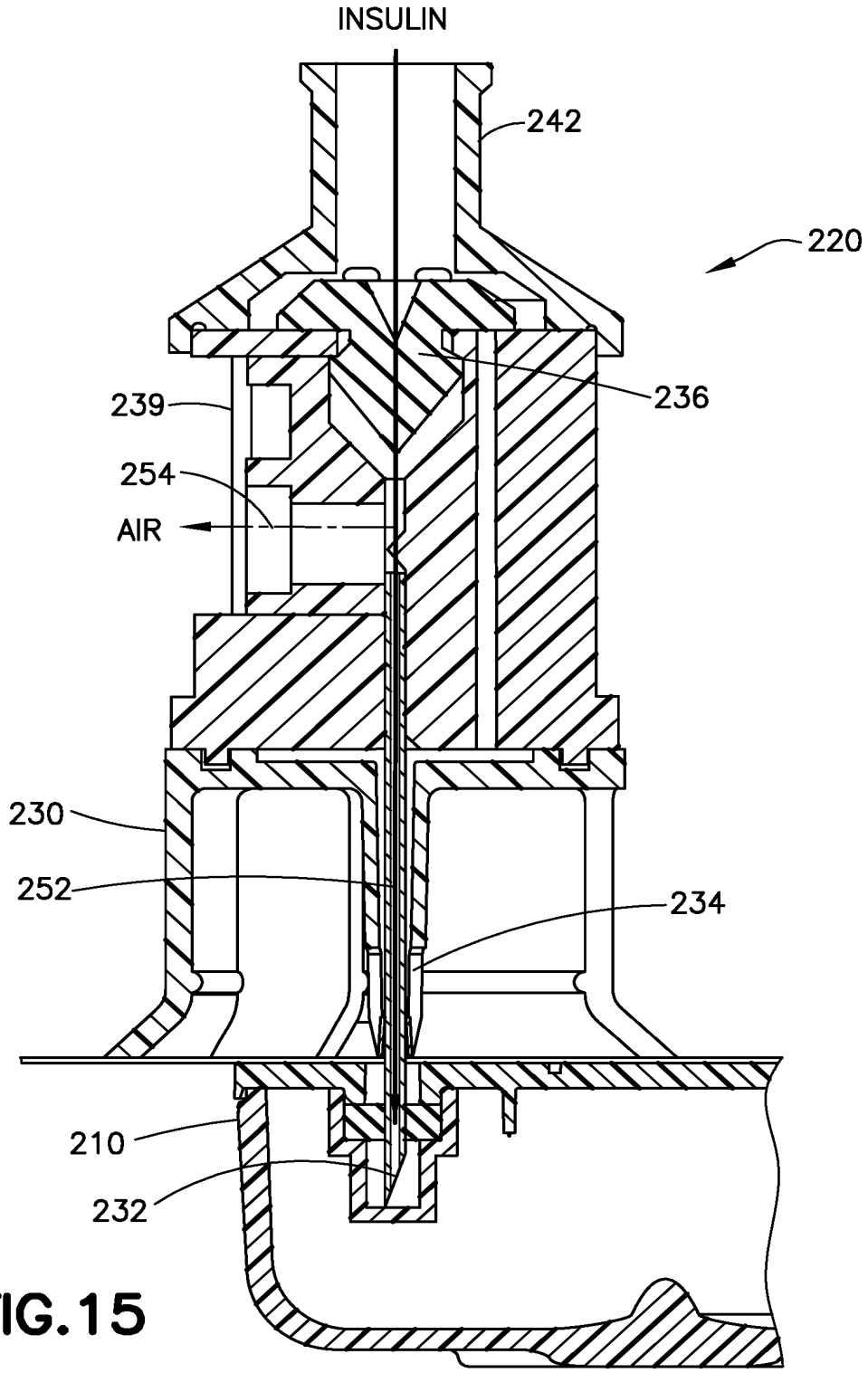


FIG.15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/52760

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 5/31; A61M 5/32; A61M 3/00; A61M 5/00 (2021.01)

CPC - A61M 5/31563; A61M 5/31536; A61M 5/32; A61M 2005/31508; A61M 2205/60; A61M 5/31591; A61M 5/31501; A61M 5/5013; A61M 5/3125; A61M 5/3126; A61M 2005/3139; A61M 5/3146; A61M 5/315; A61M 5/31525; A61M 5/31528; A61M 5/3153; A61M 5/31533; A61M 5/31536; A61M 5/3155; A61M 3/00; A61M 5/00

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)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

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 5,830,152 A (TAO) 3 November 1998 (03.11.1998); entire document, especially col 6 ln 14-51, and Fig. 1-2.	1 -- 2 -- 3-9
X -- A	WO 99/07421 A1 (GENESIS INDUSTRIES INCORPORATED) 18 February 1999 (18.02.1999); entire document, especially pg 6 ln 19 to pg 7 ln 12, and Fig. 1-2.	10 -- 11-13
X -- A	US 2010/0276034 A1 (GONNELLI et al.) 4 November 2010 (04.11.2010); entire document, especially para [0063], and Fig. 17.	14-17 -- 18-21
Y	US 4,498,904 A (TURNER et al.) 12 February 1985 (12.02.1985); especially col 3 ln 45-65, and Fig. 1-4.	2
A	US 2010/0084041 A1 (FEHR et al.) 8 April 2010 (08.04.2010); entire document.	1-21
A	US 2014/0018770 A1 (SUTKIN) 16 January 2014 (16.01.2014); entire document.	1-21

☐ 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
"D" document cited by the applicant in the international application
"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
13 January 2021	17 FEB 2021
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. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/52760

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:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-9 directed to a syringe assembly that locks a syringe to prevent backflow of medicament, having a locking assembly.

Group II: Claims 10-13 directed to a syringe assembly that provides haptic feedback during dose setting, having a plurality of axial ribs extending along a length of the plunger, a notch disposed in each axial rib, and a dose selector.

Group III: Claims 14-21 directed to a fluid transfer device, having a first needle cannula and a second needle cannula.

-*- See Supplemental Box -*-

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.:

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.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US 20/52760

-*- Box III.0 - Explanations where unity of invention is lacking -*-

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a locking assembly disposed around the barrel, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a dose selector disposed around the barrel wherein the dose selector passes through one of the notches to set a dose, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a first needle cannula that allows the medicament to exit the fluid transfer device, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of a syringe having a barrel configured to carry a medicament and a plunger connected to the barrel.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,735,825 A (STEVENS et al.) (hereinafter Stevens), which teaches a syringe (10; Fig. 1; col 5 ln 11-25) having a barrel (14; Fig. 1) configured to carry a medicament (fluid within 14; Fig. 1; col 5 ln 11-25) and a plunger connected to the barrel (12; Fig. 1).

Groups I-II share the common technical feature of a plunger head disposed on a proximal end of the plunger.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Stevens, which teaches a plunger head (32; Fig. 1) disposed on a proximal end of the plunger (12; Fig. 1).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

(12) STANDARD PATENT (11) Application No. **AU 2015210338 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
STEERABLE MEDICAL DELIVERY DEVICES AND METHODS OF USE

(51) International Patent Classification(s)
A61M 25/01 (2006.01) ***A61M 25/16*** (2006.01)
A61M 25/09 (2006.01)

(21) Application No: **2015210338** (22) Date of Filing: **2015.08.04**

(43) Publication Date: **2015.08.27**
(43) Publication Journal Date: **2015.08.27**
(44) Accepted Journal Date: **2018.02.01**

(62) Divisional of:
2010266027

(71) Applicant(s)
Shifamed Holdings, LLC

(72) Inventor(s)
Salahieh, Amr;Lepak, Jonah;Leung, Emma;Saul, Tom;Dueri, Jean-Pierre

(74) Agent / Attorney
Pizzeys Patent and Trade Mark Attorneys Pty Ltd, GPO Box 1374, BRISBANE, QLD, 4001, AU

(56) Related Art
US 5454787 A
WO 2006/122155 A1
US 6048339 A
US 2006/0241564 A1
EP 1927375 A2
WO 2006/012668 A1
US 2005/0131343 A1
US 7402151 B2

ABSTRACT

A steerable medical device, comprising a steerable portion; a first tubular member comprising a first flexible polymeric tubular member; and a second tubular member comprising a second flexible polymeric tubular member, wherein the first tubular member is disposed within the second tubular member and permanently axially fixed to the second tubular member at a fixation location distal to the steerable portion; and an external controller that is adapted to be actuated to put one of the first tubular member and the second tubular member in tension and the other of the first tubular member and the second tubular member in compression, and wherein the first and second tubular members are adapted such that the steerable portion is steered in a first direction when the external controller is actuated.

STEERABLE MEDICAL DELIVERY DEVICES AND METHODS OF USE

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. 61/220,160, filed June 24, 2009; U.S. Provisional Application No. 61/220,163, filed June 24, 2009; and U.S. Provisional Application No. 61/232,362, filed August 7, 2009, all of which are incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] Delivery devices are used to deliver, or guide, medical devices or instruments to a target location within a subject. The delivery devices provide access to target locations within the body where, for example, diagnostic, therapeutic, and interventional procedures are required. Access via these devices is generally minimally invasive, and can be either percutaneous, or through natural body orifices. The access can require providing a guiding path through a body lumen, such as, for example without limitation, a blood vessel, an esophagus, a trachea and adjoining bronchia, ducts, any portion of the gastro intestinal tract, and the lymphatics. Once the delivery device has provided access to the target location, the delivery device is then used to guide the medical device or instrument to perform the diagnostic, therapeutic, or interventional procedure. An example of such a delivery device is a guide catheter, which may be delivered by steering it to its required destination, tracking it along a previously delivered guide wire, or both. The list of components being delivered for use percutaneously is large and rapidly growing.

[0003] Minimal outer dimensions of these delivery devices are important for minimizing the injury associated with delivery. Minimizing the wall thickness of the delivery device provides additional space for the medical device to be guided, while minimizing the injury associated with entry into the subject and the closure needed. Flexibility of the delivery device is important in allowing the guiding device to track or be steered to its target destination along tortuous paths while minimizing injury to the intervening tissues. The delivery device also needs to have compressive and tensile properties sufficient to support its delivery to the target site. When tracking around bends in the body, any kinks created in the guiding device can create an obstruction to the delivery of the medical device. When used as a steerable device, the distal end of the delivery device is preferably deflectable over a range of bend radii and responsive to the steering controls. The delivery device also should support torque transmitted from the handle to the distal region.

[0004] Once the delivery device is in place the delivery device preferably also supports torque around a distal bend such that the medical device may be rotated into position while sustaining some contact loads. Additionally, once in place the guiding device preferably is sufficiently stiff to support and guide the medical device to its target destination. The guiding device should also remain stable and not shift from one state of equilibrium to another either spontaneously or under the influence of forces being imparted to it from the delivery of the medical device or its own control mechanisms. As the delivery

device often travels down fluid-filled lumens such as, for example without limitation, blood vessels, it should additionally incorporate a seal against fluids impinging upon its periphery and another at its distal end which interfaces with the medical device to maintain a seal around the delivery device.

[0005] There exists a need for improved steerable delivery devices and guiding medical devices.

SUMMARY OF THE INVENTION

[0006] One aspect of the disclosure is a steerable medical delivery device. The device includes a steerable portion comprising a first tubular member and a second tubular member, wherein one of the first and second tubular members is disposed within the other, wherein the first and second tubular elements are axially fixed relative to one another at a fixation location distal to the steerable portion, and wherein the first and second tubular members are axially movable relative to one another along the steerable portion to steer the steerable portion in a first direction, and wherein the first tubular member is adapted to preferentially bend in a first direction.

[0007] In some embodiments the second tubular member is substantially uniform and is not adapted to preferentially bend.

[0008] In some embodiments the first tubular member comprises at least one slot therein to define a first spine. The second tubular member can also include at least one slot therein to define a second spine.

[0009] In some embodiments the first tubular member comprises a braided material.

[0010] In some embodiments the first tubular member is disposed within the second elongate tubular member.

[0011] In some embodiments the first tubular member is adapted to be moved axially relative to the second tubular member to apply one of a compressive force and a tensile force to the first tubular member and the other of the compressive force and the tensile force to the second tubular member to steer the steerable portion in a first direction.

[0012] In some embodiments the second tubular member is adapted to preferentially bend in a second direction, which can be substantially opposite the first direction.

[0013] In some embodiments the second elongate tubular element is a floating tubular member.

[0014] One aspect of the disclosure is a steerable medical delivery device. The device includes a steerable portion comprising an outer tubular member and an inner tubular member, wherein the inner tubular member is disposed radially within the outer tubular member, wherein the outer tubular member includes at least one outer slot therein to define an outer spine, wherein the inner tubular member includes at least one inner slot therein to define an inner spine, the inner and outer spines being offset relative to one another, and wherein the outer tubular member and the inner tubular member are axially movable relative to one another along the steerable portion and are axially fixed relative to one another at a location distal to the steerable portion.

[0015] In some embodiments the outer tubular member comprises a plurality of discontinuous slots to define the outer spine.

[0016] In some embodiments the inner tubular member comprises a plurality of discontinuous slots to define the inner spine.

[0017] In some embodiments the inner and outer spines are offset substantially 180 degrees from one another.

[0018] In some embodiments the inner and outer spines are adapted to receive one of a compressive force and a tensile force to steer the steerable portion of the delivery device. The inner spine can be adapted to receive a compressive force thereto and the outer spine can be adapted to receive a tensile force thereto to steer the steerable portion of the delivery device in a first direction. Alternatively, the inner spine is adapted to receive a tensile force thereto and the inner spine is adapted to receive a compressive force thereto to steer the steerable portion of the delivery device in a first direction.

[0019] In some embodiments the inner and outer slots are in substantial alignment relative to a longitudinal axis of the steerable portion when the steerable portion is in a straightened configuration. The inner and outer slots can be substantially perpendicular to the longitudinal axis of the steerable portion when the steerable portion is in a straightened configuration.

[0020] In some embodiments the inner and outer slots are not in alignment relative to a longitudinal axis of the steerable portion when the steerable portion is in a straightened configuration.

[0021] In some embodiments at least one of the outer slot and the inner slot includes a first interlocking element and a second interlocking element each adapted to allow relative movement therebetween when in a first configuration and each further adapted to prevent movement therebetween when in a second configuration.

[0022] In some embodiments the delivery device further comprises a fixation element distal to the steerable portion adapted to prevent axial movement between the outer tubular element and the inner tubular element.

[0023] In some embodiments the inner tubular member has an inner surface, and wherein the inner surface is sized to allow a medical device to be advanced therethrough.

[0024] One aspect of the disclosure is a method of steering a medical delivery device. The method includes a steerable medical delivery device comprising a steerable portion with an outer tubular member and an inner tubular member, wherein the outer tubular member includes at least one outer slot therein to define an outer spine, and wherein the inner tubular members includes at least one inner slot therein to define an inner spine, the inner and outer spines being offset relative to one another. The method includes applying a compressive force to one of the inner and outer spines and a tensile force to the other of the inner and outer spines to steer the steerable portion from a first configuration to a second configuration. The method also includes preventing relative axial movement of the inner tubular member and outer tubular member at a location distal to the steerable portion while the steerable portion is being steered.

[0025] In some embodiments the applying step comprises applying the compressive force to the inner spine, and wherein applying the compressive force to the inner spine causes the tensile force to be applied to the outer spine to steer the steerable portion. Applying the compressive force to inner spine can include moving the inner tubular member distally relative to the outer tubular member.

[0026] In some embodiments the applying step comprises applying the tensile force to the inner spine, and wherein applying the tensile force to the inner spine causes the compressive force to be applied

to the outer spine to steer the steerable portion. Applying the tensile force to the inner spine can include moving the inner tubular member proximally relative to the outer tubular member.

[0027] In some embodiments the applying step comprises applying the compressive force to the outer spine, and wherein applying the compressive force to the outer spine causes the tensile force to be applied to the inner spine to steer the steerable portion. Applying the compressive force to the outer spine can include moving the outer spine distally relative to the inner tubular member.

[0028] In some embodiments the applying step comprises applying the tensile force to the outer spine, and wherein applying the tensile force to the outer spine causes the compressive force to be applied to the inner spine to steer the steerable portion. Applying the tensile force to the outer spine can include moving the outer tubular element proximally relative to the inner tubular member.

[0029] One aspect of the disclosure is a steerable medical delivery device. The medical device includes an elongate member comprising a steerable portion adapted to be steered in a first direction, and a floating element disposed within the steerable portion, wherein the floating element is axially fixed relative to the elongate member at a location proximal to the steerable portion, and is not axially fixed relative to the elongate member along the steerable portion.

[0030] In some embodiments the elongate member is a catheter.

[0031] In some embodiments the elongate member comprises an inner tubular member with an inner slot therein to define a first spine, and an outer tubular member with an outer slot therein to define an outer spine, wherein the spines are offset from one another.

INCORPORATION BY REFERENCE

[0032] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] The novel features of the invention are set forth with particularity in the disclosure herein. 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 disclosure are utilized, and the accompanying drawings of which:

[0034] FIG. 1 is a perspective view of a steerable portion of a steerable medical delivery device.

[0035] FIGS. 2a, 2b, and 2c illustrate steering of exemplary steerable portions of steerable medical delivery devices

[0036] FIG. 3 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

[0037] FIG. 4 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

[0038] FIG. 5 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

[0039] FIG. 6 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

[0040] FIGS. 7a and 7b illustrate flattened views showing exemplary slot patterns for use in a steerable portion of a delivery device.

[0041] FIG. 8 illustrates an exemplary steerable portion including an outer slotted tubular member and an inner slotted tubular member, with an intermediate tubular element therebetween.

[0042] FIG. 9 illustrates an exemplary steerable portion including an outer slotted tubular member and an inner non-slotted tubular member.

[0043] FIG. 10 illustrates an exemplary steerable portion including an inner slotted tubular member and outer non-slotted tubular member.

[0044] FIG. 11a is a representation of a pattern for use in a steerable portion capable of being cut from a tube or created by winding a ribbon into a tube.

[0045] FIG. 11b illustrates a section of a ribbon for use in the tube of FIG. 11a.

[0046] FIGS. 12a and 12b are different views of a groove pattern for use in a steerable portion.

[0047] FIGS. 13a, 13b, and 13c are various views of a cut pattern for use in a guide catheter

[0048] FIG. 14 illustrates an outer guide member and a delivery device therein.

[0049] FIG. 15 illustrates a discontinuous cut pattern for use on a tubular member that is most steerable in compression.

[0050] FIGS. 16a and 16b illustrate a portion of a tubular member formed with the cut pattern from FIG. 15, while FIG. 16c illustrates compressive and tensile forces acting thereon.

[0051] FIG. 17 is a graph illustrating Force v. Displacement behavior associated with the application of loads or displacements at various points around the tubular member shown in FIGS. 15-16c.

[0052] FIG. 18 illustrates a continuous cut pattern for use on a tubular member that is most steerable in tension.

[0053] FIG. 19 illustrates a discontinuous cut pattern for use on a tubular member most steerable in tension.

[0054] FIG. 20 illustrates a continuous cut pattern for use on a tubular member most deflectable in tension.

[0055] FIG. 21 illustrates a discontinuous cut pattern for use on a tubular member with a substantially straight, continuous spine.

[0056] FIG. 22 illustrates a discontinuous cut pattern for use on a tubular member with a helical, continuous spine.

[0057] FIG. 23 is a flattened view of an exemplary tubular member with more than one spines.

[0058] FIG. 24 is a flattened view of an exemplary member with a single substantially straight spine.

[0059] FIG. 25 illustrates a flattened portion of an exemplary tubular member. The slots create a relatively neutral pattern.

[0060] FIG. 26 illustrates a flattened portion of an exemplary tubular member including interlocking features with complimentary curved surfaces that are adapted to support rotation of the tubular member.

[0061] FIG. 27 illustrates an exemplary steerable delivery device including a floating tubular member disposed therein.

[0062] FIG. 28 illustrates an exemplary steerable medical delivery system.

[0063] FIGS. 29A and 29B illustrate an exemplary embodiment of a lockable portion of a guiding device.

[0064] FIGS. 30A-30H illustrate exemplary beads that can be used in a lockable guiding device.

DETAILED DESCRIPTION OF THE INVENTION

[0065] The disclosure relates generally to steerable delivery devices, which may be considered steerable guide devices, and their methods of use. The steerable delivery devices can be used to deliver, or guide, any type of suitable medical device or instrument therethrough to a location within a patient's body. For example, the steerable delivery devices can be used to deliver, or guide, a medical device into bodily lumens such as, for example without limitation, a blood vessel, an esophagus, a trachea and possibly adjoining bronchia, any portion of the gastrointestinal tract, an abdominal cavity, a thoracic cavity, various other ducts within the body, and the lymphatics. Once the steerable delivery device has gained access to a target location within the subject, the medical device or instrument is delivered, or guided, to the target location to carry out the medical intervention. Steerable delivery devices described herein can be tracked along a previously delivered guide wire.

[0066] Figure 1 is a perspective view of a distal portion of an exemplary steerable delivery device. Steerable device 10 includes steerable portion 12 and has distal end 15. Steerable portion 12 includes an outer tubular member 14 and inner tubular member 16. Outer tubular member 14 has an inner surface defining a lumen therein, and inner tubular member 14 is sized to be disposed within the inner lumen of outer tubular member 14. Outer tubular member 14 and inner tubular member 16 are axially fixed relative to one another at fixation location 18 along the length of steerable device 10. That is, at fixation location 18, the inner and outer tubular members are not adapted to move distally or proximally relative to one another. Fixation location 18 is located distal to steerable portion 12. At locations proximal to fixation location 18, inner tubular member 16 and outer tubular member 14 are axially movable relative to one another. That is, along steerable portion 12, inner tubular member 16 and outer tubular member 14 are adapted to move axially relative to another. Outer tubular member 14 has slots 22 formed therein to define spine 20. Spine 20 extends along a length of steerable portion 12. Slots 22 are shown substantially perpendicular to the longitudinal axis "L" of steerable portion 12, when steerable portion 12 is in a straightened configuration as shown in Figure 1. Inner tubular member 16 also has slots formed therein (not shown) in the steerable portion to define a spine (not shown).

[0067] Figures 2a and 2b illustrate an exemplary embodiment of a steerable delivery device. Steerable device 30 has a distal end 37 and includes outer tubular element 34 and inner tubular element 36 which are axially immovable relative to one another at fixation location 38, but are axially movable proximal to fixation location 38. Outer tubular element 34 includes a plurality of slots 42 formed therein to define spine 40. Inner tubular element 36 also includes a plurality of slots formed therein (not shown) to define a spine (not shown). In Figures 2a and 2b, the spines are disposed substantially 180 degrees

apart from one another. Figure 2a illustrates steerable portion 32 deflected, or steered, into a first bent configuration, while Figure 2b illustrates steerable portion 32 steered into a second bent configuration different than the first bent configuration. To steer the steerable portion into the configuration shown in Figure 2a, a proximal portion of outer tubular member 34 is moved axially, and specifically proximally, relative to inner tubular member 36, while the tubular elements 34 and 36 are axially fixed relative to one another at fixation location 38. This can be accomplished by pulling outer tubular member 23 in a proximal "P" direction while maintaining the position of inner tubular member 36, by pushing inner tubular member 36 in a distal "D" direction while maintaining the position of outer tubular member, or by a combination thereof. The relative axial movement of the inner and outer tubular members as shown in Figure 2a applies substantially opposing compressive and tensile forces to the spines of the tubular members, thus deflecting, or steering, the device in the direction of spine 40 of outer tubular member 34, as is shown in Figure 2a. Figure 2b illustrates a step of steering device 30 in the substantially opposite direction from that shown in Figure 2a. To steer device 30 into the configuration shown in Figure 2b, inner tubular member is moved proximally relative to outer tubular member 34. This can be performed by moving the outer tubular member distally, moving the inner tubular member proximally, or a combination thereof. This relative axial movement applies substantially opposing compressive and tensile forces to the spines in steerable portion 32 of device 30, thereby deflecting the device in a direction substantially opposite that of spine 40 of outer tubular member 34.

[0068] Figure 2c shows a sectional view of the steerable portion from Figure 2b, including optional floating tubular member 505 disposed within inner tubular member 504. Steerable portion 500 includes inner tubular member 504 and outer tubular member 502. Inner tubular member 504 has interrupted slots 512 formed therein to define spine 506. Outer tubular member 502 has interrupted slots 510 formed therein to define spine 508. The steerable portion is bent along the axis of spine 506. Spine 508 and spine 506 are substantially 180 degrees apart from one another (i.e., they are on substantially opposite sides of steerable portion 500).

[0069] To steer steerable portion 500 into the configuration shown in Figure 2c (also shown in Figure 2b), inner tubular member 504 is pulled in the proximal direction relative to outer tubular member 502, as is illustrated in Figure 2b. Pulling on the inner member 504 applies a tensile force to inner spine 506. Because inner and outer tubular members 504 and 502 are axially fixed relative to one another at a location distal to the steerable portion, pulling on inner member 504 relative to outer tubular member 502 results in a compressive force applied to the distal end of the steerable portion of outer tubular member 502. The compressive force begins to compress slots 510 on outer tubular member 502. Compression of outer slots 510 causes outer tubular member to bend in the direction shown in Figure 2c, and the bending stops when inner slots 510 are closed. Thus, outer slots 510 limit the degree of the bend of steerable portion 500. The same type of bending that is shown in Figures 2b and 2c would occur if outer tubular element 502 were pushed distally relative to inner tubular member 504.

[0070] If outer tubular member 502 were pulled proximally relative to inner tubular member 504 (or if inner tubular member 504 were pushed distally relative to outer tubular member 502), steerable portion

500 would bend in the manner shown in Figure 2a. The degree of the bend would be limited by inner slots 512.

[0071] Figure 2c illustrates an embodiment of a medical device including a floating tubular member, which may be referred to herein as a floating liner. In general, a floating liner is disposed within an outer structure. In the exemplary embodiment in Figure 2c, the outer structure includes the inner and outer tubular members. The outer structure generally provides structural and mechanical properties for the delivery device, and the floating liner provides lubricity for a medical device or instrument to be advanced therethrough. A floating liner is generally impermeable as well. A floating liner "floats" with a portion of the outer structure. That is, the floating liner is not fixed to a portion of the outer structure in which it floats. In the exemplary embodiment in Figures 2c, the floating liner floats within the steerable portion (i.e., is not attached to the steerable portion). In general, a floating liner is attached to the outer structure at a location proximal to the steerable or bendable portion of the device. For example, in the embodiment in Figure 2C, the floating liner is attached to the outer structure at a location proximal to the steerable portion. A floating liner doesn't impede the ability of the outer structure to move as it is steered, bent, actuated, receives forces applied thereto, etc.

[0072] In some embodiments the floating liner is a lubricious polymer tube. In some embodiments the floating liner includes wire windings and/or axially laid wires.

[0073] The outer structure in which the floating liner floats can be any suitable tubular member. For example, the outer structure can be a catheter, guiding device, a steerable device, etc. In some embodiments the outer structure has a neutral bending preference but is not intended to be steered. In this embodiment the outer structure provides axial and radial stiffness thereby limiting the likelihood of kinks while the floating liner provides lubricity and is additionally restrained from kinking by the outer structure.

[0074] Figures 2a and 2b also show proximal portion 35 of device 30, which is proximal to steerable portion 32, having a substantially neutral portion designed to have no preferential bending axis while at the same time transmitting axial force and torque applied at a proximal end of the device (not shown).

[0075] In some embodiments, the inner and outer tubular members are adapted to have opposing compressive and tensile loads applied thereto to steer the steerable portion. In some embodiments at least one of the tubular members has a neutral bending axis. A neutral bending axis, as used herein, generally refers to an axis of the tubular member along which there is substantially no axial displacement in response to a compressive and/or tensile force applied thereto. Axial displacement along the neutral bending axis, in response to a compressive and/or tensile force applied thereto, is less than axial displacement of structures elsewhere in the tubular member. In particular, axial displacement along the neutral bending axis is minimal relative to axial displacement of structures elsewhere in the tubular member. Examples of a neutral bending axis include spine 382 in Figure 21 and spines 412 and 414 in Figure 23.

[0076] In some embodiments at least one of the tubular members is adapted to offset the neutral bending axis relative to the opposite tubular member. The neutral bending axes of the tubular members

can be offset to be approximately tangent to opposite sides of the opposing members, making the neutral bending axis offset equal to the diameter of the device, thus providing the highest possible bending leverage ratio for a given device diameter.

[0077] The tubular members described herein may exhibit preferential or neutral bending behavior. Neutral bending behavior implies that the displacement for a given radially applied load (from the edge of the tubular member through the longitudinal axis of the tubular member) will be independent of the radial angle from which the load was applied. In contrast, in a non-neutral structure the displacement associated with a radial load will change as a function of the radial angle. An exemplary tubular member tending towards neutral bending behavior is shown in Figure 25 or the uninterrupted spiral pattern of Figure 25 which is essentially a spring.

[0078] In some embodiments the inner and outer tubular elements are adapted to be rotated relative to one another to enhance the steerability of the steerable portion. The tubular elements can rotate relative to one another yet remain axially fixed relative to one another at a location distal to the steerable portion. In these embodiments, in addition to axial forces being applied to one or more tubes, one or more tubular members are also rotated with respect to each other to steer the steerable portion.

[0079] In some embodiments only one of the inner and outer tubular members has at least one slot defining a spine along the steerable portion, while the other does not have any slots along the steerable portion. For example, in Figures 2a and 2b, outer tubular member 34 can have a slot and a spine while inner tubular member 36 does not have a slot formed therein. Alternatively, inner tubular member 36 can have at least one slot and a spine while outer tubular member 34 does not have a slot formed therein. The steerable portion can be steered as described herein if at least one of the inner and outer tubular members is adapted to preferentially bend in a first direction.

[0080] In the embodiment in Figures 1 and 2 the slots in both tubular members are substantially perpendicular to the longitudinal axis of the steerable portion. The slots in one or both of the tubular members can be, however, at an angle relative to the longitudinal axis that is other than substantially 90 degrees.

[0081] In some embodiments the steerable device also includes a tubular element disposed between the inner and outer tubular members. The intermediate member can be, for example without limitation, a flexible polymeric material. The intermediate member can be encasing one or both of the tubular members, or comprising one or both of the members. The intermediate member can be adapted to provide a fluid barrier and/or a low friction surface.

[0082] Slots as described herein can be formed in a tubular member by laser machining or other machining processes. Forming the slots creates at least one spine in a tubular member. A spine as used herein can be considered a region of the steerable portion that imparts axial stiffness in compression or tension, or both, and may additionally include features that provide torsional stiffness. When a single spine is created in a tubular member, the neutral bending axis of the tubular member is moved to the spine of the tubular member.

[0083] In some embodiments, a tubular member includes at least two spines, the combination of which moves the neutral bending axis of the tubular member to an axis parallel to, or tangent to when bent, the longitudinal axis of the tubular device and passing through the spines.

[0084] In some embodiments a liner, such as a flexible polymer liner, is bonded on the inner surface of the inner tubular member. In some embodiments a flexible polymer is bonded or otherwise disposed over the outer surface of the outer tubular member. A liner can also be disposed such that it is encasing the inner tubular member.

[0085] In some embodiments the steerable portion is comprised of a first tubular member that is adapted to bend preferentially in a first direction and a second tubular member that is not adapted to bend preferentially in one direction. In some instances of these embodiments, the second tubular member is a flexible polymer material with or without a braided or wire support. In some instances, a wire or other structural support is included in the first tubular member in the deflectable area to increase compressive and tensile stiffness along one side of the tubular member, thus moving the neutral bending axis from the longitudinal axis of the tubular member to the side of the tubular member that includes the structural support. In some instances wires are laid longitudinally and distributed evenly to increase axial stiffness in tension without creating a preferential bending.

[0086] In some embodiments the device includes three tubular members, having three offset neutral bending axes approximately 120 degrees radially spaced apart, thus providing the steerable device with universal steering in any direction.

[0087] Figure 3 illustrates, for ease of description, a flattened, or unrolled, portion of exemplary tubular member 50, which can be an inner or an outer tubular member. Tubular member 50 includes fixation region 52, steerable portion 54, and a proximal neutral portion 58. Steerable portion 54 includes a plurality of slots 56 formed therein to define spine 55 extending along the steerable portion. Slots 56 are sinuous-shaped slots, and spine 55 has a generally straight configuration along the length of steerable portion 54. That is, spine 55 is substantially parallel with the longitudinal axis of the tubular member. Fixation region 52 includes a plurality of holes 57 to facilitate bonding to provide for axial fixation relative to a second tubular member (not shown). Proximal portion 58 includes a plurality of multiple overlapping slots 60 to provide the desired flexibility, axial force transmission, and torque transmission characteristics.

[0088] Figure 4 illustrates a flattened, or unrolled, portion of exemplary tubular member 61, which can be an inner or an outer tubular member of a steerable portion. Tubular member 61 includes fixation region 62, steerable portion 64, and proximal neutral bending portion 68. Neutral bending portion 68 will exhibit minimal bending preference upon a compressive or tensile force applied thereto. Tubular member 61 is similar to tubular member 50 shown in Figure 3, but includes linking elements 72, which can be flexible. Each linking element extends from one side of a slot to the other side. Each linking element includes two arm portions extending from one side of the slot to the other side of the slot. The two arms meet at the point at which they are connected to one side of the slot. The linking elements extend along steerable portion 64 on substantially the opposite side as spine 65. Linking elements 72 enhance and/or

control torque response and bending of steerable portion 64. As steerable portion 64 is bent about spine 65, linking elements 72 bend and stretch under tension. As steerable portion 64 is twisted, or put in torque, linking elements 72 are put in compression. In torque, the gap between a given linking element and the section of the tubular member proximally adjacent to the given linking element collapses, effectively increasing the torsional stiffness of steerable portion 64.

[0089] Figure 5 illustrates a flattened portion of exemplary tubular member 80, including fixation portion 82, steerable portion 84, and proximal neutral portion 86. The embodiment in Figure 5 is similar to the outer tubular member as shown in Figures 2a and 2b. Steerable portion 84 includes substantially straight slots 90 that are substantially perpendicular to the longitudinal axis of tubular member 80. Spine 88 is substantially straight in configuration, extending along the length of steerable portion 84 substantially parallel to the longitudinal axis of the tubular member 80. Fixation portion 82 includes holes 92 therethrough (four shown) to facilitate bonding. Proximal portion 86 has multiple overlapping slots 94 to give the desired flexibility, axial force and torque transmission.

[0090] Figure 6 illustrates a flattened portion of exemplary tubular member 96, including fixation portion 98, steerable portion 100, and proximal neutral portion 102. Steerable portion 100 includes substantially straight slots 108 that are substantially perpendicular to the longitudinal axis of tubular member 96, but each is offset relative to the adjacent slot so that spine 106 has a sinuous shape extending along the length of steerable portion 100. Fixation portion 98 includes holes 104 therethrough (four shown) to facilitate bonding. Proximal portion 102 includes multiple overlapping slots 110 to give the desired flexibility, axial force and torque transmission characteristics.

[0091] Figures 7a and 7b illustrate exemplary portions of flattened first and second tubular members 112 and 128. First tubular member 112 can be an inner tubular member and second tubular member 128 can be an outer tubular member, or first tubular member 112 can be an outer tubular member and second tubular member 128 can be an inner tubular member. Tubular members 112 and 128 can be assembled as part of a steerable delivery device. That is, one of the first and second tubular members can be disposed within the other. First tubular member 112 includes fixation portion 114, steerable portion 116, and proximal neutral portion 118. Fixation portion 114 includes holes 120. Steerable portion 116 has slots 124 formed therein to define spine 122. Spine 122 has a generally sinuous shape. Proximal portion 118 includes a plurality of overlapping slots 126. Second tubular member 128 includes fixation portion 130, steerable portion 132, and proximal neutral portion 134. Fixation portion 130 includes holes 136. Steerable portion 132 has slots 140 formed therein to define spine 138. Spine 138 has a generally sinuous shape. Proximal portion 134 includes a plurality of overlapping slots 142.

[0092] In Figures 7a and 7b, the slots in each of tubular members 112 and 128 are offset relative to the adjacent slot, interrupted, and have a general helical configuration. Spines 122 and 138 have generally sinuous configurations. The slots in the tubular members are at the same angle relative to the longitudinal axis of the tubular member, but are formed in opposite helical patterns. A advantage of having inner and outer tubular members with slots that are not in alignment (as opposed to inner and outer tubular members that have slots perpendicular to the longitudinal axis of the tubular member) is that the

slots are less likely to get caught up on one another as the steerable portion is steered. The angled slots shown in Figures 7a and 7b also provide for an increased torque response based on a torque applied at the proximal end of the device.

[0093] Figure 8 illustrates a portion of an exemplary steerable delivery device. Steerable device 150 includes outer tubular member 152, inner tubular member 154, and intermediate tubular member 156. A portion of outer tubular member 152 and intermediate member 156 are cut away to show inner tubular member 154. Intermediate tubular member 156 can be a flexible polymeric tube. Inner and outer tubes 152 and 154 have slots 160, 164 formed therein to define spines 158 and 162. The spines are substantially 180 degrees apart, as shown. The slots formed in the respective tubular members are at an angle relative to the longitudinal axis of the steerable portion and are formed in opposite helical patterns.

[0094] Figure 9 illustrates a portion of an exemplary steerable delivery device. Steerable device 166 includes outer tubular member 168 and inner tubular member 170. Inner tubular member 170 can be a flexible polymeric tubular element. Outer tubular member 168 has a plurality of slots 174 formed therein to define spine 172. Inner tubular member 170 has no preferential bending axis. Inner tubular member 170 could alternatively have a modified bending axis offset by having, for example, a stiffening element incorporated into the wall of inner tubular member 170 approximately 180 degrees from spine 172. In some embodiments inner tubular member 170 may incorporate wire braids and or axially-laid wires which reduce kinkability and increase axial stiffness as is common in braided catheters or other similar known tubular medical devices.

[0095] Figure 10 illustrates a portion of an exemplary steerable delivery device. Steerable delivery device 178 includes outer tubular member 180 and inner tubular member 182. Outer tubular member 180 can be, for example, a flexible polymeric tubular member. Inner tubular member 182 has a plurality of slots 186 formed therein to define spine 184, which is substantially parallel to the longitudinal axis of the steerable portion. Outer tubular member 180 has no preferential bending axis. Alternatively, outer tubular member 180 can have a preferential bending axis. For example, a structural support element can be incorporated into the wall of outer tubular member 180 approximately 180 degrees from spine 184. Outer tubular member 180 can be substantially the same as inner tubular element 170 in Figure 9, but for any lubricity enhancing feature. In some embodiments inner tubular member 170 may incorporate wire braids and or axially laid wires which reduce kinkability and increase axial stiffness as is common in braided catheter or other similar known tubular medical device.

[0096] In an alternative embodiment, the device includes inner and outer slotted tubes, and additionally includes an outermost tubular member similar to 180 shown in Figure 10. The outermost tubular member can be, for example without limitation, a polymeric tubular member.

[0097] Figure 11a illustrates a portion of an exemplary embodiment of a first tubular member that can be included in a steerable delivery device. Tubular member 190 is a tubular member formed from a ribbon wire. Tubular member 190 has spine 192 formed by coiling a ribbon shaped with interlocking elements 194 and 196, which together form an interlocking feature along spine 192. Interlocking elements 194 and 196 may be press-fit to interlock the two. The interlocking elements can be encased

with a tubular member, such as a polymer tubular member, to secure them in place. The interlocking elements can also, or alternatively, have a polymer tubular member disposed therein to help secure them in place. In addition to the interlocking features, the ribbon wire has sections of decreased width 198 which once wound into a tubular structure create the steerable portion for flexibility. A second tubular member of the steerable delivery device can be created in a similar manner to the tubular member in Figure 11a. Figure 11b illustrates an embodiment of the ribbon with interlocking elements 196 and decreased width regions 200 between elements 196. The angle of interlocking elements 196 relative to the longitudinal axis of the tubular element can be varied based on the pitch of the coil. Such a pattern can additionally be fabricated by laser machining.

[0098] Figures 12a and 12b illustrate an exemplary embodiment of a tubular member. Tubular member 210 comprises a tube 214 with grooves 212 formed therein on the outer surface of tube 214. Grooves 212 do not extend all the way through tube 214. Tubular member can be, for example, a stiff polymeric tubular member. Figure 12a shows a sectional view of a portion of tubular 210 showing the depth of grooves 212 in the steerable portion. Figure 12b illustrates a flattened view of tubular member 210 showing grooves 212 formed in tube 214. Grooves 212 define a single substantially straight spine 216. Grooves 212 cut into tube 214 increase flexibility of the steerable portion to allow the steerable portion to be steered. Spine 216 provides for the application of compressive and tensile forces to steer the device. Because the cut does not go all the way through the wall of the tube, it inherently creates a fluid tight barrier and a lubricious liner. In some embodiments tubular member 210 can an inner or outer tubular member of a steerable device, and the other of the inner and outer tubular elements can also includes a tubular element with grooves formed thereon. In some embodiments the steerable device can also have a polymeric sleeve to encapsulate the outer tube to create a smooth outer surface.

[0099] Figure 13a illustrates a portion of an exemplary introducer sheath reinforcement member 220. Member 220 is formed by laser cutting a tubular member to slots or gaps therein. A helical slot 222 defines interlocking T-shaped patterns 224 formed in reinforcement member 220. The helical path is shown generally in helical path 226. Flexibility slots 228 are formed in member 220 to provide flexibility to member 220. Member 220 also includes bonding slots 230 formed therein to allow for bonding to one or more components of the device. Figure 13b illustrates member 220 from Figure 13a in a flattened pattern showing the interlocking T-shaped pattern along helical path 226, flexibility slots 228, and bonding slots 230. Figure 13c shows a close-up of the section shown in Figure 13b.

[00100] In some embodiments a guide catheter includes a relatively rigid metal or polymer reinforcement member (an example of which is shown in Figure 13a-13c) layered between an inner and an outer flexible polymer tube. The rigid reinforcement member can be laser machined or otherwise cut in a pattern in order to enhance flexibility along the longitudinal axis of the tube, to allow some limited radial compliance, and to allow bonding of the inner and outer flexible polymers. The slot pattern can include an interlocking T-shaped pattern arranged helically around the tube for flexibility and radial compliance, a slot pattern where the slots are substantially perpendicular to the tube longitudinal axis, and are patterned along the tube longitudinal axis to further enhance flexibility and bonding of said layers.

[00101] Figure 14 illustrates an exemplary embodiment of a guide system adapted to guide and deliver a therapeutic, diagnostic, interventional, or any other type of medical device 260 intraluminaly to a target location within a body. Guide system 250 includes outer guide member 252 and steerable delivery device 256, a portion of which is disposed within outer guide member 250. Steerable delivery device 256 can be, for example, any of the steerable delivery devices described herein. Outer guide member 252 has a preset bend 254 that can be formed by, for example, heat setting. Steerable delivery device 256 includes steerable portion 258, which can be formed as, for example, any of the steerable portions described herein. For example, steerable delivery device can include outer and inner tubular members, wherein at least one of the tubular members is adapted to preferentially bend in a first direction. In the embodiment shown in Figure 14, steerable portion 258 is comprised of a single steerable tubular member steered into the configuration shown in Figure 14 by actuating pull wire 264. Alternatively, steerable delivery device 256 can be comprised of the embodiment described in Figure 2, and steered by relative axial movement of inner and outer tubular members, as described herein.

[00102] Alternatively, outer guide member 252 can be adapted to be bent using optional pull wire 262, shown in Figure 14. In such an embodiment bend 254 may or may not preset. Guide member 250 comprises a tubular member incorporating a pattern of slots as described for steering portions herein. When located in position pull wire 262 is tensioned and the axial and torsional stiffness of bend 254 is thereby increased. A steerable outer guide member 252 in its delivery configuration (non-bent) is generally loose and compliant, but is tensioned or compressed to reconfigure it into a pre-set shape. Its stiffness in the bent configuration is a function of the amount of tension or compression applied and the particular slot pattern chosen.

[00103] Bend 254 in outer guide member 252 is compliant enough to be straightened for delivery, for example advanced on a guide wire, but rigid enough to be able to guide steerable delivery device 256 around bend 254. Steerable delivery device 256 is steerable and transmits torque.

[00104] The structural properties of the inner and outer tubular members of the steerable delivery device will determine the manner in which they respond to force applied thereon. The structural properties of the inner and/or outer tubes will depend on the tubing material and the design, or characteristics, of the slots created in the tubular members (unless one of the inner and outer tubular members does not have any slots therein). The design of the slot pattern is therefore a function of the required structural properties of the tubular member. For example, structural properties of the tubular member that can be modified by changing the design of the slots or slot patterns include flexural stiffness, torque transmission, steerability, radius of curvature, and allowable wall thickness of the steerable assembly.

[00105] Figure 15 is a flattened view and illustrates a portion of an exemplary steerable portion of a tubular member. Tubular member 290 can be an inner or an outer tubular member as described herein. Steerable portion 290 is typically a laser-cut tubular member, but may in fact be fabricated by any technique capable of creating the appropriate widths of cuts required (e.g., water jet, wire EDM, etc.) wherein first cut, or slot, 292 is made, defined by first surface 294 and second surface 296. Slot 292

extends almost all the way around tubular member 290, and defines spine 308. Slots 282 are thickest, along the tubular longitudinal axis, along compression axis C which allows tubular member to be compressed along compression axis C, which changes the configuration of tubular member 290. Tubular member 290 also includes interlocking features 298 (only one of which is labeled), which include first interlocking element 300 and second interlocking element 302. Slot 292 includes slot portion 304, which is defined by the first and second interlocking elements 300 and 302 and allows for movement between the two interlocking elements 300 and 302 in the axial direction. Tubular member 290 also includes stress relief slots 306, which extend across spine 308 and provide stress relief for spine 308. Stress relief slots 306 can be considered to be axially in-between slots 292. Slots 292 are not connected with slots 306. Slots 306 are substantially thinner than slots 292. As will be described in detail below, tubular member 290 is adapted to be compressed along compression axis C, which is substantially 180 degree from spine 308.

[00106] Figures 16a and 16b illustrate a portion of tubular member 290 shown in Figure 15. Figure 16b illustrates tubular member 290 with slot 292, with a greatest thickness along compression axis C. Slot 292 includes slot 304, which is defined by interlocking elements 300 and 303. Slot 292 and slot 304 allow for compression of tubular member 290, shown in Figure 16a. When a compressive force A is applied along compressive axis C surfaces 294 and 296 are brought closer towards another, as are surfaces 300 and 302. Slots 292 and 304 therefore allow for axial compression of tubular member 290, until surfaces 294 and 296 engage one another, or until surfaces 300 and 302 engage one another, whichever happens first. Slots 292 and 304 can be designed such that the slots close at the same time. Once the surfaces engage, they behave substantially like a solid tube and can no longer be compressed along the engagement points. Upon a compressive force to tubular member 290, tubular member will therefore be steered into the configuration shown in Figure 16a. Similarly, when a tensile force is applied to tubular member 290 shown in Figure 16a, tubular member 290 will straighten to the configuration shown in Figure 16b. Particularly, tubular member 290 will straighten until the interlocking features engage one another and prevent further movement. Figure 16c illustrates the tubular member from Figures 16a and 16b and indicates points of load application including those illustrated in Figures 16b and 16c. Torsional force T indicates a torsional force acting on tubular member 290 upon the application of torque at a proximal end of the device. Tensile and compressive forces are listed as "a" or "b" depending on the behavior exhibited by the tubular member as described below.

[00107] Figure 17 is a graph illustrating Force v. Displacement behavior associated with the application of loads or displacements at various points around tubular member 290 shown in Figures 15-16c. The Force/Displacement behavior of tubular member 290 for loads applied in planes passing through the longitudinal axis of the tubular member, ranges between the lines A and B in Figure 17. Curve A illustrates the behavior along a compliant axis on the surface of the tubular member and parallel to the longitudinal axis of the tubular member where the slots are widest, while curve B illustrates the behavior where the slots are vary narrow. As the tubular member is bent about spine 308 in a fashion which closes slots 292, the forces required to bend the tubular member are low and the

Force/Displacement curve has a small slope. The tubular member is compliant in this region. When the width of the slots decreases to zero the structure becomes much stiffer as indicated by the second much higher slope region of curve A. The amount of displacement associated with closing the slots is essentially indicated by point D where the slope of the Force/Displacement curve changes. Curve A indicates the behavior expected from forces applied at a point along compressive axis C, illustrating that a large amount of axial displacement follows from minimal compressive force on tubular member 290. Upon closing slots, the compressive axis becomes stiff (indicated by the large increase in Force at point D in the curve). Curve B in the graph indicates compression along the axis running through spine 308. Due to stress relief slots 306, a small amount of compressive displacement occurs before spine 308 stiffens and begins to act substantially like a solid tube, as indicated by point E in the graph. The structure will exhibit the behavior of curve B for tensional loads applied to the top of the structure on the compressive axis C as the gaps closed under this loading are very narrow. Curve B also represents the behavior of the structure to torsional loads, as the gaps impacted most by these loads are narrow.

[00108] Figure 18 illustrates a flattened view of exemplary tubular member 320. Slot 330, or cut, formed therein has a spiral (also referred to herein as helical) pattern and is un-interrupted. Tubular member 320 is shown in an as-cut compressed configuration, and is adapted to be expanded the greatest amount along expansion axis EA upon the application of a tensile force thereto. Tubular member 320 includes interlocking features 332, which include surfaces 322 and 324, and surfaces 326 and 328. Slot 330 includes the slot defined by surfaces 326 and 328, and by surfaces 322 and 324. In this embodiment the slot, or gap, defined by surfaces 326 and 328 is larger than the gap defined by surfaces 322 and 324. That is, the gap that is closer to expansion axis EA is larger than the gap that is further from expansion axis EA. Tubular member 334 also includes spine 334, which is interrupted by small slots 336. As illustrated in Figure 16c, tubular member 320, upon the application of axial loads applied thereto, will exhibit Force/Displacement curves as follows: a compressive force (downwards) applied at EA will exhibit curve B, while a tensile load at EA (upwards) will exhibit curve A. A torsional load will exhibit curve B.

[00109] Figure 19 is a flattened view and illustrates a portion of a tubular member. Tubular member 270 can be an inner or an outer tubular member as described herein. Steerable portion 270 is a laser-cut tubular member wherein first cut, or slot, 274 is made to define spine 276. Cut 274 is made almost all the way around tubular member 270. Cut 274 also defines interlocking features 278 (only one of them is labeled), which are comprised of a first interlocking element 280 and a second interlocking element 282. Cut 274 includes cut 284, which creates the interlocking features and allows for movement between the two interlocking elements. Tubular member 270 also includes stress relief 272, which extend across spine 276 and provide stress relief for spine 276. Stress relief slots 272 can be considered to be axially in-between slots 274. Slots 274 are not connected with slots 272. Tubular member 270 is adapted to be expanded along expansion axis EA, and is adapted to be minimally compressible upon the application of compressive forces thereto. Spine 276 is substantially static. Upon the application of tensile forces to

tubular member 270 along expansion axis EA, tubular member 270 will deflect from a straightened configuration into a bent configuration.

[00110] Figure 20 illustrates an embodiment similar to that shown in Figure 18 and only differences in the structure between the two will be described. All other features can be considered the same. Tubular member 350 includes interlocking features including interlocking elements 354 and 356. Slot 360 created in tubular member 350 includes the gap defined by surfaces of interlocking elements 354 and 356.

[00111] Figure 21 illustrates a flattened portion of an exemplary tubular member 380 including interrupted cuts 390 that define spine 382. Tubular member 380 includes interlocking features 384, which include interlocking elements 386 and 388. Interlocking features 384 allow for expansion along expansion axis EA upon the application of a tensile force thereto. Tubular member 380, like all tubular members described herein unless specifically stated otherwise, can be incorporated into a steerable portion as an inner or an outer tubular member.

[00112] Figure 22 illustrates a flattened portion of an exemplary tubular member 400. Interrupted slots 404 define spine 402, which has a spiral shape. Tubular member 400 does not have static axis.

[00113] Figure 23 illustrates a flattened portion of an exemplary tubular member 410. Tubular member 410 includes interrupted helical slots 418, which define spines 412 and 414. Tubular member 410 has two spines, 180 degrees around the periphery of the device from one other. The helical cut pattern repeats itself every 180 degrees to define substantially straight spines. Tubular member 410 also includes a plurality of interlocking features 420 which provide torsional stiffness. The maximal expansion/compression is at axis 416.

[00114] Figure 24 illustrates a flattened portion of an exemplary tubular member 430, which is similar to the embodiment in Figure 23 but rather than repeating every 180 degrees, the cut pattern repeats every 360 degrees. Slots 434 have an interrupted helical design, and tubular member 430 has a single spine 432. Feature 436 provides additional torsional stiffness. Tubular member 430 exhibits maximal expansion/compression along axis 438.

[00115] Figure 25 illustrates a flattened portion of an exemplary tubular member 440. Tubular member 440 includes slots 448, which repeat every 190 degrees to define spines 442 and 446. The slots have an interrupted helical pattern, and create a relatively neutral pattern.

[00116] Figure 26 illustrates a flattened portion of an exemplary tubular member 450. Tubular member 450 has uninterrupted slot 456 formed therein, which repeats every 360 degrees. Tubular member 450 also includes interlocking features 454 comprised of at least two interlocking elements as described herein. In this embodiment, the interlocking elements have complimentary curved surfaces and are adapted to support rotation. Slot 456 defines spines 452, while slot 456 allows compression and/or expansion along axes A.

[00117] Figure 27 illustrates an exemplary steerable delivery device including steerable portion 520. Steerable delivery device includes outer tubular member 522, inner tubular member 524, and floating inner member 534. Inner tubular member 524 is disposed within and coaxial to outer tubular member

522, and floating inner member 534 is disposed within and coaxial with inner tubular member 524. Floating inner member 534 is axially fixed relative to inner tubular member 524 at a location proximal to steerable portion 520. The device shown in Figure 27 can also include a liner member disposed between the outer and inner tubular members.

[00118] Figure 28 illustrates an exemplary steerable delivery system 600. System 600 includes control device 602 that is adapted to steer steerable portion 610 of a steerable delivery device. The steerable delivery device includes outer tubular member 606 and inner tubular member 608 disposed within outer tubular member 606. Control device 602 includes housing 612 with a slot therein adapted to allow for movement of actuator 604. Actuator 604 is coupled to inner tubular member 608, and is adapted to be moved axially, either distally D or proximally P to control the axial movement of inner tubular member 608. Any other suitable type of actuator can also be used including actuators incorporating mechanical advantage. Actuation of actuator 604 causes inner tubular member 608 to move axially relative to outer tubular member, which causes steerable portion 610 to bend. The control device is therefore adapted to steer steerable portion 610 inside of a subject. System 600 also includes a floating liner member 616 and hemostatic valve 614.

[00119] One aspect of the disclosure is a guide device that is adapted to be maintained, or locked, in a specific configuration to provide access for a medical device or instrument to be passed therethrough, but may or may not be steerable. In Figures 2A-2C, steerable portion 32 is adapted to be steered or deflected into any configuration between those shown in Figures 2A and 2B. Steerable portion is adapted to be steered to, for example, navigate bends or turns within a bodily lumen. In that specific embodiment, compressive and/or tensile forces are applied to the inner and/or outer tubular members to steer the steerable portion. In some embodiments, once steerable portion 32 is steered into a curved configuration, the forces applied thereto (e.g., compressive, tensile, torsional) can be released, and yet a medical device or instrument can be passed through the tubular members. In some embodiments, however, the bent configuration of the steerable portion can be maintained by maintaining the application of the forces thereto. For example, in Figures 2A-2C, steerable portion 32 can be maintained, or locked, in the bent configurations shown by maintaining the application of the compressive and/or tensile forces. By maintaining the application of the forces to the steerable portion or locking the relative displacements of the inner and outer tubes, the inner and outer tubes are substantially axially fixed relative to one another along the length of the steerable portion.

[00120] In an exemplary method of use, multiple bend portions may be incorporated and adapted to have a locked configuration that closely mimics, or resembles, a portion of the subject's anatomy. The bend portion can be advanced through the subject (e.g., over a guide wire) to a desired location, and can then be actuated into a curved configuration, such as by the application of compressive and/or tensile forces thereto. The curved configuration can be adapted to resemble the path of the anatomical lumen in which the device is positioned. Application of the actuation force maintains, or stiffens, the bend portions in the desired curved configuration. A medical device or instrument can then be advanced through the curved portion to a target location within the subject.

[00121] The device shown in Figure 14 can alternatively be configured to be operated in this manner. For example, steerable delivery device 256 in Figure 14 can be actuated to have a first bend or curved region 254 and a second bend or curved region 258. The curves, or bends, form a general S-shaped portion of the device. The delivery device 256 can be maintained, or locked, in the general S-shape to guide a medical device or instrument therethrough. The S-shape of the delivery device 256 can be used if it resembles a portion of the anatomy into which it is placed, but any other type of preformed configuration can be used, depending on the anatomical requirements. In the alternative to Figure 14, the delivery device can be actuated into the configuration shown by the application of compressive and/or tensile forces to inner and outer tubular members, as is described herein.

[00122] Figures 29A and 29B illustrate an exemplary embodiment of a portion of a lockable device adapted to be locked, or maintained, in a specific configuration that mimics that of a portion of the subject's anatomy. In the unlocked form the structure is compliant and easily guidable whereas in the locked form the device is rigid in its predetermined form. The device can then be used to provide access for a medical device or instrument to be passed therethrough to a target location within the subject. Bend portion 700 of the device includes a plurality of beads, 702, 704, and 706. Bead 702 is the distal-most bead, bead 706 is the proximal-most bead and beads 704 are disposed between the two end beads 702 and 706. The beads are separate and distinct structural features, not mechanically coupled to one another. Each bead has two bores 715 therethrough, each adapted to receive one of the two control wires 708. Control wires 708 are secured only to distal bead 702, using any suitable technique (e.g., adhesive). Wires 708 therefore are adapted to be axially moveable relative to beads 704 and 706. Proximal bead 706 has a substantially constant height H around the periphery of the bead, while beads 702 and 704 do not have a constant height. Specifically, the height of the beads 702 and 704 decreases around a portion of each of the beads. The gap between adjacent beads is therefore relatively large between bead 702 and 704, and between beads 704, while the gap between bead 706 and the adjacent bead 704 is relatively small compared to the other gaps.

[00123] To adjust the lockable portion into its predetermined form, an axially directed (i.e., distally directed) compressive force C is applied to proximal bead 706 while maintaining wires 208 is position. Maintaining wires 208 in position can occur based on a proximally directed tensile force applied to wires 208, or wires 208 may be secured to a portion of the delivery system that is not actuated. This causes the distance between surfaces 711 and 713 to decrease, until they engage one another as shown in Figure 29B. The actuation force is continued until all of the beads' adjacent surfaces are engaged, as shown in the configuration in Figure 29B. In Figure 29B, lockable portion 700 is in a bent configuration adapted to mimic a portion of the patient's anatomy in which it is to be positioned. Figure 29B also shows a section portion of one side of the beads through which one of wires 708 passes. Lockable portion is maintained in the locked configuration in Figure 29B by maintaining the distally directed compressive force to proximal bead 706 or the relative displacements between distal bead 702 and proximal bead 706. Lockable portion 208 can also be bent into the configuration shown in Figure 29B upon the application of a proximally directed tensile force applied to wires 708, while applying a distally directed compressive

force to proximal bead 706. While six beads are shown in Figures 29A and 29B, the lockable portion can have two or more beads.

[00124] Figures 30A-30H show exemplary beads that can be incorporated into a lockable portion as described herein. Figure 30A illustrates bead 716 with wire bores 717 therethrough. The height H of bead 716 is substantially constant. When the height is substantially constant, the planes through the proximal and distal ends of the beads are substantially parallel. When the height is not constant, the planes are not parallel. Bead 716 is the same as proximal bead 706 in Figure 29A. In an embodiment with a lockable portion comprised entirely of beads that have a constant height, the lockable portion would have a straight configuration under compression. Figure 30B shows bead 718 with bores therethrough, wherein the height at portion 720 is less than at portion 721. Bead 718 has the same general shape as beads 702 and 704 in Figure 29A. The height of portion 720 can be adjusted to modify the curvature of the lockable portion. Generally, as height 720 decreases, the degree of the bend increases (i.e., the radius of curvature decreases). Similarly, the height of portion 721 can be modified to modify the curvature. Figure 30C illustrates bead 722 that can be injection molded. Bead 722 includes two outer wire features 724 and two inner wire features 726 formed in bead 722. Each outer wire feature has a portion that overlaps with a portion the corresponding inner wire feature to define an opening through which a control wire can pass. Molding the bead with the wire features to create the wire bore can be easier than forming a hole the entire way through the bead. Bead 722 is formed to have 2 control wires pass therethrough. Figure 30D illustrates bead 730 that can be injection molded. Bead 730 includes two indentations 732 and two indentations 734. The indentations in bead 730 allow for the height of wire bore 736 to be less than it would be without the indentations. The indentations can make the wire bores easier to mold. Figure 30E illustrates bead 740 including tabs 742 stamped therein. The tabs are stamped in the body of bead 740 to form wire openings 744, through which a control wire is passed. Bead 740 can be, for example, a hypotube, sheet metal rolled into an annular shape, etc. Figure 30F is similar to Figure 30E and includes interlocking features including interlocking elements 754 (male) and 756 (female). The interlocking features generally enhance torque transmission. The interlocking feature could be comprised of any interlocking elements described herein or any other suitable interlocking elements. Figure 30G illustrates bead 760 including an inner corrugated member 764 and outer member 762. The spaces between inner member 764 and outer member 762 define control wire bores 768, which are adapted to receive control wires therethrough. In Figure 30G, twelve control wires can be passed through bead 760. Figure 30H shows a plurality of beads 760 (from Figure 30G) and 770, each with inner member 764 and outer member 762. In adjacent beads 760 and 770, the control wire bores are defined by peaks and valleys formed in the inner members on adjacent beads.

[00125] While the embodiments have been shown with control wires being secured relative to a single bead, all of the control wires in a lockable portion need not be secured to the same bead. For example, a control wire can be secured to any bead in the lockable portion.

[00126] The locked configuration of the lockable portion can be modified by modifying characteristics of the beads. For example, the number of beads in the lockable portion can be modified to

change the radius of curvature. The height of portion of the beads can be modified, as shown in the comparison between Figure 30A and 30B. The lockable portion additionally need not include beads of the same type. For example, a lockable portion could alternate the beads shown in Figures 30A and 30B, creating a curve with a degree of bend less than that shown in Figure 29A. Beads of similar design can be rotationally offset from one another along the length of the lockable portion. For example, in the embodiment in Figure 29A, every other bead could be rotated 90 degrees in the same direction relative to the adjacent beads. Additionally, the relative angle between the control wire bore axis and the plane of a bead end can be adjusted. For example, in Figure 30B, the axes of control wire bores 719 can be substantially 90 degrees relative to the plane of the distal end of bead 718. The axes of bores 719, can, however, be offset such that they are not substantially 90 degrees relative to the plane of the distal end of bead 718.

[00127] The beads as described herein can have almost any length. In some embodiments a bead is a section of straight tubing. Any bead can also incorporate any of the slotted cut patterns described herein

[00128] While the lockable portions have been shown to include curved, or bent sections, the lockable device can have a locked configuration in which the device is substantially straight. For example, if the lockable device included 2 or more beads as shown in Figure 30A, the lockable device would have a substantially straight locked configuration.

[00129] In some embodiments the lockable device could have a floating liner (as described herein) disposed therein. The floating liner could, in some embodiments, secured to the distal-most bead. The lockable device could alternatively or additionally have an outer liner disposed on the outside of the lockable device. The outer liner could also be secured to the distal-most bead or the outer liner could be affixed to the inner liner and the beads left to float inside.

[00130] In some embodiments the lockable device (e.g., the device shown in Figures 29A and 29B) is adapted to be advanced over a steerable device within the subject. For example, a traditional guidewire or the steerable device shown in Figures 2A-2C can be steered to a desired location within the subject. A lockable device, such as a beaded lockable device described herein, can then be tracked over the steered device. The lockable device comprising at least two beads is flexible to allow it to follow the curvature of the steered device. Once the lockable device has been advanced over the steered device to the desired position, the beads of the lockable device are locked in place as described herein, and the lockable device assumes its preset configuration.

[00131] In alternative embodiments, the lockable portion (e.g., the beaded structure in Figures 29A and 29B) includes a floating liner therein.

[00132] In an exemplary embodiment of use, a guiding element (e.g., a guidewire) is advanced to a desired location within the subject. The device comprising the lockable portion is then tracked over the guiding element until it reaches a desired position. The lockable portion is then actuated to change the configuration of the lockable portion to the desired configuration. The lockable portion is then maintained, or locked, in the desired configuration. A medical device, medical instrument, or other device is then advanced therethrough to a target location within the subject.

[00133] While preferred embodiments of the present disclosure have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the disclosure. It should be understood that various alternatives to the embodiments of the disclosure described herein may be employed in practicing the disclosure. The following claims define the scope of the disclosure and that methods and structures within the scope of these claims and their equivalents are covered thereby.

Claims

1. A steerable medical device, comprising:

a steerable portion;

a first tubular member comprising a first flexible polymeric tubular member; and

a second tubular member comprising a second flexible polymeric tubular member, wherein the first tubular member is disposed within the second tubular member and permanently axially fixed to the second tubular member at a fixation location distal to the steerable portion; and

an external controller that is adapted to be actuated to put one of the first tubular member and the second tubular member in tension and the other of the first tubular member and the second tubular member in compression, and wherein the first and second tubular members are adapted such that the steerable portion is steered in a first direction when the external controller is actuated.

2. The steerable medical delivery device of claim 1 wherein the first and second flexible polymeric tubular members each comprise a wall of solid material along the steerable portion.

3. The steerable medical delivery device of claim 2 wherein the first and second tubular members each further comprise a structural support embedded in the respective first and second flexible polymeric tubular members.

4. The steerable medical delivery device of claim 2 wherein the first and second flexible polymeric tubular members each comprise a variable structure in the steerable portion, and the variable structures impart the respective preferential bending.

5. The steerable medical delivery device of claim 4 wherein the variable structures for each is a variable thickness in the steerable portion, and the variable thicknesses impart the preferential bending in the respective first and second tubular members.

6. The steerable medical device of claim 1 wherein the first and second tubular members are configured to preferentially bend in opposite directions.

7. The steerable medical device of claim 1 wherein the external controller is adapted so that when the actuator is actuated, the first tubular member and the second tubular member are axially moved relative to one another within the external controller.

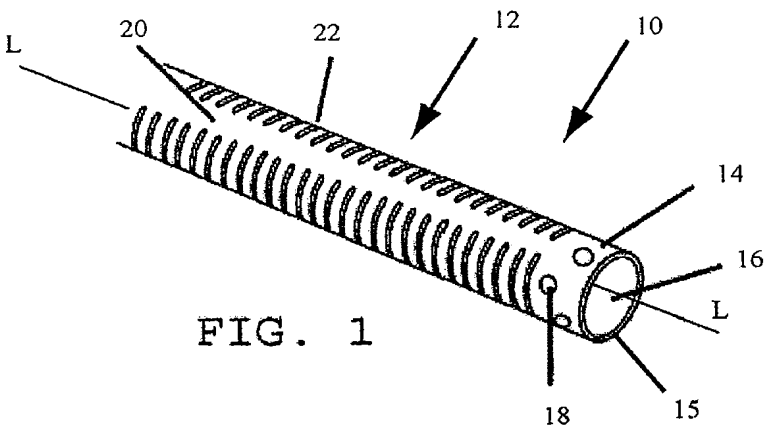


FIG. 1

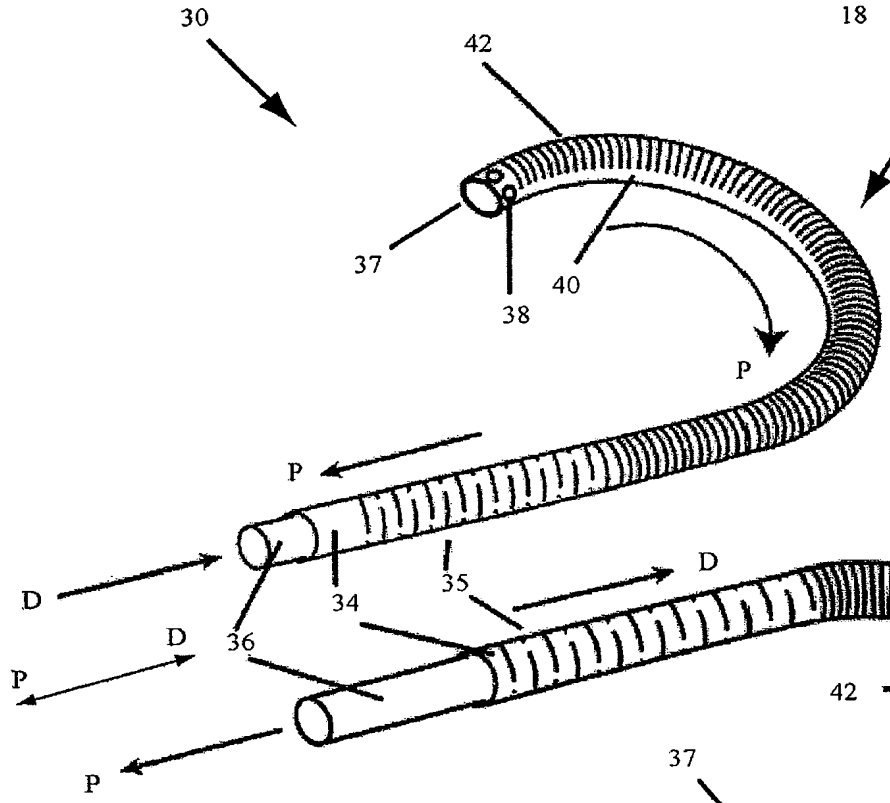


FIG. 2a

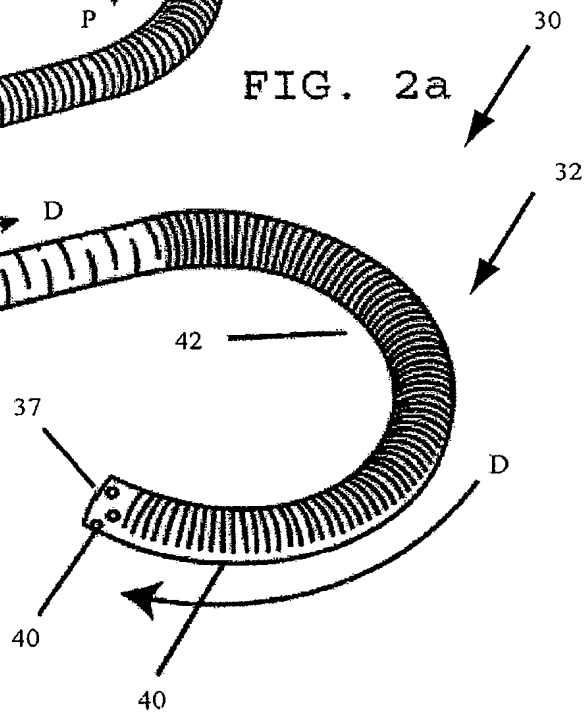


FIG. 2b

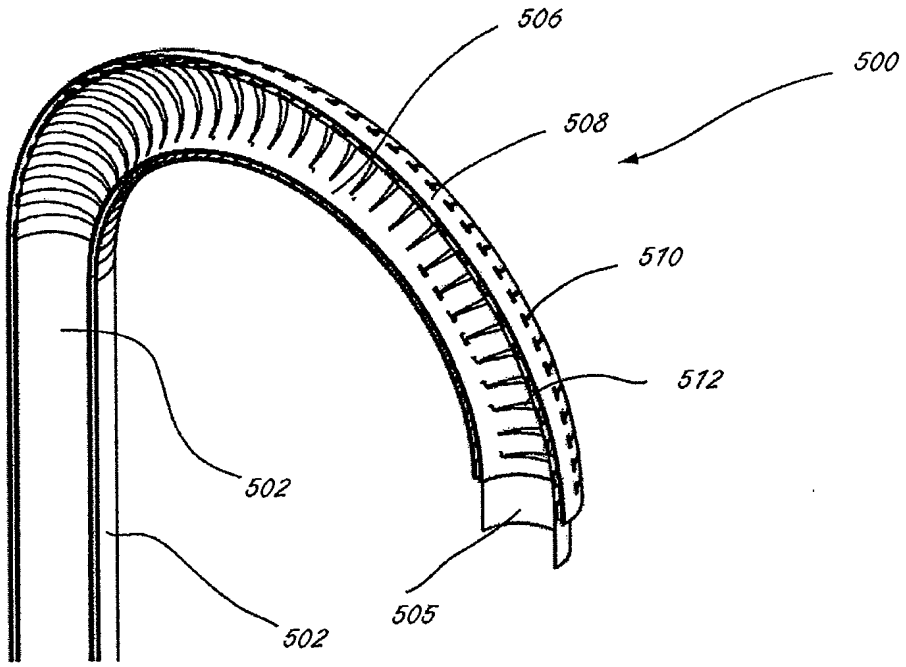


Fig 2c

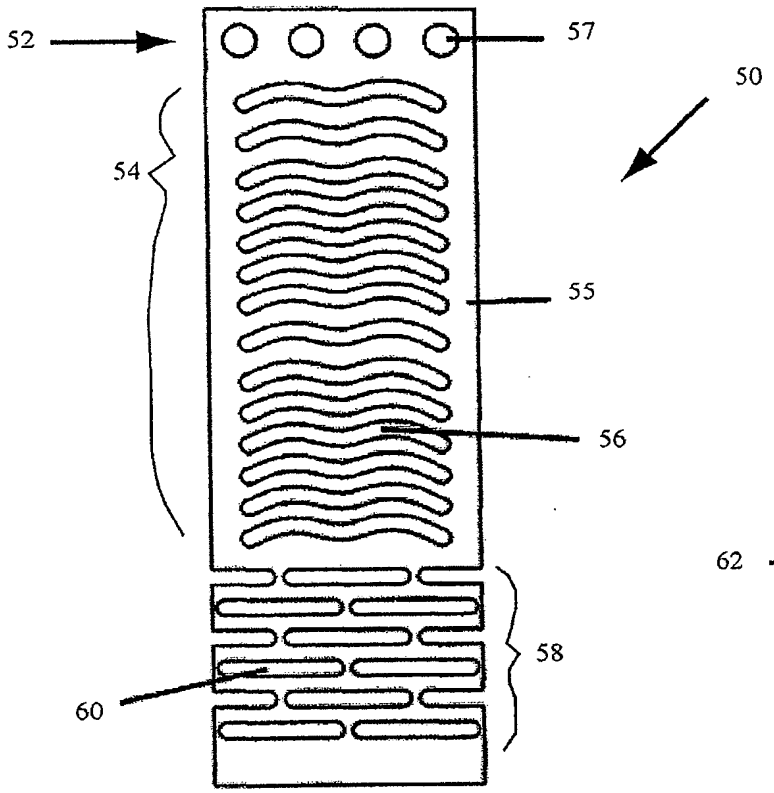


FIG. 3

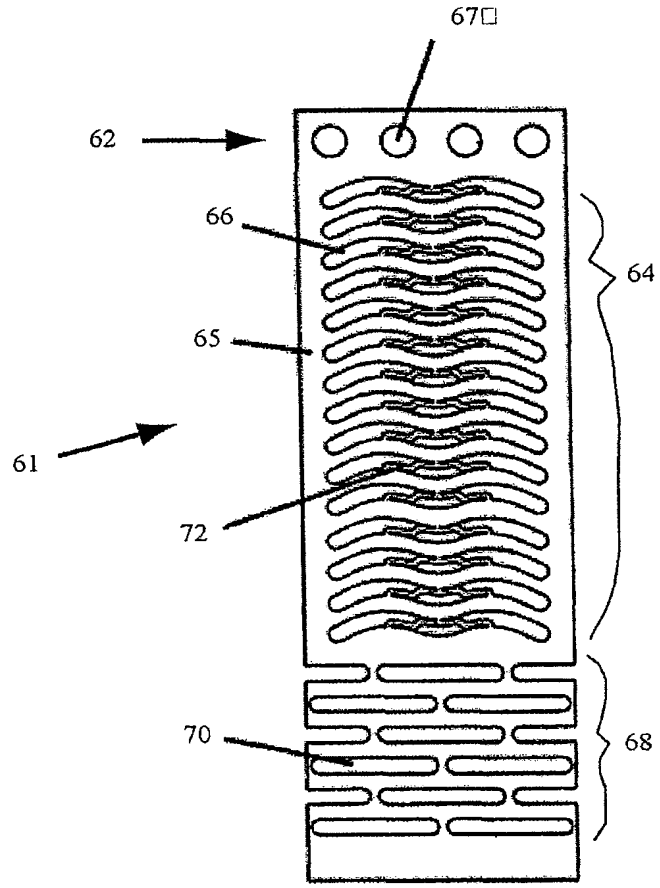


FIG. 4

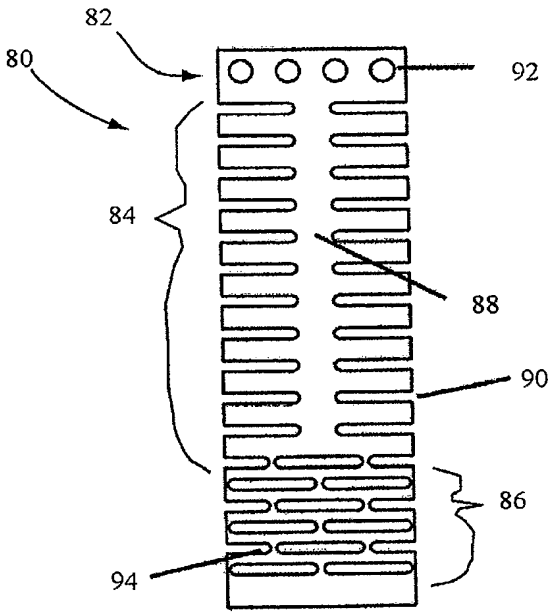


FIG. 5

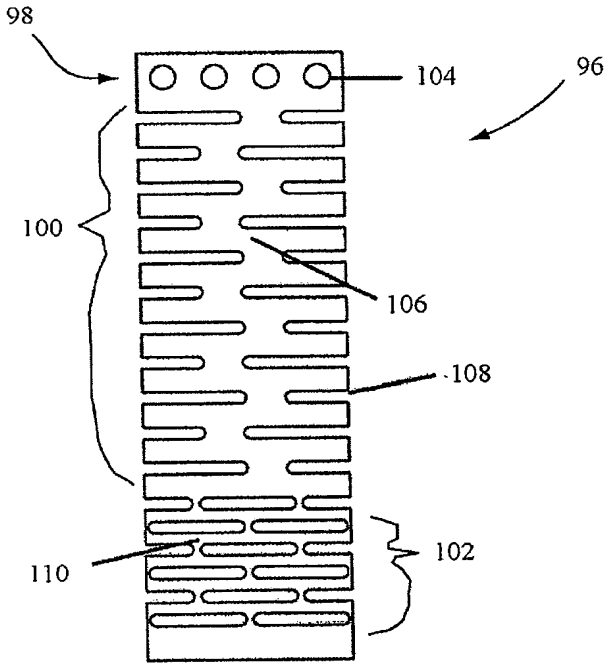


FIG. 6

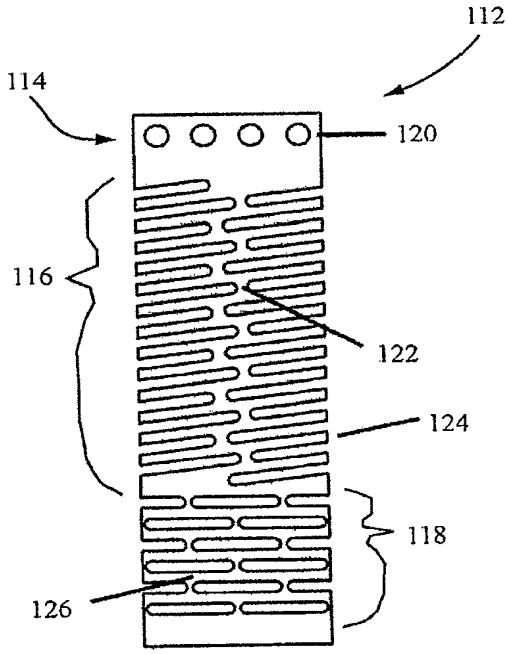


FIG. 7a

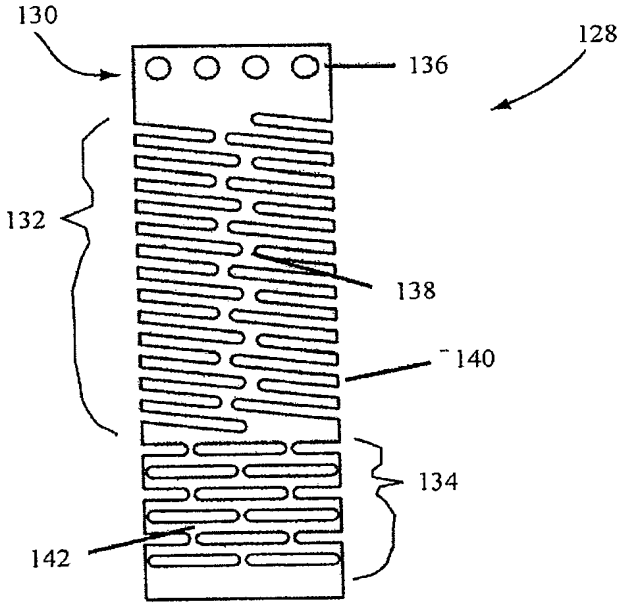


FIG. 7b

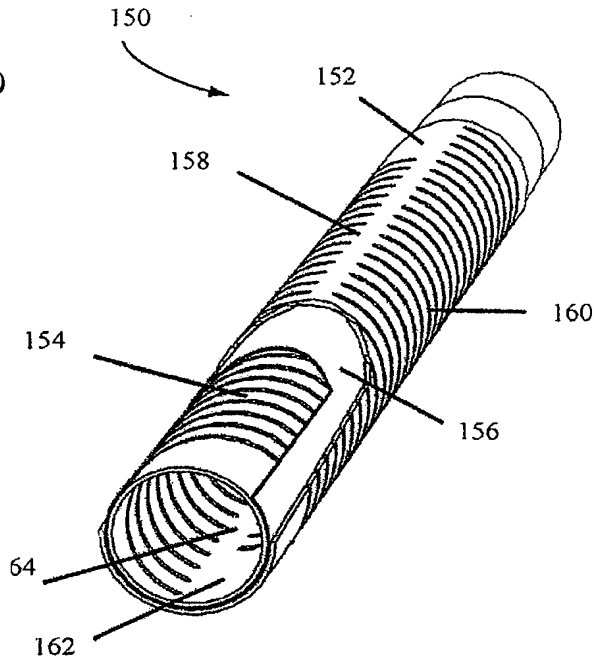


FIG. 8

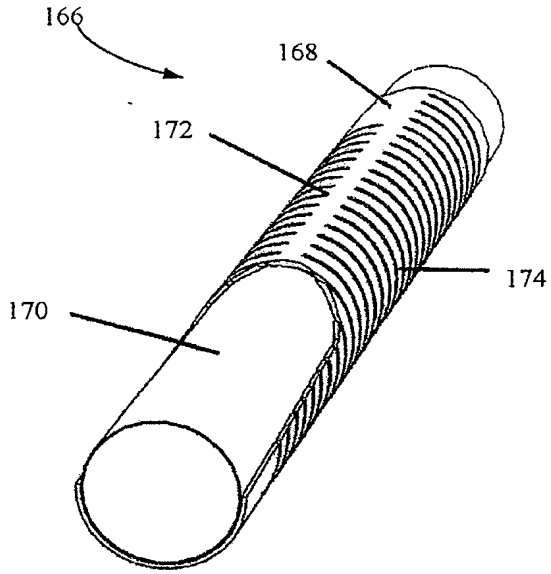


FIG. 9

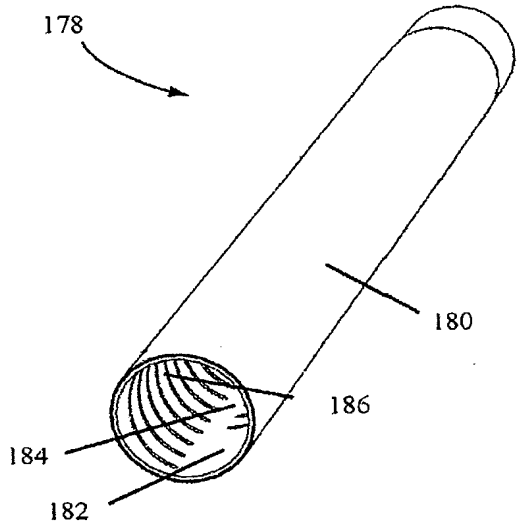


FIG. 10

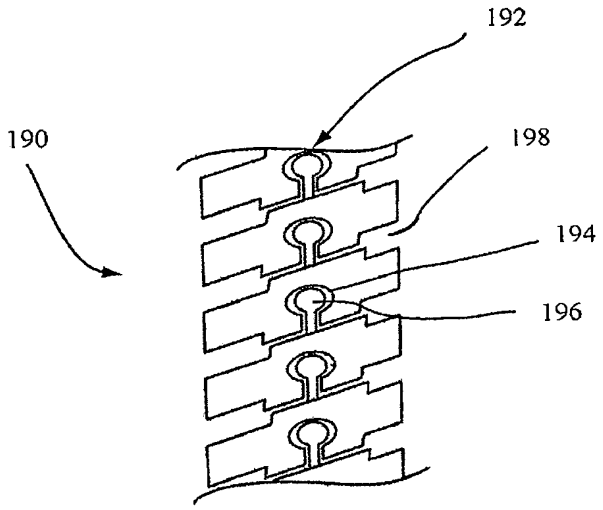


Fig 11A

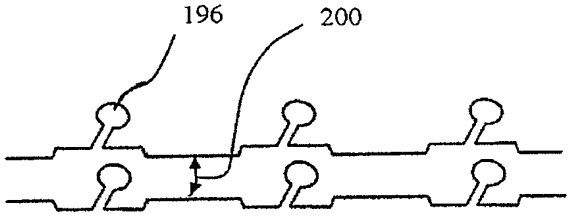


Fig 11B

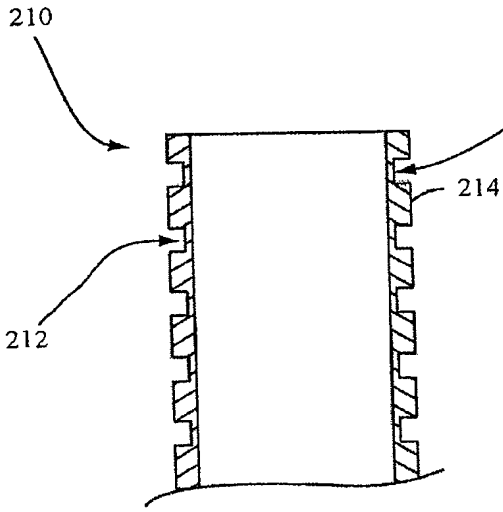


Fig 12A

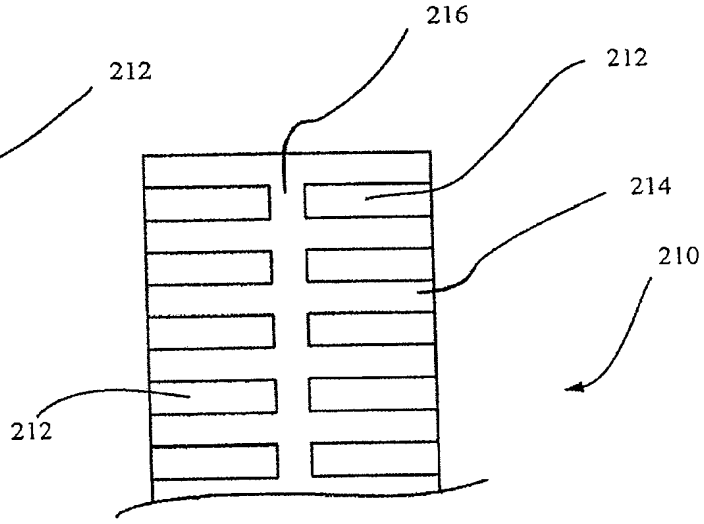


Fig 12B

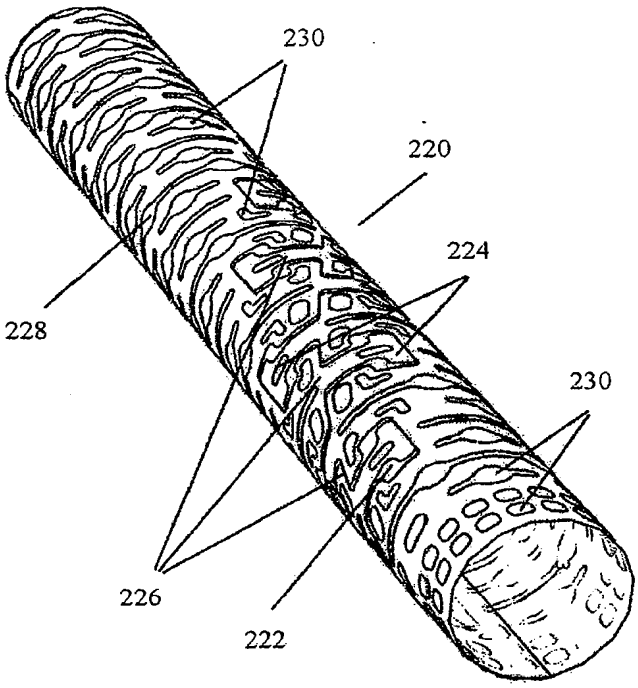


Fig 13a

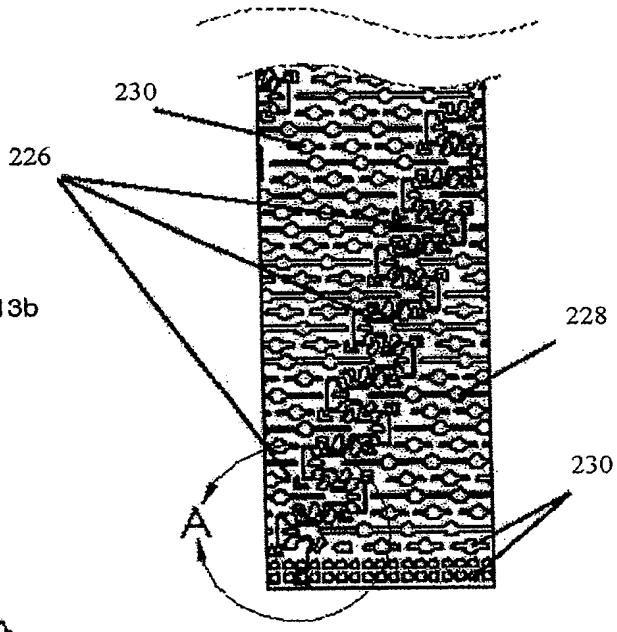


Fig 13b

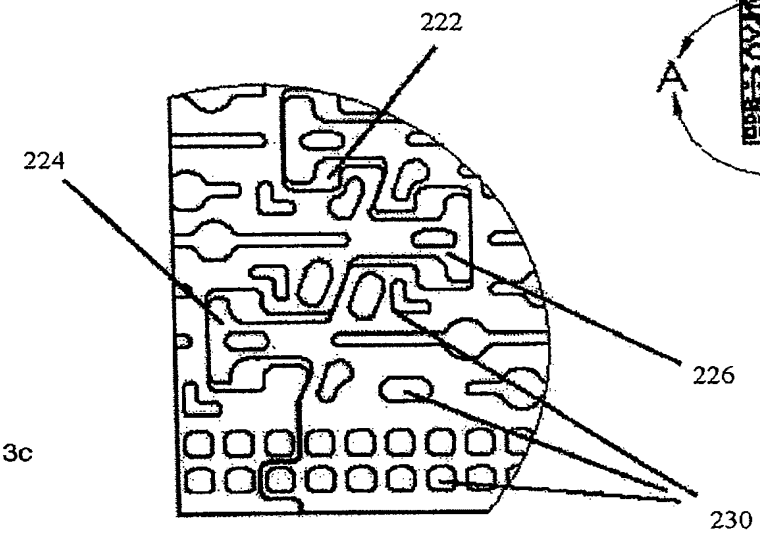


Fig 13c

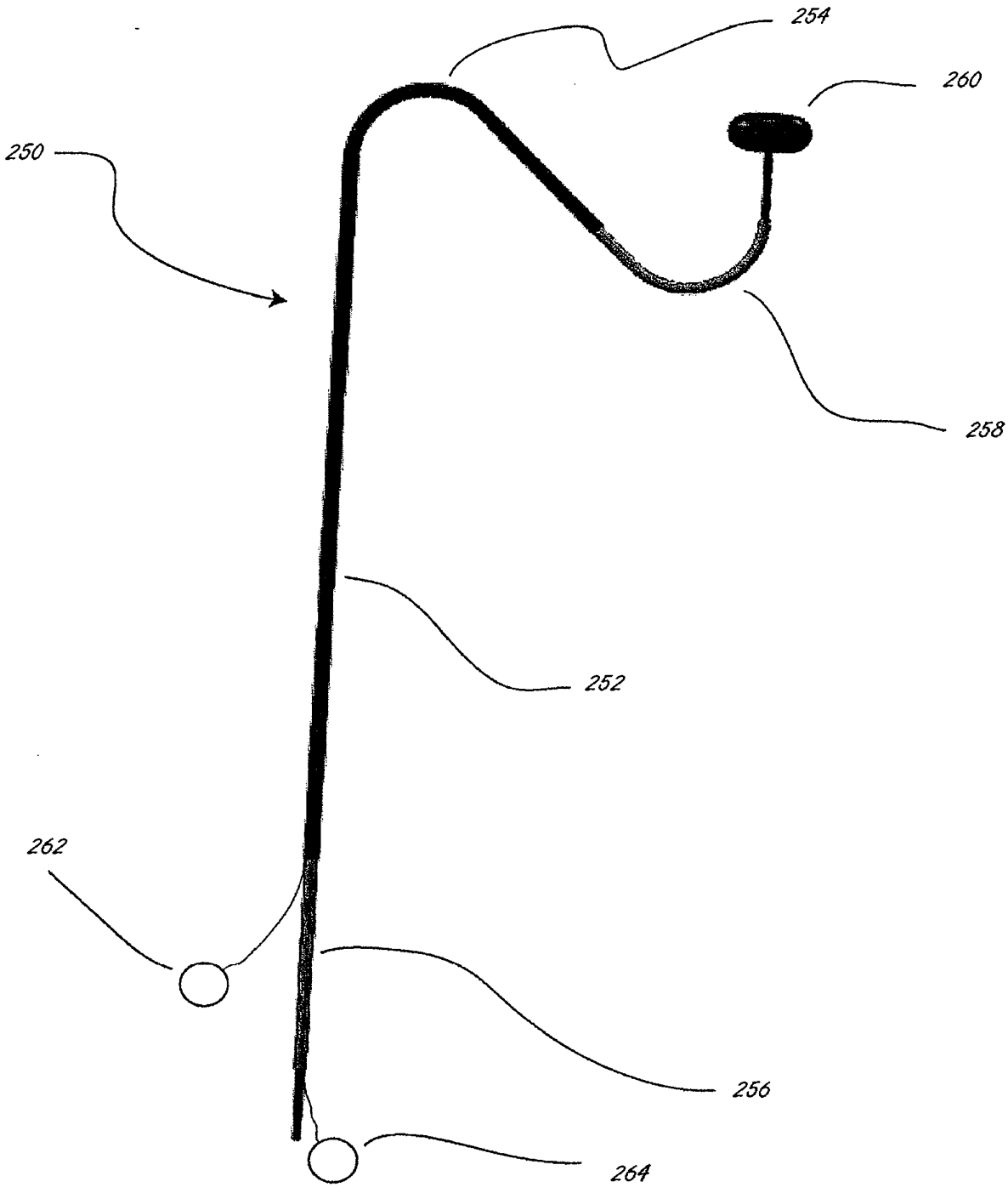


Fig 14

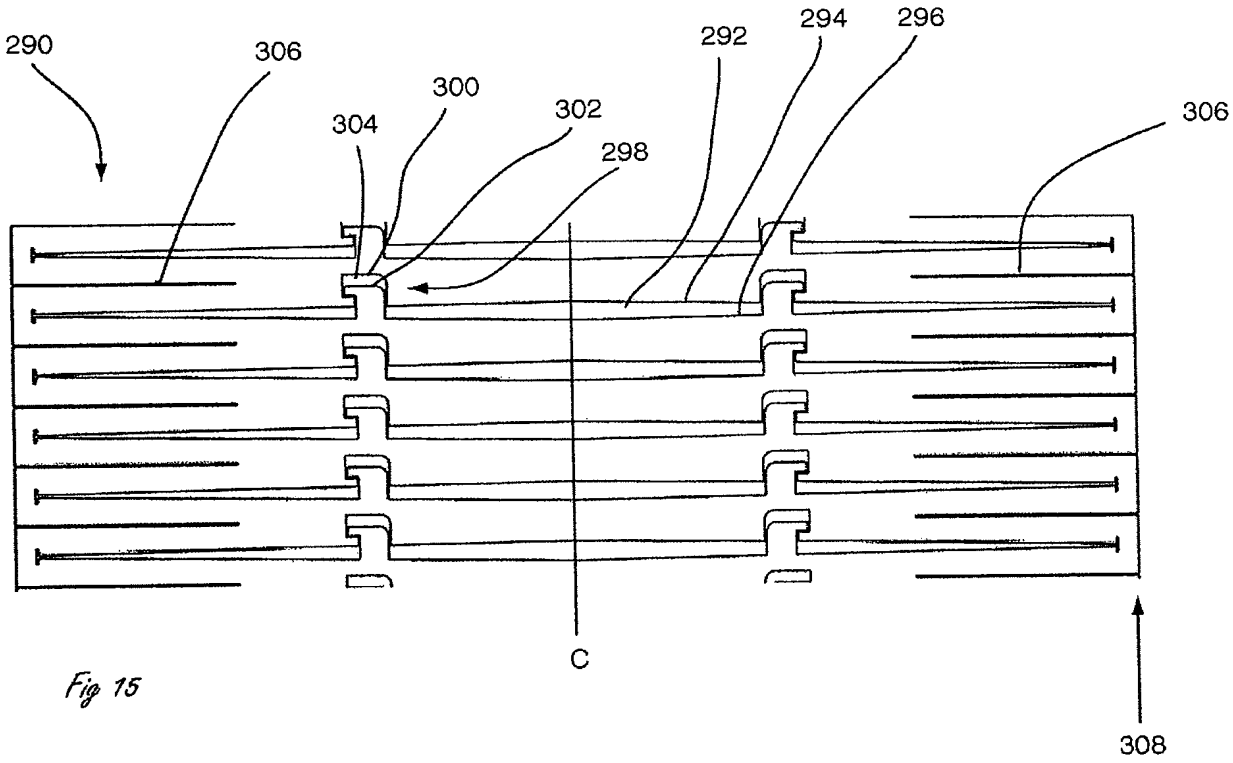


Fig 15

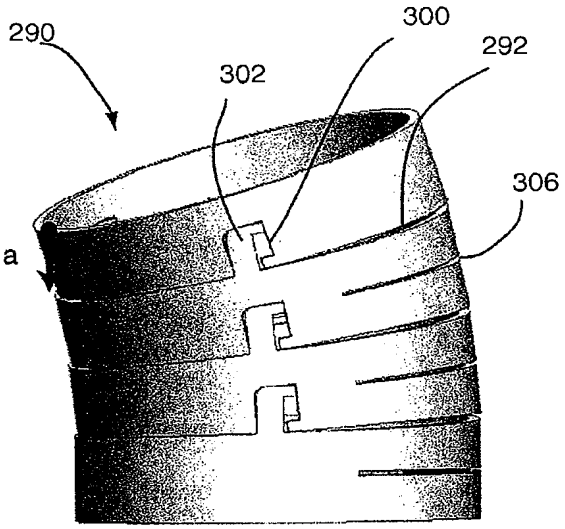


Fig 16a

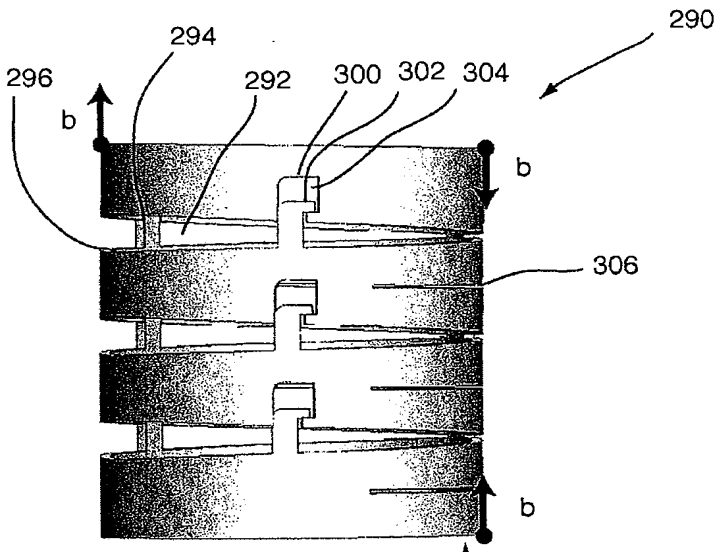


Fig 16b

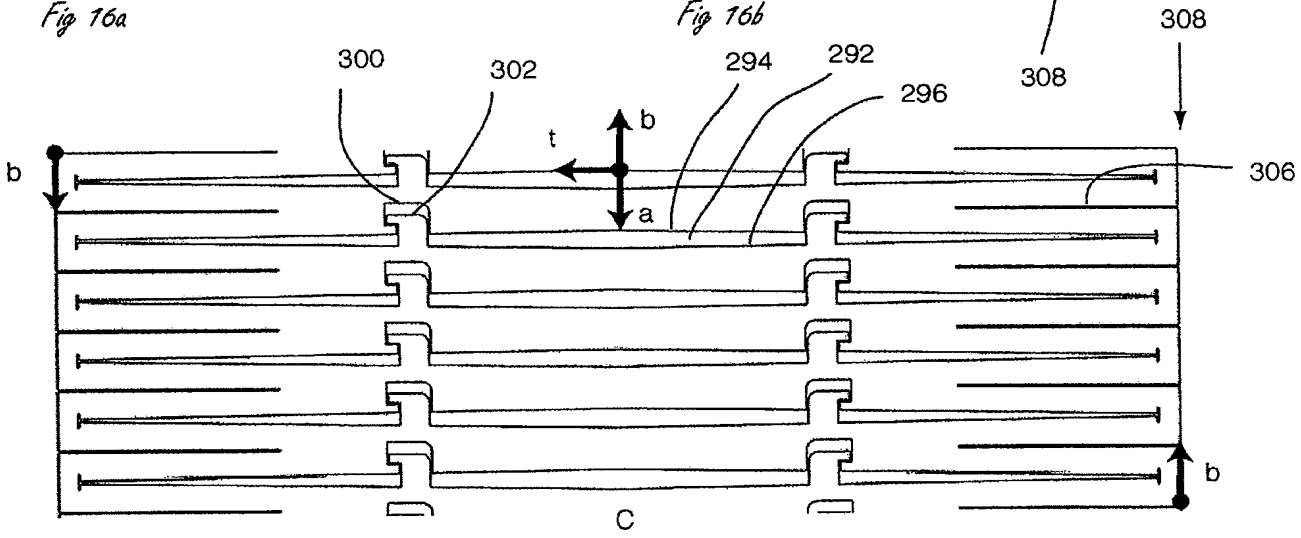


Fig 16c

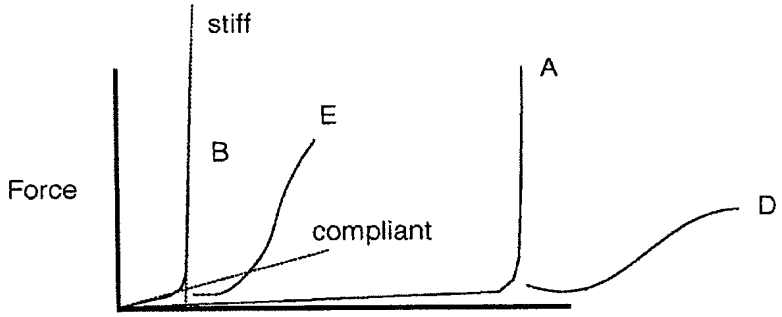


Fig 17

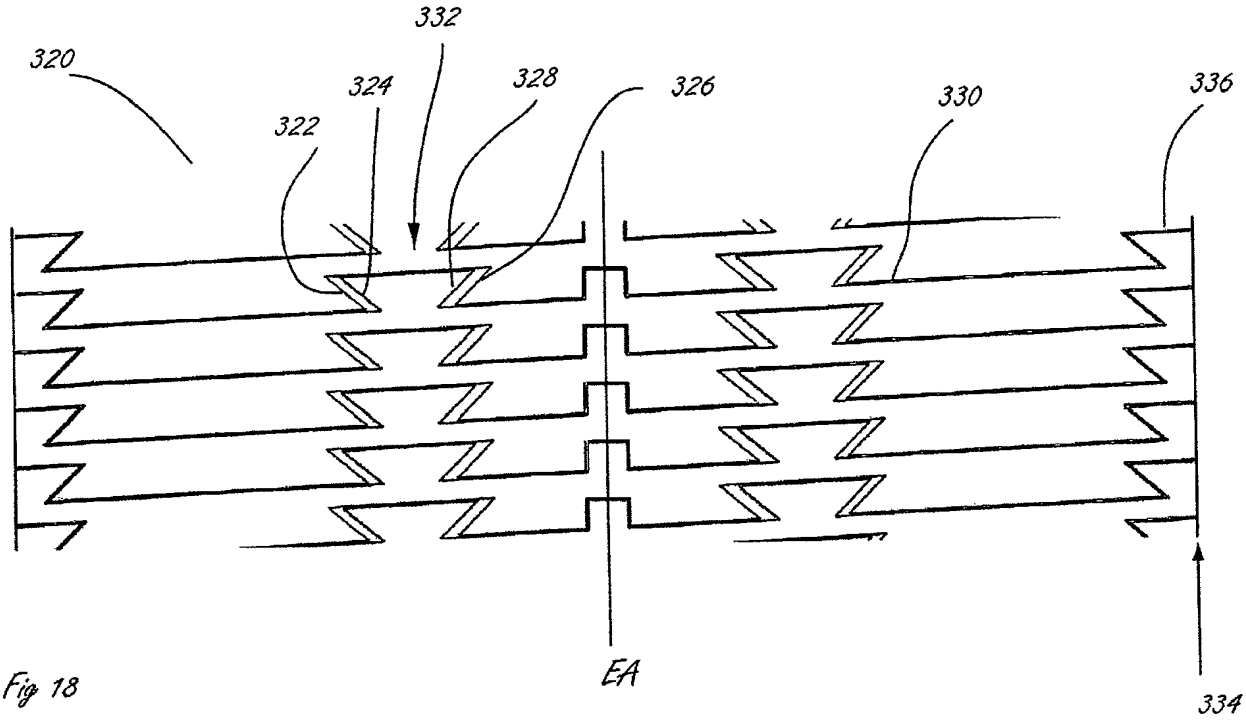


Fig 18

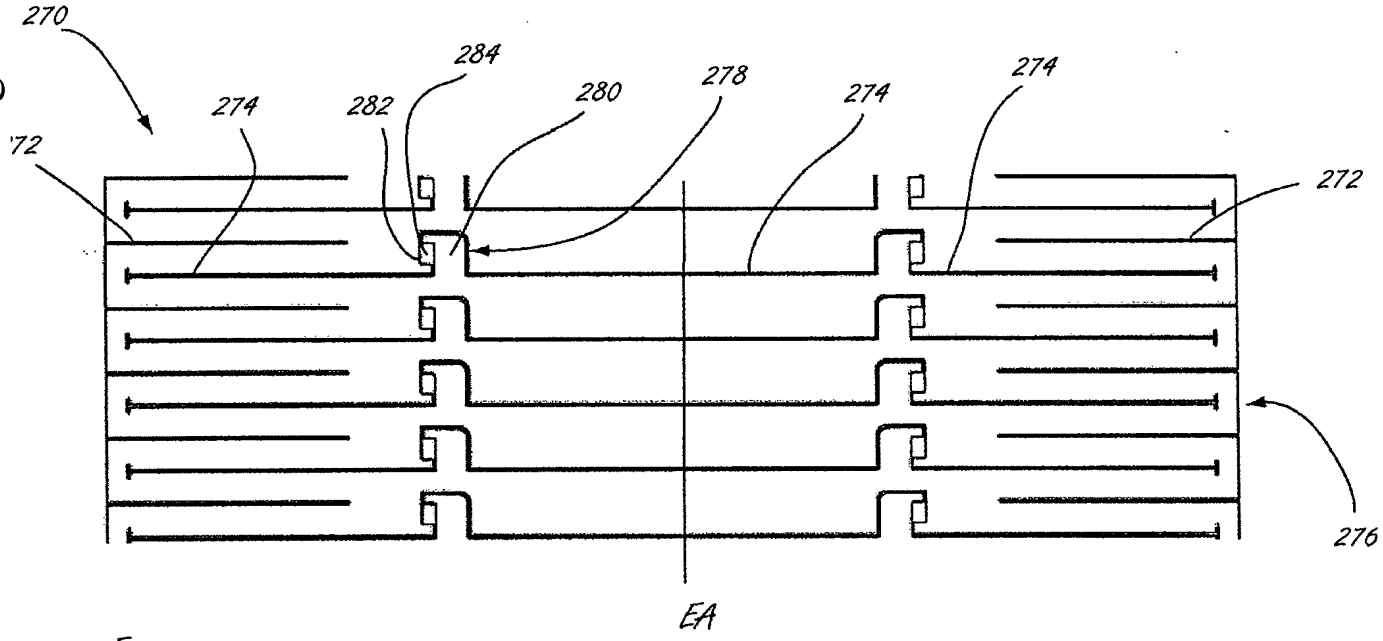


Fig 19

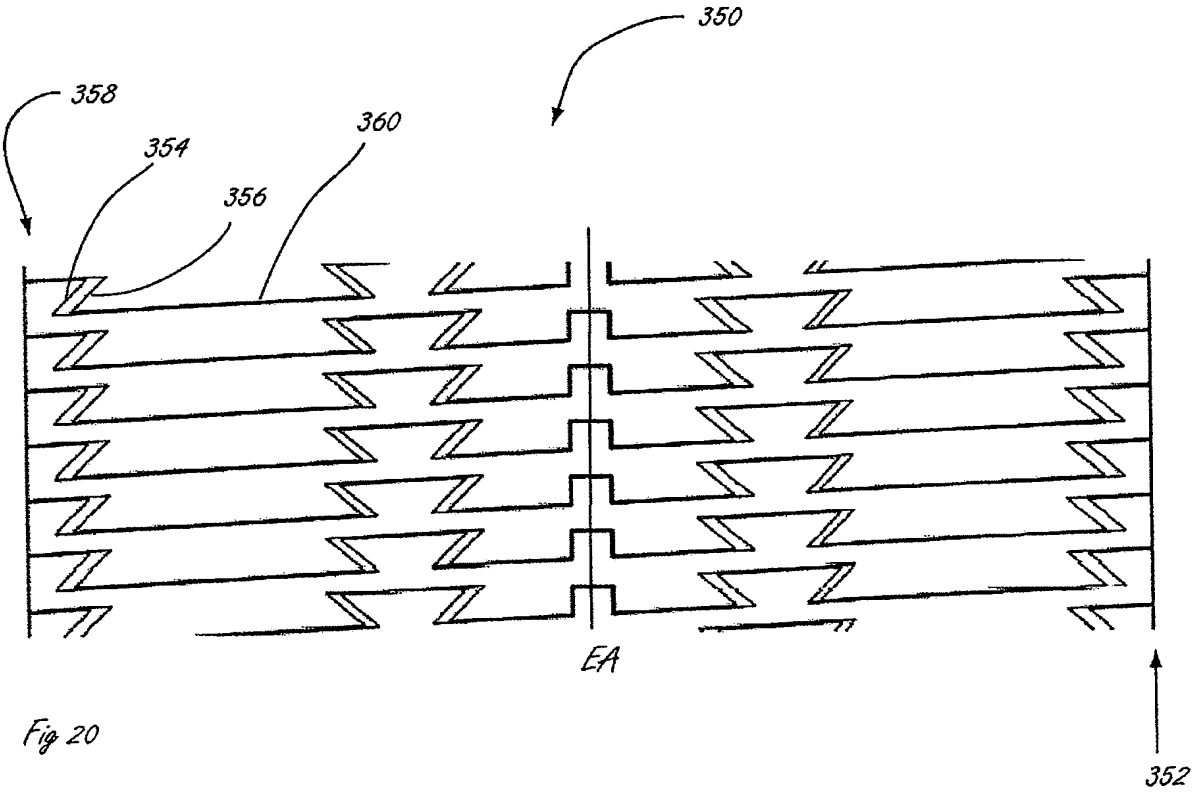


Fig 20

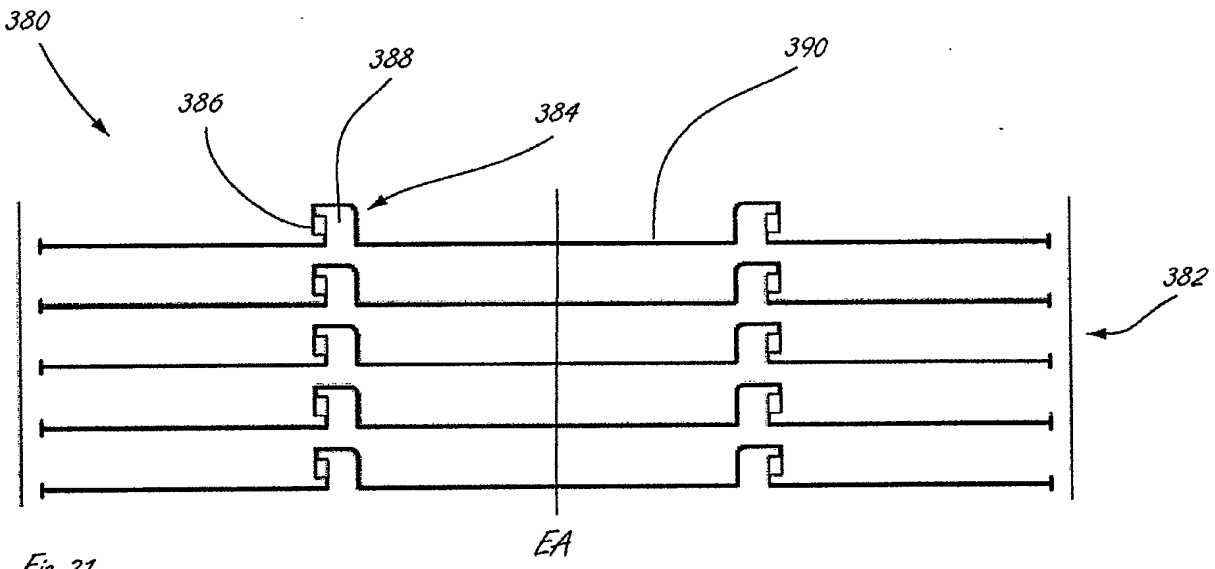


Fig 21

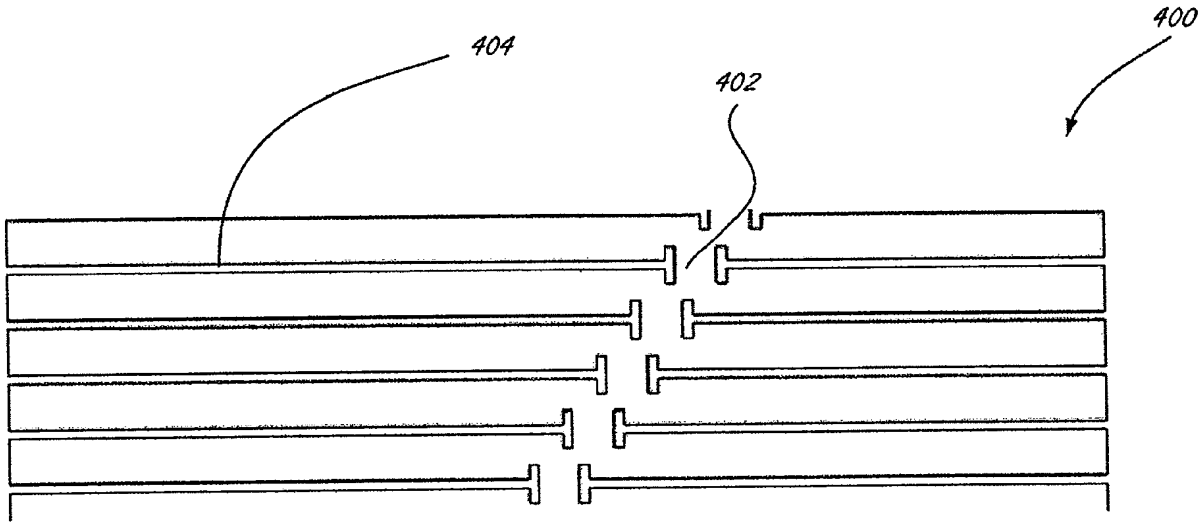


Fig 22

Fig 23

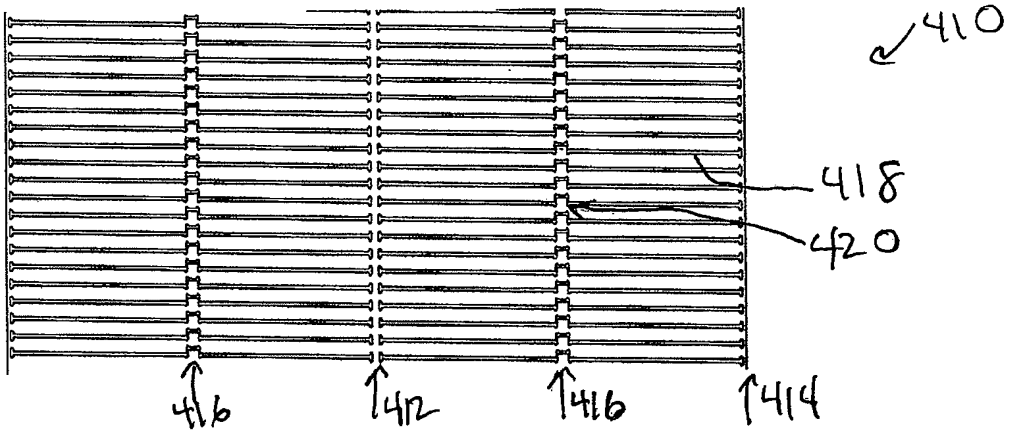


Fig 24

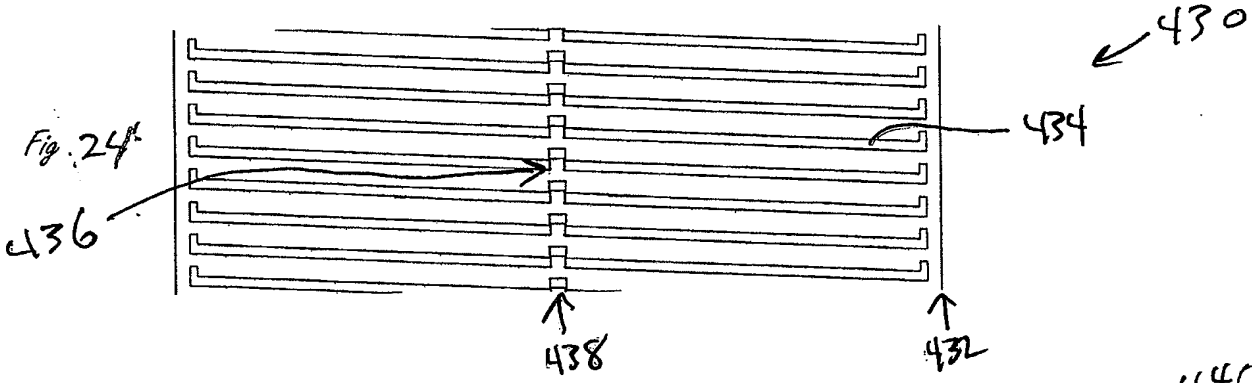


Fig 25

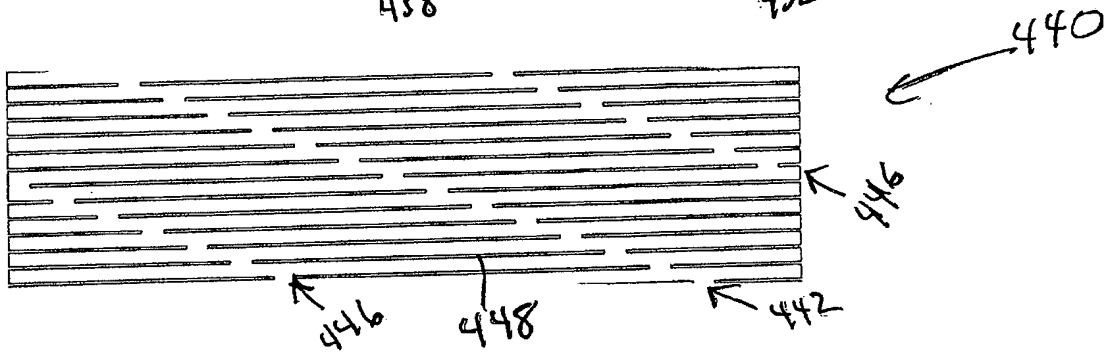
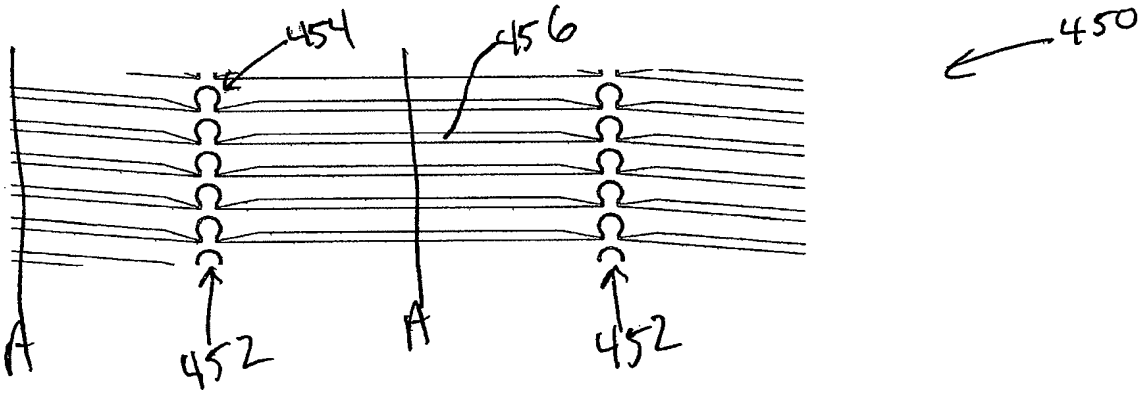


Fig 26



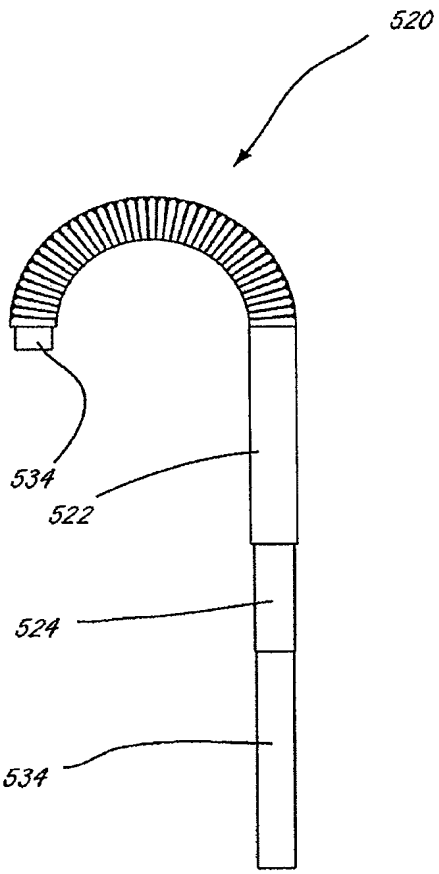


Fig 27

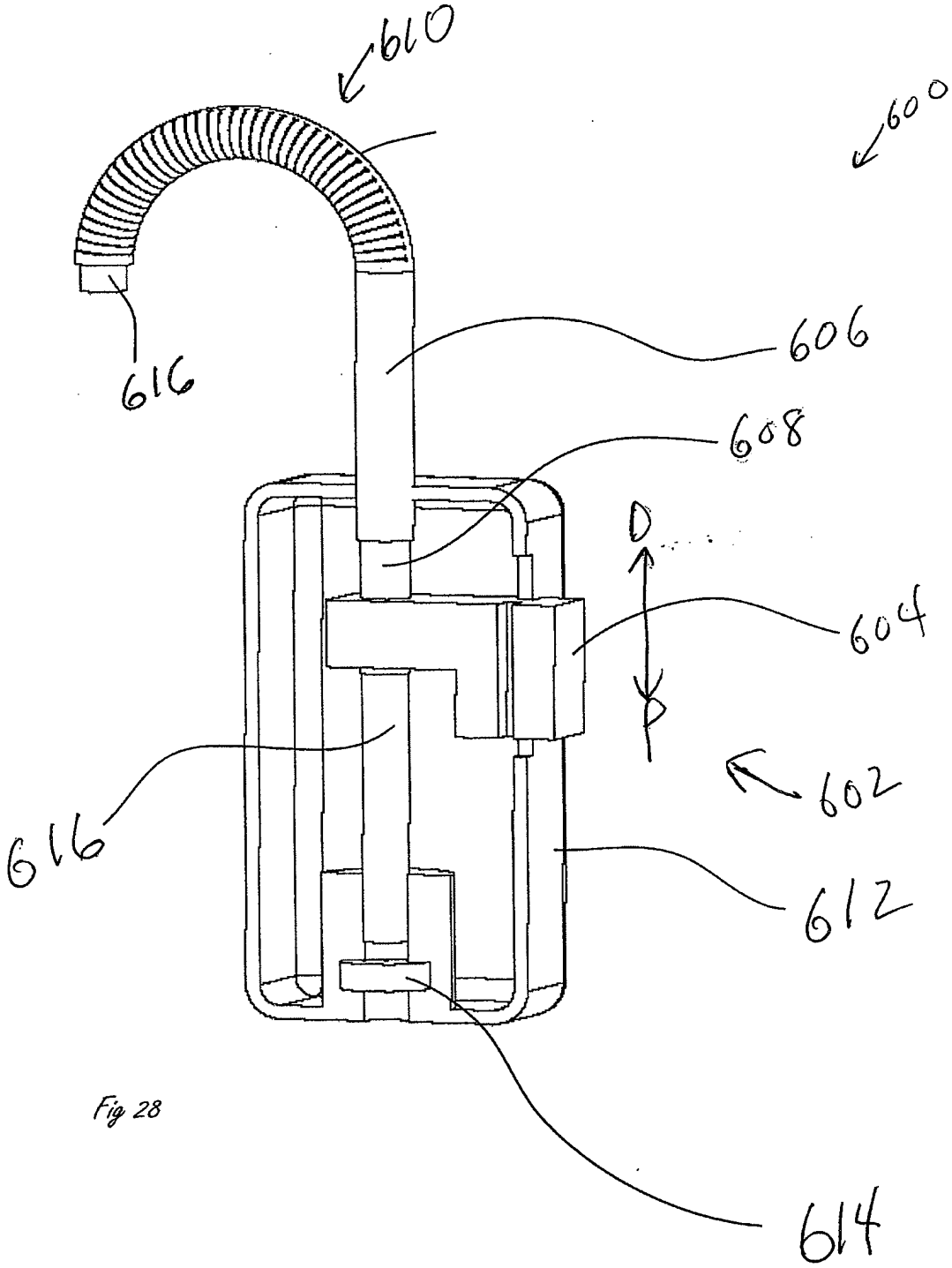


Fig 28

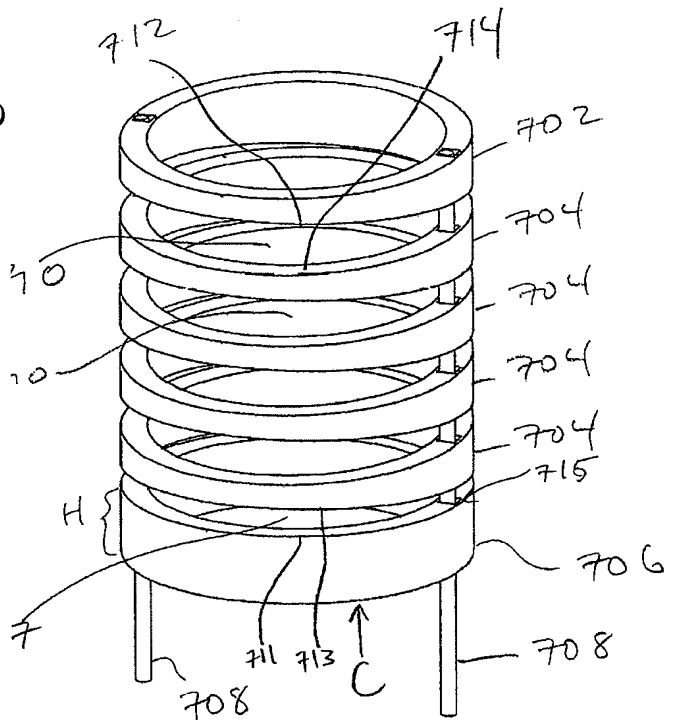


FIG. 29A

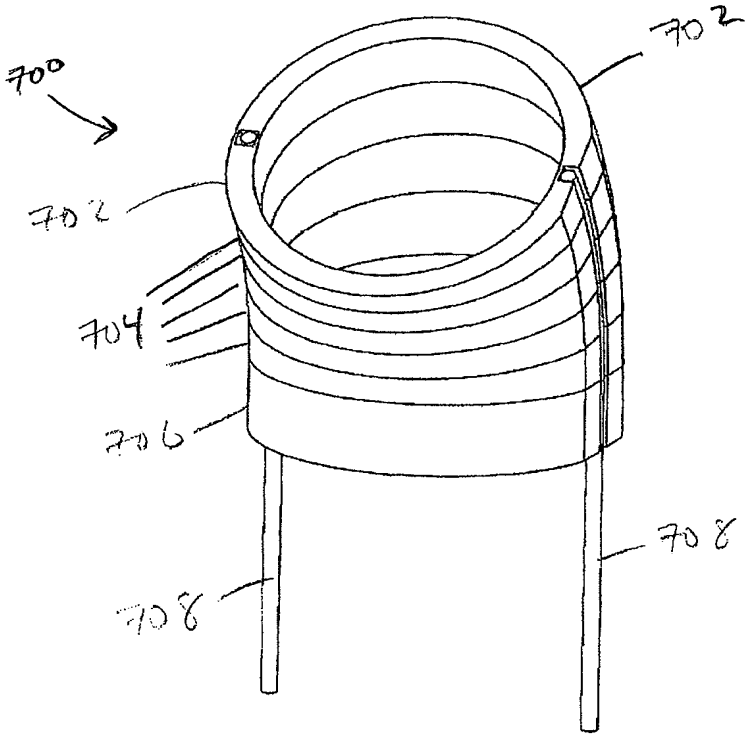


FIG. 29B

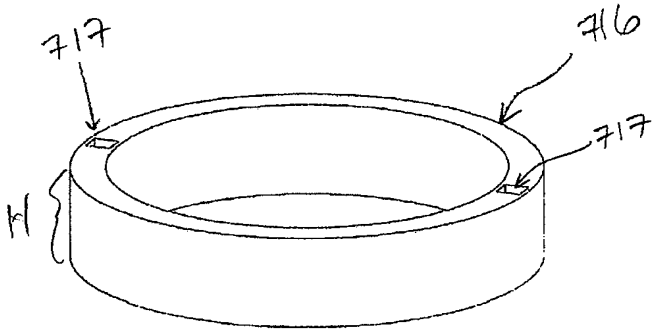


FIG. 30A

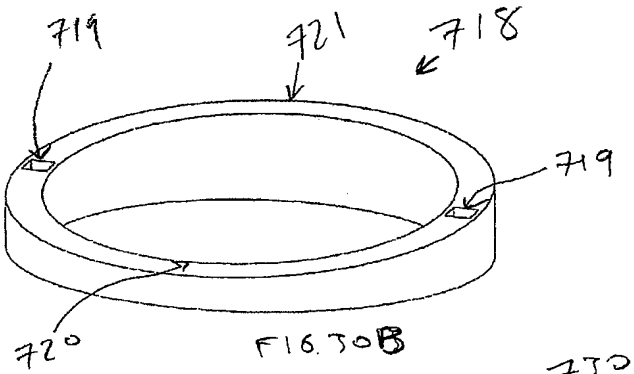


FIG. 30B

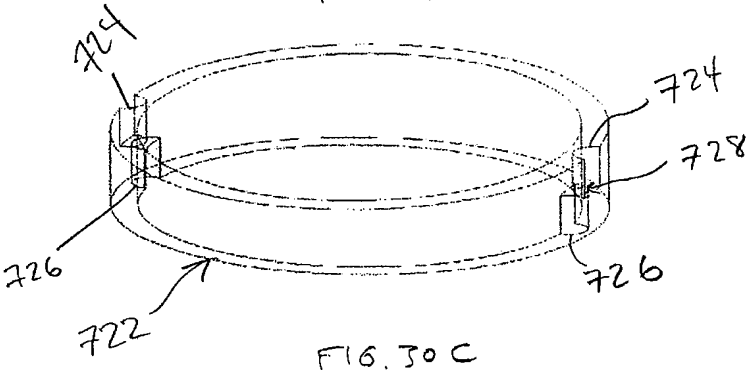


FIG. 30C

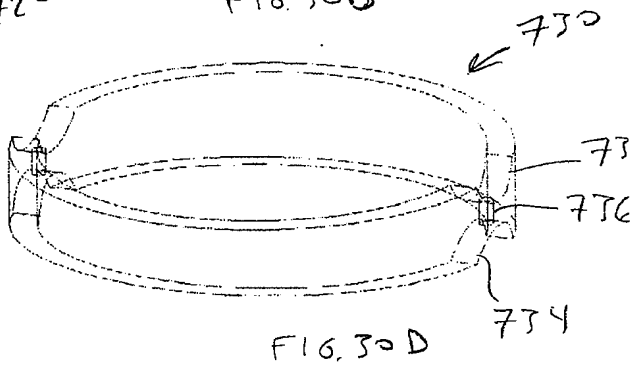


FIG. 30D

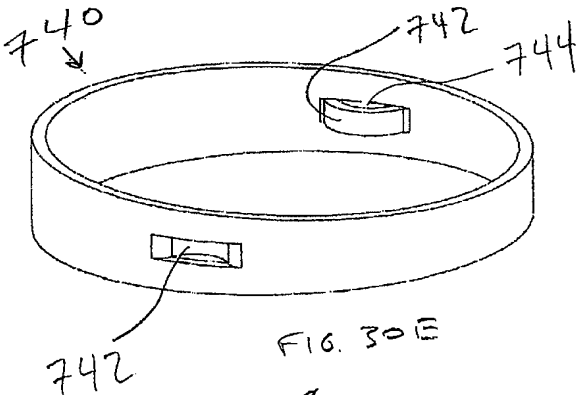


FIG. 30E

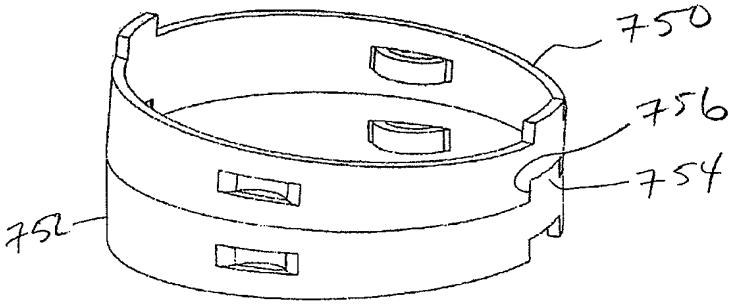


FIG. 30F

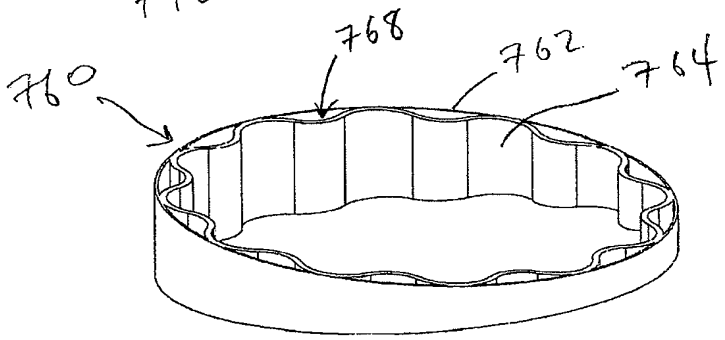


FIG. 30G

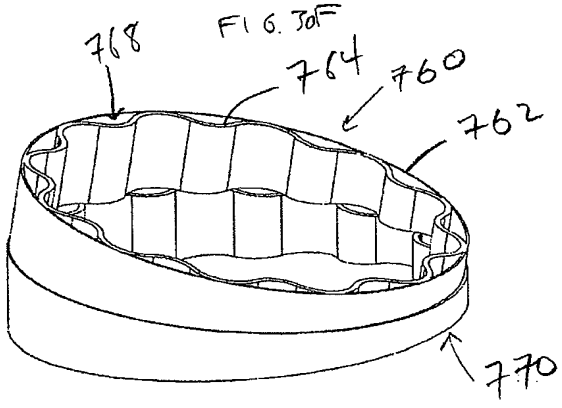


FIG. 30H

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 January 2019 (10.01.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/010318 A1

(51) International Patent Classification:
A61B 17/221 (2006.01)

(21) International Application Number:
PCT/US2018/040937

(22) International Filing Date:
05 July 2018 (05.07.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/529,386 06 July 2017 (06.07.2017) US

(71) Applicant: **STRYKER CORPORATION** [US/US]; 47900 Bayside Parkway, Fremont, California 94538 (US).

(72) Inventors: **WALLACE, Michael, P.**; 5849 Corte Margarita, Pleasanton, California 94566 (US). **GARABEDIAN, Robert, J.**; 1691 Notre Dame Drive, Mountain View, California 94040 (US). **WALLACE, Gavin, P.**; 5849 Corte Margarita, Pleasanton, California 94566 (US).

(74) Agent: **BURSE, David, T.** et al.; Vista IP Law Group LLP, 2160 Lundy Ave., Suite 230, San Jose, California 95131 (US).

(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).

(54) Title: INVERTING THROMBECTOMY APPARATUSES AND METHODS

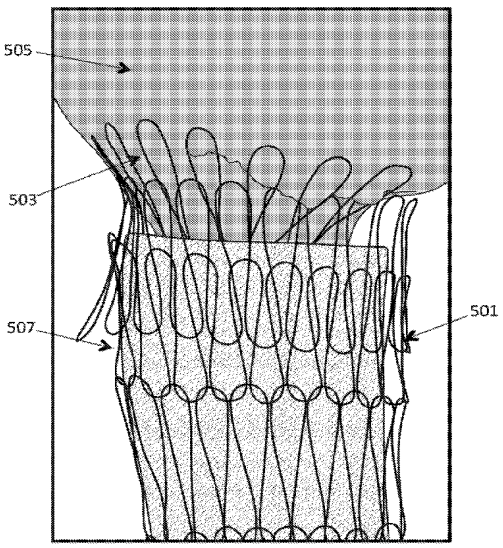


FIG. 5

(57) Abstract: A mechanical thrombectomy apparatus for removing a clot from a vessel includes an elongate inversion support catheter having a distal end opening, an elongate puller extending within the support catheter, and a knitted tractor tube (501) extending over an outer surface of the support catheter, inverting into the distal end opening of the support catheter, and attached to the elongate puller at a first end within the support catheter, wherein the portion of the knitted tractor tube extending over the support catheter comprises a wire forming a helical spiral of alternating teardrop shaped-links (503) each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facin g surface of the tractor tube, wherein the links flare outward from an outer wall of the support catheter when the puller is pulled proximally within the support catheter.

[Continued on next page]

WO 2019/010318 A1

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))*

INVERTING THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to U.S. provisional patent application no. 62/529,386, filed July 6, 2017, the content of which is herein incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

[0002] 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

[0003] The apparatuses and methods disclosed and described herein relate to mechanical removal of objects from within a body lumen, such as a blood vessel. In particular, disclosed and described herein are mechanical thrombectomy apparatuses and methods of using same.

BACKGROUND

[0004] 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.

[0005] 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.

[0006] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, interventions and procedures can reduce the need for an amputation by as much as 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.

[0007] Depending on the size, location and extent of a clot, it may be particularly advantageous to employ a mechanical thrombectomy device to remove the clot in a manner that is both safe and effective. Described herein are mechanical thrombectomy apparatuses (devices, systems and kit) and methods of using and making such apparatuses that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0008] Disclosed and described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them. In particular, described herein are mechanical thrombectomy apparatuses having improved rolling/inverting which may be particularly well adapted for removing large and hard clots, and/or difficult to grasp clots, from within a vessel. The disclosed and described apparatuses may include a low-friction (or friction-reducing) sleeve, one or more adaptations (e.g., chamfers, etc.) in the elongate inversion support catheter for pulling in larger clots, and knitted tractor tubes having woven links that are optimized for grabbing and compressing large clots without jamming. Also disclosed and described herein are mechanical thrombectomy apparatuses that may be

reusable. In particular, disclosed and described herein are mechanical thrombectomy apparatuses that include an elongate inversions support catheter over which the tractor (also referred to herein as a tractor tube, or an inverting tube) may be pulled to invert; these inversion support catheters may be configured so that they have a high degree of flexibility, but also a very high column strength.

[0009] For example, in some variations, the mechanical thrombectomy apparatuses disclosed and described herein are inverting tractor thrombectomy apparatuses that includes a tractor tube (e.g., tractor tube, inverting tube, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. In some variations this tractor tube may be knitted, and may be configured (e.g., sized, oriented, etc.) to roll smoothly over the distal end opening of the elongate inversion support catheter.

[00010] 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.

[00011] A knitted tractor tube may be configured to roll into the distal end opening of the elongate inversion support catheter without jamming by being oriented in an inverted knit, so that the adjacent rows of links are connected with the loops interlocking so that when the tube is inverted into itself, the loops are free to swing outward from the tube and are not held in place. For example, the loops of the knit are configured so that they pass under/over then over/under two loops of the adjacent rows. This arrangement may be configured as an "inverted knit" as most knitting machines will produce a tube that is woven in an over/under than under/over pattern.

[00012] For example, disclosed and described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel, the apparatus 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; and a knitted tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter, wherein the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter comprises a wire (e.g. a single wire or multiple wires) forming a helical spiral of alternating

(e.g., alternating extending proximally to distally and distally to proximally) teardrop-shaped links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, wherein the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally within the elongate inversion support catheter.

[00013] Any of these apparatuses may include a lubricious liner sleeve extending from within the elongate inversion support catheter and over the distal end opening of the elongate inversion support catheter. The pull force required to roll the knitted tractor tube over the distal end of the elongate inversion support catheter and into the elongate inversion support catheter may be less than about 250 g of force (e.g., less than about 225 g of force, less than about 215 g of force, less than about 200 g of force, less than about 190 g of force, less than about 175 g of force, less than about 150 g of force, less than about 125 g of force, less than about 100 g of force, etc.), e.g., by pulling the puller proximally to pull the tractor tube proximally into the inversion support catheter so that it rolls over and against the distal end opening of the inversion support catheter.

[00014] The lubricious liner may be, for example, a PTFE liner wrapping around the open distal end of the elongate inversion support catheter.

[00015] The knitted tractor tube may be formed of an alloy of nickel titanium.

[00016] In any of the apparatuses disclosed and described herein may be configured to easily roll over the distal end of the inversion support catheter while still extending outward to grab and pull the clot. For example, the links may have a length of L, and a grab width of W when flaring outward from the outer wall of the elongate inversion support catheter when the puller is pulled proximally, wherein W is between 30-90% of L (e.g., between 45% and 85%, of L, between 50% and 81%, etc.). The distal open end of the elongate inversion support catheter may be tapered, instead or in addition to using a lubricious sleeve.

[00017] The knitted tractor tube may include a second end (e.g., the proximal end that is pulled distally) that is unattached and free to slide over the outer surface of the elongate inversion support catheter. The second end may include a stop that is configured to prevent the second end from inverting over the distal end of the elongate inversion support catheter.

[00018] For example, disclosed and described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel, the apparatus comprising: an elongate inversion support catheter having a distal end and a tapered or rounded distal end opening; an elongate puller extending within the elongate inversion support catheter; and a knitted tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into

the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter, wherein the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter comprises a wire forming a helical spiral of alternating teardrop shaped-links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, wherein the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally within the elongate inversion support catheter, further wherein the links have a length of L, and a grab width of W when flaring outward from the outer wall of the elongate inversion support catheter when the puller is pulled proximally, wherein W is between 30-90% of L.

[00019] Also disclosed and described herein are methods of removing a clot from a vessel using an apparatus (e.g., device or system) such as those described above. For example, a method of removing a clot from a vessel may include: positioning the distal-facing end of the apparatus adjacent to the clot, and pulling the first end of a knitted tractor tube proximally (e.g., by pulling proximally on a puller attached to the tractor tube), so that the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter that forms a helical spiral of alternating teardrop-shaped links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, roll over the distal end of the device and invert so that the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally. The teardrop shaped arms may roll by seesawing over the open distal end of the inversion support catheter and swing outward with a lever arm force may grasp the clot and pull it into the device.

[00020] Also disclosed and described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that include: an elongate slotted inversion support catheter having a distal end and a distal end opening, wherein the elongate inversion support catheter comprises a spiral pattern having a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn of the spiral pattern; and a tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter; wherein the tractor tube is configured to invert over the distal end opening of the elongate inversion support catheter when pulled proximally into the elongate inversion support catheter.

[00021] In any of these apparatuses a second region of the elongate slotted inversion support catheter may be included and may comprise a second spiral pattern having a second plurality of slots arranged approximately transversely to the long axis of the elongate slotted inversion support catheter, wherein the second plurality of slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn of the spiral pattern. The second region may be adjacent to the first region and may be distally of the first region. Alternatively, the second region may be proximal to the first region.

[00022] Any of these apparatuses may include a puller that extends within the elongate inversion support catheter to which a first end of the tractor tube is attached.

[00023] In any of the apparatuses disclosed and described herein, there may be between 2 and 3 slots per circumferential turn (e.g., on average 2.5 slots). The spiral pattern may be helically arranged around the circumference of the elongate slotted inversion support catheter. The slotted inversion support catheter may be heat set into a compressed configuration so that the slots form closed cells in a relaxed configuration. The slots may extend between about 50 and 98% of each circumferential turn of the spiral pattern. In some variations, at least 1 mm of the distal end of the slotted inversion support catheter comprises the spiral pattern.

[00024] The spiral pattern may be configured so that at least 80% of a length of the slots contact and are supported by an opposite side of the slots when the elongate slotted inversion support catheter is longitudinally compressed. E.g., at least 85%, at least 90%, at least 95%, etc.). The slots may be rectangular. The elongate slotted inversion support catheter has a catheter compression yield force of greater than about 1000 g. The elongate slotted inversion support catheter may be one or both of: a nickel titanium alloy and stainless steel.

[00025] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate slotted inversion support catheter having a distal end and a distal end opening, a first region of the elongate inversion support catheter comprising a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn about the long axis; a second region of the elongate slotted inversion support catheter comprises a second plurality of slots arranged approximately transversely to the long axis of the elongate slotted inversion support catheter, wherein the second plurality of slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential

turn about the long axis; a tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter; and a puller within the elongate slotted inversion support catheter, wherein a first end of the tractor tube is attached to the puller; wherein the tractor tube is configured to invert over the distal end opening of the elongate inversion support catheter when pulled proximally into the elongate inversion support catheter.

[00026] Also disclosed and described herein are methods of removing a clot from a vessel using any of these apparatuses, including an apparatus having an elongate slotted inversion support catheter having a distal end and a distal end opening, a first region of the elongate inversion support catheter comprising a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn about the long axis; a second region of the elongate slotted inversion support catheter comprises a second plurality of slots arranged approximately transversely to the long axis of the elongate slotted inversion support catheter, wherein the second plurality of slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn about the long axis; a tractor tube extending over an outer surface of the elongate inversion support catheter. The method may include guiding the elongate slotted inversion support catheter through the patient's tortious vasculature by bending the second region more than the first region, e.g., by pushing it over a guidewire, etc.

BRIEF DESCRIPTION OF THE DRAWINGS

[00027] The various features and aspects of the inventions disclosed and described herein are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the disclosed and described apparatuses and methods will be obtained by reference to the following detailed description when read with the accompanying drawings, of which:

[00028] 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.

[00029] FIGS. 1G and 1H illustrate the use of 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.

[00030] 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).

[00031] FIG. 2A illustrates a first mechanical thrombectomy apparatus and method of using it to remove a clot. In FIG. 2A, the apparatus includes a lubricious liner that is inverted over the distal end opening of the elongate inversion support catheter. FIG. 3 is a flowchart illustrating the method shown in FIG. 2A.

[00032] FIG. 2B is the mechanical thrombectomy apparatus of FIG. 2A, and an alternative method of using it to remove a clot. In this example, the outer catheter ("intermediate catheter") is only partially withdrawn so that the distal end of the tractor tube (shown as a knit tractor tube) is still held in place against the outer wall of the elongate inversion support catheter portion by the intermediate catheter.

[00033] FIG. 3 is a schematic illustrating a method of operating a mechanical thrombectomy apparatus such as the one shown in FIG. 2A.

[00034] FIG. 4A is an example of a large (e.g., 3mm) and hard clot into a smaller ID catheter (e.g., 0.045 ID catheter of 1.2 mm opening diameter). FIG. 4B illustrates the normal forces on the inner and distal ends of the elongate inversion support catheter wall. The use of a low-friction material, such as a Teflon sleeve, extending around the distal end opening of the elongate inversion support catheter portion may prevent jamming and aid in compacting the hard clot.

[00035] FIG. 5 illustrates a knit tractor tube that may also aid in pulling a large-diameter clot into an elongate inversion support catheter. In FIG. 5, the loops forming the knit are interlocked, but may swing outward as the knit is rolled over the distal end opening of the elongate inversion support catheter, which may knead and/or masticate the clot, aiding in pulling it into the elongate inversion support catheter.

[00036] FIG. 6A illustrates an elongate inversion support catheter of a mechanical atherectomy apparatus including a low-friction liner (e.g., a PTFE liner) extended around the catheter tip to reduce pull friction.

[00037] FIG. 6B illustrates a modified tip for an elongate inversion support catheter, having a chamfer on the inner radius of the catheter to reduce pulling forces.

[00038] FIGS. 7A and 7B show an example of a knit tractor tube that undesirably includes regions where adjacent links of the knit include triple crossover points, e.g., as shown in greater detail in FIG 7B. Typically, when the diameter of the knitted tractor tube is greater than the outer diameter of the elongate inversion support catheter such that the adjacent links form triple cross-over points, as shown in FIG. 7B, the resulting tractor tube may roll move less smoothly (and/or may jam) over the distal end opening of the elongate inversion support catheter. In contrast, FIG. 7C and 7C shows an example of a knitted tractor tube having only double overlaps, which may more desirably roll over the elongate inversion support catheter. In FIG. 7D, an enlarged view of the links of the woven tractor tube is shown.

[00039] FIG. 7E and 7F illustrates a non-inverted knitted tube that is less desirable, as it may jam or prevent smooth rolling, despite having links that are the same dimension (and

formed of the same materials) as the inverted knit shown in FIG. 7C and 7D. FIG 7F is an enlarged view of FIG. 7E.

[00040] FIG. 8A is a side view of a distal end of a elongate inversion support catheter with a knitted tractor tube rolling into the distal end opening, illustrating tuning of the length, L, of the woven links to achieve a desired grab width, W, e.g., between 30-90% of L, for grabbing a clot with a woven tractor as described herein. FIG. 8B is an end-on view of the apparatus of FIG. 8A.

[00041] FIGS. 9A-9C illustrate an example of a mechanical thrombectomy apparatus that is configured as a reusable apparatus. In FIG. 9A, the apparatus includes a distal tractor stop/grip portion that prevents the tractor tube from inverting fully into the elongate inversion support catheter. Once the clot is pulled into the elongate inversion support catheter as shown in FIG. 9B, the apparatus may be removed from the body, and the clot ejected, e.g., by sliding the tractor tube along the outer diameter of the elongate inversion support catheter, as shown in FIG. 9C. The apparatus may then be re-used.

[00042] FIGS. 10A-10C illustrate variations of mechanical thrombectomy that may have improved tracking, e.g., within a vessel (e.g., lumen) and/or within the lumen of a catheter, such as an intermediate catheter. FIG. 10A show an example in which the elongate puller is adapted to include a nose region at the distal end, including a bumper. The distal nose region/bumper may extend out from the elongate inversion support catheter until the target location, near the clot, has been reached, and then retracted proximally to roll the tractor tube into the elongate inversion support catheter. FIG. 10B is another example in which the puller (e.g. pull wire or pull catheter) is slidable within a collar coupled to the tractor tube, but further includes an engagement region at or near the distal end of the puller that engages the collar and allows the puller to pull the tractor tube proximally in the elongate inversion support catheter to roll the tractor tube into the elongate inversion support catheter. FIG. 10C is another example in which the puller is a pull wire having a collar region near the distal end through which a guidewire may pass.

[00043] FIGS. 11A-11B illustrate another example of a mechanical thrombectomy that may have improved tracking, pulling of a clot and/or inverting of the tractor tube over the elongate inversion support catheter. FIG. 11A shows a puller (which may be solid or cannulated) having a distal tip region that includes a plurality of flanges or edges extending therefrom. In FIG. 11A the distal tip includes a plurality of cup-like members extending from therefrom. FIG. 11B shows another example of a puller in which the distal end includes a plurality of projections extending proximally. In FIG. 11B, the projections may be fringe or

fibers extending from the outer surface of the distal end of the puller, which may be tapered or cylindrical.

[00044] FIG. 11C shows an example of a distal tip of a puller configured to include a helical protrusion spiraling around the distal end.

[00045] FIG. 11D is an example of a distal end of a puller configured to have a stepped profile. In FIG. 11D, the stepped profile includes a plurality of (e.g., 5) different sized cones connected and arranged from larger (proximal) to smaller (distal). The cones may be separate or solid and fused together.

[00046] FIG. 12 is an example of an internal carotid artery, which has a tortious vascular path. This path may be divided up in to sub-regions, and a model of this path may be used to examine tracking of any of the apparatuses disclosed and described herein.

[00047] FIGS. 13A to 13C illustrate exemplary rectangular slots hat maybe formed in any of the inversion support catheters described herein. FIG. 13A shows slot that is in a neutral configuration, prior to heat setting in a collapsed or expanded configuration. In FIG. 13A, the slot has a width at the ends (w_1) that is approximately the same as the width in a middle region between the ends (w_2). In FIG. 13B, the slot has been compressed (e.g., by applying a longitudinal compression force on the catheter into which the slot is cut and heat setting in the compressed state) so that the width of the middle region (w_2) is less than the width of the end regions, which are not compressible (w_1). FIG. 13C shows a first open configuration, in which the slot has been pulled (e.g., by pulling a catheter in which the slot is formed in the longitudinal direction) to formed an open configuration, in which the middle region has a diameter (w_2) that is greater than the diameter of the end regions (w_1).

[00048] FIG. 14A shows three examples of inversion support catheters having a slotted pattern of cuts. FIG. 14B is an enlarged view of one of the inversion support catheters of FIG. 14A.

[00049] FIG. 14C describes a pattern used to form slotted inversion support catheter such as the ones shown in FIG. 14A.

[00050] FIG. 15 illustrates bending of a slotted inversion support catheter having a distal end region with a combination of open-cell and closed-cell slots cut cut into the distal ends; in this example, only two open-cell regions are included in the distal end region.

[00051] FIGS. 16A-16F illustrate increasing compression force applied to an exemplary slotted catheter, showing minimal compression/kinking. FIG. 16G shows the distal end of the device shown in FIGS. 16A-16F.

[00052] FIGS. 17A-17B illustrate another example of a slotted inversion support catheter undergoing 400 g of compression, showing kinking and shortening of the catheter. FIGS. 17C-17D illustrate a second example of a slotted inversion support catheter undergoing 400 g (FIG. 17C) and 300g (FIG. 17D) of compression; this example also kinked/shortened. FIG. 17D, shown for comparison, is the slotted inversion support catheter shown and described in FIG. 16A-16F, which did not substantially kink or shorten under 400g of compression. FIG. 17E illustrates another example of a slotted inversion support catheter similar to that shown in FIG. 16G, above.

[00053] FIGS. 18A-18E illustrates examples of slotted inversion support catheters having proximal regions with close-cell slots and distal regions with open-cell cut out regions (including slots).

[00054] FIG. 19A illustrates an example of an approximately rectangular slot in an open-cell (left) and closed-cell (right) configuration. FIG. 19B illustrates an example of a lobed slot (e.g., centrally tapered, hourglass-shaped, barbell-shaped) slot in an open-cell and closed-cell configuration. In FIG. 19B, even the closed-cell configuration remains open at the ends, as shown. FIG. 19C provides exemplary dimensions of the slots shown in FIGS. 19A and 19B.

[00055] FIGS. 20A-20C illustrate examples of bi-lobed slots (e.g., centrally tapered, hourglass-shaped, barbell-shaped) similar to that shown in FIG. 19B.

[00056] FIGS. 21A-21C illustrate another example of a slotted catheter having a brick-like pattern of aligned slots. FIG. 21A shows the repeating cut-out pattern that may be applied to a catheter (e.g., nitinol catheter tube). FIG 21B shows a side view of the slotted catheter. FIG. 21C shows a perspective view of the slotted catheter.

[00057] FIGS. 22A-22C illustrate another example of a slotted catheter having a spiral-like pattern of aligned slots. FIG. 22A shows the repeating cut-out pattern that may be applied to a catheter (e.g., nitinol catheter tube). FIG 22B shows a side view of the slotted catheter. FIG. 22C shows a perspective view of the slotted catheter.

[00058] FIGS. 23A-23C illustrate another example of a slotted catheter having a dog bone pattern of aligned slots. FIG. 23A shows the repeating cut-out pattern that may be applied to a catheter (e.g., nitinol catheter tube). FIG 23B shows a side view of the slotted catheter. FIG. 23C shows a perspective view of the slotted catheter.

[00059] FIGS. 24A-24C illustrate slotted catheters having different slot patterns along their length. FIG. 24A shows an alternating spiral/brick pattern. FIG. 24B shows an alternating spiral/dog bone pattern. FIG. 24C show a pattern of spiral/brick/spiral/dog bone/spiral, which may also alternate.

[00060] FIGS. 25A-25C illustrate an example of a slotted catheter having a continuous spiral slot cut into the catheter body. FIG. 25A shows the cut (slot) pattern including a notched, "bump" region that is spaced so as to align with a series of notched bumps in the long axis of the catheter, when cut in the spiral pattern, as illustrated in FIGS. 25B and 25C. In FIG. 25B a side view of the catheter is shown. FIGS. 25C shows a side perspective view of the catheter of FIGS. 25A-25C. Although three longitudinal lines of aligned bumps are sown circumferentially spaced in FIGS. 25B-25C; any number of aligned bumps (e.g., greater than 2, between 1 and 60, etc.) etc.) may be formed by the spiral cut.

[00061] FIG. 26 illustrates one example of an elongate slotted inversion support catheter of a mechanical thrombectomy apparatus for removing a clot from a vessel formed of both a stainless steel (laser cut) and NiTi (nickel titanium) that has been shape-set.

[00062] FIG. 27 illustrates a method of joining two regions of an elongate slotted inversion support catheter that are formed of different materials (e.g., stainless steel and nickel titanium).

[00063] FIG. 28 is an example illustrating the tracking (bending) of a distal end region of an elongate slotted inversion support catheter.

[00064] FIG. 29A illustrates an example of a traditional catheter exposed to a high compression force (e.g., when pulling a guidewire through the distal end of the apparatus), showing buckling along the length.

[00065] FIG. 29B is another example illustrating an apparatus configured as described herein, e.g., using a specifically configured elongate slotted inversion support catheter having a region of the elongate inversion support catheter comprising a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein there are between 2 and 4 slots per circumferential turn about the long axis.

DETAILED DESCRIPTION

[00066] In general, disclosed and described herein are mechanical thrombectomy apparatuses having an inverting flexible tractor tube that is configured to invert over an elongate inversion support catheter. One end of the tractor tube may be coupled to a puller (e.g., pull wire, pull catheter, etc.). In particular, disclosed and described herein are apparatuses including one or more adaptations to prevent jamming and/or roll smoothly, particularly when pulling a large and/or hard clot.

[00067] 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.

[00068] In many of the examples disclosed and 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 methods and 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 and methods disclosed and 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.

[00069] FIGS. 1A to 1I illustrate various components of a mechanical thrombectomy apparatus that may include any of the features disclosed and described herein. For example, FIG. 1A shows a catheter (e.g., an elongate inversion support catheter) that may form part of the apparatuses disclosed and 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.

[00070] 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 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 disclosed and 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.

[00071] 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).

[00072] 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).

[00073] 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.

[00074] 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.

[00075] 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).

[00076] 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.

[00077] In general, the mechanical thrombectomy apparatuses disclosed and 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 neuro-vasculature. Disclosed and 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, disclosed and 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.

[00078] 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. Altematively, 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.

[00079] 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.

[00080] 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.

[00081] In any of the variations disclosed and 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.

[00082] 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.

[00083] 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.

[00084] 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.

[00085] 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.

[00086] 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 (e.g., 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.

[00087] In any of the apparatuses disclosed and described herein, the catheter (e.g., the inversion support catheter) may be covered with a jacket along all or a part of its length. This jacket may be highly elastic, and may include a single layer or multiple layers. The jacket may be have a single durometer (e.g., stiffness) or multiple durometers along its length; for example the jacket durometer may be less stiff near the distal end of the catheter. The jacket

may be formed of any appropriate material, including urethane (e.g., Teflon 20A to 93A, e.g., 80-85A), PEBAX (e.g., 25A to 72D), silicone, nylon, etc. In an of these variations the jacket may be continuous or formed along with a sleeve such as described above, that transitions from the inside of the catheter and around this distal end opening and along the outer surface of the catheter. The jacket may be integrally formed and/or fused to the sleeve. The sleeve may also be referred to as a liner. As mentioned, the sleeve may be a lubricious material, such as PTFE, FEP, HDPE, Polypropylene, and/or other polymers, particularly those with modifier such as siloxane modifiers. The jacket may be bonded to the sleep/liner (e.g., through the cut frame of the catheter, such as a slotted catheter).

[00088] 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.

[00089] Any of the apparatuses disclosed and 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)

[00090] 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.

[00091] Any of the tractors disclosed and described herein may include a marker or makers (e.g., radiopaque markers, such as gold, Pt, etc.).

[00092] Any of the apparatuses disclosed and described herein may include a lubricious sleeve within the distal end of the elongate inversion support catheter to enhance rolling of the tractor tube, and particularly a knitted tractor tube into the distal end of the elongate inversion support catheter. For example, FIG. 1A illustrates a first example of a mechanical

thrombectomy apparatus including a lubricious liner 211 that wraps over the distal end of the elongate inversion support catheter 201. In this example, the inverted knitted tractor tube 203 rolls over the distal end of the elongate inversion support catheter and is attached at one end to a puller 207 (shown as a pull wire in this example). Pulling proximally on the puller rolls the tractor tube into the elongate inversion support catheter's distal end opening and pulls the clot 219 into the elongate inversion support catheter. The apparatus may include or may be operated with a guide catheter 205, so that the inner elongate inversion support catheter may be extended distally out of the guide catheter. In some variations, the guide catheter may be used to releasably secure the outer portion of the tractor tube 203 against the outer surface (outer diameter) of the elongate inversion support catheter 201 and may be retracted fully (as shown in FIG. 2A) or partially (as shown in FIG. 2B) when operating the apparatus to grab and/or remove a clot 219.

[00093] FIG. 3 schematically illustrates a method of removing a clot using an apparatus including a lubricious sleeve inverting over the distal end of the elongate inversion support catheter, similar to that shown in FIG. 2A. In FIG. 3, the method may include generally delivering a guide (or "intermediate") catheter to the face of a clot 301. This step may be optionally performed with the mechanical thrombectomy apparatus (e.g., the elongate inversion support catheter and tractor tube pre-loaded, e.g., near the distal end of the delivery catheter). Thereafter, the thrombectomy catheter may be delivered thru guide (intermediate) catheter 303 so that the elongate inversion support catheter is near the face of the clot. Once in position, the tractor may be deployed; for example, while applying some push force on the elongate inversion support catheter, the guide (intermediate) catheter may be retracted to un-sheath the tractor tube 305. This may result in the arrangement shown in FIG. 2A, for example. Optionally, aspiration may be applied through the elongate inversion support catheter (and/or the puller in variations of the puller having an inner lumen) before retracting the guide (intermediate) catheter. Aspiration may therefore be optionally through elongate inversion support catheter (and/or the intermediate catheter). Thereafter, the puller connected at one end to the tractor tube may be pulled proximally, preferably while putting forward an advancing force on the elongate inversion support catheter, to grab and remove the clot from the vessel 309.

[00094] Alternatively, as shown in FIG. 2B, the guide (intermediate) catheter 205 may be only partially withdrawn over the elongate inversion support catheter 201 so the distal end of the knitted tractor tube 203 is still contained inside the intermediate catheter. This configuration may provide additional support for the elongate inversion support catheter

when engulfing the clot with the knit tractor tube, so it is less likely to buckle or snake when it is exposed to the related compressive loads.

[00095] This configuration may also, because of the additional outside support of the intermediate catheter, allow the user to more easily advance the elongate inversion support catheter forward in the vessel as the trailing edge of the clot is engulfed. The intermediate catheter can cover 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, etc., of the tractor length on the outside of the catheter. Or the intermediate catheter can be positioned less than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 10 cm, etc. back from the distal tip of the elongate inversion support catheter.

[00096] The lubricious liner wrapping around the elongate inversion support catheter tip may be any appropriate liner. The liner typically wraps from an outer surface of the elongate inversion support catheter over to an inner surface of the elongate inversion support catheter. This may be in addition to or instead of a coating and/or shaped distal end region of the elongate inversion support catheter.

[00097] FIGS. 6A and 6B illustrate another example of a lubricious liner. For example, in FIG. 6A the lubricious liner 601 is a PTFE liner wrapping around the open distal end of the elongate inversion support catheter 603. A tractor tube (a nickel titanium knitted tractor 605) is shown inverting into the end and over the PTFE liner 601. One end of the tractor tube is connected to a puller 609 and may be drawn proximally to pull in a clot 607.

[00098] Alternatively, or additionally, the elongate inversion support catheter may be shaped to reduce the pull force need to to invert the tractor tube into the elongate inversion support catheter. For example, FIG. 6B shows an elongate inversion support catheter 613 distal end opening may be shaped (e.g., chamfered 645) to reduce the pull force/friction.

[00099] In general, larger (e.g., clots having a diameter greater than 2x the diameter of the elongate inversion support catheter) and/or hard clots may be more difficult to compress and pull into a mechanical thrombectomy apparatus. Surprisingly, the apparatuses and methods disclosed and described herein may be used to draw even larger and hard clots into the apparatus.

[000100] A hard clot typically may take a significant compressive load in order to compress the clot and engulf it in a smaller ID elongate inversion support catheter. As mentioned, hard clot may require a significant compressive load to compress the clot, generating a relatively high normal force to the distal & inner end of the catheter wall. The low friction surface (including sleeves) disclosed and described herein may help reduce the load to pull in clot to less than 300 g of force, when measured from the pull force required to pull the tractor

grabbing the clot into the elongate inversion support catheter (e.g., less than or equal to 300 g, less than or equal to 250g, less than or equal to 200 g, etc.). FIG. 4A and 4B illustrate the compression of a large-diameter (compared to the diameter of the elongate inversion support catheter) clot into an apparatus as disclosed and described herein. FIG. 4A shows a 3mm clot being pulled into a 0.045 ID catheter (having a diameter of 1.22 mm). In FIG. 4B, the arrows 403 show normal forces generated at the inner opening edge of the elongate inversion support catheter.

[000101] As mentioned above, any of the apparatuses disclosed and described herein may preferably include knitted tractor tubes. The orientation (e.g., "inside out") as well as the shape-set of the knit may be selected to prevent jamming, reduce the pull force necessary to invert the tractor into the elongate inversion support catheter, and may help knead, compress, and/or drive the clot into the opening of the elongate inversion support catheter. For example, FIG. 5 illustrates an example of a knitted tractor 501 being pulled to invert into an elongate inversion support catheter 507. The knit is formed by knitting single strand of wire (though multiple strands of one or more filaments, weaves, braids, etc. may be used) to form a plurality of rows of loops 503 that are interconnected. The loops may be pulled and inverted into the distal end opening of the elongate inversion support catheter so that, when in the inverted knit configuration, they flare outward and push the clot 505 into the elongate inversion support catheter. In FIG. 5 the clot is a large-diameter clot (>2x the diameter of the elongate inversion support catheter) and the knit tractor is shown flaring out to whip in front of the elongate inversion support catheter tip to knead the clot into catheter.

[000102] FIGS. 7A-7F illustrate an example of knitted tractor tubes. FIGS. 7A (and the enlarged view 7B) illustrate a first variation of a knitted tractor tube having a knit pattern that is less optimal, as the diameter of the knitted tractor tube is sufficiently large so that there are triple crossover points between the wire (e.g., strand, fiber, filament, etc.) forming the knit. Such "triple overlap" regions 705 may result in a thickness or OD of the tractor tube that is undesirably large. Thus, it may be better to size and/or shape set the knitted tractor tube to prevent or minimize these triple overlap regions in the links forming the knit (e.g., having less than 10% triple overlaps, <9%, <8%, <7%, <6%, <5%, <4%, etc.). FIGS. 7C (and the enlarged region shown in FIG.7D) illustrate a more optimized variation of a knitted tractor tube showing only double overlaps 707.

[000103] As mentioned above, it is also desirable to use a knitted tractor tube pattern in which the orientation of the knit is inverted (as compared to most commercially available knitted tubes), so that the links, when the tractor tube is inverted over the distal end opening

of an elongate inversion support catheter and pulled into the elongate inversion support catheter, the links flair outward. Thus, the orientation of the knit may be configured so that the apex (tip) of the loops in each row are on the outside face of the elongate inversion support catheter over which the tractor tube is inverting, compared to the adjacent pair of links that each link loop is connected to. This inverted knit configuration is shown in FIG. 7C and 7D. For example, in FIG. 7D the link 703 is formed of a filament (e.g., nitinol, polymeric material, etc.) that is knitted into a pattern of adjacent links that are interconnected (e.g., as the double crossover points 707, 707'). The knitted tractor tube is shown over an elongate inversion support catheter 709, so that the outward-facing surface of the knitted tractor tube includes all of the apexes 711 of each link. These links are therefore arranged to pass under then over a first adjacent link, then over and under a second adjacent link, as shown in FIG. 7D, leaving the apex region on the outward-facing side of this "inverted" knit configuration. In contrast, FIGS. 7E (and enlarged view 7F) show a non-inverted knit configuration, in which each link 713 includes an apex 721 that is instead underneath (on the side facing the elongate inversion support catheter, not shown). Each loop is this example is formed of a filament that is woven in an over-under and then under-over pattern relative to adjacent links of the knit. The non-inverted knitted tube shown in FIGS. 7E and 7F is constrained when inverting over an elongate inversion support catheter, so that it cannot swing outward relative to the distal end of the elongate inversion support catheter, by the adjacent links. As a result, the pulling force of the tractor tube is surprisingly higher, and the clot-grabbing of the tractor may also be greatly reduced.

[000104] FIG. 8A shows an example of an inverted knit tractor tube rolling over the distal end opening of an elongate inversion support catheter. In any of these variations, the knitted pattern may be optimized so that the stich length (L) may be tuned to get a desired grab width (W) increase that is greater than elongate inversion support catheter outer diameter (OD). This larger grab width may aid in grabbing a clot with the apparatus. In FIG. 8A, the length of each knitted link (L) is shown, as is the width (W) that the link ends outwards when inverting into the itself and the elongate inversion support catheter. Typically, it has been found to be desirable to have a width (W) of between about 30-90% of length (L). The exact dimension of the width (W) may depend on the tension in the knit used to pull in the clot (e.g., the great the tension, the smaller the W dimension), and the flexibility of the filaments used in the knit structure (e.g., the softer the filament used to form the knit, the smaller the W). The knit can be tuned through both the design and the processing so when it is tensioned at loads between 100-500 grams (g), the structure may have a limited elongation (e.g., <15%,

<12%, <10%, etc.0). When the knit structure is in this non-compliant/semi-compliant form the OD & ID of the knitted tractor tube may also be stable (e.g., having a <20%, less than 15%, less than 12%, less than 10%, etc. diameter change) under loads between 100-500 g. In this non-complaint/semi compliant form, the knit OD may be greater than the thrombectomy catheter, but less than the vessel OD. In other variations, the knit OD may be greater than the catheter OD, and the knit is rolled around and less than 5%, %10%, 20%, 30%, 40%, 50%, 60%, 70%, 80% of the same catheter OD.

[000105] Also disclosed and described herein are reusable mechanical thrombectomy apparatuses. For example, FIGS. 9A-9C illustrate one reusable mechanical thrombectomy apparatus and method of use. In FIG. 9A, the apparatus includes a tractor tube (shown here as a knitted tractor tube 903). One end of the tractor tube is coupled to a puller 909 within the inner diameter of the elongate inversion support catheter 905. The puller in this example is configured as a hollow tube, which may allow passing of a guidewire and/or vacuum. The other end of the tractor is coupled to a distal tractor stop forming a finger grip 901 that is configured to slide over the outer surface of the elongate inversion support catheter. The finger grip may be sized for ease in grabbing manually and sliding proximally to "reload" the apparatus, as described below.

[000106] In FIG. 9A, the apparatus may be positioned near the clot 911, and the puller drawn proximally to invert and roll the tractor tube 903 into the elongate inversion support catheter 905, while advancing distally, and thereby pull the clot 911 into the elongate inversion support catheter (shown by arrow. 917). Once grabbed, either fully or partially, as shown in FIG. 9B, the apparatus may be withdrawn from the vessel, the clot may be removed, as shown in FIG. 9C, by pulling the outer portion of the tractor tube proximally. The tractor tube is prevented from completely inverting into the elongate inversion support catheter by a distal stop 907 on the elongate inversion support catheter. For example, in FIG. 9C, the outer portion of the tractor tube may be manually pulled proximally 915 by sliding the distal tractor stop/grip 901 proximally, ejecting the compressed clot 911 from inside the apparatus. The device may then be rinsed and re-used to remove additional clot(s).

[000107] Any of the apparatuses disclosed and described herein may be adapted to enhance tracking with an intermediate catheter and/or a lumen of a vessel. To assist the mechanical thrombectomy apparatus in tracking inside an intermediate catheter or tracking directly inside a native vessel (e.g., in which the puller, tractor tube and elongate inversion support catheter must track inside the distal end of an intermediate catheter), it may be beneficial to allow the puller to extend distally relative to the elongate inversion support catheter without disrupting

the tractor tube. For example, FIG. 10A illustrates one example of a mechanical thrombectomy apparatus including a tractor tube 1003, elongate inversion support catheter 1005 and puller 1007, which is shown within an intermediate catheter 1010. In this variation, the distal end of the puller is configured to include a bumper region 1009 that can extend distally out past the distal end of the elongate inversion support catheter 1005. This nose element ("bumper") 1009 may be a constant stiffness or variable stiffness structure. For example, the distal end may be the softest section and the section most proximal to the distal end of the catheter may be less soft, and/or possible tuned to be of similar stiffness to the distal end of the elongate inversion support catheter. The tractor tube may be coupled proximal to the distal end, which may extend, e.g., approximately 1 cm, as shown.

[000108] In this example, the distal nose of the pull wire may be solid or cannulated (as shown). A cannulated nose may allow for guidewire access and also for aspiration through the intermediate catheter to allow vacuum forces to reach any clot or any other targeted element located in the body or vessel.

[000109] In use, the user may approach the clot within the lumen of the vessel with the nose region of the puller extended from the elongate inversion support catheter or extended within the elongate inversion support catheter. Once near the clot the nose region may be retracted inside the elongate inversion support catheter. Next the user may optionally pull a vacuum through the elongate inversion support catheter to engage the clot into the tip of the elongate inversion support catheter. Then, while slightly advancing the intermediate catheter, the tractor tube may be pulled proximally into the elongate inversion support catheter by pulling proximally on the puller.

[000110] FIG. 10B illustrates another example of a mechanical thrombectomy apparatus having a puller (elongate puller 1027) which is configured to freely extend distally relative to the tractor tube, but when pulled proximally may engage with the tractor tube 1003 at one end to pull it proximally into the elongate inversion support catheter 1005. A portion (e.g., at or near a distal end region of the puller) may include one or more engagement regions (e.g., bumps, projections, etc.) that may engage with an annular ring or collar to pull the tractor tube proximally so that it may invert into the elongate inversion support catheter and therefore pull clot into the apparatus. In FIG. 10A, the puller can be extended beyond the tip of the elongate inversion support catheter at the user's preference when advancing the system to the clot. The male bump or other grabbing mechanism will engage on the proximal end of the tractor to pull in the clot.

[000111] FIG. 10C illustrates another variation, in which the puller 1047 is configured to pass a guidewire and maybe extended or retracted using the guidewire 1055. In FIG. 10C, the construction that allows a guidewire to track through its lumen to aid in tracking within the vessel. For example, in FIG. 10C he puller includes a guidewire channel at the distal end region to which the tractor tube is attached.

[000112] In general, any of the mechanical thrombectomy apparatuses may include a modified puller that may enhance trackability, clot grabbing and/or pulling of the tractor tube into the elongate inversion support catheter. In addition to the examples shown and described in FIGS. 10A-10C, FIGS. 11A-11D show puller apparatuses that have a distal region adapted to include one or more projections.

[000113] The puller tips shown in FIG. 11A-11D may enhance the trackability of the apparatus (e.g., the elongate inversion support catheter and/or tractor tube and/or puller) through tortuous anatomy, including the lumen of the vessel and/or an intermediate catheter. For example, FIG. 11A shows an apparatus including a tractor tube 1103, an elongate inversion support catheter 1105, and a puller 1107. In this example, the apparatus is used within an intermediate catheter 1110. The distal end 1109 of the puller 1107 is tapered and includes a plurality of projections 1115 extending away from the tapered distal end of the outer surface of the puller. In this example, the projections are configured as cups 1115 that have proximal-facing edges. The projections of this distal tip region may be used to grab and/or hook onto a clot when deployed; the puller may be advanced distally as described above and projected either by itself or over a pullwire into a clot 1127, as shown in FIG. 11A. When retracting the puller, the distal tip may pull the clot to the distal opening of the elongate inversion support catheter and/or it may advance the elongate inversion support catheter and tractor towards the clot. Any of these puller embodiments may be used with or without aspiration (e.g., through the elongate inversion support catheter, intermediate catheter and/or puller). Thus, in FIG. 11A, the distal end is configured as a cup-shaped male feature. The puller distal end region may be solid or cannulated and may be tapered (as shown in FIGS. 11A-11D) or non-tapered (e.g., cylindrical). In FIG. 11A, each projection ("cup") extends all or partially around the entire tip and more distal projections may have smaller diameters.

[000114] Another example of a puller having a plurality of projections is shown in FIG. 11B. In FIG. 11B, the projections are configured as fibers or fingers extending proud (and may be angled proximally) from the outer surface of the distal tip off the puller 1107'. In any of these examples, the puller (including the distal tip region of the puller 1107') may be solid or cannulated. In FIG. 11B, the distal tip region of the puller includes one or more sets of

projections 1125 (e.g., fingers or fibers) directed proximally. The projections may be constructed from an open-end braid feature. The projections may be configured (oriented and/or soft enough) to slide into the clot when extending distally, but when retracing the puller proximally the projections may flare out and help anchor the tip of the puller the clot, as shown in FIGS. 11A and 11B. Optionally the projections may also engage with the tractor tube when pulled proximally and/or distally and may help pull the tractor and clot back through the elongate inversion support catheter.

[000115] FIGS.11C and 11D illustrate alternative variations of puller tips including protrusions. In FIG. 11C, the puller tip 1135 includes one or more helical projections 1137 extending proud of the outer surface of the puller and extending around the puller. In some variations the projections are formed of a wire wrapped around the distal tip of the puller; the wire forms the male projection. FIG. 11D shows another example of a distal tip region 1145 having a stepped profile forming projections from the distal end of the puller. In this example, the distal end is formed by a plurality (e.g., two, three, four, five, six, etc.) of cones that are arranged in progressively smaller sizes extending distally (forming a tapered tip region). The cones may be solid or cannulated. The tip may be formed of a plurality of connected elements or may be a unitary (or fused) element.

INVERSION SUPPORT CATHETERS

[000116] Ad discussed above, any of the apparatuses disclosed and described herein may include an elongate inversion support catheter having a distal end and a distal end opening, in addition a tractor tube (e.g., a knitted tractor tube). In operation, the tractor tube extends over an outer surface of the elongate inversion support catheter, and inverts into the distal end opening of the elongate inversion support catheter when the end of the tractor tube is pulled into the inversion support catheter, for example, by pulling on the elongate puller coupled to a first end of the tractor tube that is within the inversion support catheter. Thus, as mentioned above, the inversion support catheter must have a sufficient column strength so that it does not buckle or collapse as the tractor tube is pulled into the distal end of the inversion support catheter, even when pulling a hard clot.

[000117] The inversion support catheter 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), particularly when the apparatus is configured for neurovascular applications. For peripheral vascular applications, the elongate inversion support catheter 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 addition, the inversion support catheters disclosed and described herein may be configured so that they do not foreshorten substantially when the tractor tube is pulled over the distal end (e.g., do not foreshorten by more than 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, 10%, etc.).

[000118] It may also be desirable that the inversion support catheters maintain sufficient column strength even when tracked or tracking though highly tortious anatomical regions. FIG. 12 is an example of a tortious neuroanatomical region, showing a drawing of the internal carotid artery, which includes multiple regions (labeled as regions 1, 2, 3, 4 and 5 in FIG. 12). The inversion support catheters disclosed and described herein may have sufficient column strength and may have a structure configured to resist buckling and compression when pulling a tractor tube so that it rolls into the distal end opening of the inversion support catheter (often applying up to 500g of force or more in compression), yet still be sufficiently flexible to track through such tortious regions of the vasculature including regions 1-5 of an internal carotid artery such as the example shown in FIG. 12.

[000119] A number of inversion support catheter designs have been examined by the applicants. Many of the inversion support catheters tested, even those having cut-our regions that enhance flexibility, and those with support structures to enhance column strength (e.g., withstanding up to 500 g or more of compression force), do not have both a sufficient column strength to resist buckling/compression and a sufficient flexibility to navigate a region having a tortuosity equivalent to that in a model internal carotid artery, such as the one shown in FIG. 12. Disclosed and described herein are inversion support catheters configured to meet these criteria. In particular, disclosed and described herein are inversion support catheters having a plurality of slots ("slotted inversion support catheters") in which the slots are configured to provide both column strength and flexibility. Slots are typically formed substantially transverse to the long axis of the the catheter, wherein substantially transvers includes e.g., +/- a few degrees off transverse (e.g., +/- 2 degrees, +/- 3 degrees, +/- 4 degrees, +/- 5 degrees +/- 7 degrees, +/- 10 degrees, +/- 12 degrees, etc.). The slots may be cuts through the catheter that extend approximately transverse to the length of the inversion support catheter (at a pitch of between +/- a few degrees, e.g., a pitch of between 0.05 to 0, etc.). The slots may extend, for example, between 60 and 180 degrees (e.g., between 90 and 180 degrees, between 100 and 170 degrees, between 110 and 160 degrees, between 120 and 150 degrees, etc.) around the circumference of the inversion support catheter.

[000120] In some of the variations disclosed and described herein, the slots are formed, e.g., by laser cutting, rectangular cut-out regions. The slots may be configured as compressed slots, e.g., by heat-setting the catheter or a portion of the catheter into a longitudinally compressed state. In the compressed state, the slots be configured so that the ends of the slots, which are not typically compressible, have a fixed width, and the region between the ends of the slots is compressed so that the width of this region is less than the width of the ends of the slots. See, e.g., FIGS. 13A-13C. For example, In FIG. 13A a "neutral" slot is shown cut through a catheter, and typically curving around the radius of the catheter. The slot shown in FIG. 13A has end regions 1301, 1305 of the slot that each have a width (w_1) that is approximately the same width as the middle region 1303 between the ends (w_2). For example, the width may be between 0.01 and 0.0001 inches (e.g., between 0.005 and 0.0001, between 0.001 and 0.0001, etc.). The neutral slot shown in FIG. 13A may be compressed, e.g., by applying a compressive force on the long axis of the catheter and heat-setting the catheter in the compressed configuration. This may form a compressed slot, also referred to herein as a "closed" slot or "closed cell" slot. In FIG. 13B a closed rectangular slot is shown, having edge regions that have a width (w_1) that is substantially the same as in the neutral position, however the middle region 1303 between the ends 1301, 1305 has a width (w2) that is less than the width at the ends of the slot (e.g., $w2 < w_1$, e.g., $w_2 < 95\% w_1$, $w_2 < 90\% w_1$, $w_2 < 85\% w_1$, etc.).

[000121] The slot may also be opened, as shown in FIG. 13C. In some variations, the slot is opened by applying a tension (e.g., by pulling) force on all or a portion of the elongate length of the catheter into which the slot is formed, and heat-setting the slot in the resulting expanded configuration. In FIG. 13C the middle region 1303 of the slot has been expanded to have a width (w_2) that is greater than the width (w_2) of the end regions 1301, 1305. This may be referred to an an open or open cell configuration for the slot. For example, in an open configuration of a rectangular slot, $w_2 > w_1$. In some variations, in which w_2 is much larger than w_1 (e.g., $w_2 >> w_1$, e.g., w_2 is greater than about $2x\ w_1$, w_2 is greater than about $2.5x\ w_1$, w_2 is greater than about $3x\ w_1$, w_2 is greater than about $4x\ w_1$, w_2 is greater than about $5x\ w_1$, etc.) these slots may be referred to as super-open slots.

[000122] Any of the inversion support catheters disclosed and described herein may be configured so that the distribution of slots is non-uniform along the length of the catheter. For example, the distal end region of a slotted inversion support catheters (e.g., the distal most region of the catheter between 1-50 mm from the distal end, e.g., between 2-30 mm, between 2-20 mm, between 2-10 mm, etc.) may include open-cell slots (all or some open-cell slots.

The portion of the catheter proximal to this distal end may include closed cell or normal slots. In some variations, the catheter may include both open-cell and closed-cell slots arranged around and along the distal end region. The percentage of open-cell slots may be, e.g., between 0.1%-80% of the total number of slots in the distal end region (e.g., between 0.1% to 70%, between 0.1% to 60%, between 0.1% to 50%, between 0.1% to 40%, between 0.1% to 30%, between 0.1% to 20%, between 0.1% to 10%, between 0.1% to 5%, etc.).

[000123] As will be described in greater detail herein, in some variations, the catheter, and particularly the distal end region, may include super open-cell slots. In particular, the percentage of super open-cell slots to other open-cell slots and closed-cell slots may be less than 50% (e.g., less than 40%, less than 30%, less than 20%, less than 10%, less than 5%, less than 1%, less than 0.5%, etc.). As mentioned, other slots may be closed-cell slots and/or may have different dimensions. The region of the inversion support catheter proximal to the distal end region may have a slotted configuration of closed-cell slots.

[000124] It is hypothesized that closed-cell slots may help provide column strength to an inversion support catheter, since the adjacent walls of the slot are not able to compress much. However, closed-cell slots are less flexible than slots in the neutral configuration or in the open (or super open) configurations described above. Towards this end, variations of catheters having a proximal region that included primarily or exclusively closed-cell slots with a distal end region (e.g., distal 1-50 mm) that was primarily or exclusively open-cell slots were initially examined.

[000125] For example, FIG. 14A illustrates three examples of inversion support catheters, 1401, 1402, 1403. These inversion support catheters have a slotted pattern of cuts (formed by laser cutting). The inversion support catheters were laser cutting a length of NiTi tubing. The entire length of the laser-cut catheter was then compressed and heat set to close the cells formed by the laser cutting. The cut-out regions (e.g., cells) were then compressed so that the separation of the opposite sides of the cut-out region transverse to the length of the catheter had a separation of less than 95% of the original cut-out diameter (e.g., if the original cut-out diameters is 0.001", the compressed configuration is 0.0001") over at least a portion of the slot (e.g., a middle region of the slot).

[000126] Catheters having compressed cut-out regions such as this may show good column strength (e.g., resisting up to 500 g of compression force without bucking), however, they generally were not capable of tracking a tortious model of the vasculature such as shown in FIG. 12, and typically failed to track further than the first (1) or second (2) regions of the model.

[000127] To improve tracking, catheters having compressed cut-our regions such as those shown in FIGS. 14A were re-heat set at their distal ends while applying a stretching force. Expanding just the distal end region (e.g., the distal 12mm, distal 15 mm, distal 20 mm, distal 30 mm, distal 40 mm, distal 50 mm, etc.) to have larger-diameter gaps (open-cell slots) was performed on all three of the catheters shown in FIG.14A. In FIG. 14A, the middle 1402 and right devices 1403 were each first compressed and heat-set in a compressed configuration and then the distal ends were expanded to have a uniform stretching and separation of the gaps in the slotted cells, forming open-celled slots in this distal end region. The slots shown have a middle width between the ends of the slots that is the same or slightly larger than the width of the end regions (e.g., the width of the middle region of the slot is between about 100.5% and 120% of the width of the end regions of the slot). These devices 1402, 1403 performed better than catheters having just closed-cell slots, and were able to track slightly further (e.g., to the second (2) or third (3) regions in the internal carotid model show in FIG. 13).

[000128] For example, FIGS. 16A-16F illustrate a slotted inversion support catheter first formed to have uniformly closed-cell slots by heat-setting in a longitudinally compressed configuration, and then heat-setting the distal end region in a stretched (e.g., the distal 2 cm) configuration. The apparatus was then jacketed by lamination of a jacket material over the catheter. As shown in FIGS. 16A-16F, such devices had a column strength that was sufficiently high to avoid significant kinking. Although a slight bend occurred beginning at 100g of compression (FIG. 16B), this bend did not increase significantly even up to 500g of compression (FIG. 16F). FIG. 16G shows a slightly enlarged view of the distal end region of the catheter.

[000129] FIGS. 17A-17C illustrate, for comparison, other slotted catheters (e.g., catheters having cut-our regions) that kinked in compression. For example, FIG. 17A (shown enlarged in the inset FIG. 17B) is an example of a first catheter having slots cut therein (neutral slot configuration), showing substantial kinking and compression when 400 g of compression was applied. Similarly, FIG.17C (with an enlarged view of the slots shown in FIG. 17D) shows another example of a catheter having somewhat large, open-cell slots along the length of the catheter; this catheter also showed a great deal of kinking and compression. FIG. 17E is another example of a catheter of FIGS. 16A-16G), repeated here to show a side-by-side comparison.

[000130] During the process of stretching the distal end of catheters that had been heat-set in a compressed configuration, some catheters (see, e.g., the catheter 1401 on the left in FIG. 14A, shown in greater detail in FIG. 14B), were inadvertently expanded so that apparent

"defects" 1409 were formed in a small minority of some of the cells, forming super open-celled slots. These defects resulted in a subset of slots/cells that were opened to a greater degree than other slots, which were either not opened (remained closed cell, having a maximum width of the middle region that is less than the maximum width of the end regions), were neutral (in which the width of the middle region is approximately the same as the width of the end regions), or were only slightly opened by the stretching process, forming open-cell slots (e.g., sots having a maximum width of the inner region that is between 1x and 1.5x the diameter of the end regions, e.g., between 1x and 2x, between 1x and 2.5x, between 1x and 3x). Surprisingly, catheters having these "defect" regions (super open-cell regions having a maximum width of the middle region that is greater than 1.5x the width of the end regions, e.g., greater than 2x, greater than 2.5x, greater than 3x, etc.) had a greater column strength (e.g., less buckling at an applied, e.g., 500 g, compression force) and better tracking. Such devices were able to track through the model of tortious vasculature, such as the internal carotid model shown in FIG. 12, completely, e.g., to region (5) or beyond.

[000131] FIG. 15 illustrates an example of one such device including these introduced "defects" in the distal end region of the catheter. The defects in this example are formed in a subset of cells formed by cutting the slots in the distal end region of the catheter. These defects may be referred to as super open-cell slots (compared to the other closed cell and/or open-cell slots in the distal end region) in which the separation between long and opposite sides of the slot are separated by greater than 1.5x the separation of the majority of the closed cell slots in the distal end region. For example, the maximum separation between the opposite long side of the open cell configuration may be greater than 1.5x, greater than 2x, greater than 2.5x, greater than 3x, greater than 3.5x, greater than 4x, greater than 4.5x, greater than 5x, etc. the maximum separation between the opposite long side of the closed-cell slots at the ends of the rectangular slot. The super open-cell (defect) slots may be distributed within the distal end region and may be present or absent from the proximal region (which may also include slots).

[000132] For example, the distal end region of the elongate inversion support catheter may include at least two types of slots cut generally transverse to the length of the elongate inversion support catheter through the wall of the elongate inversion support catheter, based on the size of the gap between opposite walls of the slots, including open-cell slots and super open-cell slots (and/or closed-cell slots or neutral slots). The slots may extend around the circumference of the catheter so that there are between 4 and 1 slots per rotation of the catheter (e.g., between 2 and 3, approximately 2.5, etc.). The opposite walls of the slot may

be the walls that are transverse or approximately transverse to the long axis of the catheter. The closed cell slots may have a maximum separation between the opposite walls of *c* inches (e.g., *c* may be, for example, 0.0001 inches, 0.0002 inches, 0.0005 inches, 0.001 inches, etc.). The open-cell slots and may have a maximum separation between the opposite walls of *o* inches, where *o* is between 1x and 1.5x the width of the ends of the slot w_1 (e.g., *o* is between 1x and 1.5x w_1, e.g., *o* is between 1x and 2x w_1, *o* is between 1x and 2.5x w_1, *o* is between 1x and 3x w_1, etc.). The super open-cell slots may have a maximum diameter *o* that is greater than 1.5x w_1, greater than 2x w_1, greater than 2.5x w_1, greater than 3x w_1, greater than 4x w_1, greater than 5x w_1, greater than 6x w_1, greater than 7x w_1, greater than 8x w_1, greater than 10x w_1, etc. The distribution of super open cell slots to other slots may be uniform or non-uniform, including random. The majority of the slots in the distal end region may be closed and/or open-cell slots, particularly compared to super open-cell slots. For example, there may be between 0.001% and 20% super open-cell slots in the distal end region (e.g., between 0.001% and 10%, between 0.001% and 5%, between 0.01% and 5%, between 0.1% and 5%, etc., between 0.001% and 1%, etc.). For example, there may be between 0.5 and 20 super open-cell slots for every cm length of catheter (e.g., between 1 and 20, between 0.5 and 15, between 0.5 and 10, between 1 and 10, etc.). The super open-cell slots may be oriented at different radial positions around the catheter.

[000133] FIG. 14C illustrates an exemplary laser cut pattern for an inversion support catheter such as the ones shown in FIG. 14A. As mentioned above, a length of NiTi tubing may be cut (e.g., laser cut) to form slots, and these slots may be compression heat set along the entire length of the catheter to form closed-cell slots. The catheter may then be re-heat set with the distal end region stretched, to form open-cell slots. In some variations, a small number of these slots may also be formed as super open-cell slots. In FIG. 14C, a variety of pitches are shown (e.g., between 0 and 0.01) for the slots.

[000134] FIG. 15 illustrates an example of an inversion support catheter in which the distal 5 mm of the catheter were treated (by stretching and heat setting) to introduce two "defects" (super open-cell regions) 1509. Although the majority of the slots in the distal end remained simply open-cell slots, these super open-cell slots (which have a maximum width of greater than 1.5x the width of the ends of the rectangular/oval slot) greatly enhanced the flexibility and tracking of the catheter; the exemplary catheter in FIG. 15 also had a column strength sufficient so that little or no kinking resulted even when applying up to 500 g of compressive force, as may be applied when rolling a tractor tube into the catheter to capture a hard and/or large clot.

[000135] In any of the apparatuses disclosed and described herein, distal end region (e.g., the distal 1-50 mm, distal 2-10 mm, etc.) may have open-celled slots (and/or super open-cell slots) compared the more proximal regions, which may be formed of closed cell slots. For example, FIGS. 18A-18E illustrate examples of inversion support catheters having a combination of open cell and closed cell cut-out regions. In FIG. 18A, the distal end region includes open cells, which may be configured as described above. In FIG. 18A, the majority or all of the distal end region include open-celled slots, compared to the proximal region which are closed-cell slots. In FIG. 18B, a percentage of the cut-out slots are open-celled, but not all (e.g., between 0.1% and 80%, etc.) of the slots are open-cell slots. In FIG. 18C, the distal end region includes slots that are tapered in the middle (e.g., "hourglass" slots) so that each slot includes open-celled and closed-cell regions; the proximal region is shown as all closed-cell slots. Such bi-lobed slots (also referred to as hourglass, barbell and/or dog bone slots) may also have improved tracking and compression strength, comparable to the device having super open-cell slots discussed above; these will be described in greater detail below.

[000136] In FIG. 18D the distal end region includes an open coil configuration. In FIG. 18E, the distal coil region is referred to as "closed coil" as the adjacent coils are spaced (over at least a portion of their length) very close together. Although FIGS. 18A-18E show catheters having a stark transition from the proximal and distal end regions, in some variations the transition may be more gradual, so that the device transitions gradually from close cell (proximal) to open-cell (distal) cut-out regions.

[000137] FIGS. 19A and 19B illustrate open and closed cell configurations of cut-out regions that may be formed by heat-setting the catheter in compression. In FIG. 19A, a rectangular slot is cut from the catheter as described above in an open configuration, having a separation between the opposite long walls of the slot that is z_1 wide (shown on left) in the closed configuration (under compression) the slot may be heat-set to have a diameter over the middle (x_2) region that is z_2 wide. The edge region of the slot (e.g., regions x_1 and x_3) may be nearly incompressible near their edges and may therefore remain separated. As described in FIG. 19C, the design of FIG. 19A may have dimensions in the closed cell configuration so that x_2 is between about 5% of x_1 and 95% of x_1. For example, in the compressed, close-cell configuration, the compressed region x2 may be the middle 1% to 90% of the total length (x) of the slot. Similarly, the separation z_2 between in the long walls of the slot in the compressed configuration may be less than or equal to 95% of the original separation, z_1. For example, if the original separation (z_1) is 0.001 inches, the compressed separation (z_2) may be

approximately 0.0001 inches. Generally, the open cell separation may be between, for example, 0.0005 inches and 0.010 inches.

[000138] The centrally-tapered slots (hourglass configuration) shown in FIG. 19B in the open-cell and closed-cell configurations may include larger width regions (y_1) one either side of the slot, separated by a narrow region z_1. The lengths of the wider regions (x_1, x_3) and the intervening narrower region (x_2) may add up to the total length of the slot, x. In the closed cell configuration, the separation of the wider regions (y_1) may remain approximately the same, while the middle region, z_2, may be much smaller than the original, open-cell width, z_1. As exemplified in FIG. 19C, the configuration of FIG. 19B, may have a closed cell configuration in which the closed cell width z_2 is less than or equal to 90% of the original open-cell width z_1. The narrower regions is typically centered (but may be offset) within the slot, and may include the middle 5%-95% of the slot. For example, an hourglass-cut slot such as the one shown in FIG. 19B may have an open-cell maximum width of between 0.0005 inches and 0.010 inches at the wide regions on either end and a narrower central region that is between about 10% and 50% of the width of the wider ends (y_1).

[000139] FIGS. 20A-20C illustrate alternative configuration of slots that may be cut into the catheter having a centrally-tapered (e.g., hourglass- or barbell- shape) configuration. These configurations typically include an open cell region even in the compressed configuration.

[000140] FIGS. 21A-21C illustrate additional slotted catheter designs having regions of closed and open sections that may be formed by cutting or patterning, without requiring heat setting. Alternatively, or additionally, heat setting may be used. In FIG. 21A, the cut pattern 2101 is shown, with slots arranged in an overlapping pattern (a brick stacked pattern). FIG. 21B shows a side view, showing the pattern of alternating slots arranged adjacently along the length of the catheter so that there are columns of high-compression strength in the noon 2103, 3 o'clock 2103', 6 o'clock 2103'', and 9 o'clock 2103''' positions radially around the circumference of the slotted catheter (or the slotted portion of the catheter). FIG. 21C shows a side perspective view of the slotted catheter. Other overlapping patterns may be used, including patterns in which high-support regions 2103, 2103', 2103'', 2103''' line up along the long length of the catheter in more or fewer than the 4 radial locations shown in FIG. 21A-21C (e.g., in the noon, 4 o'clock, 8 o'clock position, etc.). In some variations the overlapping pattern creates a spiral or helical pattern of high-support regions along the length of the catheter. As mentioned, this pattern may also be compressed and heat-set in a closed-cell configuration. Further cells can be open-cell or closed-cell in different regions along the length of the catheter.

[000141] Another example of a slotted catheter design is shown in FIG. 22A-22C. FIG. 22A shows the cut pattern 2201 comprising a narrow spiral cut pattern. The open-cell spiral design pattern may be shaped (e.g., by applying compression and/or pulling longitudinal force and shape-setting) to be open-cell or closed-cell along the entire length of along portions of the length of the catheter. In FIGS. 22A-22C, the spiral pattern includes aligned overlapping/adjacent regions so that there are five columns of higher-support regions down the elongate length of the catheter. FIG. 22B shows a side view, and FIG. 22C shows a side perspective view.

[000142] FIGS. 23A-23C illustrate another variation of a slotted catheter pattern design. In this example, the slotted pattern is a dog bone pattern, as shown in FIG. 23A. Each cut-out slot has a distal end region with a large width between the opposite sides, and a narrow connection region, with a much smaller width between the opposite sides. The narrow-width regions may be aligned in adjacent slots along the length of the catheter, as shown in FIGS. 23B and 23C. In this example, this alignment of the narrow regions in the middle of the slot (similar to the "closed-cell rectangular slots described above) result in four columns of high-compression strength in the noon 2303, three o'clock 2303', six o'clock 2303'' and nine o'clock 2303''' positions radially around the circumference of the slotted catheter (or the slotted portion of the catheter). In this example, each cell has preferred close contact region. As mentioned above, the cells (or regions of the cells along the length of the catheter) can be compressed or stretched and heat-set in an open-cell or closed-cell configuration.

[000143] In addition to mixing regions of closed-cell and open-cell slots along the length of the catheter, any of these catheters may also include a mixture of the different patterns disclosed and described herein. For example, FIG. 24A shows an example in which the spiral pattern 2403 of FIGS. 22A-22C is shown adjacent to a region of the brick pattern 2405 of FIG. 21A-21C, which is also adjacent to another region of the spiral pattern. Similarly, FIG. 24B shows alternating spiral patterns 2403 and barbell patterns 2407 such as that shown in FIG. 23A-23C. FIG. 24C shows alternating patterns of spiral 2403, brick 2405, spiral 2403, barbell/dog bone 2407, etc. In any of these catheters, including those of FIGS. 21A-24C, regions along the length may be compressed and/or stretched to form open-cell and closed-cell slots as well.

[000144] FIGS. 25A-25C illustrate a continuous spiral-cut slotted pattern 2501 in which a slot includes plurality of narrowed regions (bumps, detents, necks, etc.) in the slot and aligned along the longitudinal axis of the catheter to form lines 2503', 2503'', 2503''' extending in the long, longitudinal axis of the catheter. As with the embodiments described

above, these lines may increase the column strength while the larger-width cut-out regions between them may enhance flexibility. In FIG. 25A, the cut pattern 2501 is shown. As mentioned, the cut pattern may be continuous, and may spiral around and through the catheter (compare to the discrete patterns of FIGS. 21A-24C, which also spiral around the catheter at a very low pitch). FIG. 25B shows a side view, including the three lines of aligned narrowed regions. Although three lines are shown, a greater or lower number of narrowed regions may be included (e.g., one or more, two or more, three or more, four or more, 2 to 60, 2 to 50, 2 to 40, 2 to 30, 2 to 25, 2 to 20, 2 to 19, etc.), and spaced so that they align to form longitudinally-extending lines. The lines may be parallel with the longitudinal axis of the catheter. In some variations, the lines may spiral around the catheter with a pitch of less than 15 degrees (e.g., less than 14 degrees, less than 12 degrees, less than 10 degrees, less than 8 degrees, less than 6 degrees, less than 5 degrees, etc.). As with the variations shown in any of FIGS. 14A to 24C, the variation shown in FIGS. 25A-25C may be used in order to achieve a high degree of flexibility and column stiffness when pulling a tractor tube into the catheter, as described above, particularly when this pattern is included on the distal end of the catheter (e.g., the distal 30 cm, the distal 25 cm, the distal 20 cm, the distal 15 cm, the distal 20 cm, etc.).

[000145] FIG. 26 illustrates another example of an apparatus including an elongate inversion support catheter comprising a plurality of slots that are arranged approximately transversely to a long axis of the elongate slotted inversion support catheter. In this example, the apparatus includes a first region of the slotted inversion support catheter that has a "crushed spiral" arrangement in which the spiral shape for the slots is formed by cutting (e.g., laser cutting) slots around the circumference, applying a compressive force along the length and heat setting it to hold the compressed format. Adjacent to this first (distal region) is a second region forming a stretch of 'crushed brick' configuration in child wherein the slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn about the long axis, and the region has been compressed (compressively loaded) then heat treated to retain the compressed form. Finally, in FIG. 26, a third slotted region is proximal to the second one is shown. In this third embodiment the third one is an "open brick" configuration in which the slots cut transversely to the long axis of the elongate slotted inversion support catheter, have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn about the long axis. Any combination of slotted regions (spirals, bricks, open, closed) may be used, in any order of particular interest. Also shown in FIG. 26 is an example of a ring of metal (e.g. shape

memory alloy, such as TiNi, or stainless steel, etc. In FIG. 26, the catheter has an ID of 0.048" and an outer diameter (OD) of about 0.062". The catheter is formed of two separate laser-cut hypotubes that have been joined together as shown in FIG. 27 (showing a stainless-steel member interlocking with a nitinol at dovetail joints; a coating or sleeve (e.g., a lamination such as with Tecoflex 80A and Pebax) may be used to secure them together without substantially modifying the flexibility of the catheter. The length of the nitinol catheter cut to form the distal end of the catheter may be approximately 65cm (e.g., between 40 cm and 100 cm, between 45cm and 90cm, between 55 cm and 85, etc.). The length of the stainless steel (SS) catheter cut to form the distal end of the catheter may be approximately 100 cm (e.g., between 50 cm and 150 cm, between 75 cm and 120 cm, between 95 cm and 105 cm, etc.). The regions of the catheter be treated to have a yield compression strength of greater than ~1000grm.

[000146] FIG. 28 illustrates an example of a catheter, e.g., an elongate inversion support catheter, such as the one shown in FIG. 26, comprising a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn about the long axis. FIG. 28, the catheter is shown making a tight turn of 2.8 mm diameter, showing good tracking which may be reflected in the body. Similarly, FIGS. 29A and 29B illustrate an example of a comparison between bending of a traditional support catheter and an elongate inversion support catheter (comprising a plurality of slots arranged approximately transversely to a long axis) as disclosed and described herein. In FIG. 29A, the traditional catheter shows buckling and ultimately fails. In contrast, in FIG. 29B the same applied force (e.g., compressive force) does not cause the device (the elongate inversion support catheter. Thus, the improved elongated inversion support catheter handles high compressive loads without snaking/accordioning/buckling when ingesting hard clot.

[000147] The methods and apparatuses disclosed and described herein may be used with all or some portions of the mechanical clot removal devices shown in each of: U.S. app. no. 15/291,015, filed on 10/11/2016 ("Mechanical Thrombectomy Apparatuses and Methods"); U.S. app. no. 15/496570, filed on 4/25/2017 ("Anti-Jamming and Macerating Thrombectomy Apparatuses and methods"), U.S. app. no. 15/496668, field on 4/25/2017 ("Pre-loaded inverting tractor Thrombectomy Apparatuses and methods"); U.S. app. no. 15/496,786, filed on 4/25/2017 ("Methods for Advancing Inverting Mechanical Thrombectomy Apparatuses IN The Vasculature"); U.S. app. no. 15/497,092, filed on 4/25/2017 ("Clot-Engulfing

Mechanical Thrombectomy Apparatuses and methods of use"); and U.S. app. no. 15/611546, filed on 6/1/2017 ("Inverting Thrombectomy Apparatuses And Methods").

[000148] 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.

[000149] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the various inventions disclosed and described herein. 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 term "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 "/".

[000150] 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.

[000151] 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 herein could be termed a second feature/element, and similarly, a second feature/element discussed herein could be termed a first feature/element without departing from the teachings of the disclosed and described embodiments.

[000152] 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.

[000153] In general, any of the apparatuses and methods disclosed and 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.

[000154] 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.

[000155] 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 disclosed inventions, which are defined 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 inventions as they are set forth in the claims.

[000156] 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, as many are, in fact, disclosed. Thus, although specific embodiments have been illustrated and disclosed 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 the various embodiments disclosed and described herein, as well as further embodiments not specifically disclosed and/or described herein, will be apparent to those of skill in the art upon reviewing the above description in conjunction with the accompanying drawings.

CLAIMS

What is claimed is:

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; and

a knitted tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter,

wherein the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter comprises a wire forming a helical spiral of alternating teardrop shaped-links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, wherein the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally within the elongate inversion support catheter.

2. The apparatus of claim 1, further comprising a lubricious liner sleeve extending from within the elongate inversion support catheter and over the distal end opening of the elongate inversion support catheter.

3. The apparatus of claim 2, wherein the pull force required to roll the knitted tractor tube over the distal end of the elongate inversion support catheter and into the elongate inversion support catheter is less than about 250 g of force.

4. The apparatus of claim 2, wherein the lubricious liner comprises a PTFE liner wrapping around the open distal end of the elongate inversion support catheter.

5. The apparatus of claim 1, wherein the knitted tractor tube is formed of an alloy of nickel titanium.

6. The apparatus of claim 1, wherein the links have a length of L, and a grab width of W when flaring outward from the outer wall of the elongate inversion support catheter when the puller is pulled proximally, wherein W is between 30-90% of L.

7. The apparatus of claim 1, wherein the distal open end of the elongate inversion support catheter is tapered.

8. The apparatus of claim 1, further comprising a second end of the knitted tractor tube is unattached and free to slide over the outer surface of the elongate inversion support catheter.

9. The apparatus of claim 8, further comprising a stop on the second end configured to prevent the second end from inverting over the distal end of the elongate inversion support catheter.

10. 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 tapered or rounded distal end opening;

an elongate puller extending within the elongate inversion support catheter; and

a knitted tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter,

wherein the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter comprises a wire forming a helical spiral of alternating teardrop shaped-links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, wherein the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally within the elongate inversion support catheter, and

wherein the links have a length of L, and a grab width of W when flaring outward from the outer wall of the elongate inversion support catheter when the puller is pulled proximally, wherein W is between 30-90% of L.

11. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate slotted inversion support catheter having a distal end and a distal end opening, wherein the elongate inversion support catheter comprises a spiral pattern having a plurality of slots arranged approximately transversely to a long axis of the elongate slotted

inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn of the spiral pattern; and

a tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter,

wherein the tractor tube is configured to invert over the distal end opening of the elongate inversion support catheter when pulled proximally into the elongate inversion support catheter.

12. The apparatus of claim 11, wherein a second region of the elongate slotted inversion support catheter comprises a second spiral pattern having a second plurality of slots arranged approximately transversely to the long axis of the elongate slotted inversion support catheter, wherein the second plurality of slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn of the spiral pattern.

13. The apparatus of claim 11, further comprising a puller extending within the elongate inversion support catheter to which a first end of the tractor tube is attached.

14. The apparatus of claim 11, wherein there are between 2 and 3 slots per circumferential turn.

15. The apparatus of claim 11, wherein the spiral pattern is helically arranged around the circumference of the elongate slotted inversion support catheter.

16. The apparatus of claim 11, further wherein the slotted inversion support catheter is heat set into a compressed configuration so that the slots form closed cells in a relaxed configuration.

17. The apparatus of claim 11, further wherein the slots extend between about 50 and 98% of each circumferential turn of the spiral pattern.

18. The apparatus of claim 11, further wherein at least 1 mm of the distal end of the slotted inversion support catheter comprises the spiral pattern.

19. The apparatus of claim 11, wherein the spiral pattern is configured so that at least 80% of a length of the slots contact and are supported by an opposite side of the slots when the elongate slotted inversion support catheter is longitudinally compressed.

20. The apparatus of claim 11, wherein elongate slotted inversion support catheter has a catheter compression yield force of greater than about 1000 g.

21. The apparatus of claim 11, wherein the elongate slotted inversion support catheter is one or both of: a nickel titanium alloy and stainless steel.

22. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an elongate slotted inversion support catheter having a distal end and a distal end opening, wherein

a first region of the elongate inversion support catheter comprises a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less, and wherein there are between 2 and 4 slots per circumferential turn about the long axis, and

a second region of the elongate slotted inversion support catheter comprises a second plurality of slots arranged approximately transversely to the long axis of the elongate slotted inversion support catheter, wherein the second plurality of slots have an open diameter of about 0.001 inches or more and wherein there are between 2 and 4 slots per circumferential turn about the long axis;

a tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter; and

a puller within the elongate slotted inversion support catheter, wherein a first end of the tractor tube is attached to the puller,

wherein the tractor tube is configured to invert over the distal end opening of the elongate inversion support catheter when pulled proximally into the elongate inversion support catheter.

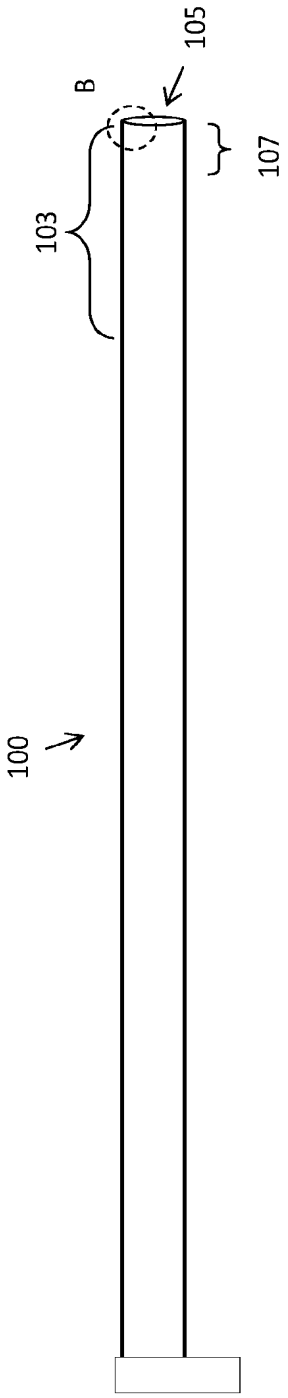


FIG. 1A

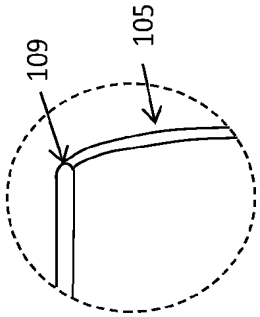


FIG. 1B

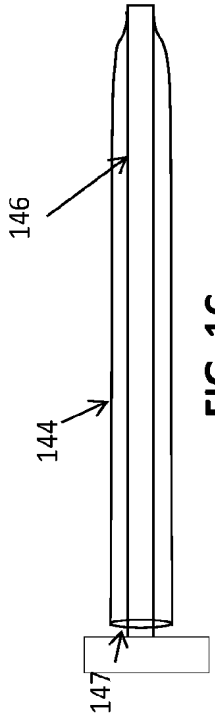


FIG. 1C

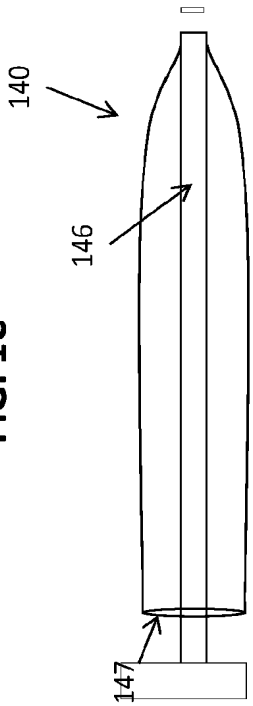


FIG. 1D

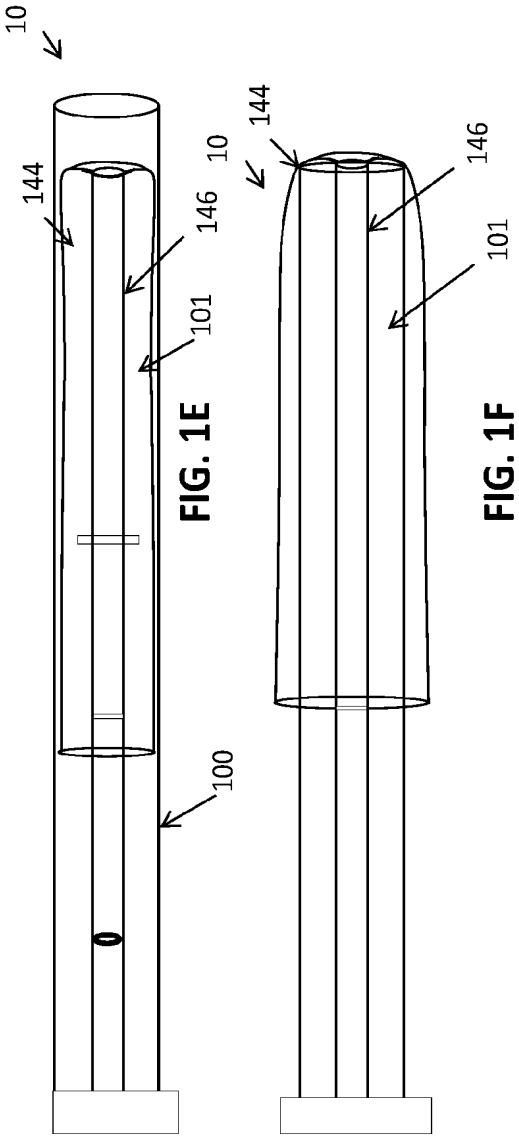


FIG. 1E

FIG. 1F

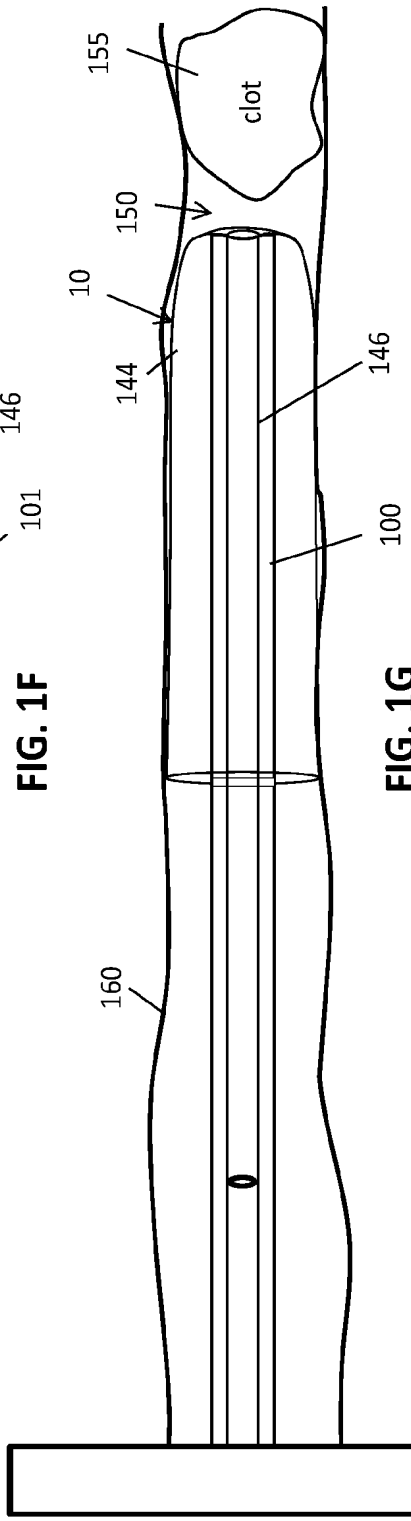


FIG. 1G

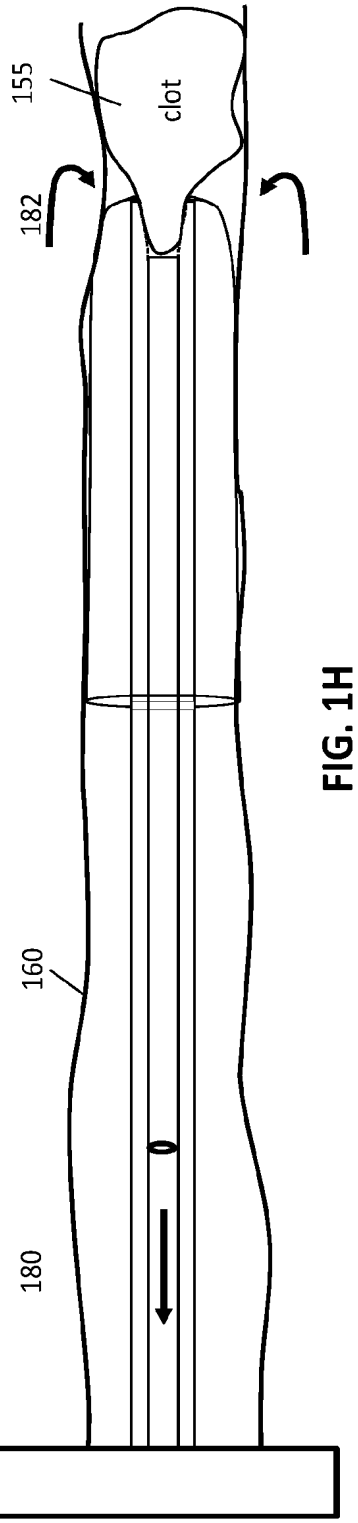


FIG. 1H

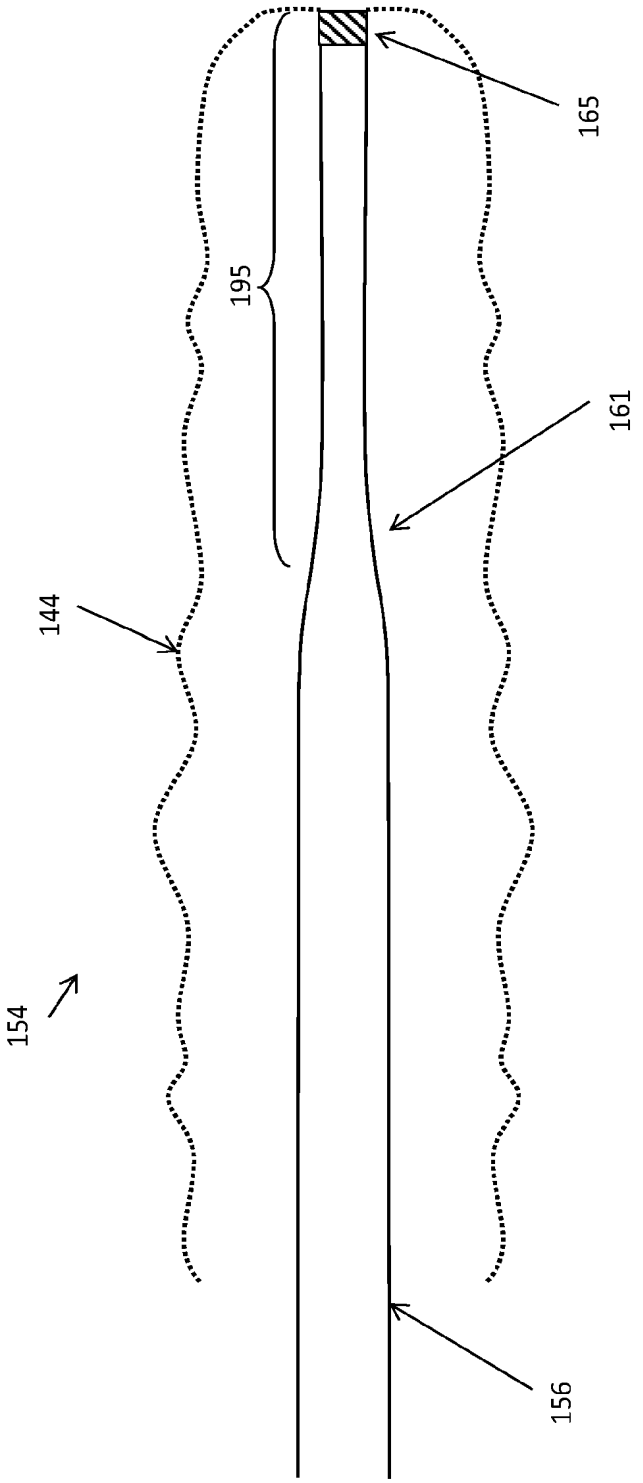


FIG. 1I

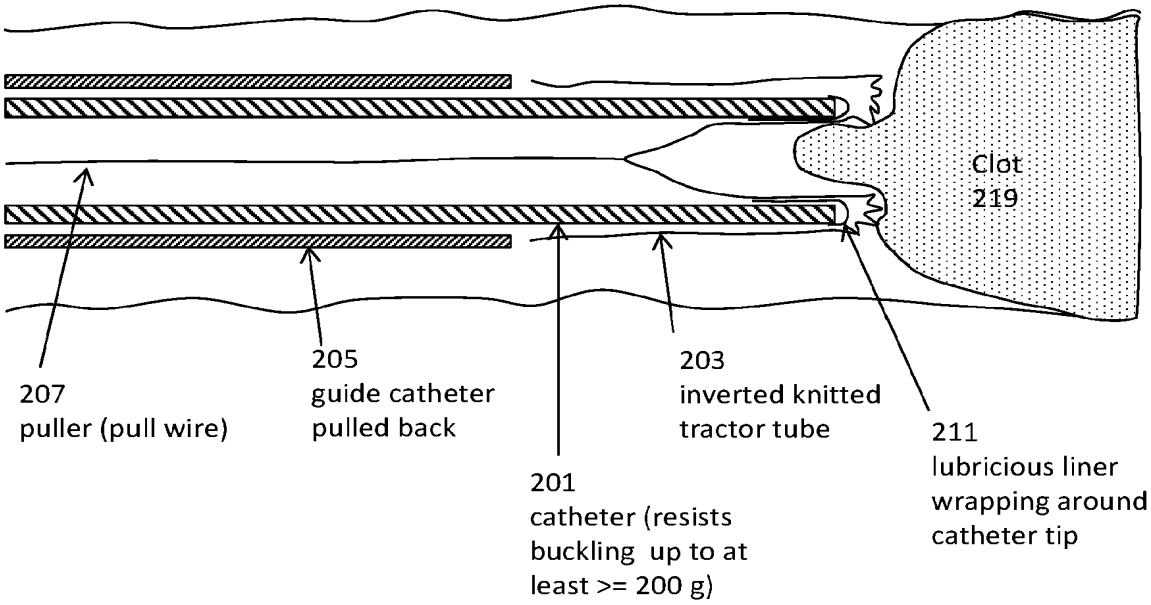

Clot
219
207
puller (pull wire)
205
guide catheter
pulled back
203
inverted knitted
tractor tube
211
lubricious liner
wrapping around
catheter tip
201
catheter (resists
buckling up to at
least >= 200 g)

FIG. 2A

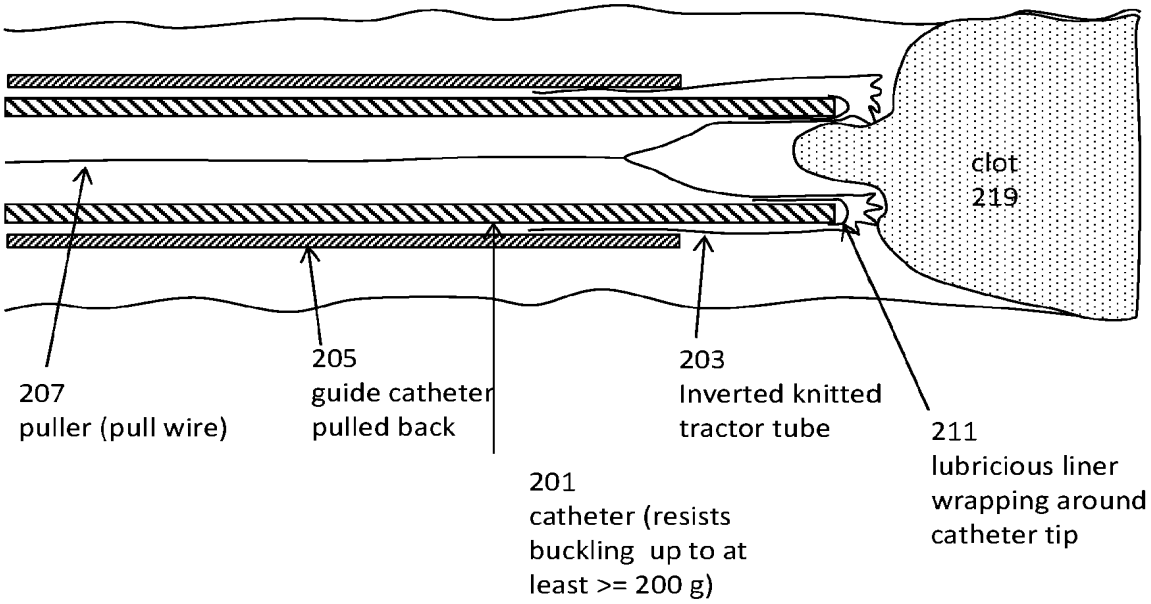

clot
219
207
puller (pull wire)
205
guide catheter
pulled back
203
Inverted knitted
tractor tube
211
lubricious liner
wrapping around
catheter tip
201
catheter (resists
buckling up to at
least >= 200 g)

FIG. 2B

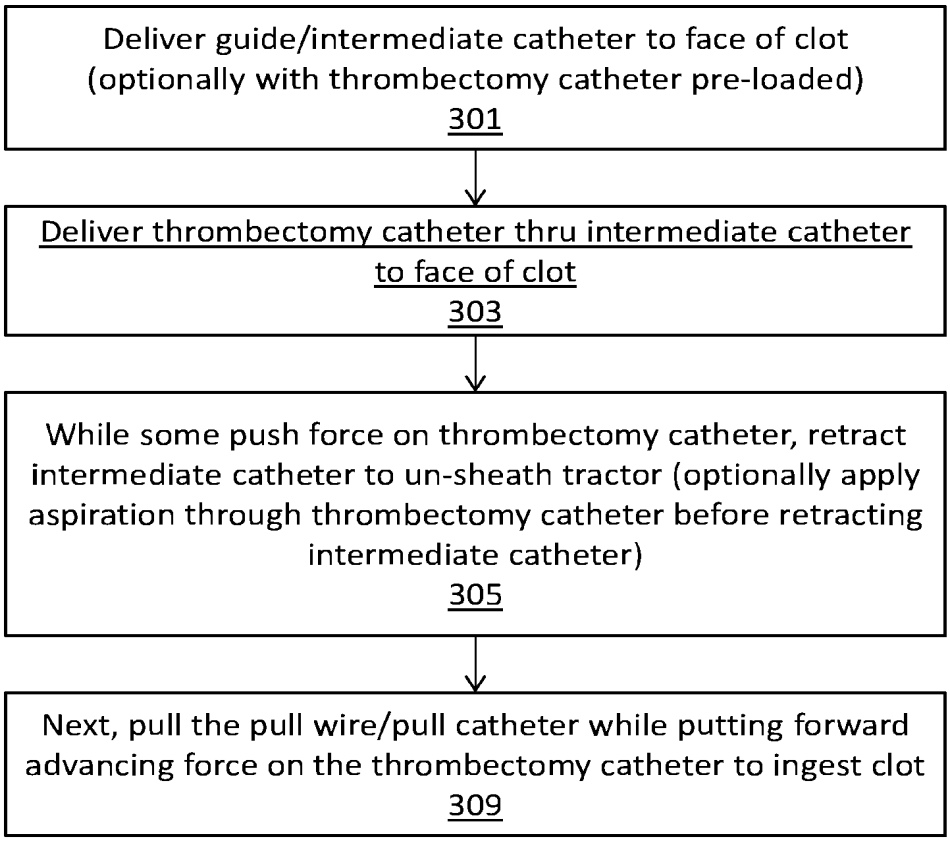

Deliver guide/intermediate catheter to face of clot (optionally with thrombectomy catheter pre-loaded)
301
Deliver thrombectomy catheter thru intermediate catheter to face of clot
303
While some push force on thrombectomy catheter, retract intermediate catheter to un-sheath tractor (optionally apply aspiration through thrombectomy catheter before retracting intermediate catheter)
305
Next, pull the pull wire/pull catheter while putting forward advancing force on the thrombectomy catheter to ingest clot
309

FIG. 3

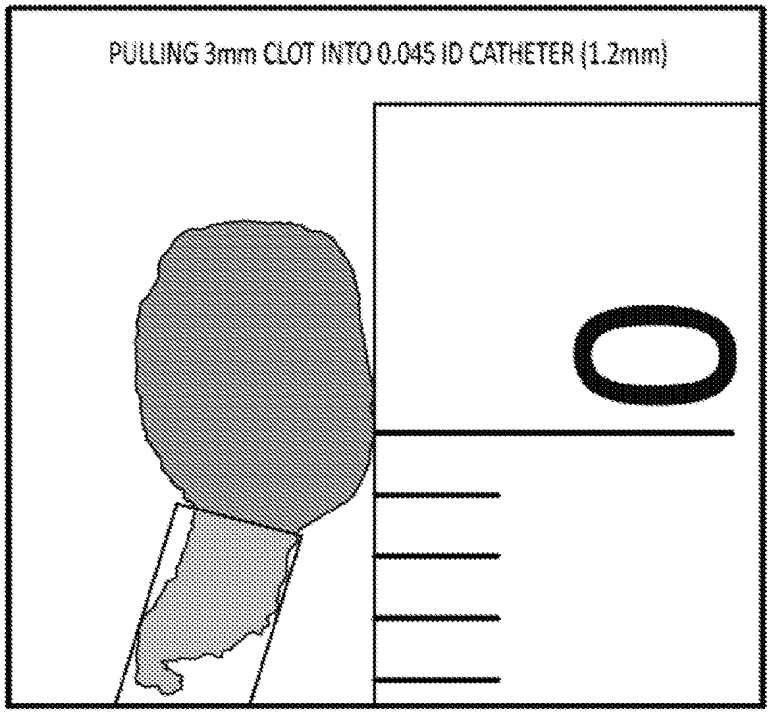


FIG. 4A

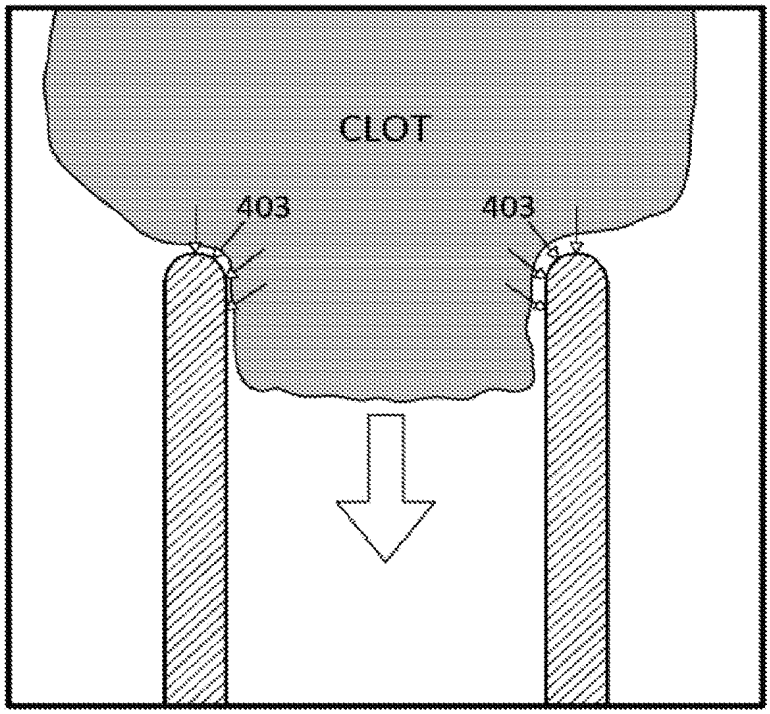


FIG. 4B

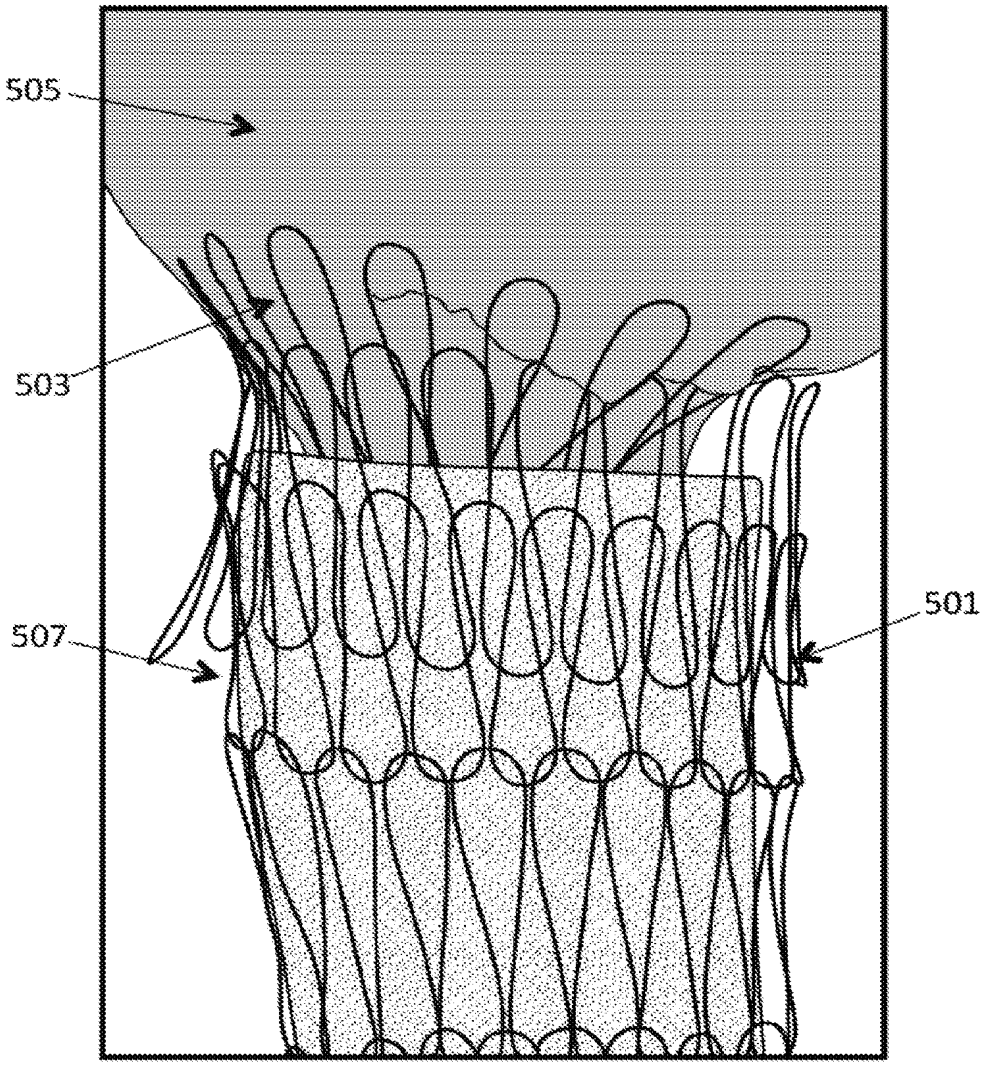


FIG. 5

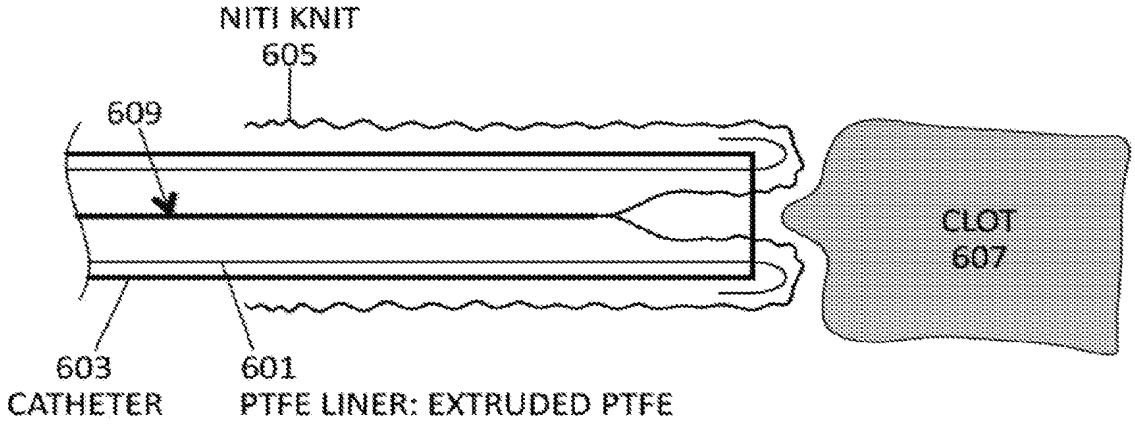

NITI KNIT
605
609
CLOT
607
603
CATHETER
601
PTFE LINER: EXTRUDED PTFE

FIG. 6A

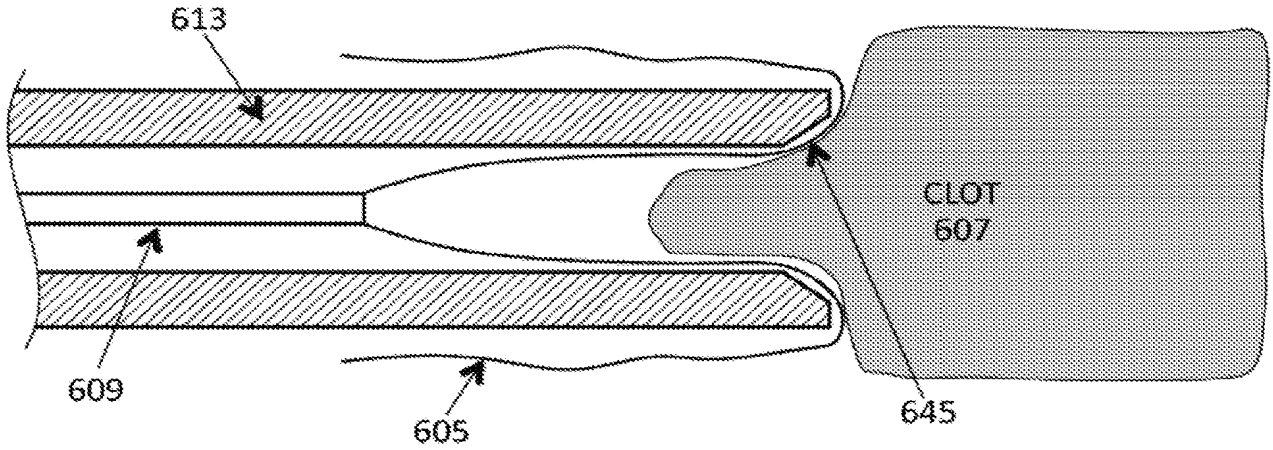

613
CLOT
607
609
605
645

FIG. 6B

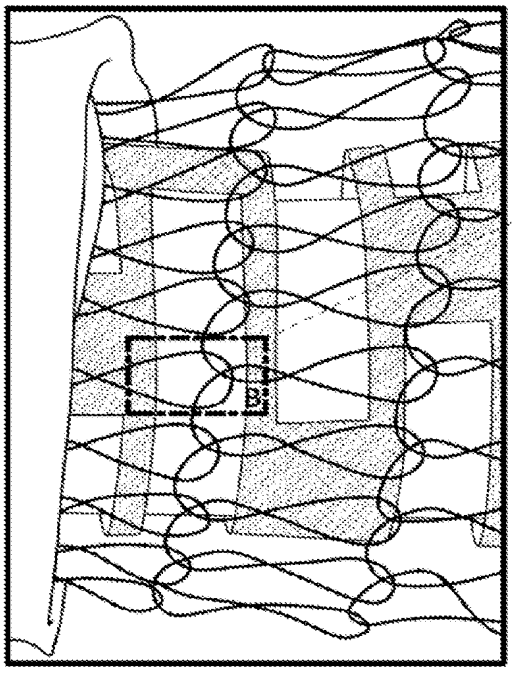


FIG. 7A

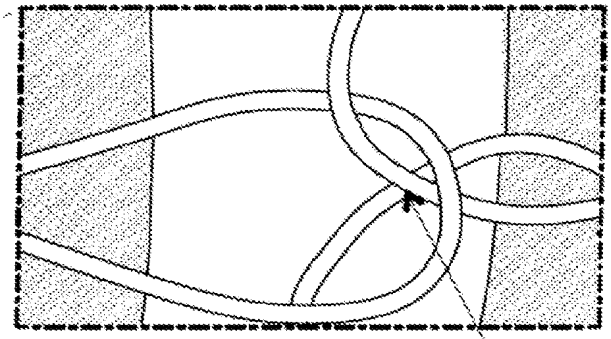


FIG. 7B

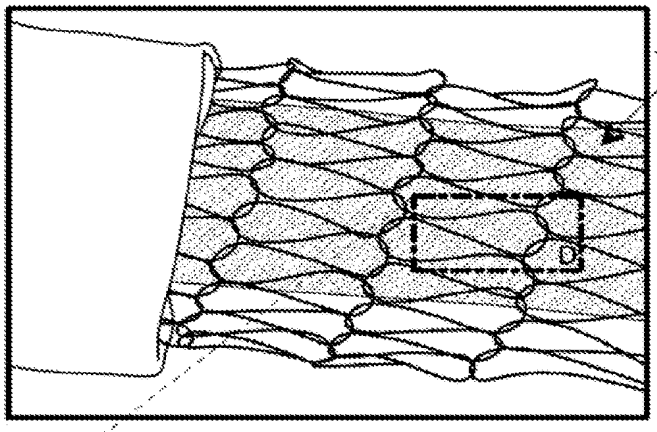


FIG. 7C

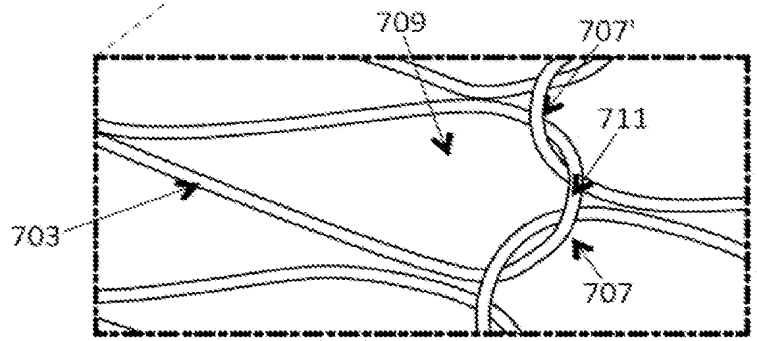


FIG. 7D

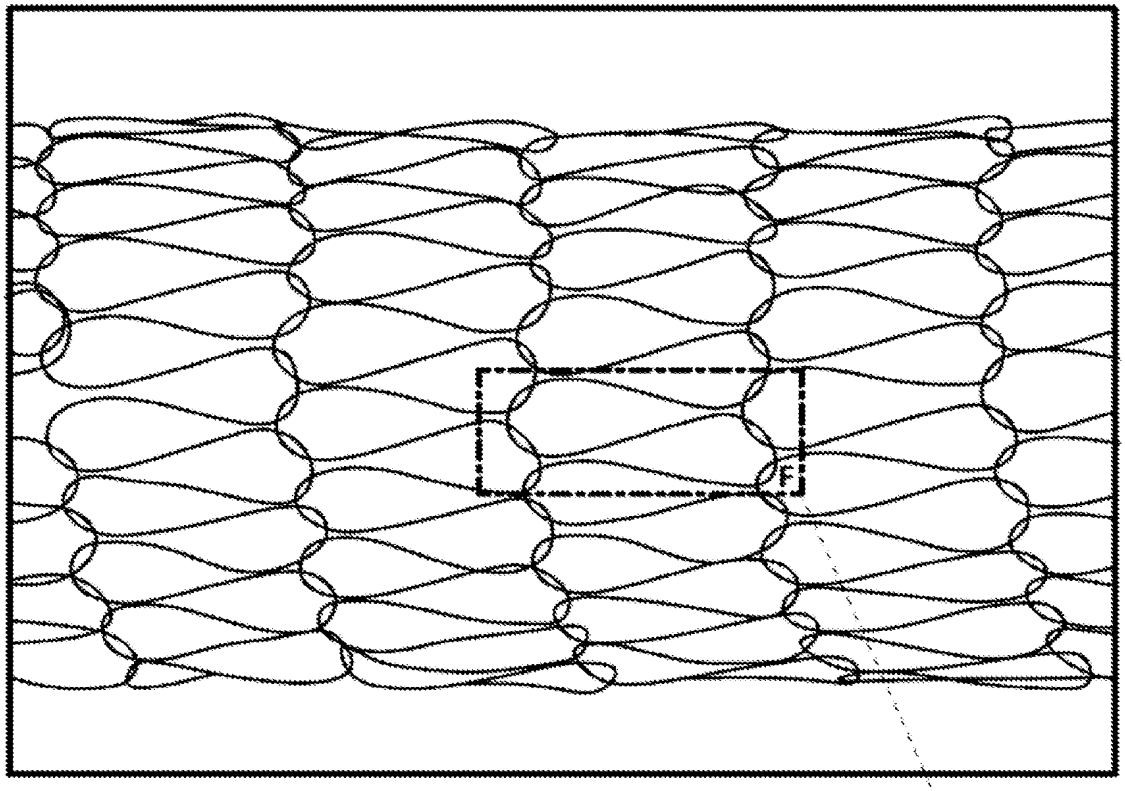


FIG. 7E

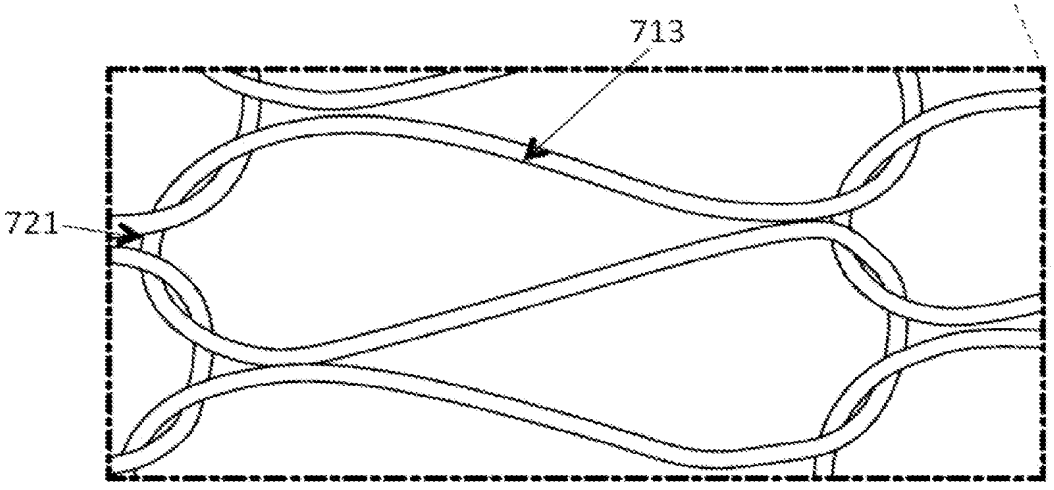


FIG. 7F

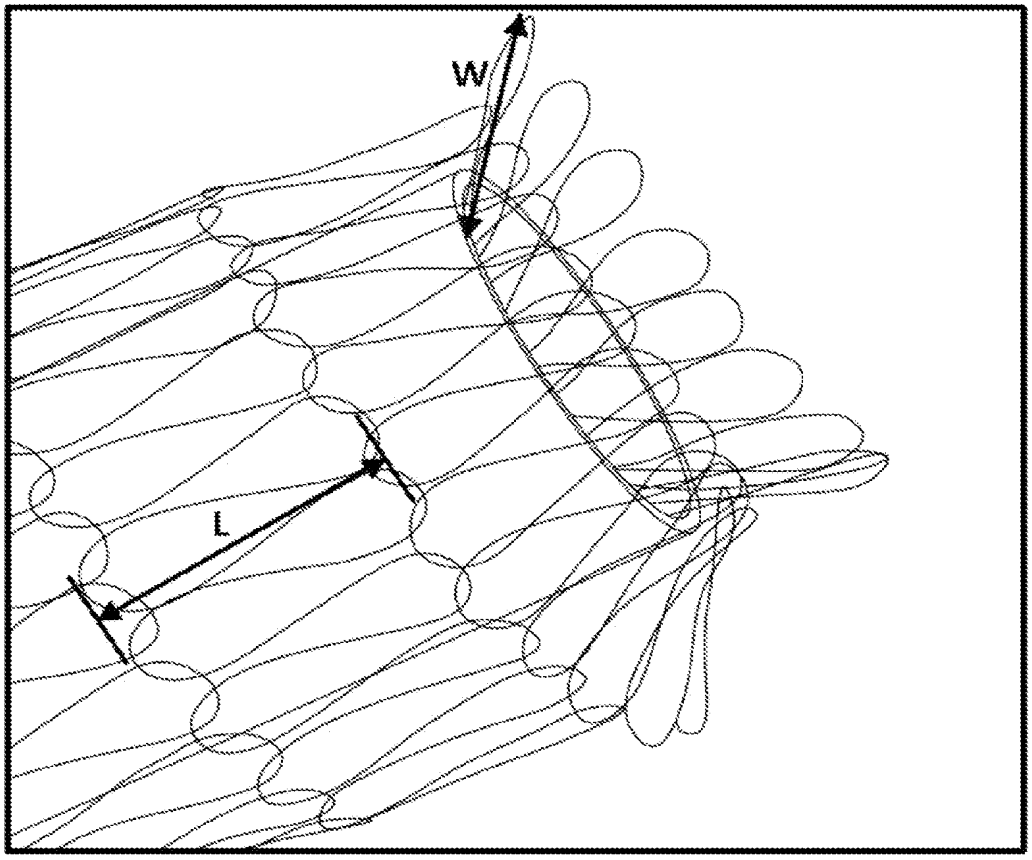


FIG. 8A

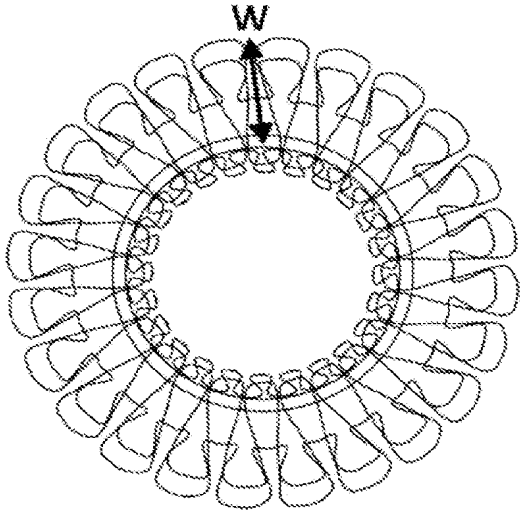


FIG. 8B

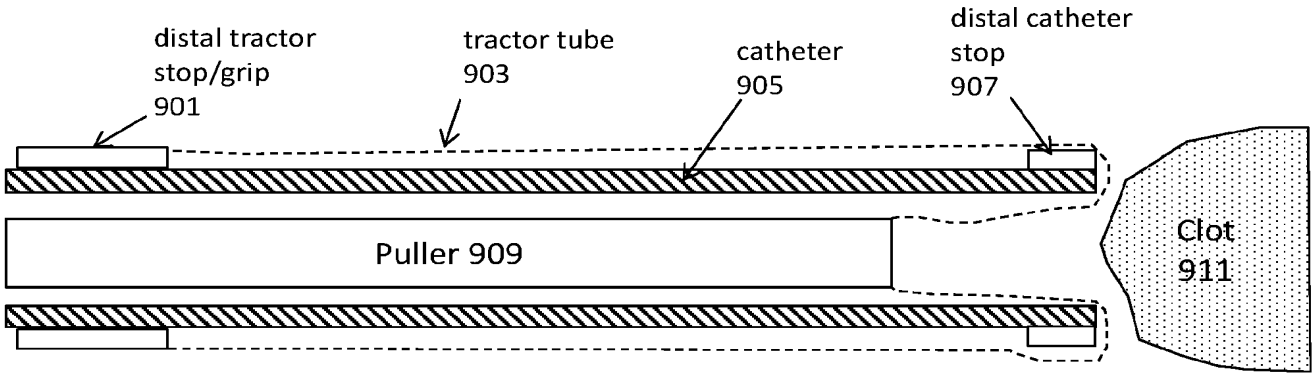


FIG. 9A

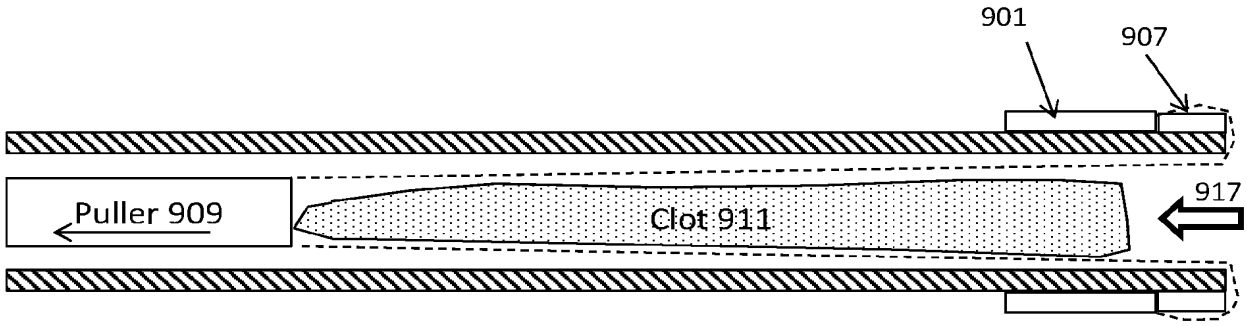


FIG. 9B

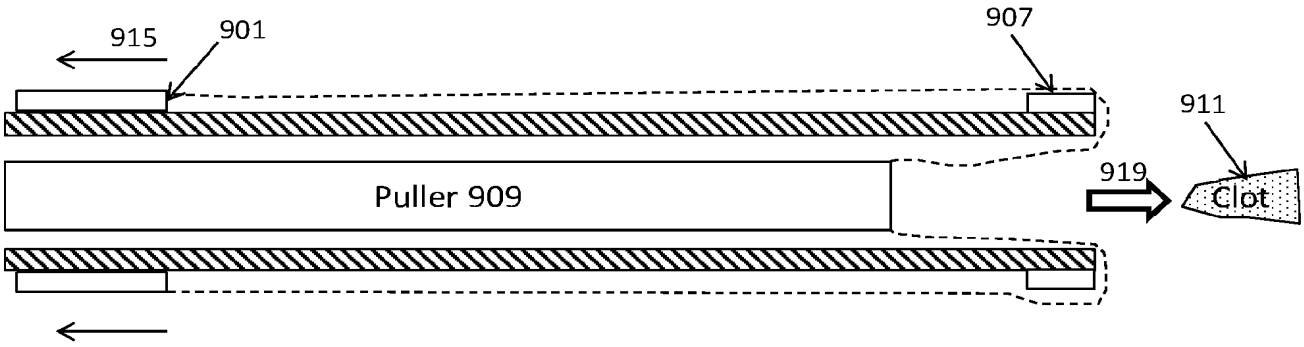


FIG. 9C

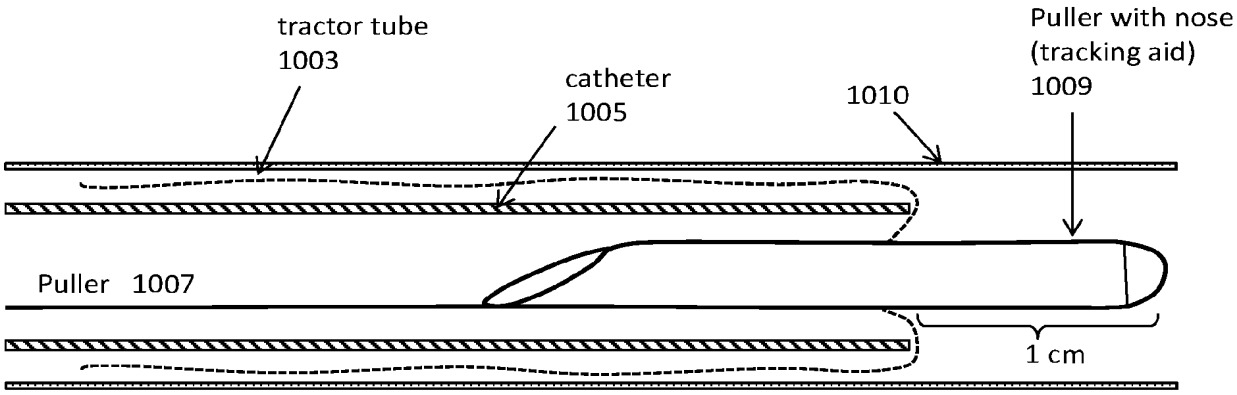


FIG. 10A

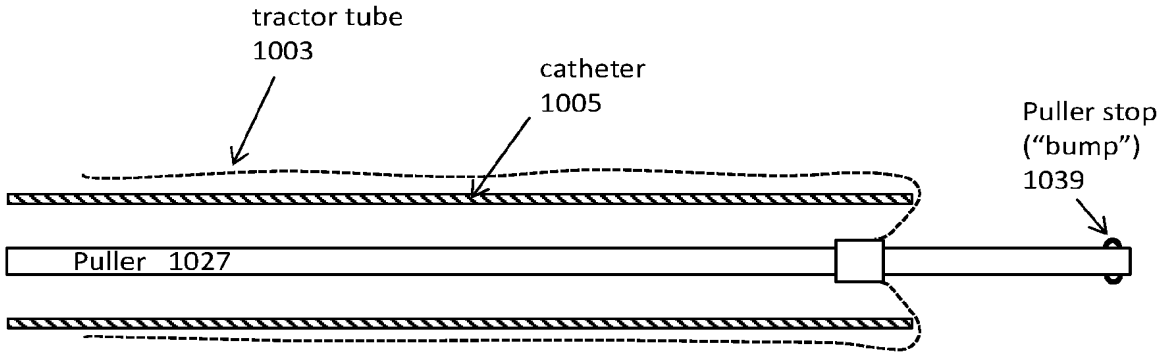


FIG. 10B

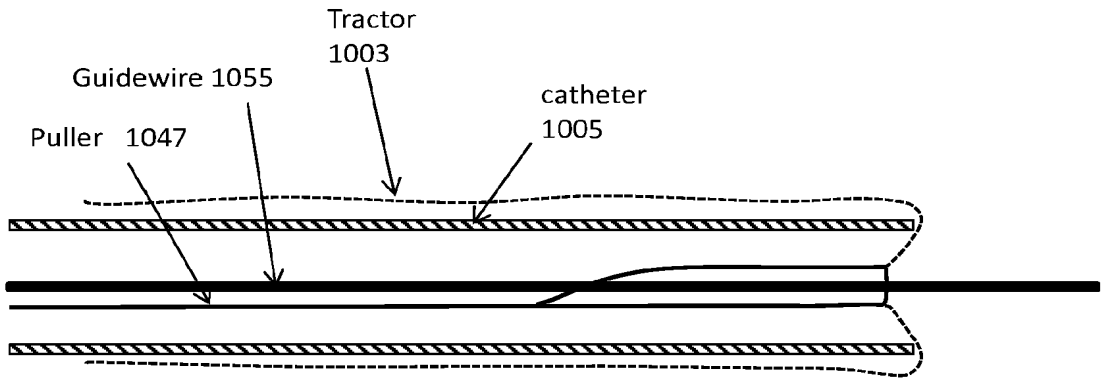


FIG. 10C

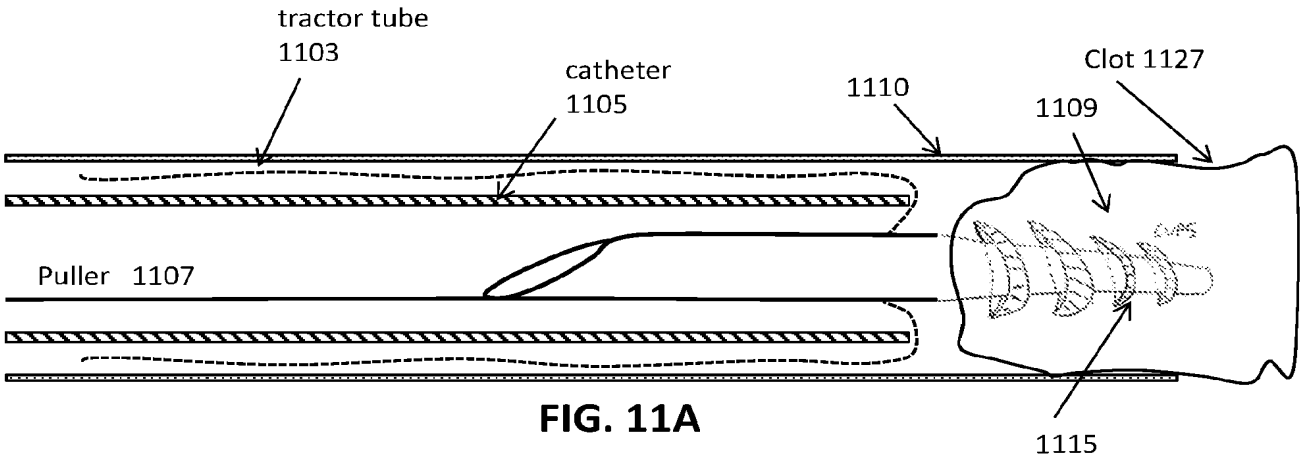


FIG. 11A

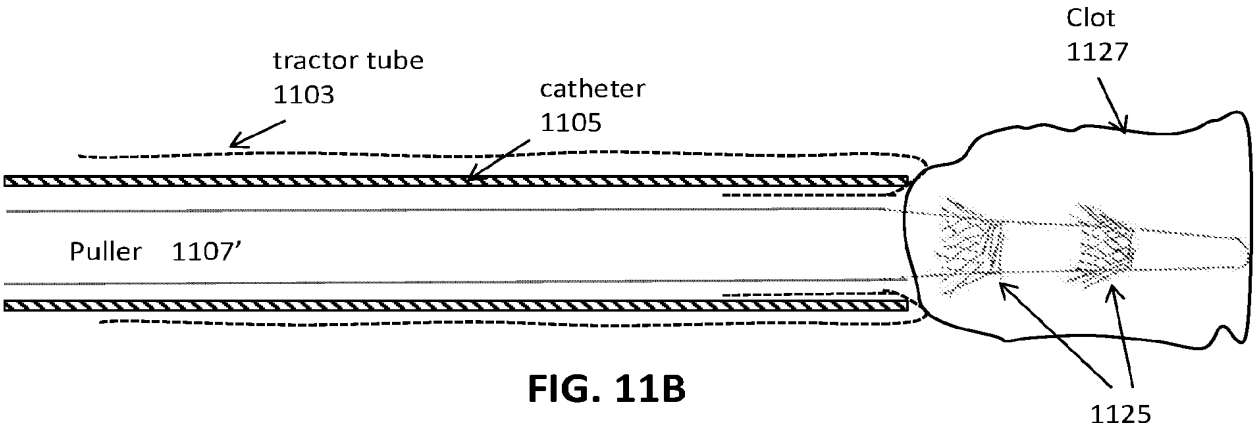


FIG. 11B

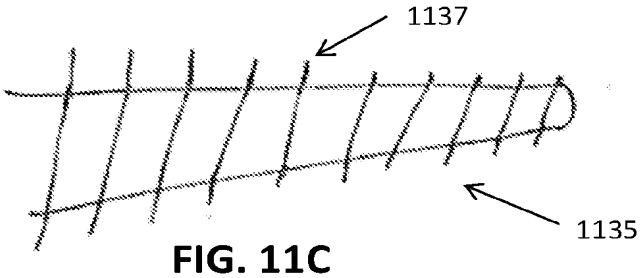


FIG. 11C

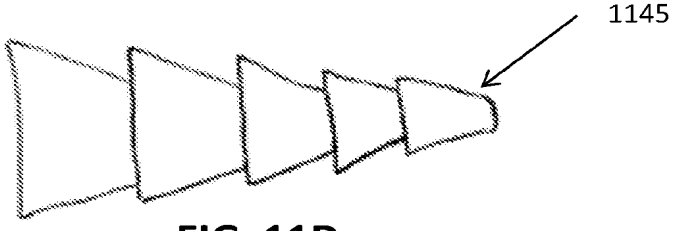


FIG. 11D

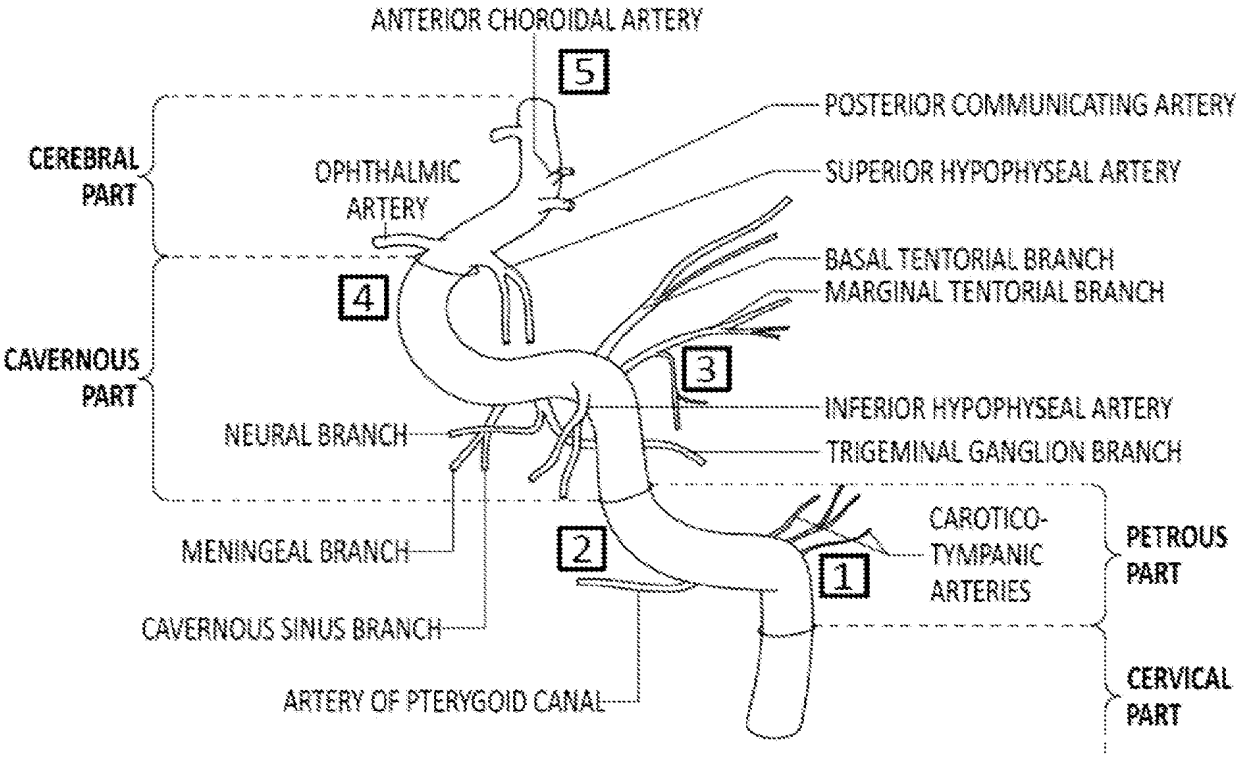


FIG. 12

FIG. 13A

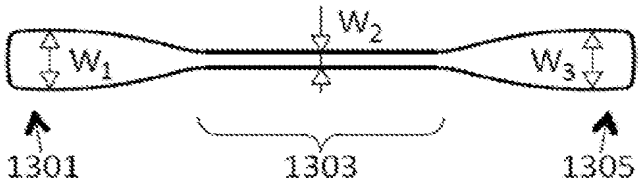


FIG. 13B

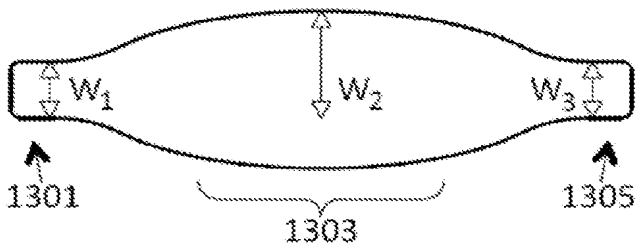


FIG. 13C

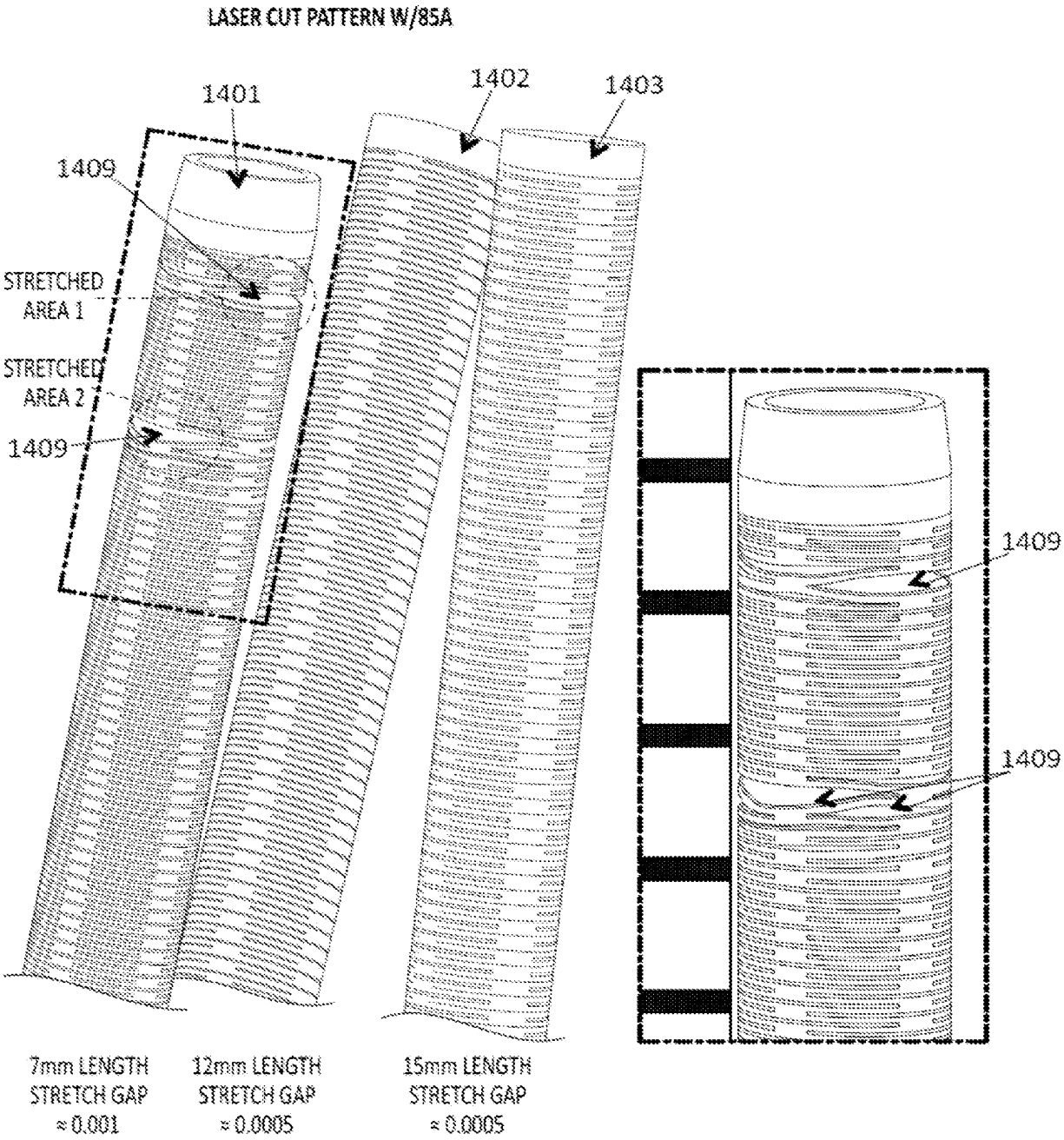


FIG. 14A

FIG. 14B

HYPOTUBE DESIGN									
TUBING MATERIAL: NITINOL				TUBING SIZE: .057x.052					
CUTS PER ROTATION: 2.5				CUT ANGLE: 121		UNCUT ANGLE: 23			
ZONE	1	2	3	4	5	6	7	8	9
PITCH	0	0.003	0.0035	0.004	0.0045	0.005	0.008	0.01	0.013
LENGTH	0.025	2	8	4	4	6	3	2	26

FIG. 14C

DESIGN W/ 80A
(WHERE THE DISTAL 5MM IS STRETCHED 8MM + TWO DEFECTS)

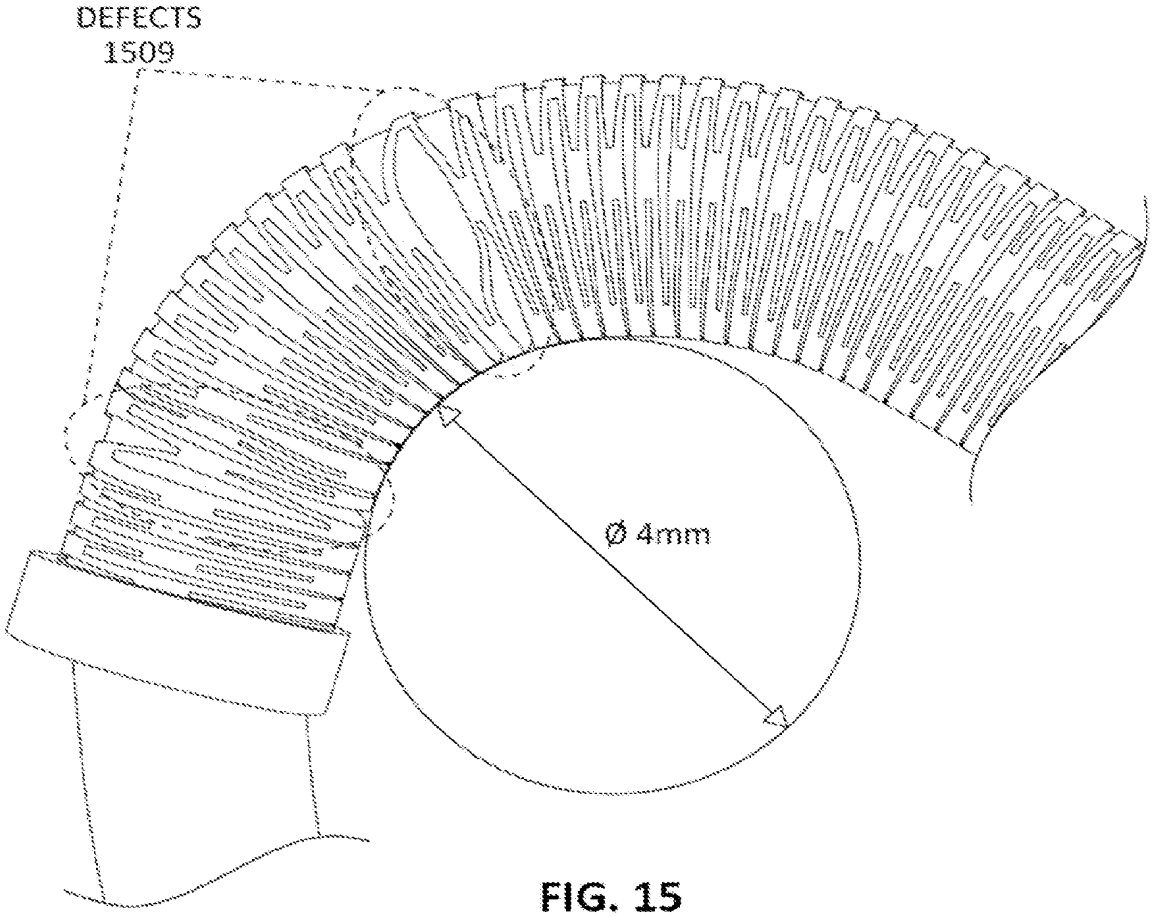


FIG. 15

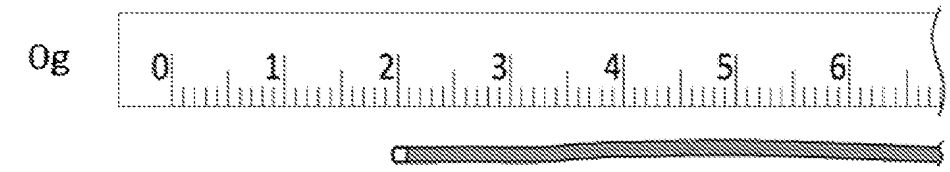


FIG. 16A

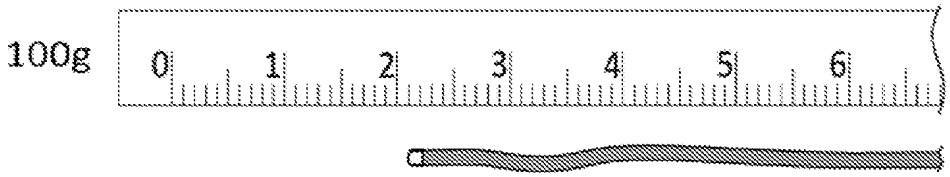


FIG. 16B

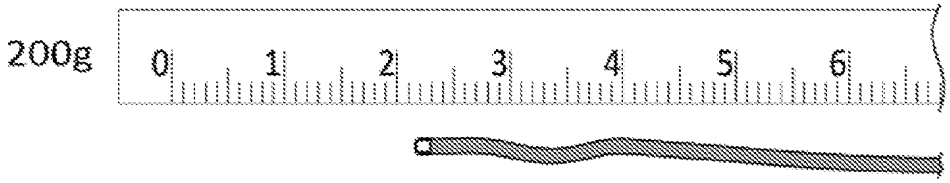


FIG. 16C

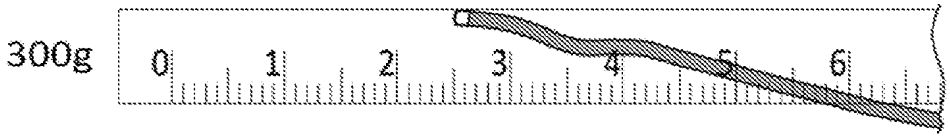


FIG. 16D

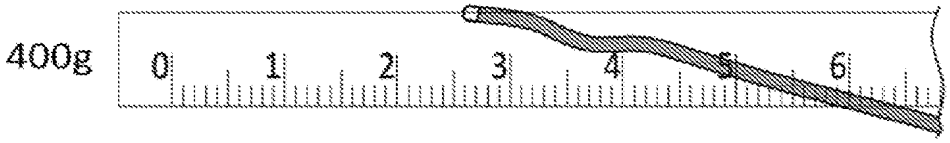


FIG. 16E

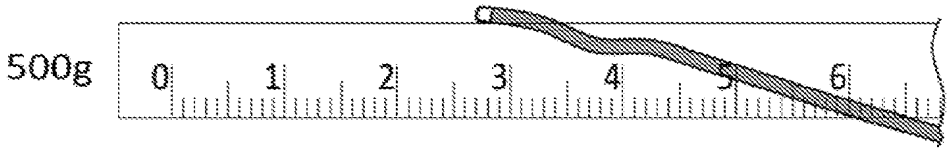


FIG. 16F

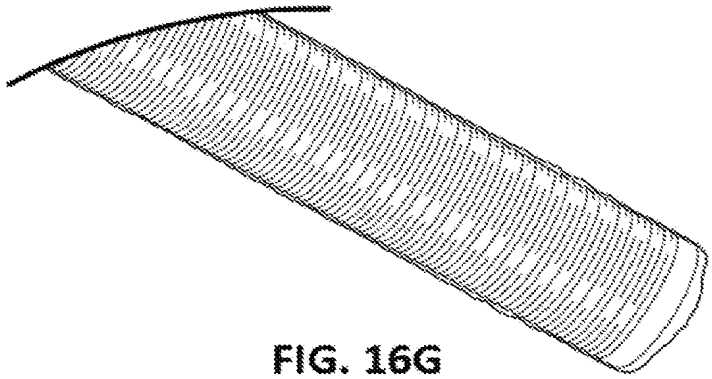


FIG. 16G

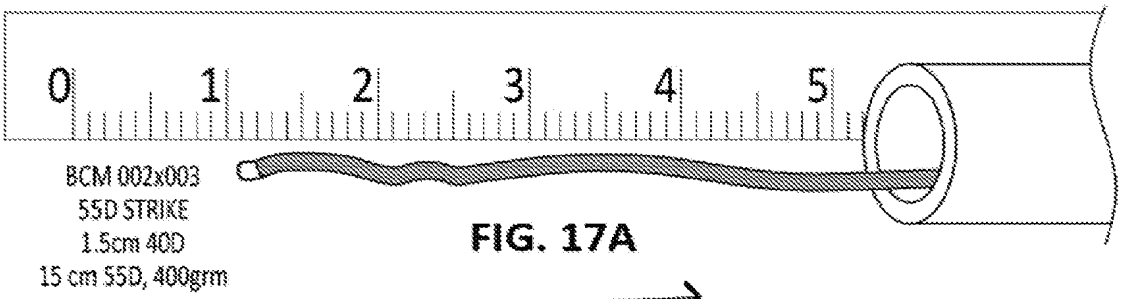


FIG. 17A

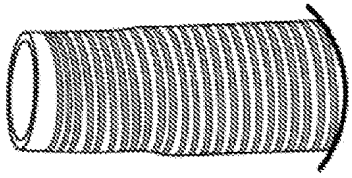


FIG. 17B

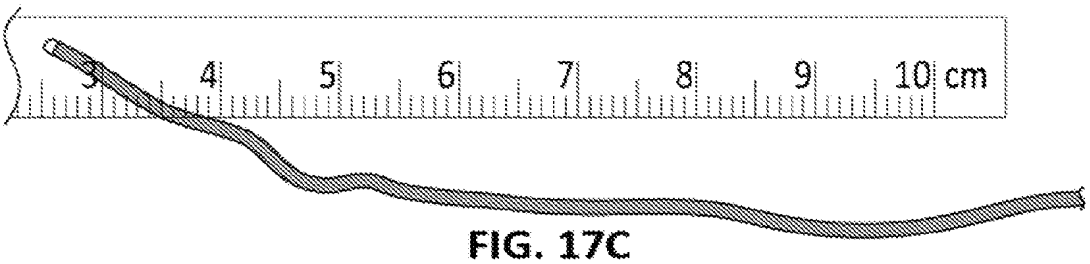


FIG. 17C

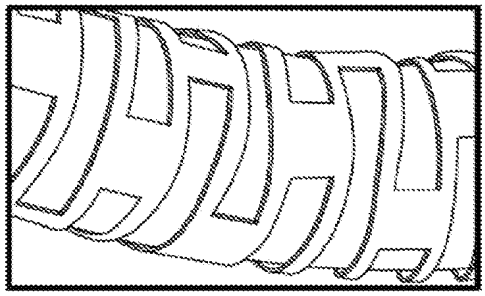


FIG. 17D

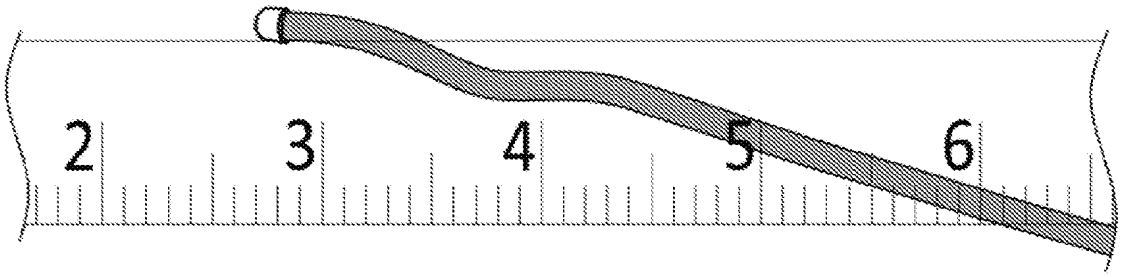


FIG. 17E

FIG. 18A

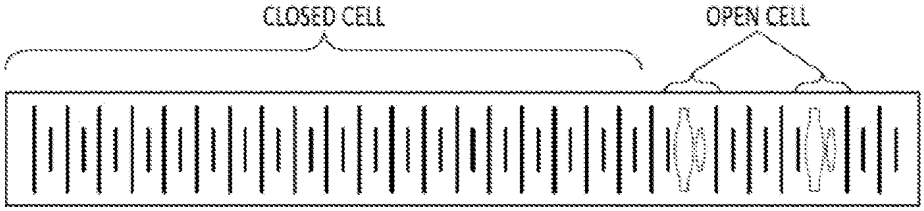


FIG. 18B

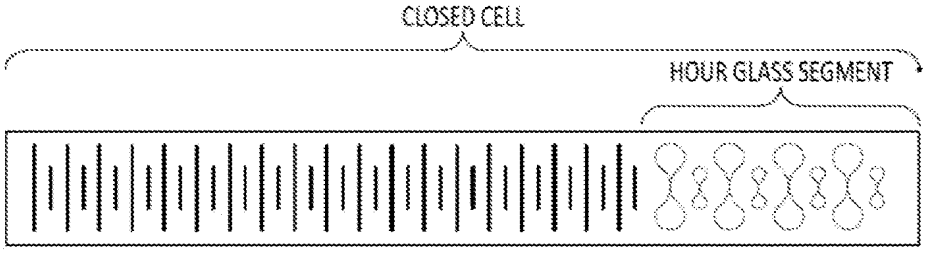


FIG. 18C

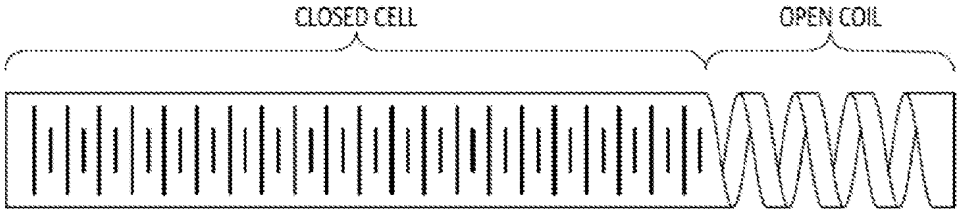


FIG. 18D

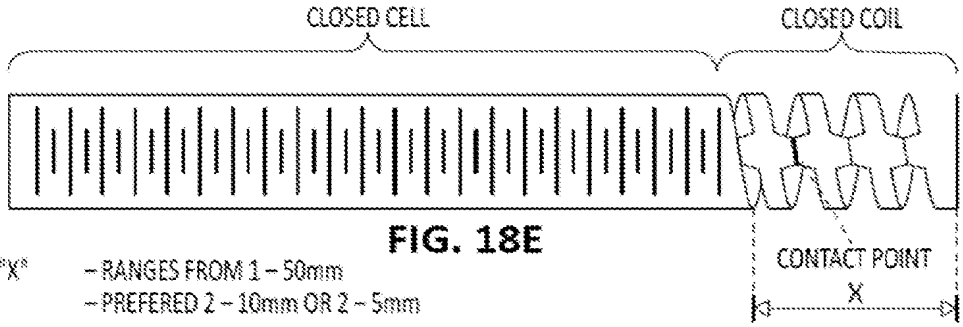


FIG. 18E

"X" – RANGES FROM 1 – 50mm
– PREFERED 2 – 10mm OR 2 – 5mm

FIG. 19A

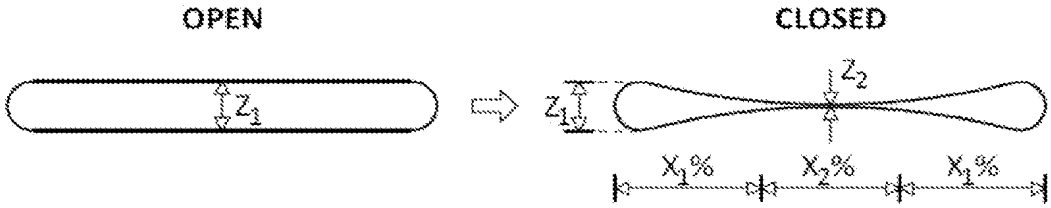
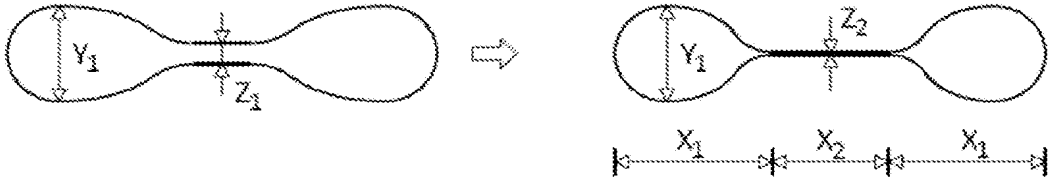


FIG. 19B



A DESIGN

– "CLOSED CELL"
- $5\% X_1 \leq X_2\% \leq 95\% X_1$
- $\emptyset \leq Z_2\% \leq 95\% Z_1$

ex $Z_1 = .001"$
$Z_2 = .0001"$

– "OPEN CELL"
- $.0005" \leq Z_1 \leq .010"$

ex $Z_1 = .001"$

B DESIGN

– "CLOSED CELL"
- $5\% X_1 \leq X_2\% \leq 95\% X_1$
- $\emptyset \leq Z_2\% \leq 90\% Z_1$

– "OPEN CELL"
- $.0005" \leq Y_1 \leq .010"$
- $10\% Y_1 \leq Z_1 \leq 500 Y_1$
- $5\% X_1 \leq X_2 \leq 95\% X_1$

FIG. 19C

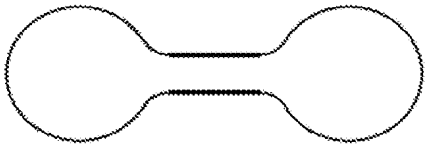


FIG. 20A

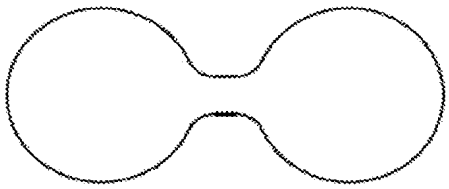


FIG. 20B

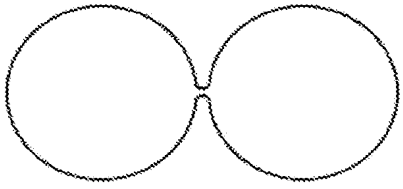


FIG. 20C

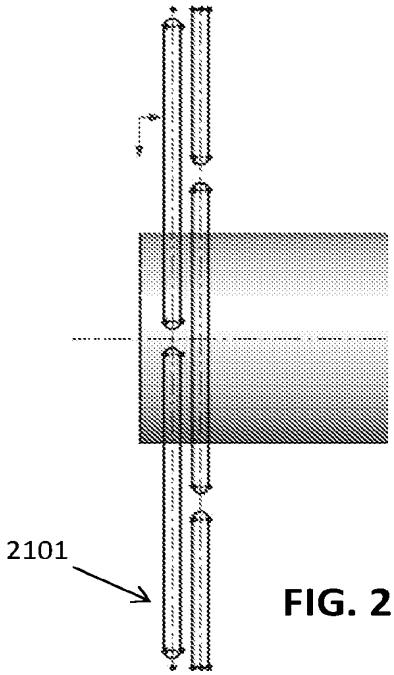


FIG. 21A

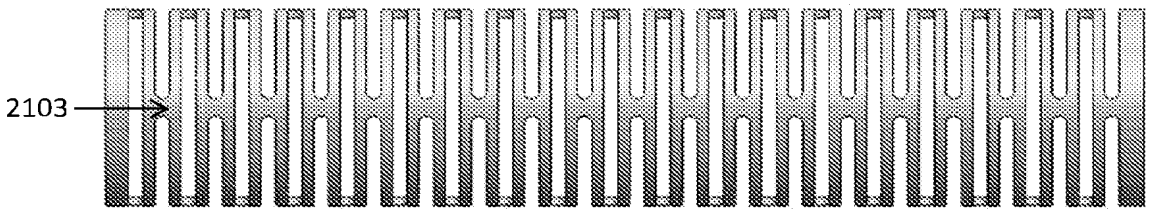


FIG. 21B

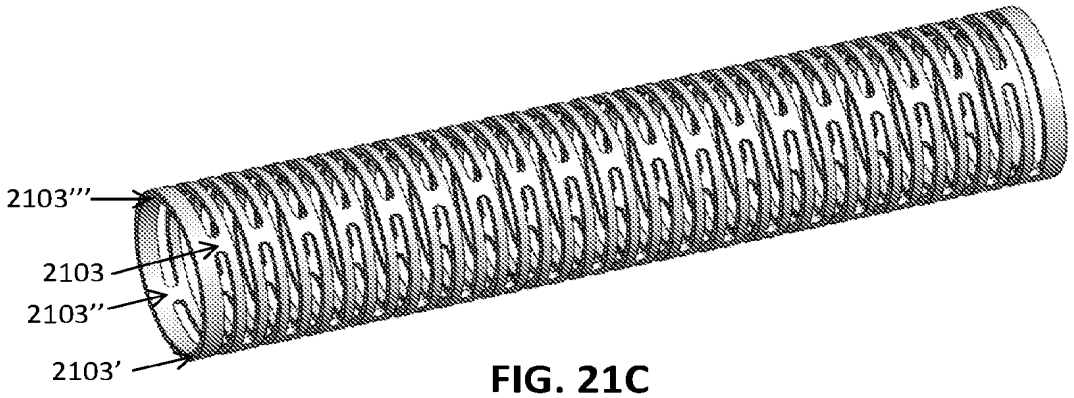


FIG. 21C

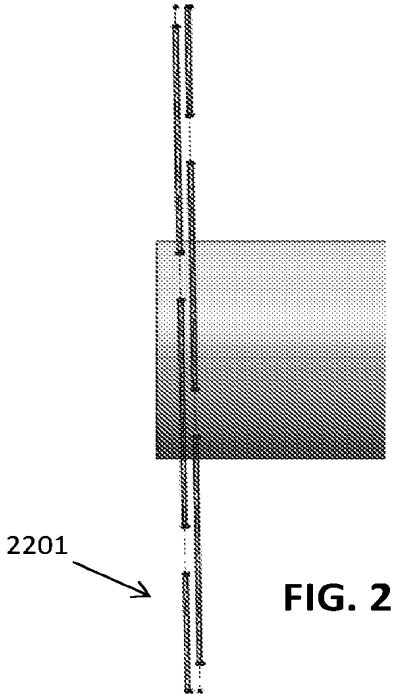


FIG. 22A

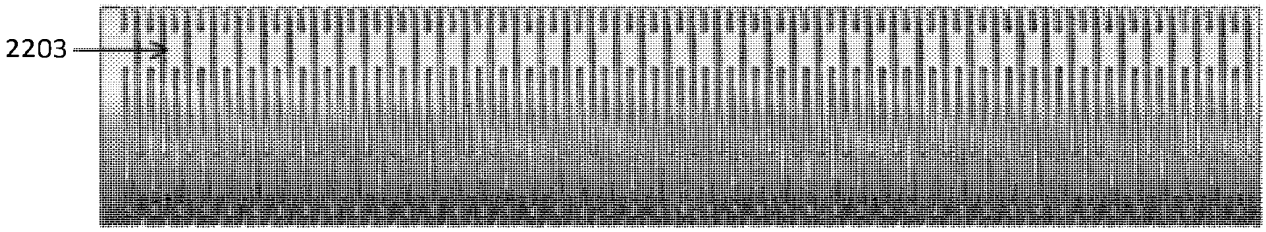


FIG. 22B

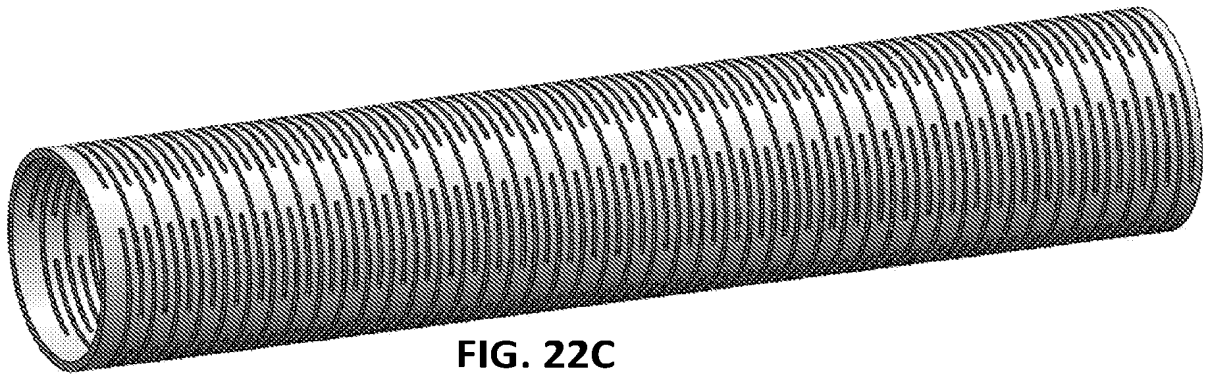


FIG. 22C

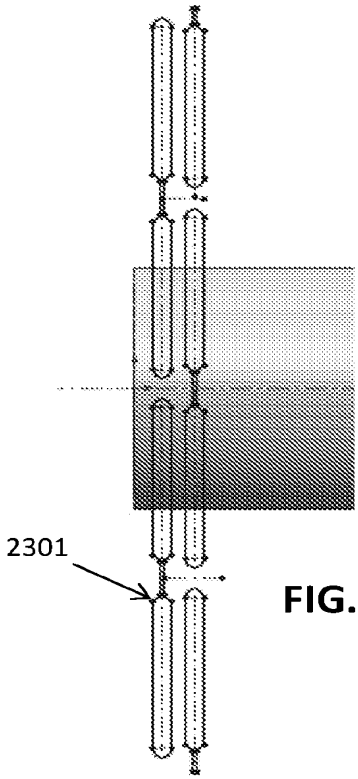


FIG. 23A

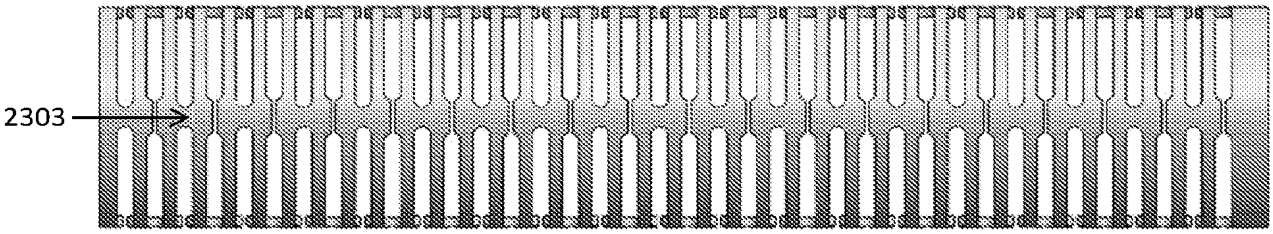


FIG. 23B

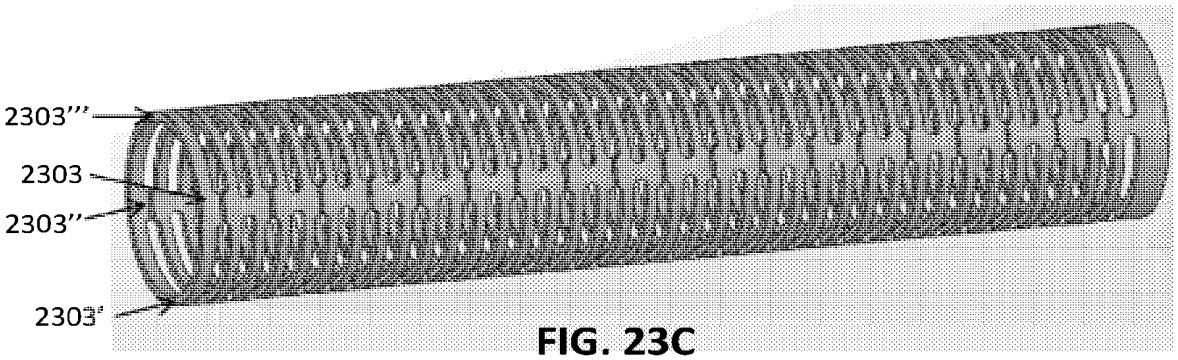


FIG. 23C

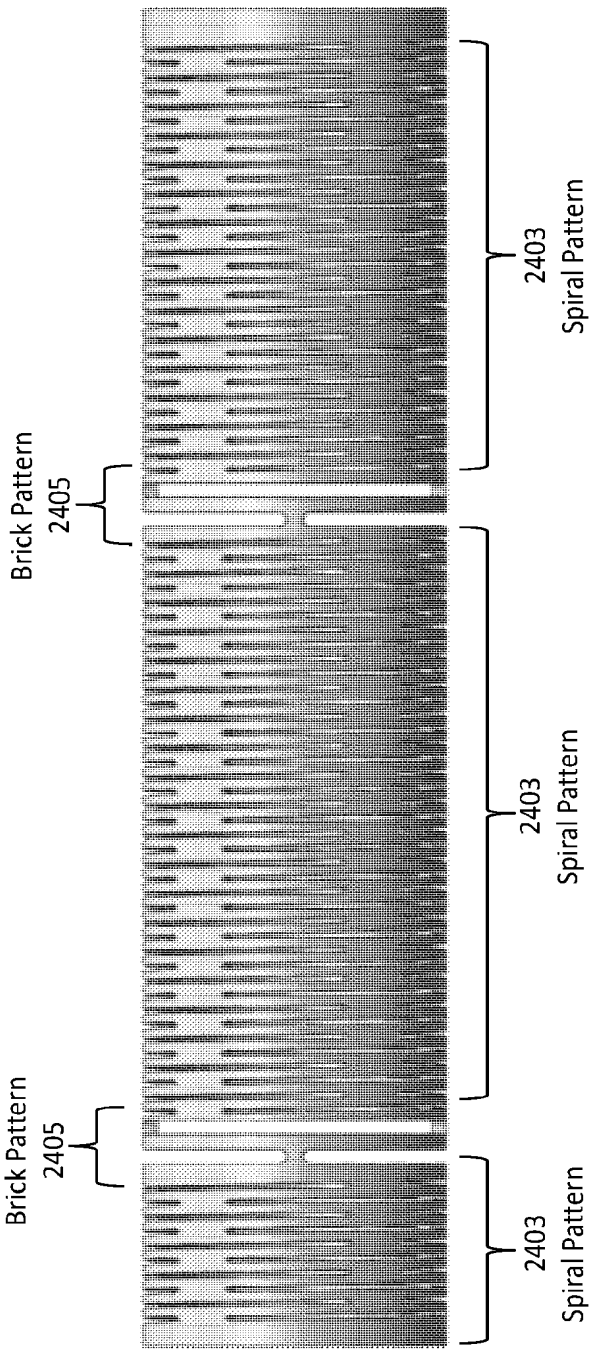


FIG. 24A

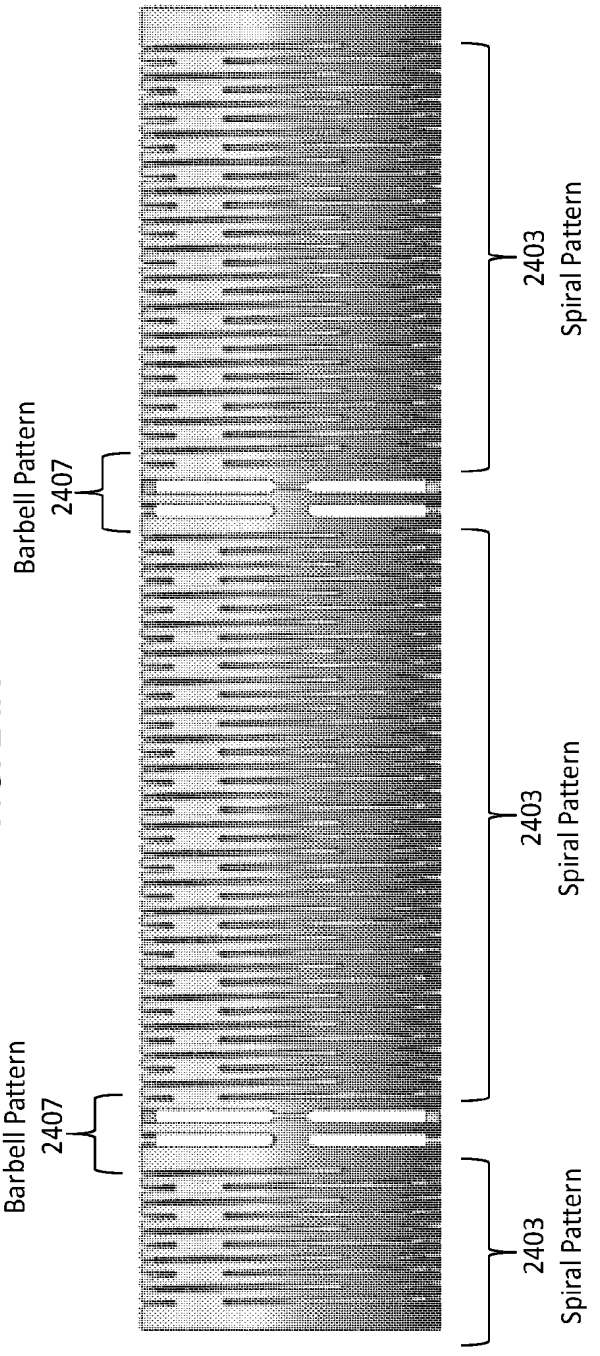


FIG. 24B

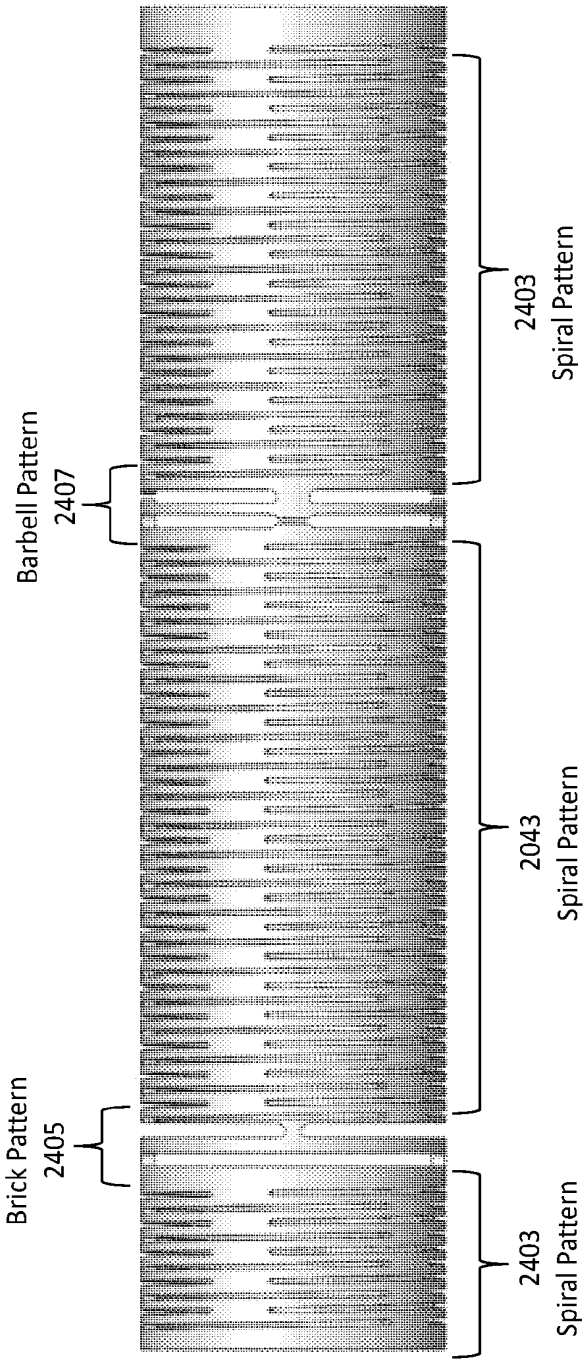

Barbell Pattern
2407
2403
Spiral Pattern
2043
Spiral Pattern
Brick Pattern
2405
2403
Spiral Pattern

FIG. 24C

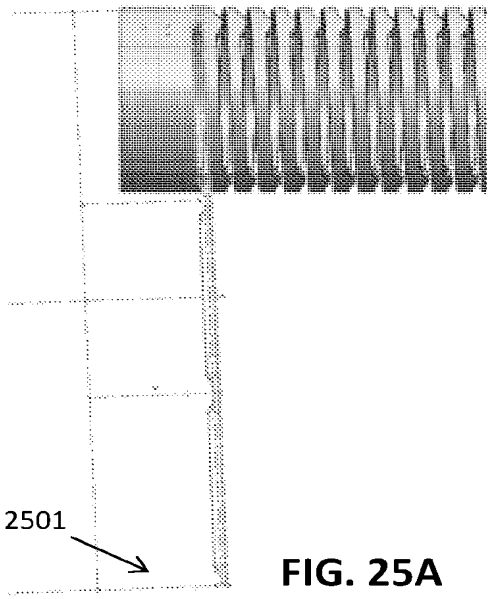


FIG. 25A

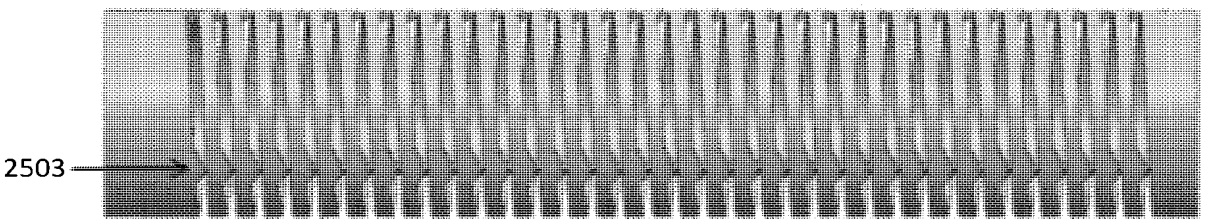


FIG. 25B

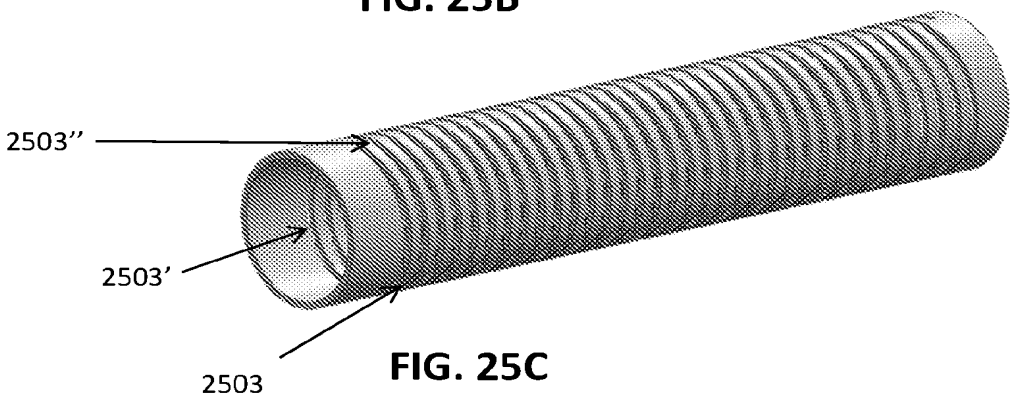


FIG. 25C

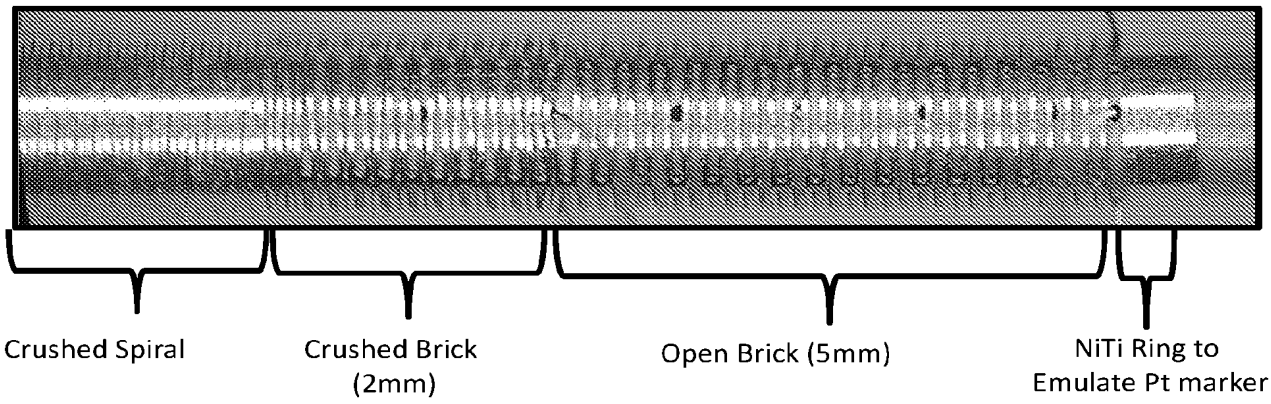

Crushed Spiral
Crushed Brick (2mm)
Open Brick (5mm)
NiTi Ring to Emulate Pt marker

FIG. 26

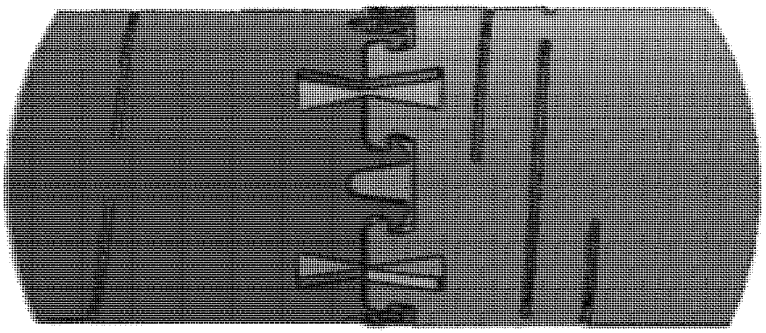


FIG. 27

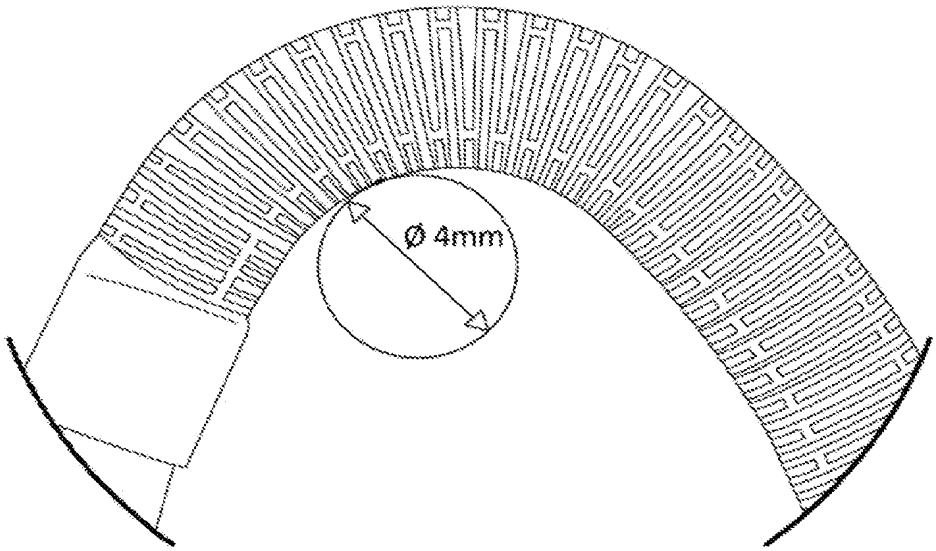


FIG. 28

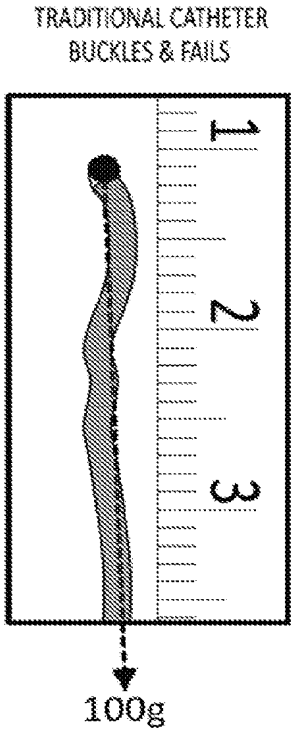


FIG. 29A

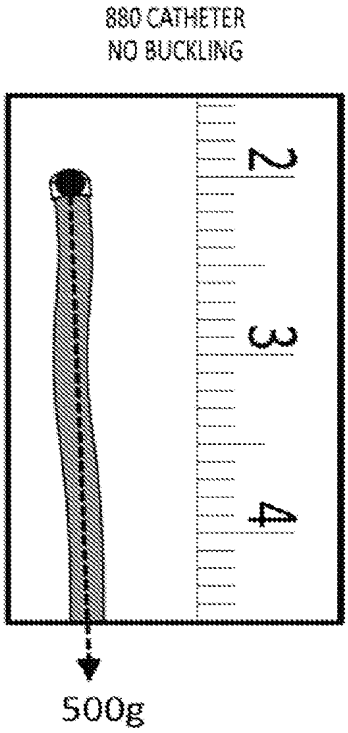


FIG. 29B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/040937

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.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/040937

A. CLASSIFICATION OF SUBJECT MATTER
INV. 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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2017/086864 A1 (GREENHALGH E SKOTT [US] ET AL) 30 March 2017 (2017-03-30) paragraph [0021]; figures 1-6 paragraph [0064] paragraph [0121] - paragraph [0125] paragraph [0164] -----	1-22
Y	US 2013/226196 A1 (SMITH JAMES [ZA]) 29 August 2013 (2013-08-29) paragraph [0112] - paragraph [0114]; figures 4, 10 -----	1-10
A	US 2010/249815 A1 (JANTZEN ALEXANDRA E [US] ET AL) 30 September 2010 (2010-09-30) abstract; figures 1, 2 -----	1,10
	-/--	

[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
25 October 2018	14/11/2018

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	Moers, Roelof

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.
Y	US 2016/074627 A1 (COTTONE ROBERT J [US]) 17 March 2016 (2016-03-17) paragraph [0095] - paragraph [0100]; figures 7A-8D	11-22
A	AU 2015 210 338 A1 (SHIFAMED HOLDINGS LLC) 27 August 2015 (2015-08-27) paragraph [0087] - paragraph [0092]; figures 3-7b	11-22
A	US 2005/177132 A1 (LENTZ DAVID J [US] ET AL) 11 August 2005 (2005-08-11) paragraph [0027]; figures 1-7	11,22

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/040937

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2017086864 A1	30-03-2017	CN 108348319 A	31-07-2018
		EP 3355829 A1	08-08-2018
		JP 2018529495 A	11-10-2018
		US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		WO 2017058280 A1	06-04-2017
US 2013226196 A1	29-08-2013	US 2013226196 A1	29-08-2013
		WO 2012049652 A1	19-04-2012
		ZA 201302264 B	30-04-2014
US 2010249815 A1	30-09-2010	NONE	
US 2016074627 A1	17-03-2016	CN 107148289 A	08-09-2017
		EP 3194003 A1	26-07-2017
		JP 2017532104 A	02-11-2017
		US 2016074627 A1	17-03-2016
		WO 2016044211 A1	24-03-2016
AU 2015210338 A1	27-08-2015	AU 2015210338 A1	27-08-2015
		AU 2018203003 A1	17-05-2018
US 2005177132 A1	11-08-2005	EP 1768732 A2	04-04-2007
		US 2005177132 A1	11-08-2005
		US 2010100073 A1	22-04-2010
		WO 2006009588 A2	26-01-2006

Form PCT/ISA/210 (patent family annex) (April 2005)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10

Thrombectomy apparatus having knitted tractor tube.

---

2. claims: 11-22

Thrombectomy apparatus having slotted inversion support catheter.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/22

A1

(11) International Publication Number: **WO 98/33443**

(43) International Publication Date: 6 August 1998 (06.08.98)

(21) International Application Number: PCT/US98/01894

(22) International Filing Date: 3 February 1998 (03.02.98)

(30) Priority Data:
08/794,011 3 February 1997 (03.02.97) US

(71) Applicant *(for all designated States except US)*: ANGIO-GUARD, INC. [US/US]; 735 Aran Drive, Roswell, GA 30076 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: YADAV, Jay, S. [US/US]; 735 Aran Drive, Roswell, GA 30076 (US).

(74) Agents: DIPPERT, William, H. et al.; Cowan, Liebowitz & Lataman, P.C., 1133 Avenue of the Americas, New York, NY 10036–6799 (US).

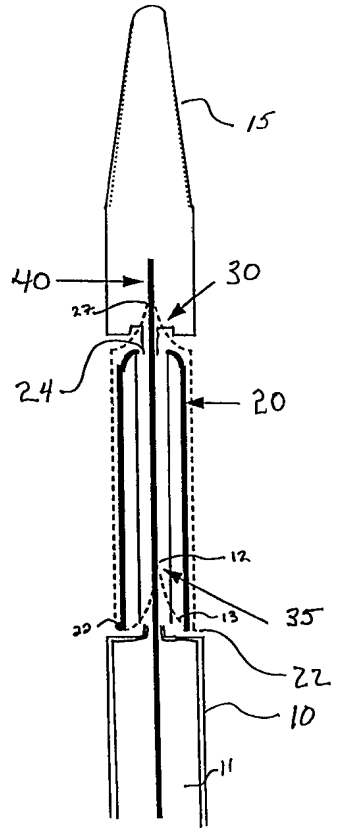
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: VASCULAR FILTER

(57) Abstract

A removable vascular filter for blocking micro–emboli, and macro–emboli while allowing the continued perfusion of blood comprising a filter membrane (20), wherein the free end of the membrane sits tightly against the guide wire (10) when the filter membrane is in a collapsed state, and wherein the filter has a means for deploying the filter membrane in the interior of a lumen which is comprised of cables or spines (30) operable with a movable core (40), or fibers inside the guide wire which transitions the filter membrane from the collapsed state to the deployed state. The filter membrane is comprised of a fine mesh material which has a pore size capable of blocking emboli while allowing continued blood flow.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

VASCULAR FILTER

FIELD OF THE INVENTION

The present invention relates to the treatment of vascular disease of either surgery or percutaneous angioplasty and stenting. More particularly, the invention relates to a device that reduces macro- and micro-embolism during the treatment of vascular stenosis.

BACKGROUND OF THE INVENTION

A variety of surgical and non-surgical angioplasty procedures have been developed for removing obstructions from blood vessels. Balloon angioplasty utilizes a balloon-tipped catheter which may be inserted within a stenosed region of the blood vessel. By inflation of the balloon, the stenosed region is dilated. Surgery involves either removing the plaque from the artery or attaching a graft to the artery so as to bypass the obstructing plaque. Other techniques, such as atherectomy, have also been proposed. In atherectomy, a rotating blade is used to shave plaque from an arterial wall.

One problem common with all of these techniques is the accidental release of portions of the plaque or thrombus, resulting in emboli which can lodge elsewhere in the vascular system. Such emboli are, of course, extremely dangerous to the patient, frequently causing severe impairment of the distal circulatory bed. Depending upon the vessel being treated, this may result in a stroke or myocardial infarction or limb ischemia.

Vascular filters or embolism traps for implantation into the vena cava of a patient are well known, being illustrated by, for example, U.S. Patents. Nos. 4,727,873 and 4,688,553. Additionally, there is a substantial amount of medical literature describing various designs of vascular filters and reporting the results of the clinical and experimented use thereof. See, for example, the article by Eichelter & Schenk entitled "Prophylaxis of Pulmonary Embolism," Archives of

Surgery, Vol. 97, August 1968, pp. 348 et seq. See, also, the article by Greenfield, et al., entitled "A New Intracaval Filter Permitting Continued Flow and Resolution of Emboli", Surgery, Vol. 73, No. 4, pp. 599-606 (1973).

Vascular filters are used, often during a postoperative period, when there is a perceived risk of a patient encountering a pulmonary embolus resulting from clots generated at the surgical site or the like. As a typical use of vascular filters, the filter is mounted in the vena cava to catch large emboli passing from the surgical site to the lungs.

The vascular filters of the prior art are usually permanently implanted in the venous system of the patient, so that even after the need for the filter has abated, the filter remains in place for the lifetime of the patient, absent surgical removal. U.S. Pat. No. 3,952,747 describes a stainless steel filtering device which is permanently implanted transvenously within the inferior vena cava. The filtering device is intended to treat recurrent pulmonary embolism. U.S. Pat. No. 4,873,978 describes a catheter device comprising a catheter body having a strainer mounted at it distal end. The strainer is shiftable between an opened configuration where it extends substantially across the blood vessel to entrap passing emboli, and a closed configuration where it retains the captured emboli during removal of the catheter. A mechanism actuable at the proximate end of the catheter body allows selective opening and closing of the strainer. Typically, the strainer is a collapsible cone having an apex attached to a wire running from the distal end to the proximate end of the catheter body.

Permanent implantation is often deemed medically undesirable, but it has been done because vascular filters are implanted in patients primarily in response to potentially life threatening situations. Accordingly, the disadvantages of permanent implantations of a vascular filter are often accepted.

To avoid permanent implantation, it would be highly desirable to provide an apparatus and method for preventing

embolisms associated with conventional surgery and angioplasty procedures. In particular, it would be desirable to provide a device which could be located within the vascular system to collect and retrieve portions of plaque and thrombus which have dislodged during the surgery or angioplasty procedure.

OBJECT OF THE INVENTION

It is an object of this invention to provide a vascular filter for reducing macro- and micro-embolism.

It is also an object of the invention to provide a vascular filter which is readily removable from the vascular system, or elsewhere, of a patient when the filter is no longer needed.

It is a further object of the invention to provide a vascular filter having a configuration which does not require hooks to penetrate and grip the blood vessel walls, so that the implantation results in less blood vessel injury.

It is a yet further object of the invention to provide a vascular filter of very low profile which is part of a guidewire and can be used in small vessels

These and other objects of the invention will become more apparent from the description below.

SUMMARY OF THE INVENTION

The present invention generally relates to the surgical and interventional treatment of vascular disease. For example, during angioplasty and stenting of carotid stenosis, there is occurrence of macro- and micro-embolism which increases the risk of a minor or major stroke. The device of the present invention for reducing macro- and micro-embolism is very useful in helping to prevent the risk of stroke. However, this device would also be useful in any angioplasty or surgical procedure where embolization is a risk.

The filters of the present invention will decrease embolism while allowing brain, or other distal tissue, perfusion. The filters are incorporated into a guidewire which

is used for the entire procedure from crossing a lesion to deploying a stent. The filter consists of a thin membrane attached to the guidewire and supported by fine metal spines. The filter membrane has a pore size such that blood flow is not impeded when the filter membrane is expanded but micro- and macro-emboli are blocked. The attachments of the filter membrane to the guidewire allow expansion of the filter membrane with a firm fit inside the artery. Expansion of the filter membrane is aided by the forward flow of blood against the filter. The attachments also allow for collapse of the filter membrane at the end of the procedure so it fits tightly against the guidewire and can be withdrawn through the guide catheter. The filter design results in a very low profile so that the initial crossing of the lesion is minimally traumatic. Also, the small diameter and small profile facilitate use of the device in small or larger arteries with minimal or no obstruction of blood flow.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects and advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which the reference characters refer to like parts throughout and in which:

Fig. 1 is a lateral, partly cross-sectional view of the distal end of a guidewire of one embodiment of the invention with the filter membrane in a collapsed position;

Fig. 2 is a lateral, partly cross-sectional view of the distal end of a guidewire of Fig. 1 with the filter membrane in an expanded, deployed position;

Fig. 3 is a proximal end-on view of the filter membrane shown in Fig. 2;

Fig. 4 is a lateral, partly cross-sectional view of another embodiment of the invention;

Fig. 5A is a lateral, partly cross-sectional view of a further embodiment of the invention;

Fig. 5B is a lateral, partly cross-sectional view of the embodiment of the invention shown in Fig. 5A with the filter membrane in an expanded, deployed position;

Fig. 6 is a partly cross-sectional view of a control handle for the invention;

Fig. 7 is a partly cross-sectional view of another embodiment of the invention;

Fig. 8 is a partial cross-sectional view of an embodiment of the invention wherein the filter membrane has curved supports;

Fig. 9 is a partial cross-sectional view of yet another embodiment of the invention wherein the filter membrane has a spiral wire;

Fig. 10 is a top, cross-sectional view of the embodiment of the invention shown in Fig. 9;

Fig. 11 is a partial cross-sectional view of another embodiment of the invention having inflatable support spines; and

Figs. 12 and 13 represent partial cross-sectional views of another embodiment of the invention in collapsed and deployed positions, respectively.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a vascular filter for use in percutaneous angioplasty and stenting and provides for the prevention of distal embolism during endovascular procedures. Further, the filter device of the invention allows for distal perfusion while preventing embolism.

The device consists of a thin, perforated filter membrane which is capable of blocking emboli and which is attached to the distal end of a guidewire. The device preferably uses thin fibers which are moveable and are attached to the filter membrane to deploy and collapse the filter membrane. The invention also contemplates the use of metal spines or inflatable spines attached to the filter membrane to deploy the

filter membrane. The fibers or spines can also be attached to a moveable core which is slidable within the guidewire and is used to deploy and collapse the filter membrane.

The filter membrane deploys in an umbrella-like fashion with the unattached edge of the membrane moving upward, i.e., distally, and outward until it is in firm contact with an artery wall. When the filter membrane is deployed, it spans the cross-sectional area of the vessel lumen being treated for a stenosis such as carotid stenosis, or another condition likely to produce emboli.

The invention can perhaps be appreciated better by referring to the drawings. Fig. 1 illustrates a lateral, cross-sectional view of a distal end of a guidewire 10 with a filter membrane 20 attached thereto. Fig. 1 shows guidewire 10 with a shapeable, tapered soft tip 15 at its extreme distal end which provides flexibility and maneuverability to guidewire 10. The filter membrane in Fig. 1 is in a collapsed position. Filter membrane 20 has a fixed portion 24 which is movably attached to guidewire 10, and filter membrane 20 lies adjacent guidewire 10 proximal to fixed portion 24 when filter membrane 20 is in the collapsed state. A moveable core 40 runs through a center lumen 11 of guidewire 10 and preferably extends distally a short distance beyond fixed portion 24 of filter membrane 20. Deploying wires or fibers 30 are each firmly attached at one end 27 to moveable core 40 distal to fixed portion 21 of filter membrane 20. The deploying fibers 30 are attached at their other ends to filter membrane 20 at attachment points 22.

Collapsing fibers 35 are each firmly attached at one end 12 to the portion of moveable core wire 40 which is interior to filter membrane 20 when it is in the collapsed state. Collapsing fibers 35 are each attached at their other end 13 to filter membrane 20 at attachment points 22. Accordingly, collapsing fibers 35 lie interior to filter membrane 20 when filter membrane 20 is in the collapsed state.

Filter membrane 20 is deployed when the operator pulls moveable core 40 proximally through the interior of guidewire

10. Prior to retraction of moveable core 40, deploying fibers 30 are sufficiently relaxed so as not to create any tension at filter membrane attachment points 22. Upon retraction of moveable core 40, tension is created in deploying fibers 30.

There will preferably be from 2 to 6 each of evenly-spaced deploying fibers 30 and collapsing fibers 35, 3 or 4 being most preferred. The deploying fibers 30 and collapsing fibers 35 can be made of any flexible, medically acceptable material, including stainless steel, nitinol, or another metal or metallic alloy or a non-metallic substance such as graphite or a suitable polymer. In addition, guidewire 10 and moveable core 40 can be made from similar materials, as would be appreciated by those skilled in the art. Typically, guidewire 10 could have an external diameter of from about 0.014 mm to about 0.035 mm, a wall thickness of from about 0.002 mm to about 0.010 mm, and a length of from about 25 cm to about 300 cm. Also, moveable core 40 could have a diameter of from about 0.003 mm to about 0.010 mm and a length of from about 30 cm to about 350 cm.

Fig. 2 illustrates the filter device of the invention in a deployed position on the inside of an artery wall 60. Moveable core 40 is in a retracted state, i.e., pulled proximally through the interior of guidewire 10. Tension is created in deploying fibers 30, and filter membrane 20 extends to a deployed position where the outer edge 14 of filter membrane 20 contacts artery wall 60. In this deployed position, collapsing fibers 35 are in a relaxed state and extend from filter membrane attachment points 22 to fixed attachment points 28 on moveable core 40.

The flow of blood in Fig. 2 is toward the distal end of guidewire 10. As such, the force of the flow of blood pushes on deployed filter membrane 20 and helps to maintain filter membrane 20 in the deployed position.

For withdrawal of guidewire 10 and the filter device, filter membrane 20 is collapsed so that it sits tightly against guidewire 10. This is accomplished by extending moveable core 40 distally through guidewire 10, thus relaxing deploying

fibers 30 and creating tension in collapsing fibers 35. The tension in collapsing fibers 35 collapses the filter membrane 20, allowing it to fit tightly against guidewire 10 in recess 16 as depicted in FIG. 1.

Fig. 3 illustrates the filter device of the invention from a distal end view in Fig. 2 with filter membrane 20 deployed. Guidewire 10 is centrally located, and structural wires 50 are seen extending from guidewire 10 to the outer edge 14 of filter membrane 20. These wires 50 provide structural integrity and rigidity to filter membrane 20. Fig. 3 depicts four, evenly-spaced structural wires 50, but there can be more or less structural wires 50. Preferably there are from two to six structural wires 50, which may be spaced regularly or irregularly. The wires 50 may preferably be comprised of stainless steel or another medically acceptable metal or alloy.

Filter membrane 20 of the invention is preferably a mesh such as that depicted in Fig. 3. The mesh should have pores of a size sufficient to block and capture any micro- and macro-emboli which may flow downstream from the site where the stenosis is being treated, but large enough such that blood flow is not impeded. The mesh used in the filter device of the invention can have a pore size of from about 20 to about 300 microns, preferably from about 30 to about 100 microns, more preferably from about 40 to 60 microns. Moreover, the size of filter membrane 20, i.e., the distance from guidewire 10 to free ends 22, is such as to allow a firm fit between filter membrane 20 and artery wall 60. The diameter of filter membrane 20 will be directly related to the artery being treated, with typical diameters ranging from about 2 mm to about 40 mm, most preferably from about 2 mm to about 20 mm.

The membrane can be comprised of fabric or non-fabric meshes, such as those used in known hemodialysis filters or heart-lung bypass machine filters. Suitable materials include polymers or physiologically acceptable metals or alloys.

In alternative embodiments of the invention shown in Figs. 4, 5A and 5B, filter membrane 20 will be suspended between from two to six, preferably three or four, thin metal wires 51 which

serve as spines for filter membrane 20. Wires 51 may be comprised of stainless steel or another metallic alloy, nitinol, or another shape-memory material. Wires 51 will be constructed so that they assume a 90° angle with guidewire 10 when they are in an unconstrained state. This will result in expansion of the filter membrane 20 to a position normal to guidewire 10. A set of thin fibers 17 are attached at attachment points 18 to filter membrane outer edge 14 and are used to collapse filter membrane 20.

Fig. 4 shows an embodiment of this invention in which metal wires 51 are allowed to regain their 90° angle unconstrained state by use of a moveable core 40 that runs through guidewire 10. Prior to retraction of moveable core 40, fibers 17 are sufficiently tensed so as to restrain wires 51. Upon retraction of moveable core 40, tension in fibers 17 is released and wires 51 are allowed to revert to their relaxed shape, which will result in expansion of filter membrane 20 to a position normal to guidewire 10.

Figs. 5A and 5B show an embodiment of the invention wherein wires 51 are restrained by fibers 17 that run through guidewire 10 and that are controlled at a remote location. In Fig. 5A, there is sufficient tension in fibers 17 to maintain wires 51 in a constrained position. In Fig. 5B, tension in fibers 17 has been relaxed such that wires 51 are allowed to revert to their relaxed shape, which will result in expansion of filter membrane 20 to a position normal to guidewire 10.

Fig. 6 depicts a control handle especially suitable for the embodiment of the invention shown in Figs. 5A and 5B. The proximal end 32 of guidewire 10 is rotatably attached to handle 33, such that rotation of handle 33 causes handle 33 to move distally or proximally relative to proximal guidewire end 32. For example, handle 33 may have threads 34 which engage threads 35 on guidewire proximal end 32. Fibers 17 attached to filter membrane 20 are secured in a base 36 of handle 33. Then, as handle 33 is turned, the fibers 17 move distally or proximally to open or close filter membrane 20.

As handle 33 is turned clockwise in the direction of arrow A and fibers 17 are allowed to move distally in the direction of arrow C, the tension on the filter membrane fibers 17 decreases and wires 51 are allowed to assume their natural 90° angle with respect to the guidewire, resulting in opening of filter membrane 20. Similarly, when handle 33 is turned counter-clockwise in the direction of arrow B and fibers 17 are pulled proximally in the direction of arrow D, the tension on filter fibers 17 increases, causing filter membrane 20 to collapse tightly against guidewire 10. Of course, the direction of turn of handle 33 as discussed above can be reversed, as long as threads 34,35 are properly formed to allow appropriate movement of handle 33 relative to guidewire proximal end 32.

In yet another embodiment of the invention, shown in Fig. 11, filter membrane 20 can be supported by inflatable spines 135 supporting the filter membrane 20. Spines 135 supporting the filter membrane 20 are from two to six hollow plastic tubes which are inflatable using, for example, a standard balloon angioplasty inflation device or endoflator in fluid connection through channel 137 with spines 135. Inflation of spines 135 causes them to become rigid and deploys filter membrane 20. The underside of the filter membrane is attached to very thin fibers 17 which are attached to moveable core 40 inside hollow guidewire 10. Filter membrane 20 is collapsed by deflating the spines 135 and withdrawing the moveable core 40 in the direction of arrow E until the membrane 20 fits tightly against guidewire 10.

A catheter-based configuration is also possible, as shown in FIG. 7. In this design, the guidewire is not part of the filter catheter; the guidewire and filter catheter are two separate components. The filter catheter has an entry hole for the guidewire below the attachment of the filter membrane and the guidewire exits out the end of the filter catheter. The filter catheter could be designed to accommodate a variety of guidewire sizes, most commonly a 0.014 inch guidewire. The advantages of this design are that a variety of guidewires

could be used; the lesion could be crossed with the guidewire prior to crossing with the filter catheter; the filter catheter could be removed from the artery without removing the guidewire; and the filter catheter could be made smaller.

In the embodiment of the invention shown in Fig. 7 a catheter 101 comprises a longitudinally extending lumen 103, which has an annular recess 105 adjacent the distal end of catheter 101. Positioned within recess 105 is a filter 107 comprised of structural wires 109 and a filter membrane 111. The distal end of each of wires 109 is attached at point 113 in recess 105. Fibers 117 extend from the proximal ends 119 of wires 109 proximally to a control means such as described in Fig. 6.

Catheter 101 contains guidewire port 125 located proximal to recess 105. It is intended that in use the distal portion 128 of a guidewire 127 will be threaded into the distal end 129 of catheter 101 and out through port 125.

Alternatively, and not shown here, a catheter 101 could comprise a longitudinally extending lumen and a shorter tracking lumen that extends from distal end 129 to a point proximal to recess 105. The distal end of guidewire 127 would then be threaded into the distal opening of the tracking lumen and out the proximal end of the tracking lumen.

Spiral or curved structural wires may be used to deploy the filter membrane instead of straight wires. Fig. 8 illustrates the use of four curved wires 120. The angulation of the filter attachment point of wires 120 relative to their guidewire attachment has the effect of wrapping the filter fabric around the guidewire in the undeployed state. This leads to a lower profile for the undeployed filter.

Figs. 9 and 10 illustrate the use of a single spiral structural wire 130 which is attached to the filter 107. As tension fiber 131 is released, wire 130 unwinds and deploys filter 107 in a conical configuration. This configuration has the simplicity of using a single wire and, when the tension on fiber 131 is increased, allows filter 107 to be wrapped very

tightly around the guidewire shaft 131, resulting in filter 107 having a low profile in its undeployed state.

Another modification shown in Figs. 12 and 13 comprises a retractable sheath 140 at the distal end of guidewire 142 which covers filter membrane 144 in the collapsed state. Sheath 140, the distal portion of which is affixed to guidewire tip 146, which is affixed to the distal end of moveable core 148, would prevent an edge 150 of filter membrane 144 from becoming entangled in an artery or guide catheter as it was being withdrawn from a patient.

More specifically, when guidewire 142 with tapered tip 146 is inserted percutaneously into a patient, sheath 140 covers collapsed filter membrane 144. After the filter membrane is determined by fluoroscopy to be in proper position, moveable core 148 is pushed distally to cause sheath 140 to "release" filter membrane 144, which has spines 152, to cause filter membrane 144 to deploy, as shown in Fig. 13.

It will be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in carrying out the method and in the apparatus set forth without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features herein and described and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

ITEM LISTING

No.	Item
10	Guidewire
11	Guidewire lumen
12	End of collapsing fiber
13	End of collapsing fiber
14	Filter membrane outer edge
15	Guidewire soft tip
17	Collapsing fiber
18	Attachment point
20	Filter membrane
22	Filter membrane attachment point
24	Filter membrane fixed portion
27	Fiber attachment point
28	Fiber attachment point
30	Deploying fibers
32	Guidewire proximal end
33	Handle
34	Handle threads
35	Guidewire proximal end threads
36	Handle base
40	Moveable core wire
50	Structural wires
51	Deploying wires
60	Artery wall
101	Catheter
103	Lumen
105	Recess
107	Filter mesh structure
109	Filter wire
111	Mesh
113	Attachment point
117	Deployment collapse wire
120	Curved filter structural wires
125	Guidewire port
127	Guidewire

128	Guidewire distal end
129	Spiral wire
131	Fiber
132	Guidewire shaft
135	Inflatable spines
137	Inflation channel
140	Sheath
142	Guidewire
144	Filter member
146	Tapered guidewire tip
148	Moveable core
150	Filter membrane edge
152	Filter membrane spine

I claim:

1. A removable vascular filter device for blocking micro-and macro-emboli while allowing continued perfusion of blood, comprising:

a guidewire having distal and proximal portions, wherein there is a recess in the distal portion, the recess having distal and proximal ends,

a filter membrane having a fixed inner portion and a free outer portion, wherein the fixed inner portion is movably attached toward the distal end of the guidewire recess and wherein the free outer portion is positioned in the recess when the filter membrane is in a collapsed state; and

a deploying means for causing the filter membrane to assume a position substantially normal to the longitudinal axis of the guidewire.

2. The vascular filter of Claim 1, wherein the filter membrane is comprised of a porous mesh.

3. The vascular filter of Claim 2, wherein the pore size of the porous mesh is from about 40 to about 300 microns.

4. The vascular filter of Claim 1, wherein the guidewire is hollow and wherein the deploying means comprises a moveable core, the moveable core being slidably positioned in the interior of the guidewire.

5. The vascular filter of Claim 4, wherein the deploying means further comprises deploying fibers each having first and second ends and said filter membrane further comprises an outer edge, and wherein said deploying fibers are each attached at a first end to the moveable core and are attached at a second end to the outer edge of the filter membrane.

6. The vascular filter of Claim 4, wherein the moveable core creates a tension in the deploying fibers when it slides proximally in relation to the guidewire, and said tension causes the filter membrane to expand outwardly until the outer edge of the filter membrane is in firm contact with the lumen wall.

7. The vascular filter of Claim 5 further comprising a means for collapsing the filter membrane from a deployed state to a collapsed state.

8. The vascular filter of Claim 7, wherein the collapsing means further comprises collapsing fibers each having first and second ends, wherein said collapsing fibers are each attached at a first end to the moveable core and are further attached at a second end to the outer edge of the filter membrane.

9. The vascular filter of Claim 8, wherein the moveable core creates a tension in the collapsing fibers when it slides distally in relation to the guidewire, and said tension causes the filter membrane to collapse tightly against the guidewire.

10. The vascular filter of Claim 1, wherein the guidewire has a lumen extending distally from the proximal portion of the guidewire to at least the recess.

11. The vascular filter of Claim 1, wherein the guidewire has a tapered distal tip.

12. A removable vascular filter device for blocking micro-and macro-emboli while allowing continued perfusion of blood, comprising:

a guidewire having distal and proximal portions, wherein there is a recess in the distal portion, the recess having distal and proximal ends,

a filter membrane having a fixed inner portion and a free outer portion, wherein the fixed inner portion is attached toward the distal end of the guidewire recess and wherein the free outer portion is positioned in the recess when the filter membrane is in a collapsed state, and wherein the filter membrane in an unstressed position assumes a position substantially normal to the longitudinal axis of the guidewire, and

means for collapsing the filter membrane from a deployed state to a collapsed state.

13. The vascular filter of Claim 12, wherein the filter membrane comprises wires which assume a 90° angle with respect to the longitudinal axis of the guidewire in an unconstrained state.

14. The vascular filter of Claim 12, wherein the filter membrane comprises from 2 to 6 arcing wires.

15. The vascular filter of Claim 13, wherein the filter membrane comprises a single spiral wire.

16. The vascular filter of Claim 12, wherein the collapsing means comprises collapsing fibers each having first and second ends, wherein said collapsing fibers are each attached at a first end to the outer edge of the filter membrane and the second end of each fiber extends proximally through the guidewire to an actuator.

17. The vascular filter of Claim 16, wherein the actuator is a handle or shaft that can be rotated clockwise or counter-clockwise to release or collapse the filter membrane.

18. The vascular filter of Claim 12, wherein the filter membrane comprises a set of inflatable spines, said spines being hollow plastic tubes.

19. The vascular filter of Claim 18 which further comprises an inflator for inflating the spines, wherein said inflator is in fluid communication with said spines, which become rigid upon inflation.

20. The vascular filter of Claim 19, where the means of inflation is an endoflator.

21. The vascular filter of Claim 12, wherein the guidewire has a lumen extending distally from the proximal portion of the guidewire to at least the recess.

22. The vascular filter of Claim 12, wherein the guidewire has a tapered distal tip.

23. The vascular filter of Claim 12, which also comprises a sheath positioned concentric to the collapsed filter membrane, wherein said membrane causes the filter

member to be in a collapsed state but can be moved distally to allow the filter member to extend radially.

24. The vascular filter of Claim 23, wherein the sheath has proximal and distal portions and is attached at its distal end to a distal guidewire tip that is affixed to a moveable core extending proximally through the guidewire.

25. A removable vascular filter device for blocking micro-and macro-emboli while allowing continued perfusion of blood, comprising:

a catheter having distal and proximal portions, wherein there is a recess in the distal portion, the recess having distal and proximal ends, and the catheter has a longitudinally extending lumen;

a filter membrane having a fixed inner portion and a free outer portion, wherein the fixed inner portion is movably attached toward the distal end of the catheter recess, wherein the free outer portion is positioned in the recess when the filter membrane is in a collapsed state, and wherein the filter membrane is unstressed and extends substantially normal to the outer surface of the catheter; and

a collapsing means for causing the filter membrane to collapse into the catheter recess,

wherein the outer surface of the catheter has a guidewire port for receipt of a guidewire.

26. The vascular filter of Claim 25, wherein the filter membrane comprises a porous mesh.

27. The vascular filter of Claim 26, wherein the pore size of the porous mesh is from about 40 to about 300 microns.

28. The vascular filter of Claim 25, wherein the collapsing means comprises fibers each having first and second ends and said filter membrane further comprises an outer edge, and wherein said collapsing fibers are each attached at a first end to a control mechanism and are attached at a second end to the outer edge of the filter membrane.

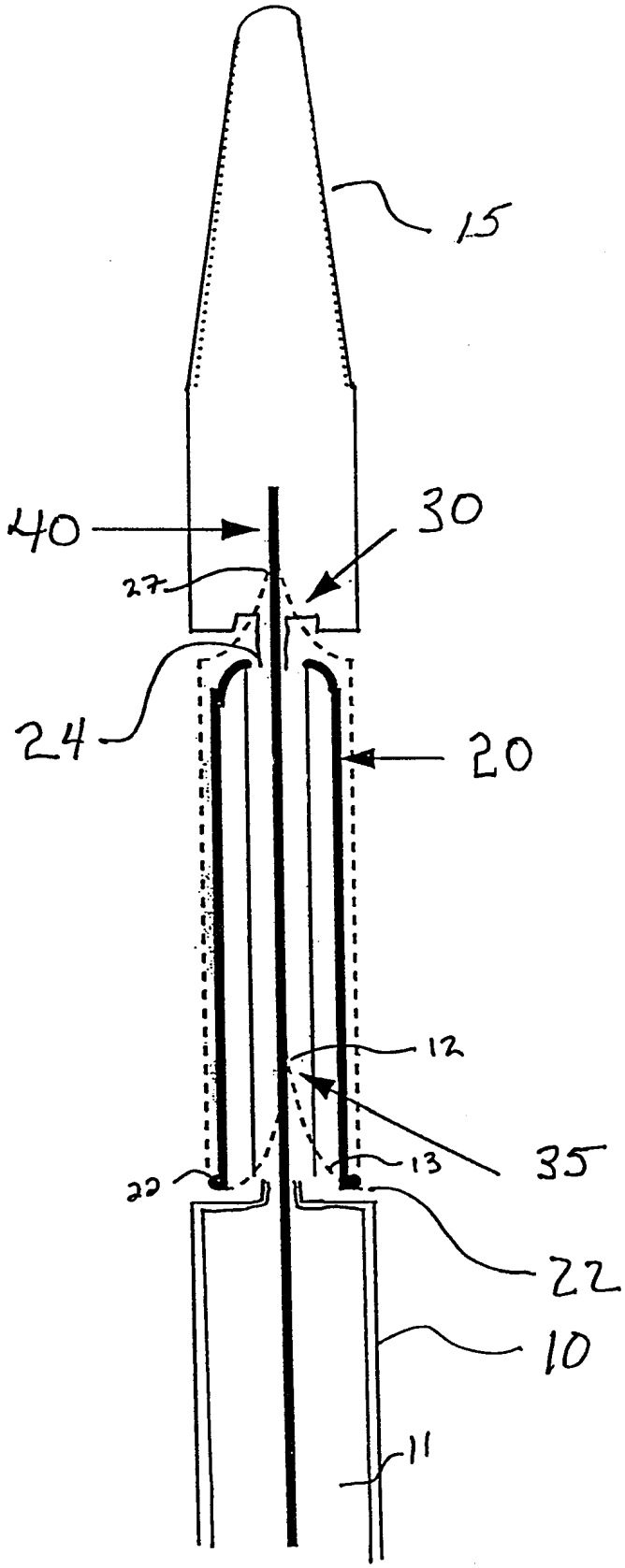


FIG. 1

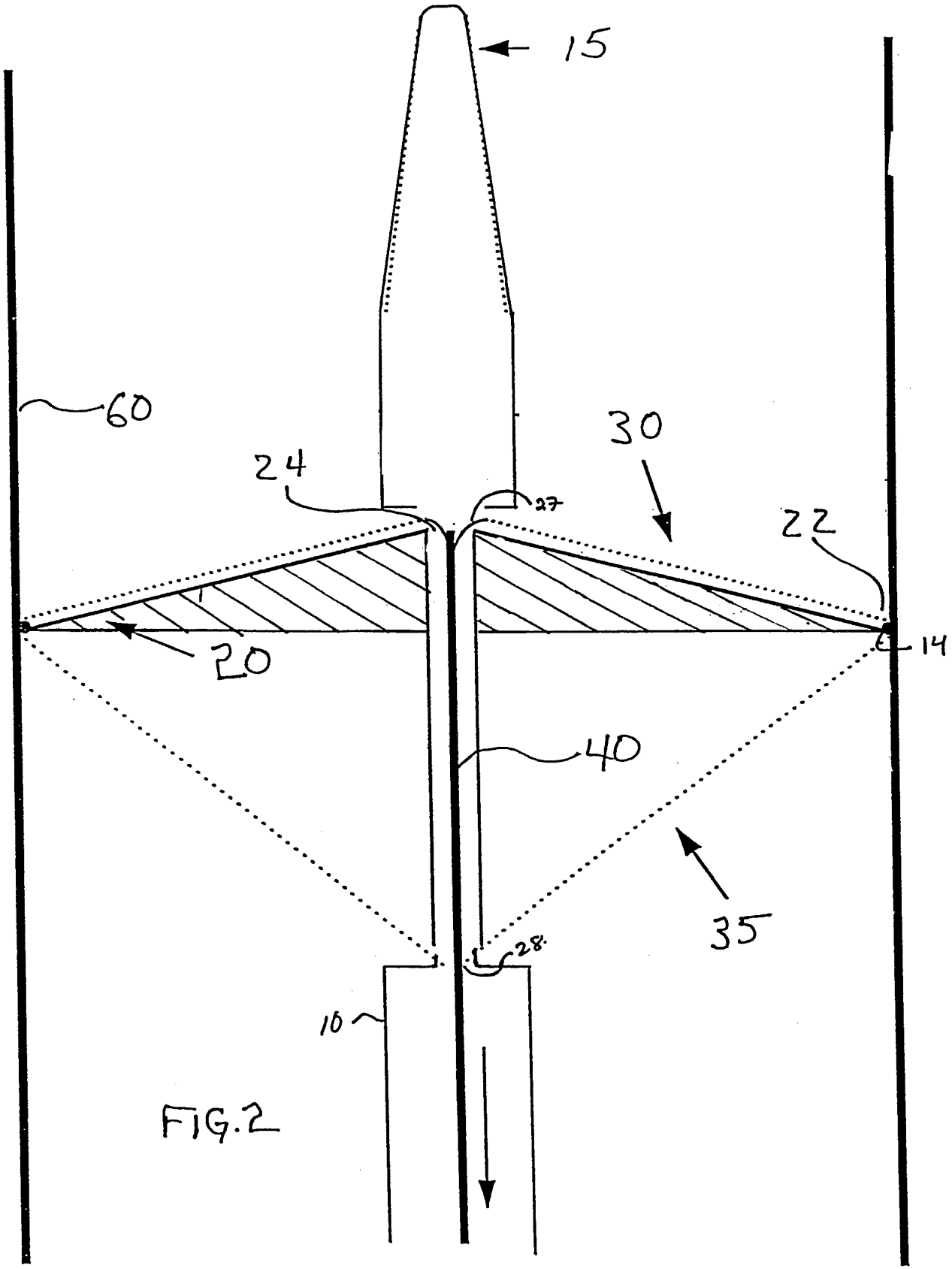


FIG.2

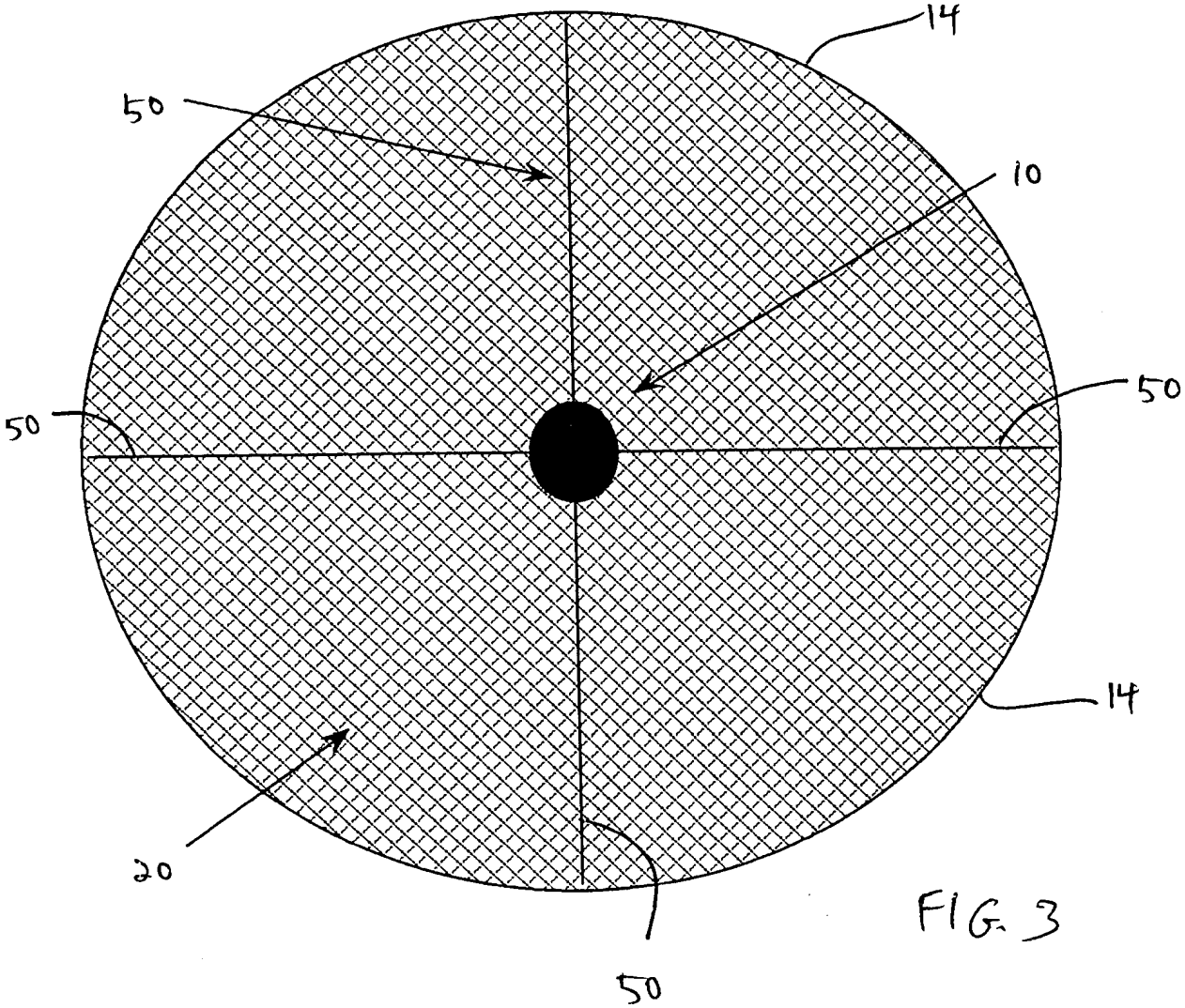


FIG. 3

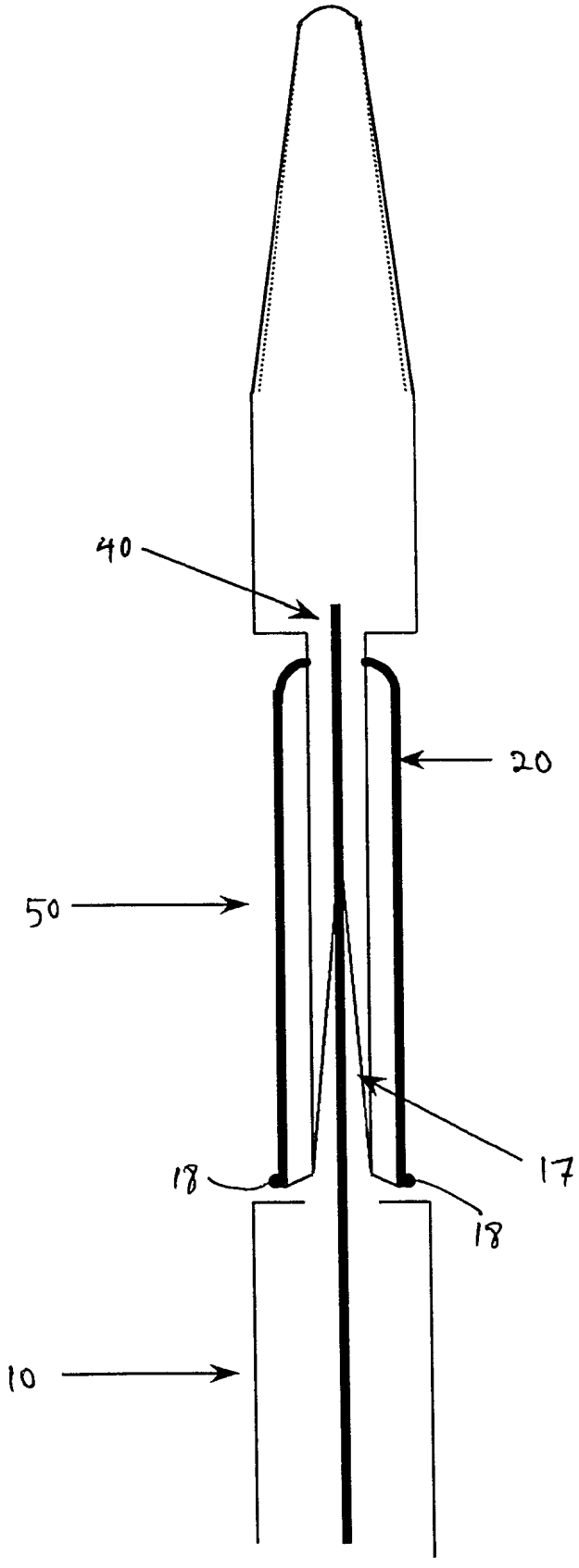


FIG. 4

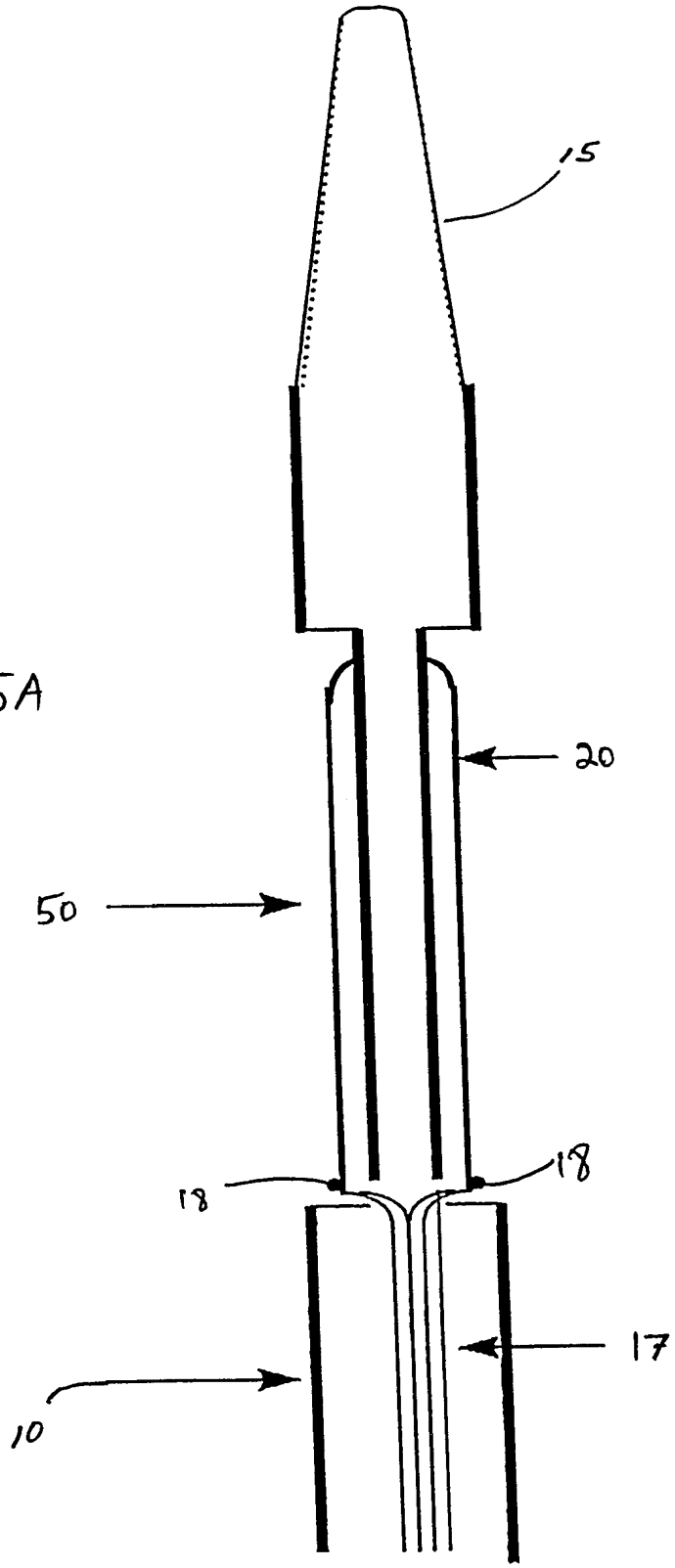


Fig. 5A

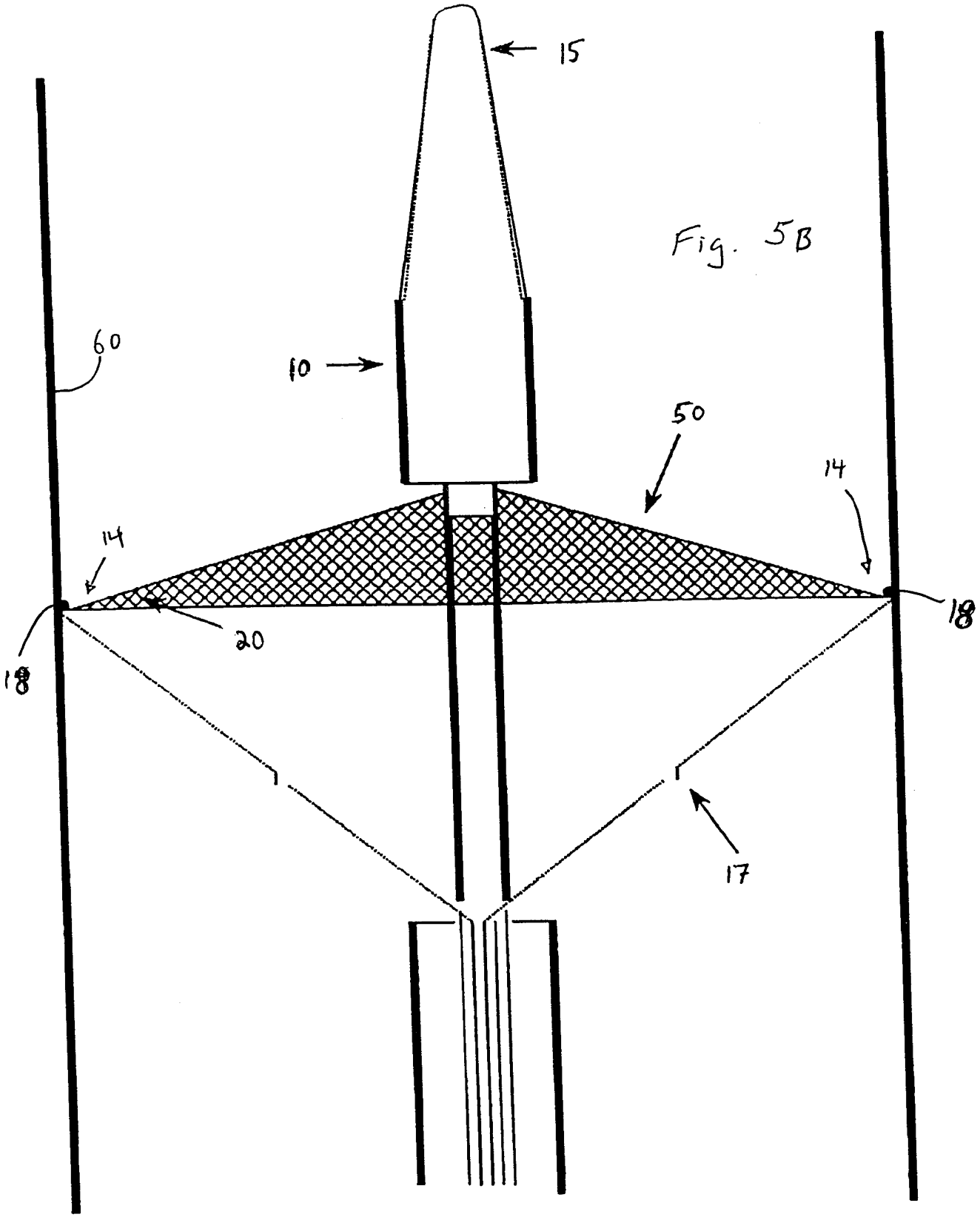


Fig. 5B

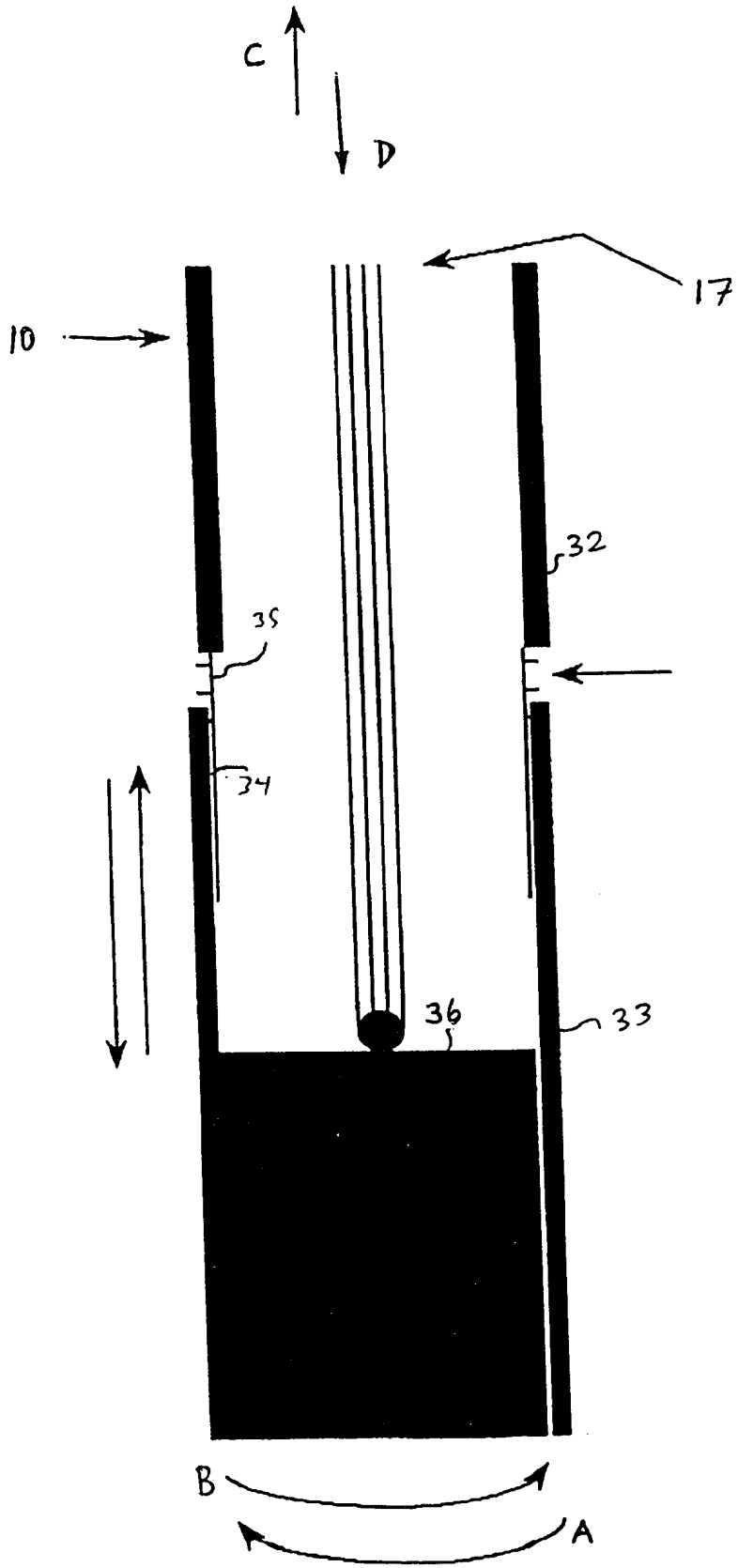


Fig. 6

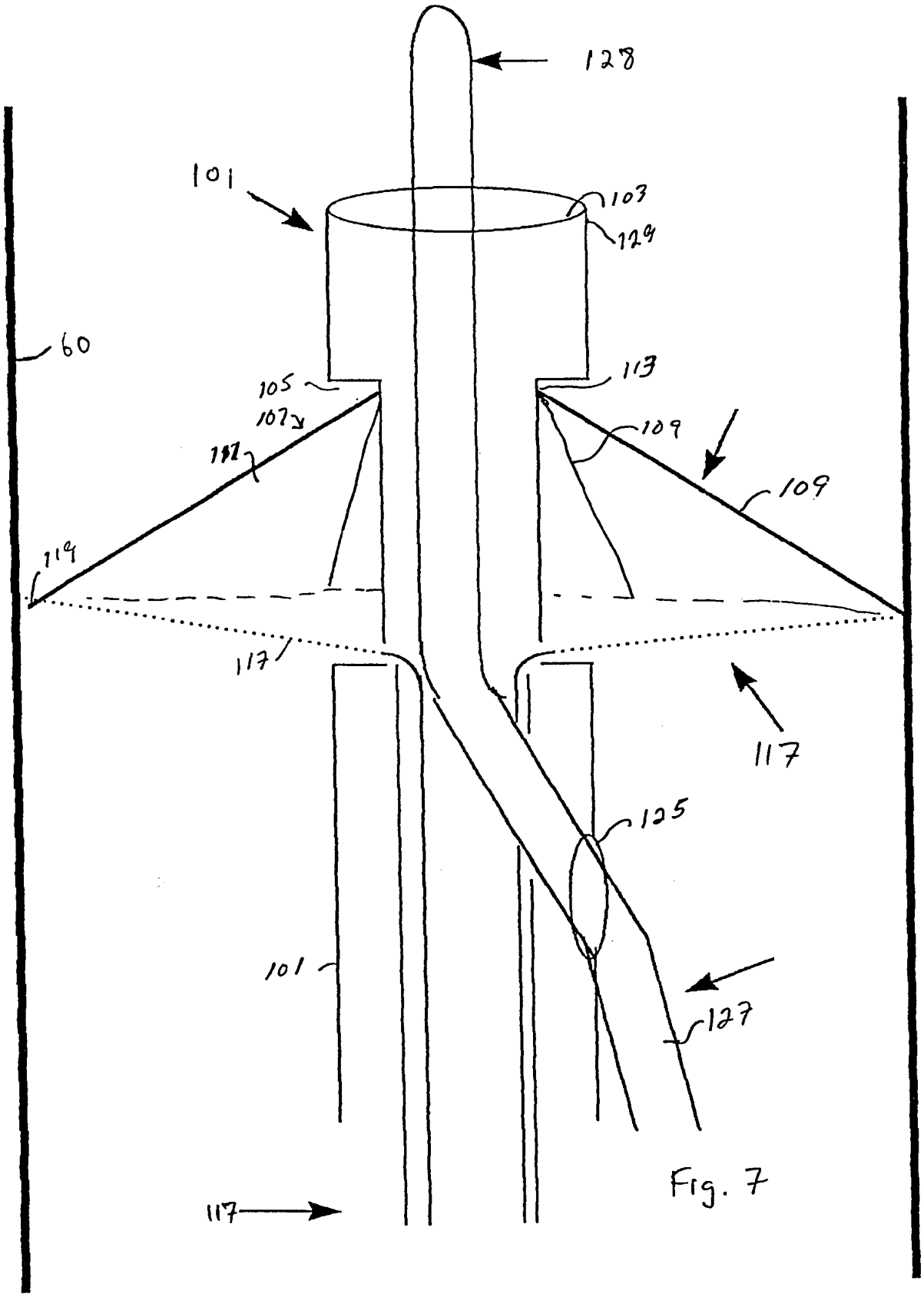

128
101
103
129
60
105
113
107
109
111
109
119
117
117
125
101
127
117

Fig. 7

FIG. 8

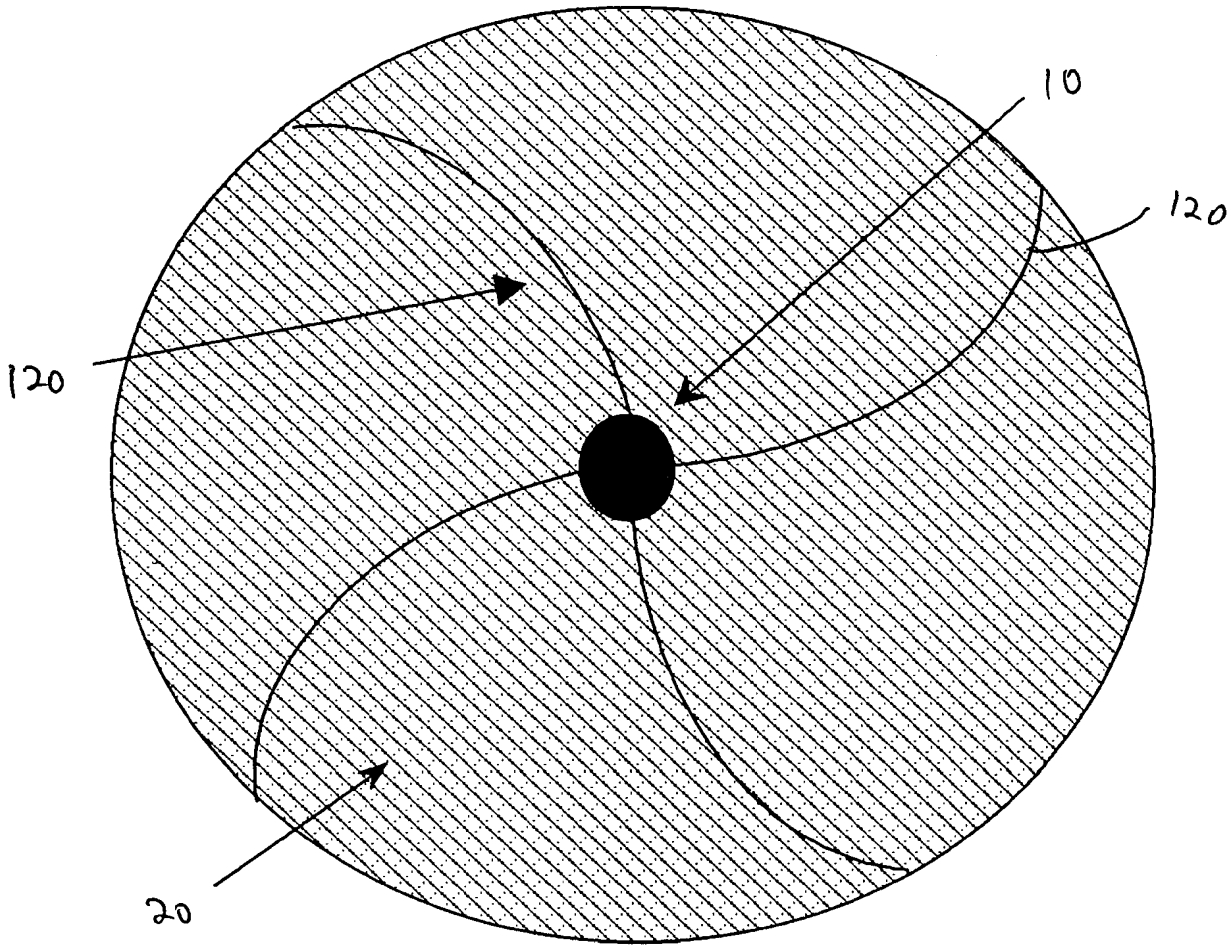


FIG. 9

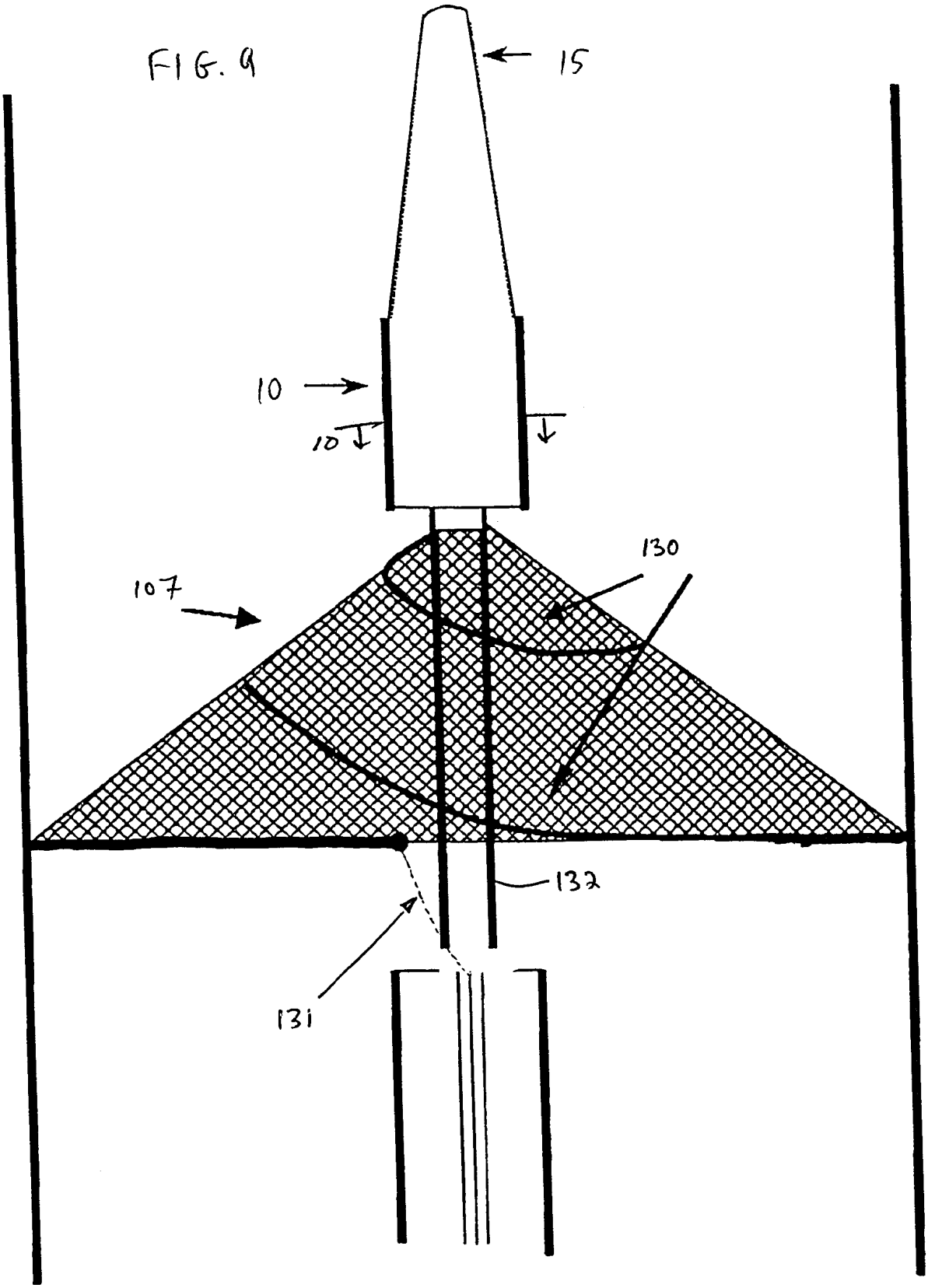
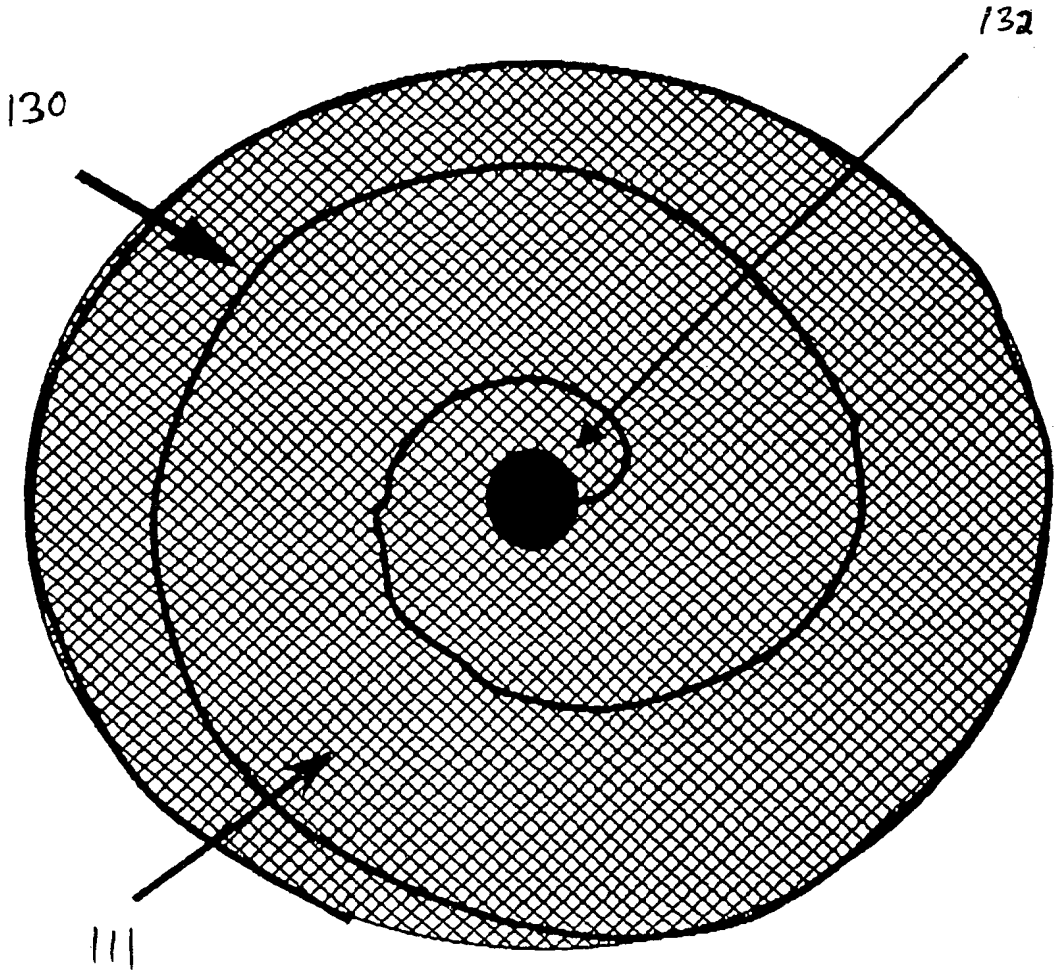


FIG. 10



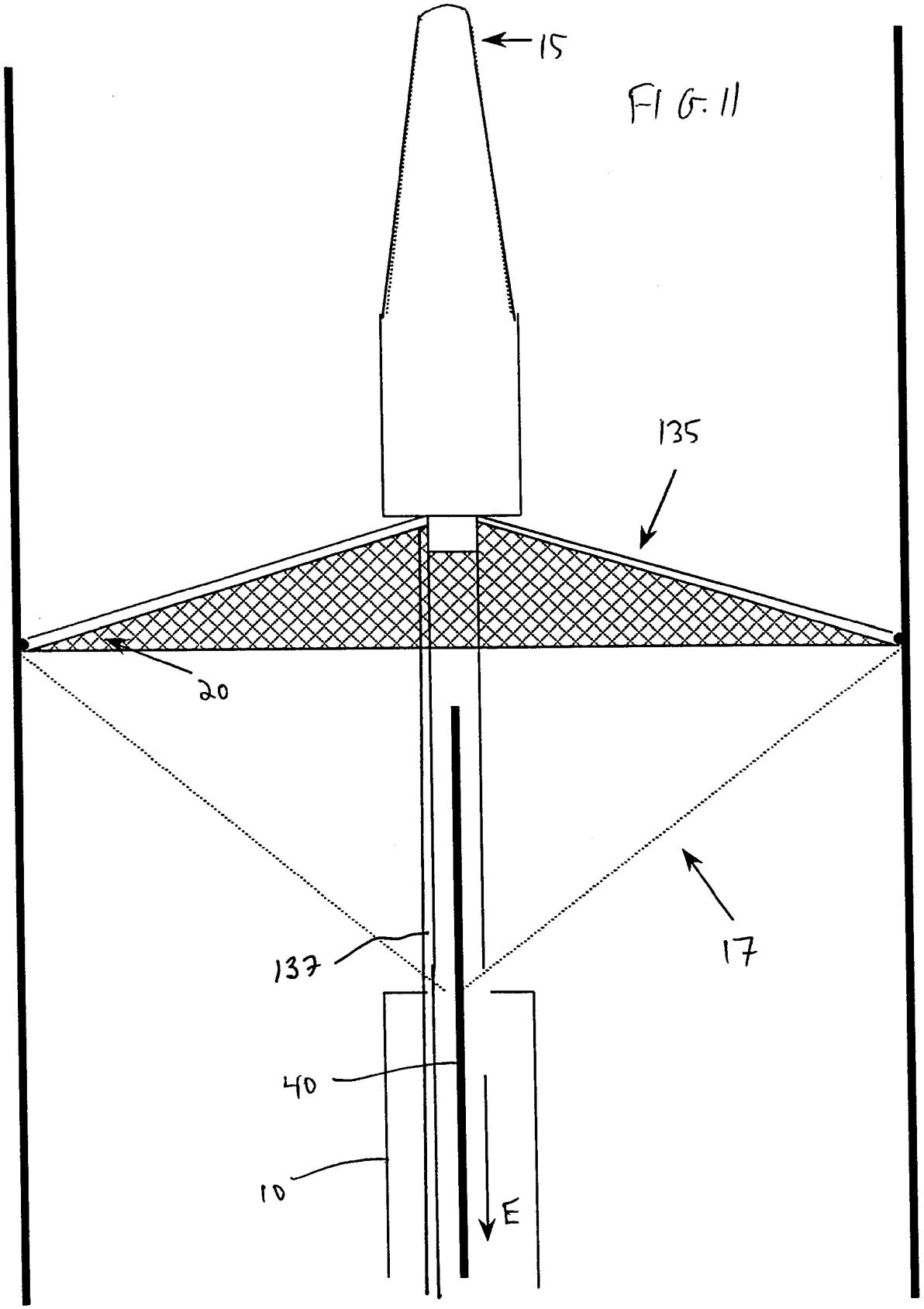


FIG. 11

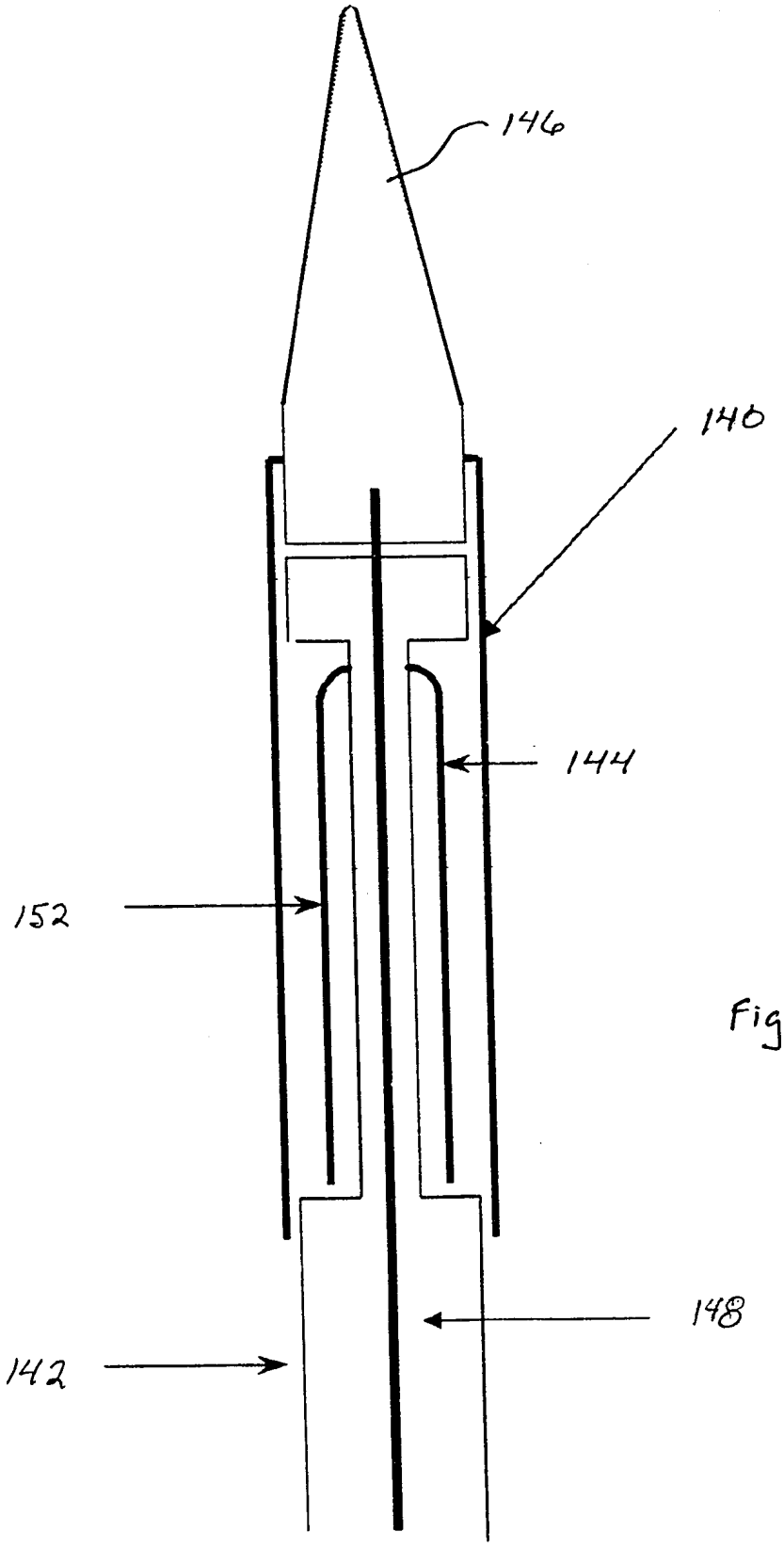


Fig. 12

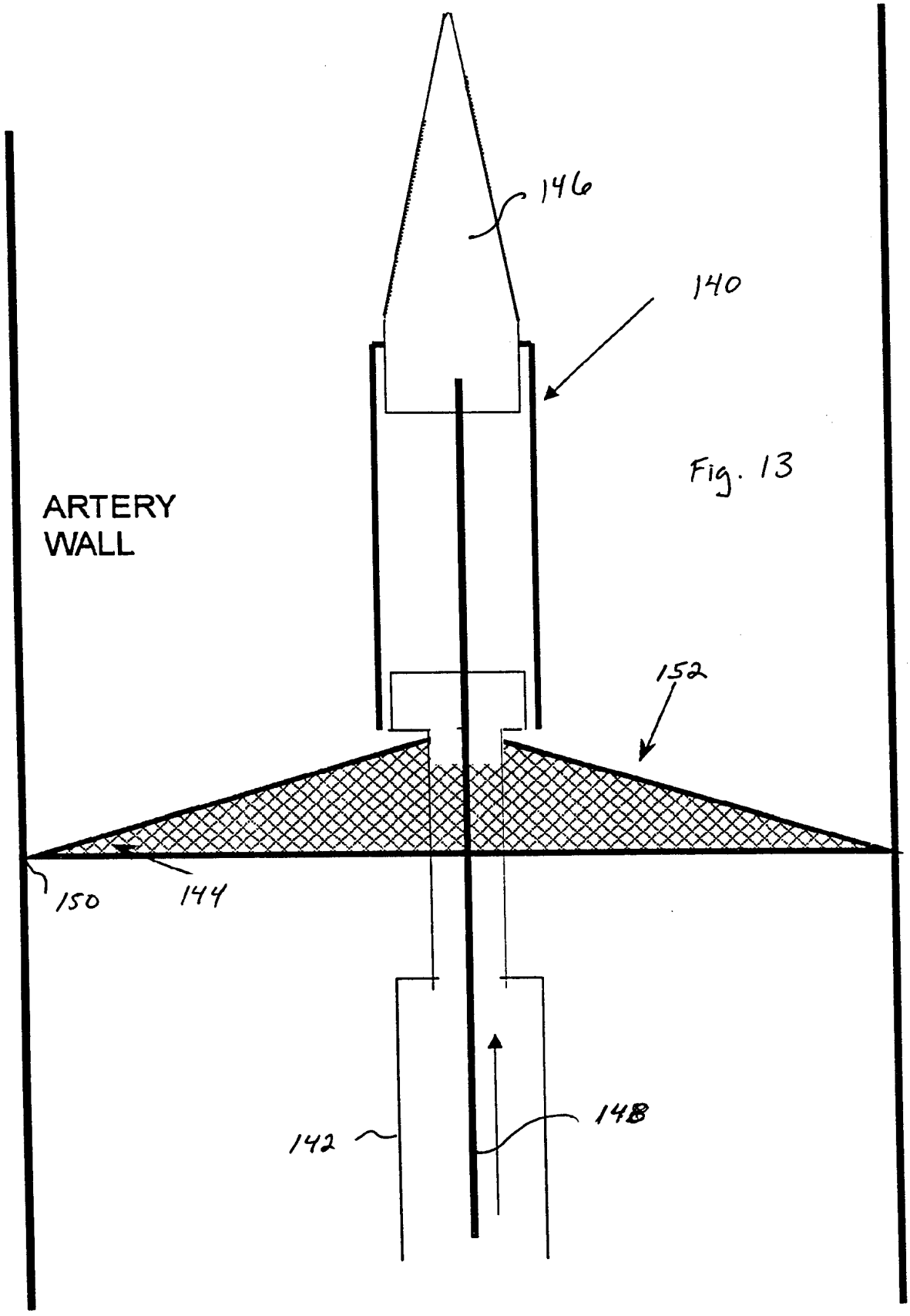


Fig. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01894

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/22
US CL :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)

U.S. : 606/200

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,723,549 A (WHOLEY et al) 09 February 1988, entire document.	1-3 --- 4-19
Y	US 5,053,008 A (BAJAJ) 01 October 1991, entire document.	4-19

☐ 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 21 APRIL 1998	Date of mailing of the international search report 07 MAY 1998
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 MICHAEL THALER Telephone No. (703) 308-2981

Form PCT/ISA/210 (second sheet)(July 1992)★

(19)中华人民共和国国家知识产权局

(12)发明专利

(10)授权公告号 CN 108348319 B
(45)授权公告日 2020.03.10

(21)申请号 201680056752.7

(22)申请日 2016.02.15

(65)同一申请的已公布的文献号
申请公布号 CN 108348319 A

(43)申请公布日 2018.07.31

(30)优先权数据
62/284,300 2015.09.28 US
62/284,752 2015.10.08 US
62/245,560 2015.10.23 US

(85)PCT国际申请进入国家阶段日
2018.03.28

(86)PCT国际申请的申请数据
PCT/US2016/017982 2016.02.15

(87)PCT国际申请的公布数据
WO2017/058280 EN 2017.04.06

(73)专利权人 斯瑞克公司
地址 美国加利福尼亚州

(72)发明人 E·斯科特·格林哈尔希
迈克尔·P·华莱士

(74)专利代理机构 北京康信知识产权代理有限责任公司 11240
代理人 陈鹏 刘凤迪

(51)Int.Cl.
A61F 2/01(2006.01)

审查员 付林峰

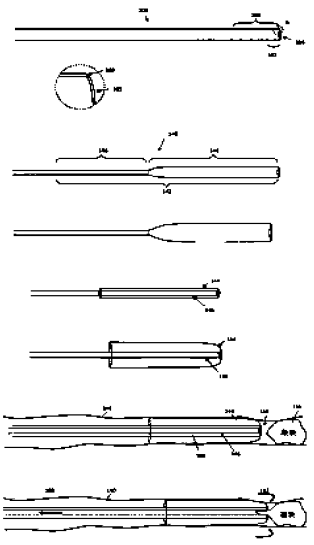
权利要求书2页 说明书31页 附图83页

(54)发明名称

机械取栓装置和方法

(57)摘要

用于从身体机械地去除物体的方法和装置。具体地,本文描述了用于从血管的腔内去除血凝块的取栓方法和机械取栓装置。



CN 108348319 B

1.一种用于从血管去除凝块而不导致堵塞的机械取栓装置,所述机械取栓装置包括:

导管,具有远侧端部、远侧端部开口和内径;

柔性管,延伸穿过所述导管并且在所述导管的所述远侧端部上翻折回来,其中,所述柔性管被配置成当在所述导管内向近侧拉动所述柔性管的第一端部时在所述远侧端部开口上翻转,所述柔性管具有低泊松比,使得所述柔性管当被用足够的力在所述导管内向近侧拉动时的直径大于所述导管的所述内径的一半,以在所述远侧端部开口上翻转;以及

穿过所述导管和所述柔性管的导丝腔,被配置成使导丝通过。

2.根据权利要求1所述的机械取栓装置,其中,所述柔性管包括针织管。

3.根据权利要求1所述的机械取栓装置,其中,所述柔性管的在所述导管的所述远侧端部上翻折回来的区域形成唇缘,所述唇缘相对于所述导管的长轴线的滚动角度为5度到60度之间。

4.根据权利要求1所述的机械取栓装置,其中,延伸穿过所述导管并且在所述导管的所述远侧端部上翻折回来的所述柔性管使所述导管的远侧5cm的刚度增加小于没有被所述柔性管延伸穿过所述导管并在所述导管的所述远侧端部上翻折回来的所述导管的所述远侧5cm的所述刚度的15%。

5.根据权利要求1所述的机械取栓装置,其中,所述柔性管的长度大于5cm,并且所述柔性管被配置成使得能通过将小于1000克的力施加到所述柔性管的远侧端部而将所述柔性管收回到所述导管中。

6.根据权利要求1所述的机械取栓装置,其中,所述柔性管被能释放地保持并且被配置成当用大于0.01N的预定力阈值的力拉动所述柔性管时释放。

7.根据权利要求1所述的机械取栓装置,还包括在所述导管和所述柔性管上延伸的外导管。

8.根据权利要求1所述的机械取栓装置,还包括在所述导管内并耦接到所述柔性管的远侧端部的细长拉动器,其中,所述细长拉动器包括具有内腔的海波管,所述内腔与穿过所述柔性管的所述导丝腔连续。

9.根据权利要求1所述的机械取栓装置,还包括驱动手柄,所述驱动手柄耦接到所述导管的近侧端部区域,其中,所述驱动手柄包括控制器,所述控制器被配置成当被致动时协调在向远侧的推进所述导管的同时向近侧收回所述柔性管。

10.根据权利要求1所述的机械取栓装置,还包括围绕所述柔性管的远侧端部区域的保持环,所述保持环被配置成将所述柔性管保持抵靠在所述导管上。

11.根据权利要求1所述的机械取栓装置,其中,所述柔性管为3cm至50cm。

12.根据权利要求1所述的机械取栓装置,还包括将所述导丝腔耦接到真空的真空连接以通过所述导丝腔施加真空。

13.根据权利要求1所述的机械取栓装置,还包括外导管真空泵,所述外导管真空泵耦接到所述导管与所述柔性管之间的空间并且被配置成在所述导管的位于所述导管的内壁与所述柔性管之间的腔内施加真空。

14.根据权利要求1所述的机械取栓装置,还包括:拉动器,其中,所述柔性管的远侧端部耦接到所述拉动器的远侧端部;以及外导管,所述外导管布置在所述导管上且邻近于所述柔性管的近侧端部,所述装置还包括具有控制器的手柄,所述控制器被配置成协调推进

所述外导管以向远侧推动所述柔性管的所述近侧端部和向近侧拉动所述拉动器以将所述柔性管的所述近侧端部拉入所述导管。

15.根据权利要求1所述的机械取栓装置，其中，所述柔性管被配置成当在所述导管中轴向且向近侧拉动所述柔性管时径向压缩5％到20％。

机械取栓装置和方法

[0001] 相关申请的交叉引用

[0002] 本专利申请要求以下临时专利申请中的每一个的优先权，其中的每一个的全部内容通过引证结合于本文：2015年9月28日提交的美国临时专利申请第62/284,300号；2015年10月8日提交的美国临时专利申请第62/284,752号；以及2015年10月23日提交的美国临时专利申请第62/245,560号。

[0003] 通过引用结合

[0004] 本说明书中提到的所有公开和专利申请的全部内容都通过引用结合于本文，其程度如同每个单独的公开或专利申请被特定地和单独地指示通过引用结合。

技术领域

[0005] 本文所描述的装置和方法涉及从身体内机械去除物体。具体地，本文描述了机械取栓装置和方法。

背景技术

[0006] 通常希望尽可能以微创方式从身体中去除组织，以免损伤其他组织。例如，从脉管系统去除组织(例如，血凝块)可改善患者状况和生活质量。

[0007] 许多脉管系统问题源于流过血管的血液不足。造成血液流量不足或不规则的一个原因是血管内的阻塞，这被称为血凝块或血栓。出现血栓的原因很多，包括诸如手术的创伤之后或由于其他原因。例如，在美国超过120万的心脏病发作中很大一部分是由冠状动脉内形成的血凝块(血栓)引起的。

[0008] 当形成血栓时，它可以有效地阻止血液流过形成区域。如果血栓横过脉的内径延伸，则其可以切断通过动脉的血液流动。如果冠状动脉中的一个是100％形成血栓，则血液流动在该动脉中停止，导致携带红血球的氧气短缺，例如用于供应心脏壁的肌肉(心肌)。此类血栓形成对于防止血液损失是不必要的，但是可能由于动脉粥样硬化疾病对动脉壁的损伤而在动脉内被不期望地引发。因此，动脉粥样硬化的潜在疾病可能不会引起急性缺氧(缺血)，但可经由诱导血栓形成引发急性缺血。类似地，颈动脉中的一个的血栓形成可导致中风，这是因为颅内重要神经中枢的供氧不足。缺氧会降低或禁止肌肉活动，会引起胸痛(心绞痛)，并可导致心肌死亡，这在某种程度上会永久地使心脏失去活力。如果心肌细胞死亡很广泛，则心脏将不能泵送足够的血液以供应人体的生命维持需求。局部缺血的程度受许多因素影响，包括可以提供必要氧气的侧支血管和血流的存在。

[0009] 临床数据表明，去除凝块对于改善预后可能是有益的，甚至是必要的。例如，在外周脉管系统中，发明和程序可以减少80％的截肢需求。治疗这些动脉或静脉系统状况的任何方式的最终目标是快速、安全且经济有效地去除堵塞或恢复通畅。这可以通过血栓溶解、碎裂、血栓抽吸或这些方法的组合来实现。

[0010] 导管导向取栓术和溶栓治疗通常被认为创伤小，不太可能降低与常规手术技术相关的发病率和死亡率。近年来，将化学溶解剂直接给予冠状动脉已经显示出对具有血栓形

成冠状动脉的患者有益处。在此过程中，将导管立即置于堵塞物的前方，并将链激酶滴定位成在血栓的上游侧定向。链激酶是一种能够及时溶解纤维蛋白分子的酶。该程序可能需要几个小时，并不总是成功地打破血栓。此外，其可能导致下游血栓碎片(栓子)，这可能导致小直径分支的堵塞。美国专利第4,646,736号公开了一种取栓设备，其可以快速去除阻塞性血栓。然而，该装置的特征在于小的导管尖端尺寸，并因此不能对凝块施加显著的总力。而且，在旋转线材的“火线”中，未处于在血管壁上取得的良好位置的凝块不会被纤维切除。对于血流中游离的凝块尤其如此，这是因为在不存在诸如手指的限制的情况下，在这些凝块内旋转几乎是不可能的。

[0011] 该取栓设备的其它缺点包括当在旋转期间线材侧向移动时难以在所有旋转角度期间将凝块保持在线材上方的空间中，这对于扫动动脉腔有时是需要的。实际上，除了最小的动脉(即直径小于1.5mm)之外，几乎不可能用旋转线材扫出整个动脉腔。附加的严重的可能的缺点是凝块的碎片可能在下游成为栓塞。

[0012] 美国专利申请2015/0005781中描述了用于捕获栓子的另一种方法。该申请描述了具有从远侧端部延伸的篮状件的导管。可以向近侧拉动诸如杆或线缆的致动器以将篮状件收回到导管中。不幸的是，篮状件阻塞腔的内部，阻止与定位和/或支撑导丝同时使用，并且篮状件必须保持在导管的远侧端部中或在其附近。取决于被去除的材料(例如凝块)的硬度，篮状件的取回通常会使导管的远侧端部收缩，阻止其使用，并且篮状件可能难以拉入导管中，特别是当保持凝块时。这可能会导致使凝块偏向。最后，在插入血管中之前，篮状件必须被预加载到导管的远侧端部中，并且预加载可能既困难又耗时，并且可能在展开之前破坏设备。

[0013] 因此，确实需要一种可以更有效地从身体内去除诸如凝块的组织的取栓设备，特别是机械取栓设备。本文所描述的是可以解决上面论述的需要和问题的装置(设备、系统和套件)以及使用它们的方法。

发明内容

[0014] 通常，本文描述了医疗装置，包括医疗设备和包括这些医疗设备的系统，以及操作这些医疗设备以用于收集对象的方法，所述对象包括但不限于血凝块(血栓)、组织(活组织检查、小肿瘤、息肉、钙化物、肾结石等)。本文所描述的装置通常包括细长导管，其具有腔和远侧端部并具有通向腔中的远侧端部开口。导管可以是具有任何适当直径(例如<1Fr、1Fr至6Fr、1Fr至9Fr等)的低轮廓神经脉管导管(例如微导管、插入导管等)。柔性牵引器组件或部分(例如，在本文中可被称为柔性牵引器管或简单地为柔性管)通常定位在导管内并且可在导管内纵向滑动，并且布置成使得远侧端部区域(“远侧牵引器区域”)在导管的远侧端部上翻折回来。柔性管(“牵引器管”)通常是细长和中空的，并且被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上滑动和翻转。形成远侧牵引器区域的远侧端部可以是管状的或不是管状的(例如，它可以由材料条等形成)。组合式导管和柔性牵引器组件还形成穿过导管和柔性管的导丝腔，该导丝腔被配置成使导丝穿过。

[0015] 在使用中，导丝可以被配置成滑动穿过该装置(并且可以形成装置的一部分)以允许定位并且在一些变型中支撑，通常在不干扰牵引器管的操作的情况下将诸如血凝块的物体拉入导管的主体。

[0016] 除了具有布置在导管内并且在导管的远侧端部上翻转或翻折的柔性牵引器管的导管之外，本文所描述的装置还可以包括一个或多个特征或元件，其允许这些设备在脉管系统内操作而不收缩，特别是在其远侧端部处，尽管在优选地相当柔软的远侧端部的远侧边缘/开口上施加拉力矩。进一步地，这些装置可以适用于最小化将远侧牵引器区域取回到导管中并在导管的远侧端部开口上翻转而不损坏或减弱远侧牵引器区域所需的力，从而防止装置内的柔性牵引器管在其本身上或与导管一起破裂、束缚、堵塞或缠结。例如，如下面将更详细描述的，这些装置中的任一个可以包括在导管的远侧端部处或附近的选择性润滑区域。导管端部可以被成形为允许管的远侧端部的柔性牵引器区域的翻转。另外，导管的端部轮廓(例如，最远侧5mm、4mm、3mm、2mm、1mm等)可以具有防止导管的收缩/屈曲的刚度(例如硬度)的布置。可替代地或附加地，柔性牵引器管可以适于在导管周围“扫动”血管的尽可能大部分以从血管内收集物体，同时仍然允许相对较低的力收回到导管中并且在导管的远侧端部上翻转。柔性管的牵引器部分(可指代管的在导管内的远侧部分)通常可包括邻近于第二可较少扩张(或不可扩张)的端部区域的远侧可扩张(第一)端区，其要么紧邻要么由间隔区域分开。第二端部区域靠近于第一端部区域(当第一端部区域和第二端部区域两者都被拉入导管时)。柔性牵引器管可以一直延伸穿过导管到达近侧端部和/或近侧手柄，或者其可以在导管的近侧端部之前终止并且连接到拉动器。拉动器可以是另一个可能较少柔性管，或者线材、杆、绳等。柔性牵引器管通常被配置成具有穿过其的腔(例如，中心腔或径向偏移的腔)，导丝可以穿过该腔通过，穿过包括导管和柔性牵引器管的装置。当导丝位于该腔内时，通常可以操作柔性牵引器管(例如，向近侧拉动并且在一些变型中向远侧推动)。

[0017] 装置可预先加载以用于远侧牵引器区域的展开以及物体在脉管内的捕获，或者在一些变型中，装置可以在将导丝和/或导管定位在血管内之后或期间在体内加载。例如，在一些变型中，通过保持远侧牵引器区域收回到导管中直到导管位于脉管内，并且优选地在待去除的物体附近，该装置可以适于体内使用。一旦定位，柔性管的在导管内的远侧牵引器区域可以从导管向远侧延伸，扩张以形成捕获形状，其可以在向远侧推进导管或不向远侧推进导管的情况下被拉入并且在导管的远侧端部上翻转。因此，远侧牵引器部分可以被安全且可靠地输送至腔内的必要部位，而没有损坏装置或身体的风险。

[0018] 例如，执行机械取栓以从血管去除凝块的方法可以包括：将导管的远侧端部朝向凝块推进通过血管；将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露，其中，远侧牵引器区域包括可扩张的第一端部区域以及靠近于可扩张的第一端部区域的可较少扩张的第二端部区域；允许可扩张的第一端部区域在血管内扩张；将导管的远侧端部定位成使得导管的远侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张的第一端部区域之间，同时可扩张的第一端部区域在可较少扩张的第二端部区域上翻折；以及通过将可扩张的第一端部区域在导管的远侧端部上滚动使得可扩张的第一端部区域在可扩张的第一端部区域被拉动到导管中时翻转，将凝块拉入导管。

[0019] 如上所述，将导管的远侧端部朝向凝块推进通过血管的步骤可以包括在导丝上推进。导管可以在导丝上向远侧滑动或者与导丝一起向远侧延伸(或向近侧收回)。内(牵引器)管可以被保持在导管内(例如，在远侧端部附近、中间区域或者在近侧端部附近)，或者在一些变型中，可以在将导管定位在脉管内之后插入。导管的远侧端部可以定位在待去除的物体(例如，凝块)处、附近或邻近，或者它可以分开预定的距离，例如以允许通过将远侧

牵引器区域延伸出导管的远侧端部之外并且扩张以准备将物体取回到导管中来设定用于装置的空间。

[0020] 因此，一旦定位，就可以通过暴露远侧牵引器区域并且定位导管的远侧端部以及在一些变型中的导丝来展开该装置，以允许物体被捕获并被拉入导管。通过向近侧拉动导管，同时保持包括远侧牵引器区域的柔性管静止(例如相对于血管)和/或通过向远侧延伸柔性管，可以暴露远侧牵引器区域。

[0021] 如上所述，柔性管可以包括远侧牵引器区域，该远侧牵引器区域包括可扩张的第一端部区域。该端部区域通常是多孔的(例如，由网状物、针织物、机织物或其他材料形成，包括具有穿设有多个开口的固体材料)并且适于抓取待去除的物体(例如血块)。该第一端部区域通常可扩张至导管的内径的约1.3倍至约10倍之间(例如，在约1.5倍至约7倍之间、约1.5倍至约5倍之间、约1.5倍至约4倍之间、约1.5倍至约3倍等)。形成牵引器部分的该第一远侧端部区域通常邻近于可较少扩张(或基本上不可扩张的)的第二端部区域。第二区域可以使导管向近侧一直向下延伸，或者使导管部分向下延伸。通常，牵引器部分的第一端部区域暴露于导管之外并用于捕获凝块或其他物体；第二端部区域可在定位期间暴露，但在操作期间可保持在导管内。

[0022] 因此，将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域延伸或推出导管的远侧端部之外。在一些变型中，远侧牵引器区域被预先形成为使得第一可扩张的远侧端部区域在第二远侧端部区域上翻折；在其他变型中，第一远侧端部区域与可较少扩张的第二远侧端部区域在同一直线上且远离。然后可以向远侧移动导管，使得导管的远侧端部区域(包括远侧端部)在远侧牵引器区域的扩张的可扩张的第一端部区域与可较少扩张的第二端部区域之间的径向间隙中延伸。

[0023] 在远侧牵引器区域被推出导管的远侧端部之外的任何变型中，例如在该初始体内设置阶段期间，柔性管(特别是远侧牵引器区域)可以被配置成或以其他方式适于允许推出导管之外而不束缚。如果可扩张的第一端部区域特别地被捕获在导管的内壁上，则可能发生可扩张的管的导管内的束缚，从而阻止展开。在一些变型中，可扩张的第一端部区域被配置成具有细丝(例如镍钛诺、聚合物等)的网状管状构件，该网状管状构件在具有约24至144个股线，股线在直径上的厚度为0.0005英寸至0.005英寸，其中，网状管状构件在纵向轴线上延伸，进一步其中，网状管状构件的长度大于5cm，当围绕导管的远侧端部被拉动和翻转时，在纵向轴线的方向上的交叉股线之间形成35度的编织角度，并且当不受约束时在导管的外部扩张到大于导管的内径的1.5倍的直径。在该配置下，管状构件被发现是可推动的。

[0024] 在其他变型中，当可扩张的第一远侧端部区域被推出或延伸出导管的远侧端部之外时，其可以被配置(例如，预成形、形状设定等)成在导管的远侧端部上翻转并扩张。导管可以向远侧移动，帮助将远侧牵引器区域的该可扩张的第一端部区域相对于导管的外侧向近侧推动。

[0025] 在这些方法中的任一种中，远侧牵引器区域可以包括可扩张的第一端部区域以及靠近于可扩张的第一端部区域的可较少扩张的第二端部区域，并且可扩张的第一端部区域被允许在血管内扩张。

[0026] 因此，在展开阶段即将结束之际，导管的远侧端部通常被定位成使得导管的远侧端部区域径向地位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张的第一端部

区域之间，同时可扩张的第一端部区域在可较少扩张的第二端部区域上翻折。

[0027] 此后，可以通过将可扩张的第一端部区域在导管的远侧端部上滚动来将物体(例如凝块)拉入导管，使得当可扩张的第一端部区域被拉东东啊导管中时，可扩张的第一端部区域翻转。

[0028] 如上所述，定位可以包括向远侧推进导管的远侧端部，使得导管的远侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张的第一端部区域之间。

[0029] 导丝可以与本文所描述的任何方法一起使用。对于本文所描述的任何方法而言，可以包括将血管内的导丝推进至凝块，其中，推进导管的远侧端部包括在导丝上推进导管通过血管，直到导管的远侧端部靠近于凝块。导丝可以插入或穿过凝块，或者其可以刚好位于凝块之前。导丝可以在凝块去除期间被留下，或者其首先可以部分或完全取回。例如，这些方法中的任一种可以包括将血管内的导丝推进至凝块，其中，推进导管的远侧端部包括在导丝上推进导管穿过血管，直到导管的远侧端部靠近于凝块。进一步其中，将凝块拉入导管包括在将可扩张的第一端部区域在导管的远侧端部上滚动的同时在导丝上朝向凝块推进导管。

[0030] 将凝块拉入导管通常包括将远侧牵引器区域(例如，可扩张的第一端部区域)在导管的远侧端部上滚动。该装置也可以在远侧牵引器区域的致动期间向远侧移动。例如，将血块拉入导管可以包括向近侧取回管(以将远侧牵引器区域在远侧端部上滚动)和/或在向远侧推进导管的同时向近侧取回管。

[0031] 在这些方法中的任一种中，将凝块拉入导管可包括在向远侧推进导管的同时向近侧取回管，其中，以与推进导管不同的速率取回该管。在一些配置中，比向近侧拉管(远侧牵引器区域)更迅速地向远侧推进导管可能是有益的。在一些变型中，可以比向近侧取回管(远侧牵引器区域)更慢地推进导管。可替代地在一些变型中，它们以相同的速率移动。通过观察导管内的近侧运动(例如，第二端部区域的近侧运动)可以确定柔性管的运动速率。

[0032] 通常，远侧牵引器区域的可扩张的第一端部区域是可扩张的并且可以形成可以与诸如凝块的物体接合的面向远侧的嘴部或唇缘。可扩张的牵引器区域的唇缘的嘴部可相对于导管外径(OD)的长轴线形成5度至60度、并且优选地至少为10度(例如10°至60°、10°至50°、10°至45°等)范围内的切向角度或滚动角度(如下面参考图18和图21D更详细描述的)。只要滚动角度至少为10度并且管收回到导管中，则管应该不会束缚或阻塞导管尖端。网状管可以通过改变刚度以确保滚动角度大于10度而构造。可替代地或与保持最小滚动角度组合，可能期望在导管的最远侧尖端处保持导管材料ID和导管的O.D之间的物理空间或间隙(如下面在图18中更详细描述的)。该间隙可能需要大于例如0.1mm、0.2mm、0.3mm、0.4mm、0.5mm、0.7mm、0.8mm、0.9mm、1.0mm等，以确保当管被收回时管围绕导管的远侧端部滚动。扩张材料(例如网状材料、机织材料、编织材料、针织材料、穿孔材料等)可以允许其本身在血管内扩张。因此可扩张的第一区域可以是可自扩张的。远侧牵引器区域的可扩张的第一端部区域可以被预先偏置以扩张。在一些变型中，使用形状记忆材料(例如，形状记忆合金)。在一些变型中，偏置元件被包括在可扩张的第一端部区域中或与可扩张的第一端部区域成一体以扩张使得远侧牵引器区域。可扩张的第一端部区域可以扩张至接触血管的内膜。在一些变型中，装置可以被配置(例如，设定尺寸，包括确定可扩张的第一端部区域的尺寸)，使得远侧牵引器区域的最远侧端部与血管腔接触。因此，本文所描述的变型中的任一个可

以附加地或可替代地包括偏置元件，诸如圈、环、支架等以推动可扩张的远侧端部区域，使得其可以通过施加增加的径向力将其扩张开来而与脉管接触。在一些变型中，该开口偏置(圈、螺旋、环等)位于远侧牵引器区域的可扩张的第一端部区域的远侧端部处或附近。

[0033] 本文所描述的变型中的任一个可以包括可扩张的导管尖端。例如，在一些变型中，导管尖端的硬度可以足够柔软以当远侧牵引器区域被向近侧拉入导管时向近侧压缩；轴向压缩远侧端部尖端可使其在远侧端部处略微扩张(例如，使得其可扩张)。

[0034] 如上所述，将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外。可替代地或附加地，将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外可以包括向近侧拉动导管。例如，将管的导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外以暴露已经在可较少扩张的第二端部区域上翻转的可扩张的第一端部区域。

[0035] 在一些变型中，将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露包括将可扩张的第一端部区域延伸出导管的远侧端部之外，使得当可扩张的第一端部区域延伸时，可扩张的第一端部区域在导管的远侧端部上翻转。

[0036] 远侧牵引器区域的可扩张的第一端部区域可以是任何适当的长度，并且该长度的任何部分(全部、90％、80％、70％、60％、50％、40％等)可能在该设定时段期间暴露。例如，在一些变型中，暴露管的远侧牵引器区域可以包括暴露至少5mm的可扩张的第一端部。可扩张的第一端部区域可以是例如5mm或更大(例如，在约5mm至500mm之间的6mm、7mm、8mm、9mm、10mm、11mm、12mm、13mm、14mm、15mm、16mm、17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm、300mm、400mm、500mm等，在约5mm、6mm、7mm、8mm、9mm、10mm、11mm、12mm、13mm、14mm、15mm、16mm、17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm的任何较小值与10mm、11mm、12mm、13mm、14mm、15mm、16mm、17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm、300mm、400mm、500mm的任何较大值之间，其中较小值总是小于较大值)。在这些变型中的任一个中，当暴露远侧牵引器区域时，仅可扩张的第一远侧端部区域可以暴露出导管之外(例如，当将可扩张的远侧端部区域向远侧推出并且允许其在导管的远侧端部上翻转)，或者可扩张的第一远侧端部区域和可较少扩张的第二远侧端部区域两者都可以全部或部分暴露。例如，暴露至少1cm的可扩张的第一端部区域和至少1cm的可较少扩张的第二端部区域。可扩张的第一端部区域可以在可较少扩张的第二端部区域上翻转(翻折回来)。

[0037] 如上所述，可扩张的第一端部区域可以包括既可扩张又能够抓取物体(例如凝块)的任何适当材料。例如，远侧牵引器区域的可扩张的第一端部区域可以包括邻近于可较少扩张的第二端部区域耦接的网状物。例如，可扩张的第一端部区域可以是以下中的一种或多种：机织材料、网状编织材料、针织材料或穿设有多个开口的膜材料。可较少扩张的第二端部区域可以由相同的材料制成，或者其可以由不同的材料制成。可较少扩张的第二端部区域可以具有相同的结构(例如机织等)或者其可以具有不同的结构，包括可扩张的第一端部区域的结构的可较少扩张变型。例如，可较少扩张的第二端部区域可以是非多孔的(例如非机织的、非针织的等，或固体材料)或较少多孔的(例如，紧密机织的小空隙针织孔、紧密

编织物)。在一些变型中,可较少扩张的第二端部区域可包括位于可扩张的第一端部区域(例如,具有中间可扩张性)与第二端部区域的不可扩张部分之间的过渡区域。通常,远侧牵引器区域的可较少扩张的第二端部包括不可扩张的结构和材料。

[0038] 执行机械取栓以从血管去除凝块的方法可以包括:将导管的远侧端部朝向凝块推进通过血管;将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露,其中,远侧牵引器区域包括可扩张的第一端部区域和靠近于可扩张的第一端部区域的可较少扩张的第二端部区域,并且被配置成使得可扩张的第一端部区域在可较少扩张的第二端部区域上翻转;允许可扩张的第一端部区域在血管内扩张,使得导管的远侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域与可扩张的第一端部区域之间;以及通过向远侧端部推进导管并在导管内向近侧取回导管使得可扩张的第一端部区域在导管的远侧端部上滚动并在可扩张的第一端部区域被拉动到导管中时翻转,将凝块拉入导管。

[0039] 如上所述,在暴露远侧牵引器区域之前,可扩张的第一端部区域可以在可较少扩张的第二端部区域上翻转。可替代地,暴露远侧牵引器区域可以包括当暴露远侧牵引器区域时使可扩张的远侧端部区域在可较少扩张的第二端部区域上翻转。通常,将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外。将管的位于导管内的远侧牵引器区域暴露在导管的远侧端部之外可包括向近侧牵拉动导管。

[0040] 执行机械取栓以从血管去除凝块的方法可包括:将导管的远侧端部朝向凝块推进通过血管;将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外,其中,远侧牵引器区域包括可扩张的第一端部区域和可较少扩张的第二端部区域,其中,暴露包括将可扩张的第一端部区域延伸导管的远侧端部之外,使得当可扩张的第一端部区域延伸时,可扩张的第一端部区域在导管的远侧端部上翻转;允许可扩张的第一端部区域当延伸出导管的远侧端部之外时在血管内扩张,使得导管的远侧端部区域位于可较少扩张的第二端部区域与可扩张的第一端部区域之间;以及通过在导管内向近侧取回管使得当可扩张的远侧端部区域被拉入导管中时可扩张的远侧端部区域在导管的远侧端部上滚动、收缩和翻转,将凝块拉动到导管中。将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外。可替代地或附加地,将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外可以包括相对于管的远侧牵引器区域向近侧取回导管。

[0041] 本文还描述了用于从血管去除凝块的机械取栓设备,该设备包括:导管,其具有远侧端部和远侧端部开口,其中导管具有内径和外径;管的位于导管内的远侧牵引器区域,其中,远侧牵引器区域包括可扩张的远侧端部区域以及靠近于可扩张的远侧端部区域的可较少扩张的远侧端部区域,远侧牵引器区域被配置成使得可扩张的远侧端部区域在可较少扩张的远侧端部区域上翻转;穿过导管和管的导丝腔,该导丝腔包括远侧牵引器区域,其中,导丝腔被配置成使导丝通过;以及近侧手柄,其耦接至管并且被配置成引起导管与管之间的相对运动,使得从导管的内径内释放远侧牵引器区域,使得可扩张的远侧端部区域可以扩张至大于外径的直径,使得可以在可扩张的远侧端部区域与可较少扩张的远侧端部区域之间推进导管,并且可以向近侧拉该管以在导管的远侧端部上拉动可扩张的远侧端部区域,使得可扩张的远侧端部区域滚动到导管的远侧端部中、翻转、收缩并被拉入导管。

[0042] 例如，用于从脉管去除凝块的机械取栓设备可以包括：导管，其具有远侧端部和远侧端部开口，其中，导管具有内径和外径；管，其具有位于导管内的远侧牵引器区域，其中，远侧牵引器区域包括可扩张的远侧端部区域和靠近于可扩张的远侧端部区域的可较少扩张的远侧端部区域，进一步其中，可扩张的远侧端部区域被偏置成当其从导管的远侧端部暴露时在可较少扩张的远侧端部区域上翻转；穿过导管和管的导丝腔，该导丝腔包括远侧牵引器区域，其中，导丝腔被配置成使导丝通过；以及近侧手柄，其耦接至管并且被配置成引起导管与管之间的相对运动，使得从导管的内径内释放远侧牵引器区域，使得可扩张的远侧端部区域可以扩张至大于外径的直径，并且可以向近侧拉该管以在导管的远侧端部上拉动可扩张的远侧端部区域，使得可扩张的远侧端部区域滚动到导管的远侧端部中、翻转、收缩并被拉入导管中。

[0043] 本文还概括描述了机械取栓装置。例如，本文描述了用于从脉管去除凝块的机械取栓装置，包括：导管，其具有远侧端部和远侧端部开口；柔性管，其在导管内延伸并且在导管的远侧端部上翻折回来，其中，柔性管被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上滑动并翻转；以及穿过导管和柔性管的导丝腔，被配置成使导丝通过。

[0044] 用于从脉管中去除凝块的机械血栓装置可包括：导管，其具有远侧端部和远侧端部开口，其中远侧开口的硬度大于紧邻远侧端部的区域的硬度，进一步其中远侧端部开口具有圆形唇缘轮廓；柔性管，其在导管内延伸并且在导管的远侧端部上翻折回来，其中柔性管被配置以当柔性管的第一端部在导管内向近侧被拉动时在远侧端部开口上翻转；以及导丝腔，其穿过导管以及被配置以通过导丝的柔性管。导管远侧端部硬度可以大于60A肖氏硬度或大于40D肖氏硬度。

[0045] 用于从脉管去除凝块的机械取栓装置，其包括：内导管，其具有远侧端部和远侧端部开口；柔性管，其延伸穿过导管并且在内导管的远侧端部上翻折回来，其中，柔性管被配置成当在内导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转；外导管，其在内导管和柔性管上延伸；柔性管的在外导管的远侧端部与内导管的远侧端部开口之间延伸的润滑区域，其中，大部分柔性管是未润滑的；以及穿过导管和柔性管的导丝腔，其被配置成使导丝通过。

[0046] 用于从脉管去除凝块的机械取栓装置可以包括：内导管，其具有远侧端部和远侧端部开口；柔性管，其延伸穿过导管并且在内导管的远侧端部上翻折回来，其中，柔性管被配置成当在内导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转；可释放附件，其位于柔性管和导管的外表面之间，被配置成当以预定力(例如，大于0.01N)拉动柔性管时释放；以及穿过导管和柔性管的导丝腔，其被配置成使导丝通过。

[0047] 用于从脉管去除凝块的机械取栓装置可包括：导管，其具有远侧端部、远侧端部开口和内径；柔性管，其延伸穿过导管并且在导管的远侧端部上翻折回来，其中，柔性管被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转，柔性管具有低泊松比，使得柔性管当被用足够的力在导管内向近侧拉动时的直径大于导管的内径的一半，以在远侧端部开口上翻转；以及穿过导管和柔性管的导丝腔，被配置成使导丝通过。具有低泊松比的柔性管可以小于0.5或者在0.05至0.5或0.1至0.3的范围内。

[0048] 如上清楚所述，柔性管通常包括远侧牵引器区域，远侧牵引器区域具有可扩张的

第一端部区域以及邻近于第一端部区域的可较少(或不可)扩张的第二端部区域。因此,柔性管可以包括网状管。

[0049] 通常,形成本文所描述的装置的一部分的导管是高度灵活的,如适用于所采取的侵害路径,例如,通过神经脉管导管。在一些变型中,组装装置(具有缠绕在远侧端部上并准备好操作的柔性管)的总体刚度在不具有柔性管的导管的原始刚度的预定百分比内(例如,在10%内、在12%内、在15%内、在16%内,在17%内、在18%内、在19%内、在20%内、在25%内、在30%内等)。例如,延伸穿过导管并且在导管的远侧端部上翻折回来的柔性管可以将导管的远侧5cm的刚度增加小于导管的远侧5cm的刚度的预定百分比(例如15%),而不使柔性管延伸穿过其中和在导管的远侧端部上翻折回来。

[0050] 在本文所描述的变型中的任一个中,柔性管的远侧牵引器区域适于抓取物体,例如凝块。特别地,柔性管可以是多孔的或者具有至少一个多孔区段,所述多孔区段具有孔隙图案,所述孔隙图案在宽度小于预定距离(例如,约0.005英寸)的孔隙之间具有纵向间隔。如在该示例中所使用的,"孔隙"包括网状物(机织物等)的股线之间的窗口、开口、间隙等以及穿过固体片形成的孔隙。通常,对于机织(并且特别是编织)的可扩张的第一端部区域材料,较小的细丝在抓取时可能更好,并且因此较小的孔隙尺寸可能是优选的。最佳尺寸可以取决于材料,包括细丝尺寸、孔隙百分比、孔隙间距的尺寸、孔径等。例如,在一些变型中,孔隙率大于>60%(大于70%、大于75%、大于80%、大于85%等,在60%至95%、65%至95%、70%至95%等之间)以及纤维直径(对于机织材料)为<0.005是有利的。确保凝块或异物被抓取所需的柔性管状构件的有效孔径可以在50微米至1000微米(μm)的范围内,或者在100μm至200μm、100μm至300μm、100μm至500μm或500μm至1000μm的范围内。柔性管状构件可沿其长度具有各种孔径。

[0051] 通常,如本文所用,机织材料包括通过以交织图案(例如,交织股线、细丝、材料长度等)编织多股材料而形成的任何材料。网状物是一种机织材料。取决于形成织物的材料的弹性,机织材料通常在某些方向上(在偏置方向上)更可伸展/可扩张。机织材料通常以平行或几乎平行的路径行进。针织材料可以更柔性并且通常指的是曲折的单个路径或路线,从而形成可以对称布置和互锁的环路。机织材料可以非常可拉伸/柔性的。针织结构区域可较少拉伸,但仍然非常柔性。

[0052] 在本文所描述的装置中的任一个中,并且特别是预加载或预成形的版本中,该装置可以包括位于柔性管与导管的外表面之间的可释放附件,其被配置成当用大于预定力阈值的力拉动柔性管时释放。例如,可释放力阈值可以大于约0.001N、大于约0.005N、大于约0.01N、大于约0.03N、大于约0.05N、大于约0.08N、大于约0.1N、大于约0.3N、大于约0.5N等)。

[0053] 在本文所描述的装置中的任一个中,柔性管可以包括多个柔性材料条,其中,条被布置成与柔性管的长轴平行。可替代地或附加地,在这些变型中的任一个中,远侧端部开口可以包括多个凹口或通道,当柔性管在远侧端部开口上翻转时,形成柔性管的纤维或条被拉入该凹口或通道。

[0054] 在本文所描述的装置中的任一个中,柔性管可以包括具有穿设有多个孔的聚合物管。例如,柔性管可以包括远侧端部、近侧端部以及在远侧端部与近侧端部之间的主体区域,其中,主体区域从较柔性的远侧端部过渡到较刚性的近侧端部。

[0055] 如上所述，在本文所描述的变型中的任一个中，导管的远侧端部(例如，远侧端部开口区域)可以适于防止当在导管开口上翻转时收缩但仍然足够柔软以为神经脉管应用提供合适的使用。例如，本文所述的装置中的任一个在远侧端部(例如，在远侧端部开口/边缘处)处的硬度可大于紧邻远侧端部的区域的硬度。这些远侧端部开口中的任一个都可以具有圆形唇缘轮廓。通常，尽管远侧端部区域的硬度可能降低(变得“较软”)，但是非常最远侧端部(开口)的硬度可能较高。这与圆形端部形状一起可以减小在将远侧牵引器区域(例如，可扩张的第一端部区域)拉入导管时使其翻转所需的力，同时防止导管的远侧端部区域收缩。

[0056] 本文所描述的装置中的任一个还可以包括适于相对于导管向近侧拉入柔性管的手柄。手柄可以附接到或可附接到导管和/或柔性管，并且可以包括用于独立地或者更优选地以协调的方式(或者在这两个模式之间切换)而致动的单独的控制器。例如，这些装置中的任一个可以包括耦接到导管的近侧端部区域的驱动手柄，其中，驱动手柄包括控制器，该控制器被配置成在被致动时协调在向近侧收回柔性管的同时向远侧推进导管。

[0057] 这些装置中的任一个还可以包括在导管和柔性管上延伸的外导管。外导管可以在导管和柔性管上延伸，并且可以保持远侧牵引器区域(导管外部)的外部部分收缩，直到其已经被输送。这些装置中的任一个都可以包括在外导管的远侧端部和远侧端部开口之间延伸的柔性管的润滑区域，其中，大部分柔性管是未润滑的。该润滑区域可以减小致动该装置所需的初始力。

[0058] 在本文所描述的装置中的任一个中，柔性管可被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上翻转，并且柔性管可具有低泊松比，使得柔性管(其可以是网状管)当被用足够的力在导管内向近侧拉动时的直径大于导管的内径的一半，以在远侧端部开口上翻转。

[0059] 这些装置中的任一个可以包括位于导管内的拉动器(例如细长拉动器)并且耦接到柔性管的远侧端部。拉动器通常被配置成向近侧拉入柔性管，但是在一些变型中它可以向远侧移动柔性管。例如，这些装置中的任一个还可包括位于导管内并耦接到柔性管的远侧端部的细长拉动器，其中，细长拉动器包括具有内腔的海波管，该内腔与穿过柔性管的导丝腔连续。

[0060] 如上所述，在一些变型中，柔性管包括可推动的柔软外部网状物。例如，远侧牵引器区域(并且特别是可扩张的第一端部区域)可以由24至144个股线形成，股线在直径上具有0.0020英寸或更小的厚度，其中，网状管状构件在纵向轴线上延伸，进一步其中，网状物管状构件的长度大于5cm，网状管状构件当围绕导管的远侧端部被拉动和翻转时在纵向轴线的方向上的交叉股线之间形成约35度或更小的编织角度，并且当不受约束时在导管的外部扩张到大于导管的内径的1.5倍的直径。

[0061] 当柔性管由股线(例如机织、编织等)形成时，股线可以由以下中的任一者形成：单丝聚合物、复丝聚合物、镍钛(NiTi)丝、具有不透射线金属中心的镍钛管、钴铬合金丝、具有不透射线金属中心的钴铬合金管、尼龙、聚酯、聚对苯二甲酸乙二醇酯和聚丙烯。

[0062] 如上所述，这些装置中的任一个都可以被配置成使得柔性管(例如可扩张的远侧端部区域)可释放地保持在导管上。例如，这些装置中的任一个可以包括围绕柔性管的远侧端部区域的保持环，该保持环被配置成将柔性管可释放地保持抵靠在导管上。

[0063] 在这些变型中的任一个中，柔性管的形状可以被设定成当在导管内被向近侧拉入导管之后时具有不同的直径。通常，柔性管可以包括多个机织丝或一个(或多个)针织丝。在一些变型中，整个(或大部分)柔性管由机织或针织细丝形成，并且柔性管的近侧端部可形成与形成拉线的细丝或细丝束相反的渐缩开口。可替代地或附加地，柔性管可以由具有小于0.020英寸的厚度的聚合物套筒形成，其中，套筒包括穿孔图案，其中，穿孔延伸穿过聚合物。穿孔图案可以包括具有由以下一个或多个构成的形状的穿孔：圆形孔、矩形孔和锯齿形状。

[0064] 这些装置中的任一个可以包括耦接到柔性管的近侧端部的一侧的拉线，该拉线被配置成被向近侧拉以将柔性管拉动到导管内。

[0065] 通常，柔性管可以是任何适当的长度。例如，柔性管可以在3cm至200cm之间(例如，3cm至150cm、3cm至100cm、3cm至50cm等)。

[0066] 在本文所描述的装置中的任一个中，装置的柔性管可被配置成使得可通过向柔性管的远侧端部施加小于预定量的力(例如500克的力、450克的力、400克的力、350克的力、300克的力、250克的力、200克的力、150克的力等)将柔性管收回到导管中。

[0067] 在这些变型中的任一个中，柔性管可以包括位于柔性管的第一端部与第二端部之间的渐缩部。在一些变型中，柔性管可以在导管的整个长度内延伸，使得柔性管的近侧端部被配置成远离导管的近侧端部向近侧被拉动以使柔性管在远侧端部开口上滑动并翻转。

[0068] 本文所描述的装置中的任一个还可以包括真空源。例如，这些装置中的任一个可以包括导丝真空泵，该导丝真空泵耦接到导丝腔的近侧端部并且被配置成通过其施加真空。例如，这些装置中的任一个可以包括外导管真空泵，该外导管真空泵耦接到导管与柔性管之间的空间并且被配置成在导管的位于导管的内壁与柔性管之间的腔内施加真空。

[0069] 如上所述，该装置可以包括拉动器，其中，柔性管的远侧端部耦接到拉动器的远侧端部。外导管可以布置在导管上且邻近于柔性管的近侧端部。这些装置中的任一个还可以包括具有控制器的手柄，该控制器被配置成协调推进外导管以向远侧推动柔性管的近侧端部和向近侧拉动拉动器以将柔性管的近侧端部拉入导管。例如，如本文所描述的装置可以包括：拉动器，其中，柔性管的远侧端部耦接到拉动器的远侧端部；外导管，其可滑动地布置在偶接到柔性管的近侧端部的导管上；以及手柄，其具有控制器，该控制器被配置成协调在向近侧拉动拉动器以将柔性管的近侧端部拉入导管的同时向远侧推进外导管以向远侧推动柔性管的近侧端部，或者在向远侧推动拉动器以将柔性管的近侧端部推出导管之外的同时向近侧拉动外导管以向近侧拉动柔性管的近侧端部。

[0070] 本文还描述了机械地去除取栓的方法，包括：将导丝至少推进到血管中的凝块的近侧端部；在导丝上向远侧推进取栓(例如凝块去除)装置，其中，取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管，使得导丝穿过导管的腔以及柔性管；从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中，使得柔性管在远侧端部开口上滑动并翻转；以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0071] 机械地去除取栓的方法可以包括：推进导丝邻近血管中的凝块；在导丝上向远侧推进取栓装置，其中，取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管，使得导丝穿过导管的腔以及柔性管；从离开导

管的外径向近侧拉动柔性管并在导管的远侧端部开口的圆形唇缘上将柔性管拉动到导管腔中，使得柔性管在远侧端部开口上滑动并翻转，其中，远侧端部开口的硬度大于紧邻远侧端部的区域的硬度；以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0072] 机械地去除取栓术的方法可以包括：推进导丝邻近血管中的凝块；在导丝上向远侧推进取栓装置，其中，取栓装置包括具有远侧端部和远侧端部开口的内导管、沿着内导管的外径且在导管的远侧端部上延伸的柔性管，以及将柔性管的远侧端部区域固定抵靠在内导管的外径上的外导管，使得导丝穿过导管的腔和柔性管；从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中，使得柔性管的润滑近侧引导区域在远侧端开口上滑动并翻转，直到柔性管的未润滑远侧区域被拉入内导管；以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0073] 机械地去除取栓术的方法可以包括：推进导丝邻近血管中的凝块；在导丝上向远侧推进取栓装置，其中，取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管，使得导丝穿过导管的腔和柔性管；从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中，使得柔性管在远侧端部开口上滑动并翻转；将柔性管向远侧拉出或推出导管的远侧端部，使得柔性管在远侧端开口上滑动并翻转；以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0074] 在本文所描述的方法中的任一个中，导丝可以至少部分地定位在血管中的凝块内。

附图说明

[0075] 在所附权利要求中特别阐述了本发明的新颖特征。通过参考以下详细描述来获得对本发明的特征和优点的更好理解，所述详细描述阐述了利用本发明原理的说明性实施例以及附图，附图中：

[0076] 图1A至图1H示出了用于机械地去除诸如形成身体区域的凝块的物体的装置的一个变型。图1A示出了该装置的导管部分；图1B示出了导管的远侧端部(开口)的放大视图；图1C示出了柔性管(牵引器管)的远侧牵引器区域的示例，其示出了处于收缩(未扩张)配置的柔性管的可扩张的第一端部区域，而图1D示出了具有可扩张的第一端部区域的相同的远侧牵引器区域。图1E示出了组装的机械取栓装置，其中柔性管延伸穿过导管并且在导管的远侧端部上翻折回来，使得柔性管的可扩张的第一端部区域(形成远侧牵引器区域的一部分)至少部分地位于导管外侧并处于非扩张状态。图1F示出了图1E的装置，其中可扩张的第一端部区域扩张。图1G和图1H示出了图1E和图1F的装置的使用以通过向近侧拉柔性管和/或向远侧朝向凝块推进导管而去除凝块，使得可扩张的第一端部区域当其被拉入导管的远侧端部中时翻转，将凝块拉动到导管中。

[0077] 图2A至图2D示出了可以是本文所描述的装置的一部分的柔性管(牵引器管)的变型。图2A示出了包括远侧牵引器区域的柔性管的远侧端部，远侧牵引器区域在远侧端部处包括可扩张的第一端部区域，其邻近于可较少扩张的第二端部区域。在图2B中，可扩张的第一端部区域由多个机织纤维形成。在图2C中，可扩张的第一端部区域由整个具有多个小孔的材料片形成。在图2D中，可扩张的第一端部区域在可较少扩张的第二端部区域上翻折(doubled over，对折)。

[0078] 图3A至图3F示出了机械取栓装置的一个示例的体内展开和操作。在该示例中，在将导管定位在凝块附近之后，远侧牵引器区域被推动穿过导管，直到远侧牵引器区域从凝块的远侧端部暴露(图3A至图3D)，使得可扩张的第一端部区域扩张至血管的内膜；然后在可扩张的第一端部区域与可较少扩张的第二端部区域之间推进导管(图3D至图3E)，并且可扩张的第一端部区域被拉入导管中，使得其翻转并将凝块拉入导管中(图3E至图3F)。

[0079] 图4A至图4F示出了机械取栓装置的另一个示例的体内展开和操作。在该示例中，柔性(牵引器)管的可扩张的第一端部区域在通过将可扩张的第一端部区域延伸出导管的远侧端部而定位导管部分(图4A至图4B)之后被展开，使得可扩张的第一端部区域在导管的远侧端部区域上翻折回来(图4C至图4D)。一旦暴露和展开，可扩张的第一端部区域可以在向远侧推进导管或不向远侧推进导管的情况下被拉回到导管中以将凝块拉动到导管中(图4F)。

[0080] 图5A至图5E示出了机械取栓装置的另一个示例的体内展开和操作，其中可扩张的第一端部区域在定位在凝块附近的血管内之后向远侧延伸出导管的端部(图5A至图5C)。一旦可扩张的第一端部区域已经延伸并允许在脉管内扩张，则可以向远侧推进导管和导管内的柔性管的其余部分(图5D)，使得可扩张的第一端部区域在远侧端部上翻折，如图所示。此后，在向远侧推进导管或不向远侧推进导管的情况下，可扩张的第一端部区域可以被拉回到导管中，以将凝块拉动到导管中(图5E)。

[0081] 图6A和图6B示出了一种机械取栓装置，其包括导管以及延伸穿过导管并在导管的远侧端部(形成远侧牵引器区域)上翻折回来的柔性管(牵引器管)，以及在远侧牵引器区域上的外导管或释放保护器导管。图6A示出了定位在凝块附近的装置；图6B示出了与导丝一起使用的装置，该导丝穿过装置的导丝腔以用于定位和操作该装置。

[0082] 图7A至图7D示出了如图6A至图6B所示的取栓装置的操作，其示出了邻近凝块定位远侧端部/远侧牵引器区域(图7A)，然后将凝块拉动到导管中(图7B至图7C)并且最终去除凝块和柔性牵引器管(图7D)。

[0083] 图8示出了包括可选真空源的取栓装置。

[0084] 图9A至图9D示出了本文所描述的取栓装置与导丝结合的操作。导丝可以完全或部分地经过凝块，并且该装置可以在导丝上被致动，从而提供增强的稳定性和功效。

[0085] 图10A示出了用于致动诸如本文所描述的取栓装置的装置的手柄(近侧)手柄的一个变型。手柄可以被耦接并且可以单独地或以协调的方式致动导管和柔性(牵引器)管(包括远端侧牵引器区域)的运动。

[0086] 图10B示出了用于如本文所描述的装置的近侧手柄的另一示例，其包括用于控制(单独或一起)导管和/或内柔性牵引器管的致动的控制器。

[0087] 图11A示出了用于包括如本文所描述的取栓装置的装置的近侧手柄的另一示例。

[0088] 图11B是示出用于如本文所描述的装置的手柄的操作的机械示意图。

[0089] 图12A和图12B示出了变型，其中装置的柔性牵引器管的可扩张的第一端部区域可释放地固定到导管的外表面；在装置的致动使得远侧牵引器区域可以被拉入导管的远侧端部中之前，可以分离可释放附件。在图12A中，外管(例如，远侧牵引器区域上的外导管或释放保护器导管)至少覆盖可扩张的远侧端部区域的端部。在图12B中，远侧牵引器区域的可扩张的第一端部区域可包括可释放地将可扩张的第一端部区域固定到导管的外径的带、粘

合剂、焊接件(例如,脆的粘合剂或其他附件)、卡扣配合件、抓持件等。

[0090] 图13A和图13B示出了本文所描述的装置的柔性(例如牵引器)管的近侧端部区域(牵引器区域)的示例。图13A示出了其中牵引器管的近侧端部形成与管的腔径向偏离的拉线的示例;如图所示,导丝仍然可以经过管(和导管)的腔以用于该装置的操作。图13B示出了其中拉线(或杆、构件等)由与柔性牵引器管的其余部分不同的材料形成的示例。

[0091] 图14示出了远侧牵引器区域,其包括远侧牵引器区域的可扩张的第一端部区域的近侧端部区域附近的有限润滑区域;可扩张的第一端部区域的其他部分可能不是润滑的,远侧牵引器区域的其余部分也可能不是润滑的。

[0092] 图15A至图15D示出了具有成形的可扩张的第一端部区域的柔性(牵引器)管。特别地,这些不同的可扩张的第一端部区域可以被预先设定为不同的直径,这可以帮助拉入和/或破坏导管内的凝块。图15A示出了第一示例,其中可扩张的第一端部区域通过多个拉线耦接到拉动器部分。在这些示例中,可扩张的第一端部区域被示出未在柔性管状构件(牵引器管)的较近侧部分上翻转。图15B示出了由不可径向扩张的多个拉线连接的多个可扩张的端部区域。图15C示出了具有多个预先设定直径的可扩张的第一端部区域。图15D示出了通过形成可扩张的第一端部区域的两束或多束细丝耦接到牵引器管的较近侧拉动器部分的可扩张的第一端部区域。

[0093] 图16示出了可扩张的第一端部区域的另一示例,其包括到导管的外径的多个可释放附件;这些可释放附件(其可以是脆的、弹性的等)可以通过施加足够的力而被释放,以允许将远侧牵引器区域拉动到导管中以用于致动该装置。

[0094] 图17示出了其中可扩张的第一端部区域在导管的远侧端部区域的外径上被加载(例如弹簧加载,压缩等)并且被可释放地锁定或以其他方式(例如,通过可靠的附件)保持在位(in place,在适当位置)的示例;该可释放附件可以防止装置在致动之前的展开,并且可扩张的第一端部区域的加载可以使得远侧牵引器区域更容易在导管的远侧端部上翻转以将凝块拉入装置中。

[0095] 图18A至图18C示出了具有不同刚度的可扩张的第一端部区域的示例。

[0096] 图19A和图18B示出了用于组装如本文所述的装置的组装方法。

[0097] 图20A和图20B示出了可用作本文所描述的装置的远侧牵引器区域的一部分的可扩张的第一端部区域的示例性轮廓。

[0098] 图21A至图21D示出了用于去除凝块的装置的示例。图21A示出了在耦接到导管之前的可扩张的第一端部区域的示例。图21B示出了通过拉动柔性(牵引器)管的近侧端部而将血管(玻璃管)内的可扩张的第一端区域拉入导管中。图21C示出了装置的远侧端部区域,其包括在导管的远侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉入导管中的图21C的装置。

[0099] 图22示出了图21D的可扩张的第一端部区域,其在将其向近侧拉出导管之后具有所捕获的凝块。

[0100] 图23A至图23D示出了如本文所描述的机械取栓装置,其捕获血凝块并将其拉入装置中。

[0101] 图23E示出了柔性牵引器管已经从导管去除(例如近侧)之后保持在柔性牵引器管内的凝块。

[0102] 图24是包括柔性牵引器构件的装置的另一个示例，其中，远侧牵引器区域由多个细丝形成，多个细丝布置成未机织或编织材料的条(纵向平行)。这些条(strip)可以是细丝或管等。

[0103] 图25A至图25F示出了柔性牵引器组件的远侧牵引器区域的另一变型，其中，可扩张的第一端部区域(例如，远侧牵引器区域的远侧端部区域)由多个细丝或条形成，类似于在图24中所示的；导管的远侧端部包括通道，如图25A至图24B所示；这些条可以装配在这些通道内，如25C至图25D所示。图25E和图25F示出了穿过25C和图25D的截面图。。

[0104] 图26A和图26B示出了具有外套筒(例如，外导管或释放保护器导管或其他外套筒/保护器)的图25A至图25F的装置的变型

[0105] 图27A和图27B示出了穿过26A至图26B的装置的截面图。

[0106] 图28是包括柔性牵引器组件的远侧牵引器区域的装置，该柔性牵引器组件具有多个纵向平行的(非机织/编织的)细丝或条，其中细丝或条的远侧端部通过远侧连接件彼此连接。

[0107] 图29示出了装置中的柔性牵引器组件的远侧牵引器区域，其中纵向平行的(非机织/编织的)细丝或条包括抓取元件。

[0108] 图30A至图30C示出了具有抓取元件的细丝/条的示例。抓取元件(和/或包括它们的细丝)可以用作本文所描述的变型中的任一个的一部分，包括机织或编织的远侧牵引器区域。

[0109] 图31示出了一种变型，其中远侧牵引器区域适于往复运动(例如，推动和拉动)使得可扩张的第一端部区域可被拉入导管中并从导管翻转出。

[0110] 图32示出了如本文所述的装置的另一示例，其中可扩张的第一端部区域的最远侧端部固定到导管的远侧端部的一部分；可扩张的第一端部区域的其余部分具有足够的弹性/柔性以被拉入导管中(用其拉动凝块)。然后柔性牵引器组件可以被收回并且整个装置被拉出。该示例可能包括可选的真空。

[0111] 图33是装置的另一个示例，其中柔性牵引器组件的拉动器部分由与远侧牵引器区域相同的材料形成，但可以被层压或以其他方式被增强以具有比远侧牵引器区域更小的柔性/可拉伸性。

[0112] 图34示出了其中远侧牵引器区域适于在被拉入导管中时压缩凝块的另一个示例。

[0113] 图35A至图35C示出了如图34所示的装置的操作，其中通过将远侧牵引器区域的可扩张的第一端部区域拉回到压缩凝块(图35A至图35B)的导管中(例如，在牵引器组件的拉动器区域上拉动)而将凝块拉入导管；释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并将其从远侧牵引器区域释放，使得其可以利用手动或动力真空源向近侧抽吸(图35C)。

[0114] 图36示出了一种使用装置和方法的示例，其中向近侧拉入柔性牵引器组件可以使装置向远侧行进通过导丝上的主体(例如血管)，该导丝可以被处理以接合远侧牵引器区域。

[0115] 图37A至图37C示出了一种使用装置和方法，其中向近侧拉柔性牵引器组件可以使装置向远侧行进。

[0116] 图38A和图38B示出了装置和使用该装置从血管中去除材料的方法的另一变型，其

中该装置是“无限”牵引机构，其中大量的牵引器材料（例如，网状物）储存在一个外保持区域中，其被卷起但在扩充使用上不是必须的。

具体实施方式

[0117] 通常，本文描述了用于从身体机械地去除物体的方法和装置。虽然这些方法和装置可以适用于从身体的各种区域去除各种物体，但它们可能特别适合于从血管的腔内去除血凝块。因此本文所描述的是机械取栓装置（例如设备和系统）。

[0118] 本文所描述的装置（例如，用于从血管去除凝块的机械取栓装置）可以是包括具有远侧端部和远侧端部开口的细长导管的组件以及至少部分位于导管内的柔性牵引器组件，其中，牵引器组件的远侧端部区域被配置为远侧牵引器区域，远侧牵引器区域至少部分地在导管内延伸并且在导管的远侧端部上翻折回来。牵引器组件可以包括连接到远侧牵引器区域的近侧推动器区域。柔性牵引器组件包括配置成允许导丝通过的细长腔。柔性牵引器组件还被配置成在近侧端部区域被向近侧拉动时沿着导管腔内的长轴线滑动并且在导管的远侧端部开口上翻转。牵引器组件在本文可被称为柔性牵引器组件、柔性牵引器部分、柔性牵引器管或简单的柔性管，并且典型地定位在导管内并且可在导管内纵向可滑动，并且布置成使得远侧端部区域（“远侧牵引器区域”）在导管的远侧端部上翻折回来。

[0119] 例如，图1A示出了可形成本文所描述的装置的一部分的导管的一种变型。在该示例中，导管100包括远侧端部区域103，远侧端部区域包括远侧端部105。除了非常远侧尖端（远侧端部105）可以实质上比紧邻其的区域较不柔软之外，远侧端部区域可以具有增加的柔软度（通过硬度计测量，例如肖氏硬度计）。因此，虽然远侧尖端区域（例如，最远侧的x线性尺寸，其中x为10cm、7cm、5cm、4cm、3cm、2cm、1cm、9mm、8mm、7mm、6mm、5mm、4mm、3mm）具有从近侧端部到远侧端部延伸的增加的柔软度/减小的硬度，非常远侧端部区域107（例如，测量为最远侧的z线性尺寸，其中z为1cm、9mm、8mm、7mm、6mm、5mm、4mm、3mm、2mm、1mm、0.8mm、0.5mm、0.3mm、0.2mm等，并且z总是比x小至少三倍）的硬度大于紧邻其的区域的硬度，并且可以与远侧尖端区域的最近侧区域一样硬或比其更硬。

[0120] 导管100也可以被称为内导管或牵引器导管。可以使用任何适当类型的导管，包括适用于神经血管使用的微导管。

[0121] 在一些变型中，导管的远侧端部105适于使得远侧牵引器区域可以在导管的远侧端部上滑动并翻转而不被捕获（束缚）或没有实质摩擦。例如，在一些变型中，远侧尖端（端部）可以是弯曲的或倒圆的109，如图1B所示。特别是在外表面上（例如从外径到内径的过渡）。在一些变型中，远侧尖端包括一个或多个通道，如图25A至图28所示和所述的，包括围绕面向远侧的边缘的通道，以引导远侧牵引器区域的滑动。

[0122] 图1C示出了柔性牵引器管140的示例。在图1C中，管是柔性的并且细长（具有通常比导管101大的长度），并且包括远侧牵引器区域142，该远侧牵引器区域包括配置成紧邻近侧区域146上折叠的最远侧可扩张的第一端部区域144，其可以是可较少扩张的第二端部区域。通常，可扩张的远侧端部区域被配置成在不受约束时扩张至介于导管的内径的直径的1.3倍至10倍之间的径向直径。图1D示出了处于扩张配置的图1C的可扩张的远侧端部区域。因此可扩张的远侧端部区域可以被偏置以扩张打开。可扩张的远侧端部区域可以形成为网状物、机织物或材料片，并且通常适于抓取待去除的物体（例如血凝块）。

[0123] 图1C中一般性示出的柔性牵引器管被示出为图1E中的可扩张的远侧端部区域在其本身上(例如在更近侧的可较少扩张的第二端部区域上)翻折回来。在图1E中,可扩张的远侧端部区域收缩,而在图1F中,可扩张的远侧端部区域扩张。通常,可扩张的远侧端部区域可以与近侧的可较少扩张的第二端部区域区分开,然而在一些变型中,整个柔性牵引器管可以包括在导管内被推动和/或拉动且不包括近侧的可较少扩张的远侧端部区域的可扩张的材料(例如,网状物、机织物等)。

[0124] 图1G和图1H示出了使用诸如由图1A和图1E的部件组装的装置的装置去除凝块。在该示例中,该装置被配置为包括导管101和柔性牵引器管的取栓装置,该柔性牵引器管包括可扩张的远侧端部区域144,该可扩张的远侧端部区域在导管的远侧端部区域上延伸并且在导管的远侧端部上翻折,使得可扩张的远侧端部区域与内近侧的可较少扩张的(在该示例中,可较少扩张的包括不可扩张的)第二远侧端部区域146连续,该第二远侧端部区域在导管内向近侧延伸并形成可使导丝通过的内腔。柔性牵引器管(未示出)的近侧端部可以包括推动器/拉动器构件,该推动器/拉动器构件可以是与远侧端部区域(远侧牵引器区域140)连续的杆或其它构件。在图1G中,装置被示出在凝块155附近的血管160内定位并展开。通过将远侧牵引器区域140取回到导管101中,可以将凝块拉入导管中,如箭头180所示,其示出了柔性牵引器管的内部部分的拉动(例如,使用手柄,未示出),从而导致将可扩张的远侧端部区域拉动到导管远侧端部中并翻转可扩张的远侧端部区域,使得其被拉动到导管中,如箭头182所示。可扩张的远侧端部区域的远侧端部可相对于导管的外壁“松动”,或者其可被去除附接或在一些变型中永久附接。

[0125] 通常,定位这些装置并致动它们可能是具有挑战性的,这是因为它们在致动之前和操作期间都必须是高度柔性的。例如,一般来说,柔性牵引器管必须不能增加导管的刚度/柔性,并且特别是导管的远侧端部区域过多,或者对于操纵来说过于困难和/或危险,特别是在神经血管系统的侵蚀血管内。本文所描述的是柔性牵引器管部分,其增加了小于预定百分比(例如,小于10%、12%、15%、18%、20%、25%、30%等)的导管的最后ycm(例如,最远侧的20cm、18cm、15cm、12cm、10cm、9cm、8cm、7cm、6cm、5cm、4cm、3cm、2cm、1cm等)的刚度。例如,本文所描述的是柔性牵引器管部分,其穿过导管并且在导管的远侧端部上翻折回来,但是在没有柔性管延伸穿过其中并且在导管的远侧端部上翻折回来的情况下,将导管的远侧5cm的刚度增加小于导管的远侧5cm的刚度的15%。

[0126] 例如,图2A示出了柔性牵引器管201。在该示例中,柔性牵引器管包括在近侧推动器区域201的远侧的远侧牵引器区域242,该远侧牵引器区域具有可扩张的第一端部区域244以及可较少扩张的第二端部区域246。整个柔性牵引器管是中空的并且可以使导丝通过(未示出)。柔性牵引器管的各个区域可以由相同的材料(例如,机织的、编织的等细丝(filament)或多个细丝)制成,或者它们可以由不同的材料制成。

[0127] 图2B示出了具有远侧牵引器区域的柔性牵引器管,或者至少由多个机织纤维形成的可扩张的第一端部区域244'。可替代地,可扩张的第一端部区域可由一个(或多个)针织纤维或机织和针织纤维的组合形成。可扩张的第一端部区域可以通过纤维或机织/针织图案的形状设定特性或通过包含一个或多个偏置构件(例如,环、弹簧、带、细丝等)而被偏置地打开(如图所示),其倾向于至少将可扩张的第一端部区域的远侧端部区域偏置打开。

[0128] 图2C示出了由包括多个开口(例如,孔、穿孔、通道、窗口等)的材料片形成的可扩

张的第一端部区域的另一变型。这些开口可以是任何尺寸，包括不均匀尺寸(例如尺寸的范围)或均匀尺寸。穿过片的这些开口的尺寸可取决于所使用的材料，例如聚合物材料(PTFE)、硅树脂材料、聚氨酯、形状记忆合金等。在一些变型中，片的孔隙率大于>60％(大于70％、大于75％、大于80％、大于85％等、在60％至95％之间、在65％至95％之间、在70％至95％之间等)是有益的。

[0129] 在这些变型中的任一个中，远侧牵引器区域被配置成使得其可以在其本身上被翻转(例如，翻折)，如图2D所示。在一些变型中，该装置可被执行为使得可扩张的第一端部区域在其本身上和/或在导管的远侧端部区域上翻转，或者其可以被配置成使得其可以在体内(例如在血管内)在导管的远侧端部展开和翻转。通常，在装置可被致动之前，导管可以插入可扩张的第一端部区域与柔性牵引器管上的可扩张的第一端部区域的近侧的区域之间，在一些变型中，其可以是可较少扩张的第二远侧端部区域。该空间289可以通过在可扩张的第一端部区域的远侧端部处或附近的偏置构件而保持打开。如所提到的，该可扩张的第一端部区域开口偏置构件可以是环、带、弹簧、线圈等，并且可以由偏置元件(例如，形状设定材料，诸如形状记忆合金)、橡胶或其他聚合物材料等制成。

[0130] 尽管存在相关的挑战，但是本文所描述的装置的体内展开可以为操作装置的用户提供许多优点。图3A至图3F示出了配置用于体内展开的取栓装置的一个示例。在该示例中，该装置包括导管301，该导管可以使用导丝313定位(如同本文所描述的变型中的任一个)。导丝可以延伸到或进入(或穿过)待去除的物体，其示出为在血管360内的图3A中的凝块355。装置的导管可以与导丝一起插入或在导丝之后插入，并且在有或没有柔性牵引器管在导管的远侧端部处或附近的情况下，可以将导管定位在凝块附近(例如，邻近或紧邻)。在图3A中，在导丝已经定位之后，定位导管，并且如图3B所示，从血管中取出导管。导丝可以是线材，较小的导管或可以定位(例如，操纵)到凝块和/或穿过凝块的装置的组合。在定位导管之后，包括远侧牵引器区域342的内柔性牵引器管340被推动穿过导管至导管的远侧端部区域，如图3C所示。在该示例中，形成远侧牵引器区域的柔性牵引器管的远侧端部包括示出为网状物344的可扩张的第一端部区域，该网状物在近侧端部处(推动器区域305)连接到与柔性牵引器管的其余部分连续的近侧的不可扩张的第二端部区域。可扩张的第一端部区域的机织网状物344在收缩(非扩张)配置中在管状第二端部区域/推动器区域的外侧上预先翻转，并且可以滑动穿过导管的腔，并且(当导丝留在适当的位置或用于调节该位置时)在导丝(未示出)上滑动。如图3D所示，柔性牵引器管的远侧牵引器区域然后可以通过延伸(在该示例中，向远侧推动柔性牵引器管和/或向近侧拉动导管)而暴露于导管的外侧，从而允许远侧牵引器区域(示为网状物)344的可扩张的第一端部区域沿着第一端部区域的长度扩张。在图3D中，这显示为可以完全扩张至血管的内膜的支架状结构，在可扩张的第一端部区域与可较少扩张的(在此情况下是不可扩张的)第二端区域346之间形成分离。特别地，第一端部区域的扩张可以大于导管的内腔的直径的1.3倍(例如，大于1.5倍、大于2倍、大于2.2倍、大于2.5倍、大于3倍、大于3.5倍、大于4倍、大于5倍、大于6倍、大于7倍、大于8倍、大于9倍、大于10倍等)。

[0131] 在图3D中，导管在远侧牵引器区域的第一端部区域与第二端部区域之间向远侧滑动。然后可以通过向近侧拉动柔性牵引器管(例如，近侧牵引器区域)和/或向远侧推进导管中的一者或两者，而可以通过将可扩张的第一端部区域向近侧取回到导管中来移除凝块。

在一些变型中，既推进该装置(特别是导管)，同时又取回可扩张的第一端部区域并将其翻转到导管中可能是有益的。可以比取回柔性牵引器管更快地推进导管。

[0132] 如图3F所示，凝块355可以被拉入到具有可扩张的第一端部区域的导管中。

[0133] 体内展开方法和装置的另一种变型示于图4A至图4F中。在该示例中，柔性牵引器管的自扩张的第一端部区域被配置成当其被推出导管时在导管的端部上自扩张，使得它将在导管的远侧端部上滑动。如以上对于图3A至图3B所描述，可以使用导丝413等来定位该装置。在图4A中，将导管401定位在邻近待去除的凝块455的导丝413上。在图4B中，导丝可以(可选地)被去除，或者(优选地)保留在位。包括远侧牵引器区域的柔性牵引器管434然后可以在导管内向远侧移动并且以可扩张的第一端部区域444延伸出远侧端部，使得其在远侧端部上翻转466并且在远侧端部区域上向近侧滑动，如图4C所示。该过程可以通过在脉管的腔内向远侧推动装置来辅助，因为第一端部区域444的扩张可以帮助将其抵靠血管的壁固定，如图4D至图4E所示。一旦暴露，通过向近侧拉动柔性牵引器管434和/或向远侧端部推进组件(或至少导管)，可扩张的第一端部区域可以取回到装置中，如图4F所示。凝块455然后可以被拉入装置中。

[0134] 图5A至图5E示出了使用机械取栓装置的体内展开和取栓(凝块去除)方法的另一变型。在图5A中，包括导管501和内柔性牵引器管534的装置500(例如，在导丝上，未示出)被推进至凝块555附近。在该示例中(其可以与本文所描述的方法中的任一个相关)，该装置与柔性牵引器构件一起定位，该柔性牵引器构件具有未展开的远侧牵引器区域，该远侧牵引器区域已经在远侧定位在装置的远侧端部区域附近。如图5B所示，处于图5A中导管501内的收缩配置的可扩张的第一端部区域544被推出导管的远侧端部并扩张至腔的壁，如图5B和图5C所示。一旦推出并扩张，可向远侧推进导管和导管内的柔性牵引器管的部分，如图5D所示，导致可扩张的第一端部区域544翻转，在导管501的远侧端部区域上翻折。通过图5E，装置已经在凝块555附近展开并且可以如已经描述的那样被致动以去除凝块，但是将远侧牵引器区域的可扩张的第一端部区域拉动到导管中，使得它翻转并将凝块拉入导管中。导管可以可选地同时被推进。注意，上述体内展开的方法也可以用于加载用于插入体内的装置，以便将导管径向地定位在柔性牵引器管的可扩张的第一端部区域与较近侧部分之间。

[0135] 图6A示出了具有柔性牵引器管634的取栓装置的另一变型的示例，该柔性牵引器管634具有形成于编织(例如机织)或针织材料的该示例中的柔性第一(远侧)端部区域644，其中，柔性第一端部区域(牵引器区域)在导管601的远侧端部上翻转并且附接到柔性牵引器管634的近侧端部区域。如在本文所描述的装置中的任一个中，柔性牵引器管的该近侧端部区域可以是海波管、导管或者在导管内可推动/可拉动并且在其远侧端部附接到柔性牵引器区域(例如，远侧牵引器区域)(包括在一些变型中的可扩张的第一端部区域)的层压机织物/网状物或机织材料。注意，在一些变型中，远侧牵引器区域(第一端部区域)可以是不可扩张的，但是可以只是柔性的。

[0136] 在图6A中，附接到柔性牵引器管的远侧牵引器区域的第一端部区域被外导管或套筒(保护器)677覆盖。在该示例中，该装置还包括在内导管601与保护器导管或套筒677之间的中间导管679。在一些变型中，柔性第一端部区域644可以附接到该中间导管，包括可拆卸地附接使得向近侧拉动柔性牵引器管634将使其脱离并允许网状物(柔性第一端部区域644)在血管中展开。在图6A所示的变型中，柔性第一端部区域644未附接至中间导管679。

[0137] 本文所描述的装置中的任一个，包括图6A中所示的装置，可以与如图6B所示的导丝633一起使用(并且可以包括导丝)。图7A至7D示出了图6A至图6B中所示的设备的操作以去除凝块755。在该装置中，柔性牵引器管734的近侧端部可以耦接到真空源(未示出)，该真空源当向近侧取回牵引器管734以在导管的端部上翻转远侧牵引器区域时可以被致动。在图7A中，装置位于凝块755附近。在图7B中，通过如箭头所示拉动柔性牵引器管734而翻转远侧牵引器区域并将其拉动到导管中。在该示例中，远侧牵引器区域不被扩张，这是因为它仍然被外套筒777覆盖，如图7B和图7C所示。可以通过推动或通过向近侧拉动远侧牵引器端部区域(在该示例中示为网状物744)的动作以使其在导管的远侧端部上翻转中的一者或两者，向远侧朝向凝块或者在凝块上推进该装置。一旦凝块被去除，装置可以被取回并从血管中被拉出，如图7D所示。

[0138] 如上所述，这些变型中的任一个可以包括一个或多个真空源。图8示出了包括真空源的一个示例，其示出了耦接到柔性牵引器管834的腔的近侧端部处的第一可选真空源。例如，与真空和牵引器管834耦接的可以是旋转止血阀(RHV)，如图所示。在图8中，在(可选)外导管877和内导管801或(可选)中间导管878之间形成第二(可选)真空连接。可以在该方法的任何适当部分处施加真空，包括在柔性牵引器管834的收回期间去除凝块。

[0139] 如上所述，本文所描述的装置中的任一个可以包括导丝并且可以在手术期间将导丝留在适当的位置。图9A至9D示出了当导丝913留在适当的位置时去除物体(例如凝块)的方法。在该示例中，该装置类似于图6A至图6B中所示的装置，并且可以包括可选的真空源。在图9A中，包括远侧牵引器区域944的柔性第一端部区域944的翻转部分的导管的远侧端部定位成邻近凝块，并且通过向近侧拉动而被致动以将凝块拉入导管中，如图9B所示。在该示例中，凝块已经被导丝913穿透，因此具有翻转的牵引器区域的导管尖端可以通过推动导管927和/或通过向近侧拉动牵引器管919而在导丝上被向前推进。这可以继续直到整个凝块在导管内，如图9C所示。

[0140] 在本文所描述的变型中的任一个中，该装置可以包括一个或多个标记，或者可以被配置成与一种或多种对比剂一起使用以帮助使所描述的方法可视化。进一步地，这些方法中的任一种都可以包括可视化。可视化可以是间接的(例如，使用荧光镜检查或等效技术)，或者可以是直接的，例如使用一个光纤用于直接使该装置可视化(例如，通过装置的腔)。

[0141] 在图9D中，具有捕获物体(例如凝块)的牵引器管可以从装置的近侧去除并且可以检查所去除的材料(例如，通过组织学/细胞学检查)。随后或同时去除导管。如上所述，当去除物体(例如凝块)时，可能期望在柔性牵引器管向近侧拉回(未示出)的同时(向近侧)拉回导丝。在一些变型中，远侧牵引器区域(例如，编织/机织或针织区域)可以抓取导管内的导丝并且还可以帮助在凝块上或朝向凝块向远侧推进该装置，如下面在图36以及图37A至图37C中更详细地描述的。

[0142] 通常，抓取器(远侧牵引器区域)的滚动效果通过导管相对于远侧牵引器区域的运动而被致动。如果远侧牵引器区域向近侧固定并且导管被推进，则远侧牵引器区域可以具有1:1的抓取比。如果远侧牵引器区域被拉动通过导管，则抓取效果可能被放大。例如，当远侧牵引器区域被拉回(通过拉动牵引器管)并且当内导管被向远侧推动1个单元时翻转进入内导管中在导管内的近侧的1个单元，抓取效果大约是2倍。如果当内导管向远侧推进一个

单元时，远侧牵引器区域被取回到导管中向近侧两个单元，则抓取效果可以是大约3倍。远侧牵引器区域和导管的同时运动可以通过手柄来协调。

[0143] 通常，本文所描述的装置中的任一个可以包括手柄。手柄可以与柔性牵引器管和/或导管(例如内导管)和/或任何外导管(例如保护器、套筒等)耦接。手柄可被配置成允许柔性牵引器管和/或导管的选择性的分开致动和/或这些部件的协调运动。图10A和图10B示出了可以使用的手柄的示例。在图10A中，手柄包括驱动机构以拉回牵引器管，并且因此在导管的远侧端部上翻转远侧牵引器区域和/或相对于远侧牵引器区域推进导管。在图10A中，手柄包括可旋转手柄1001，该可旋转手柄与导管驱动器1003耦接。手柄连接到导管1005和具有远侧牵引器区域1011的内部柔性牵引器管1009两者。手柄可以被配置成使得导管的推进(向远侧)与牵引器管的拉动(向近侧)的比率可以被选择和/或可以取决于导管驱动螺纹的螺距或其他机械机构。

[0144] 手柄的另一个变型在图10B中示出。在该示例中，手柄可以附接到牵引器管以拉动(或推动)牵引器管1017，并且因此在导管的远侧端部上翻转远侧牵引器区域，并且手柄的另一部分可以耦接到导管以推动/拉动导管1015。

[0145] 图11A示出了手柄机构1107的另一个变型，该手柄机构被配置成通过在附件部位1105处耦接到牵引器管的近侧端部来拉动本文所述的装置中的任一个的抓取器(远侧牵引器区域)，和/或通过耦接到导管的近侧端部来推进导管。手柄机构的另一个示例在图11B中示意性地示出，其示出了杠杆机构1109和与可以固定或可调节的内牵引器管耦接的耦接件。

[0146] 在本文所描述的装置中的任一个(例如，机械取栓装置)中，远侧牵引器区域可以被预加载在导管中/上，使得它可以通过向近侧拉动耦接到远侧牵引器区域的牵引器管和/或向远侧推进导管而被致动。在其中远侧牵引器区域包括在导管的远侧端部上翻折的柔性和/或可扩张的第一端部区域(例如，由网状物和/或机织物材料形成)的预加载变型中，装置可以是适于防止第一端部区域在已经被定位在凝块处或凝块附近之前无意地移位和/或扩张。

[0147] 图12A和图12B示出了附接到导管外侧的远侧牵引器区域的可释放附件的示例。通过施加应用于柔性牵引器管的近侧端部的适当量的力(例如拉力)可以释放这些附件中的任一个。例如，如图12A所示，远侧牵引器区域(示为网状物1204)的外远侧端部被从外导管或管1203延伸的肩部或衬垫覆盖)。类似地，在图12B中，远侧牵引器区域(示为网状物1204)的外远侧端部被单独的带、环或衬垫1209覆盖。通过添加细丝(例如在编织或机织变型中，附加编织细丝)、通过添加涂层、通过热定形至较大直径，和/或通过添加轴向编织间拉线，当张紧(例如在牵引器管上向近侧拉动)时，可以防止远侧牵引器区域收缩或直径减小。

[0148] 本文所描述的变型中的任一个可包括作为柔性牵引器管的一部分的近侧拉杆或拉线。进一步地，牵引器管的近侧端部区域可能比远侧端部(远侧牵引器区域)柔性更小。图13A和图13B示出了柔性牵引器管的示例。在图13A中，管包括近侧锥形区域，其中，远侧牵引器区域1305由向近侧1307渐缩(tapered，锥化)到拉线的材料(例如，网状物/机织材料)形成，为导丝1309留出空间并允许远侧牵引器区域在导管上翻转。近侧拉线部分可由形成远侧牵引器区域的细丝形成，例如，在其中机织或编织远侧牵引器区域的变型中。这些细丝可以通过例如其他材料(诸如有助于使其更硬或更柔顺的聚合物)来增强。图13B示出了另一

个示例，其中，柔性牵引器管的近侧端部由拉线1315形成，该拉线可以是单独的材料或附接到拉线的远侧端部并形成远侧牵引器区域1317的编织线束的延伸部。

[0149] 本文所描述的装置中的任一个可以被处理或适应为减少在导管端部上翻转远侧牵引器区域所需的力。例如，在一些变型中，远侧端部可以被处理为润滑的，或者远侧牵引器区域的全部或一部分可以被处理以提高费力性。例如，在一些变型中，仅远侧牵引器区域的一部分（例如最初在导管的远侧端部上相互作用/翻转的部分）被处理；远侧牵引器区域的其余部分不被处理。图14示出了此类装置的一个示例。在图14中，可扩张和/或柔性第一端部区域（其定位于导管外侧）的最近侧端部1405用润滑涂层处理或由润滑材料形成。第一端部区域的剩余部分（未按比例示出）不是润滑的1403。由于较近侧区域1405暴露于血管和导管的远侧端部，所以它可以更有效地追踪目标或者允许装置追踪目标以及更有效地开始在远侧端部上翻转。该区域可以以任何适当的方式制成润滑的，包括但不限于涂层，诸如疏水/亲水涂层，并且形成或包括更润滑的聚合物材料（例如PTFE）。

[0150] 通常，本文所描述的远侧牵引器区域中的任一个可以适于包括不同的轮廓，包括预先设定以具有（例如，形状设定）可以更容易地在远侧端部上滑动/移动和/或抓取凝块或其他目标物体以用于去除的轮廓。例如，图15A至图15D示出了具有形成不同远侧牵引器区域的不同远侧端部轮廓的牵引器管。例如，在图15A中，远侧牵引器区域包括由通过多个拉线连接到牵引器管的近侧端部的由编织/网状或机织材料形成的最远侧可扩张和/或柔性第一端部区域1505。这些拉线1517可以由形成编织/网状或机织的远侧端部区域的相同线材或细丝形成。图15B示出了另一种变型，其中，多个离散的编织/网状或机织的远侧端部区域通过拉线1515连接；这些拉线区域1515可以是比编织/网状或机织区域1516更少可扩张的和/或柔性的。在图15C中，远侧端部区域被编织/网状或机织，但预先设定为具有不同的直径。因此这些区域沿其长度可以具有不同的形状；当这些形状被拉入导管中时，这些形状可被热定形以更好地抓取或破碎凝块。图15D示出了编织或支架状第一端部区域1521的示例，其通过形成编织/网状或机织的远侧牵引器的相同细丝的相同细丝或束连接到牵引器管1520的海波管或其他更近侧端部区域1523。

[0151] 本文所描述的装置中的任一个还可以或可替代地包括附接到导管的外表面上的多个可释放附件，从而将远侧牵引器区域（并且特别是远侧端部部分）固定到外表面。在图16中，示出了形成可释放附件的三个环1603、16.3’、1603”，其将远侧牵引器区域1644的远侧端部固定到导管1601的外侧。在该示例中，聚合物涂层/膜与编织物附接或成一体，形成远侧牵引器区域以帮助防止其过早地滑出或滑离导管（例如，直到由使用者拉动）。该装置可以包括沿着导管的长度径向定位的多个附件，如图所示，以帮助其保持固定到导管输送系统的外径。在一些变型中，这些可释放附件是弹性构件（例如聚氨酯环），但可以是脆的，并且允许破坏以释放远侧牵引器区域。

[0152] 图17示出了另一种变型，其中，可释放附件定位成使得远侧牵引器区域的一部分被弹簧加载（偏置）以驱动它在导管远侧端部上滚动并进入导管腔中。在图17中，远侧牵引器区域1704的远侧端部可被固定（固定、附接或松动但受约束），并且在导管的远侧端部附近的较近侧端部区域可被可释放地固定到导管1707。例如，聚合物涂层或膜可以附接到远侧牵引器区域（在图17中示出为编织物1744）并且被耦接以使远侧牵引器区域1705的在远侧端部1704与可释放附接部位1707之间的一部分保持张紧（例如，压缩）。然后释放可释放

附件1707可以施加驱动围绕导管远侧端部的远侧牵引器区域的力，以帮助将凝块拉入装置中，并减小翻转远侧牵引器区域所需的力。

[0153] 如上所述，形成远侧牵引器区域(并且特别是最远侧柔性和/或可扩张的第一端部区域)的材料可以由任何适当的材料形成。例如，该材料可以包括织物、机织物、针织物、编织物、缝合物、管和/或平片。该材料可以具有任何合适的厚度，例如在0.0005”至0.015”的壁厚之间，并且可以具有从低至高孔隙率的任何合适间隔/尺寸(孔隙率)的孔。远侧牵引器区域的全部或一部分可以是不透射线的或无线电透明的。在机织、针织、编织或缝制的变型中，材料可以由多丝或单丝形成。不同尺寸的细丝可以混合在一起(例如，大和/或小)以通过增加或减少织物表面纹理来改变抓取效果。在一些变型中，材料(包括形成材料的细丝)可以是基于聚合物的(例如PET、尼龙、聚丙烯、PTFE、ePTFE)、弹性和非弹性的(例如PU、硅酮、橡胶、莱卡)、金属细丝(例如镍钛、包括DFT的拉伸充填的镍钛，即带Pt内芯的镍钛、钢、不锈钢、钴铬合金等)以及金属和聚合物细丝的混合物。织物的端部可以是激光切割/焊接或自由切割。在一些变型中，远侧牵引器区域的全部或部分包括膜或片。该膜可以在0.0005”至0.008”厚度之间。该膜可以通过管挤出或片形成并且卷成管。在一些变型中，膜是纱线增强的。膜可以是开槽的(例如，可以包括被切割的孔和/或狭缝以改进抓持或滑入导管)。在一些变型中，膜具有纹理化表面(例如，翻转时暴露的纹理化内表面)。膜可形成具有沿长度具有脊和/或环(径向环)

[0154] 和/或线和/或具有锯齿形图案的管。纹理化内表面可以包括大丝和小丝的混合物，和/或可以由更多孔的较密度的织物形成。

[0155] 在一些变型中，抓取器元件的可视性是期望的，但并非始终需要。例如，如上所述，标记可以位于设备上。在一些变型中，可能期望看到结构的整个结构或近侧端部和远侧端部。例如，材料可以是镍钛诺或在铂材料(DFT)上拉制的镍钛诺以增强可视性。

[0156] 变型中的任一个可以包括位于编织结构中的任一个的内侧的旋转螺旋钻元件以协助将凝块拉回到毂。如上所述，这些装置中的任一个都可以包括真空源。向系统添加真空可能有助于远侧牵引器区域将凝块/栓塞拉入导管中的能力。所施加的真空可以是稳定的/恒定的、倾斜的或脉动的。

[0157] 在一些变型中，使用它们的装置和方法可以包括阻流近侧球囊(例如，定位在凝块附近)，其可以在手术期间减少凝块上的压力。

[0158] 本文所描述的装置和方法可以用于捕获活检样品(例如，来自乳房或任何其他器官)。例如，当执行腹腔镜手术时，可以使用这些装置去除较大的组织段(例如，癌症、胆囊等)。

[0159] 当形成远侧牵引器区域的材料是机织/编织材料时，所得到的网状结构可具有范围从1cm到100cm长以围绕导管的外径(OD)的编织物长度，优选地长度为在约3cm至30cm之间。

[0160] 在这些变型中的任一种中，牵引器管和/或导管(包括远侧牵引器区域)可以被构造成使得可以拉动远侧牵引器区域，使得远侧牵引器区域以最小的力在导管远侧端部的外径周围被拉入(翻转)，使得导管尖端不会在血管中弯曲或显著变形(例如，蛇形扭动)，其中，拉力小于约：50克、100克、300克、500克、800克、1000克、2千克、3千克、5千克、8千克、10千克、15千克、20千克等。

[0161] 在其中抓取器(远侧牵引器区域)至少在远侧端部(例如,可扩张的和/或柔性第一端部区域)上构造为机织(例如编织)结构的变型中,形成机织结构的细丝的示例可以包括:镍钛、镍钛-PT DFT线材(Pt内部的镍钛管)、PET、PP、尼龙、Algiloy、SS、混合材料。当使用时,镍钛可能被蚀刻以使其非常平滑。细丝端部的数量可以是约:16、24、36、48、77、96、144或这些整数之间的任何数量。任何编织结构都可以使用。例如,示例性编织结构可以包括1×1(1×1)、1×2、2×2等。在一些变型中,形成机织和/或针织材料的细丝包括单丝,例如所具有的外径(O.D.)尺寸约为:0.0005”、0.00075”、0.001”、0.0015”、0.002”、0.003”或在本文列出的整数之间的尺寸或直径尺寸的组合。如上所述,这些装置可以适用于使用的神经脉管系统,例如假设2mm至3mm脉管内径(ID)。例如,如本文所描述的适于神经脉管应用的装置可以包括韧炼至3mm至7mm OD的0.001”至0.002”聚合物编织物的36个至72个端部。在一些变型中,远侧牵引器区域包括24个编织线材,其具有以45度角度编织的在2mm心轴上韧炼的0.0005”至0.0015”或0.002”的扁平镍钛线材。可替代地,在一个变型中,远侧牵引器区域包括编织材料,该编织材料由以45度角度编织的在2mm心轴上韧炼的0.002”厚度的镍钛线材的24个线材形成。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括以45度角度编织的在2mm心轴上韧炼的0.002”DFT镍钛线材的24个线材。在一个示例中,远侧牵引器区域包括机织材料,该机织材料包括与在2mm心轴上的0.002”镍钛线材的8个附加端部混合的0.003”线材的8个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括在2mm心轴上韧炼的0.002”铂铱线材的16个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括具有0.002”直径的外径的PP单丝的24个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括0.003”PP单丝的12个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括0.003”PP单丝的16个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、90度编织角度、8mm心轴的0.001”PET或PP的72个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、75度编织角度、6mm心轴的0.001”PET或PP的36个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、90度编织角度、8mm心轴的0.002”PET或PP的48个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、70度编织角度、6mm心轴的0.002”PET或PP的48个端部。

[0162] 在其中远侧牵引器区域包括网状物的变型中,管状网状物可由针织或替代结构形成,该针织或替代结构被构造成使得当网状牵引器被轴向拉动并且围绕导管尖端的外侧并进入导管ID中时,径向压缩(管状网状物内径ID的变化)经受直径减小5%至20%。这种5%至20%网状物直径的减小可以有助于在将网状物拉动到导管中时抓取凝块或异物,而不会产生很大的径向压缩力使得在拉动时管状网状物结合在导管尖端上并且不容易围绕导管尖端滚动。相反,当向近侧拉入时,机织的网状物可在导管内收缩20%至60%之间,这可提供其他所去除材料的凝块的大量压缩。

[0163] 在其中该装置被配置用于外围血管(例如,具有4mm至8mm血管ID)的变型中,远侧牵引器区域可以被配置用于该应用。例如,远侧牵引器区域可以包括具有形成在4mm心轴上并被韧炼的0.009”PP单丝的24个端部的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的0.008”PP单丝的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的0.006”PP单丝的72个端部的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的36个端部的编

织材料。远侧牵引器区域可以包括具有心轴韧炼的0.004”DFT镍钛的48个端部的编织材料。

[0164] 在其中装置被配置为活检装置(例如,具有4mm至12mm样本大小)的变型中,该装置可以是机织材料,其包括在10mm心轴上形成的PP 007”单丝的72个端部。在一些变型中,装置(例如,远侧牵引器区域)可以包括在1mm心轴上形成的0.004”镍钛的48个端部。在一些变型中,装置(例如,远侧牵引器区域)可以包括在12mm心轴上的PP 0.008”单丝的48个端部。

[0165] 在本文所描述的变型中的任一个中,所述装置可以被配置成具有相对低的摩擦。特别地,远侧牵引器区域可以具有低摩擦力以允许在收回凝块时更容易和/或可靠地拉动穿过导管。如上所述,这些变型中的任一个可以包括润滑材料和/或涂层,包括在抓取器(远侧牵引器区域)上使用或涂覆一种或多种以下材料:PET、PP、PTFE、ePTFE。当形成装置的材料是小直径细丝金属结构时,细丝的直径可以在0.0005”至0.003”之间。材料可以是镍钛、不锈钢、MP35n、Ti、铂、铂铱、钴铬合金等。

[0166] 在远侧牵引器区域是网状物(例如,机织和/或针织材料)的变型中,远侧牵引器区域相对于导管直径的直径可以取决于机织/针织结构。例如,当编织时,比率可以在2至1之间或更大;当经编时,比率在1.5至1之间或更大。当形成为激光管时,比例在1.1至1之间或更大。类似地,对于编织管或带结构,导管内部的编织角度应该在导管内侧在编织角度的0度至45度之间,并且在导管外侧在编织角度的约20度至90度之间。在远侧牵引器区域包括针织编织(例如,经编)管的变型中,该装置可以包括每英寸12个至16个端部。对于具有0.0035”ID导管的装置:可以使用20至40D PET复丝的12个至16个端部,或者可以使用0.0007”至0.003”PET或聚丙烯(Polypro)或PTFE单丝的12个至16个端部,或者可以使用0.0007”至0.002”镍钛、不锈钢、MP35n等的12个至16个端部。

[0167] 如上所述,在一些变型中,远侧牵引器区域由ePTFE形成为片(例如,形成为管或带)。这种材料可以是薄壁的(例如厚度在0.0005”至0.003”之间),被认为是有壁厚的(在0.0005”至0.002”之间),并且可以在导管尖端上折叠/起作用。该材料可能包括0.001”至0.004”,带有支架状的激光图案。

[0168] 包括不同形状的远侧牵引器区域的装置的设计的其他示例可以是导管ID的功能。例如,在一些变型中,装置可以选择导管ID、细丝的数量、细丝的直径/长度、弯曲/滚动刚度的刚度、泊松比、抓取器的内表面的摩擦(和/或纹理)等。较小直径的导管比较大直径的导管可能需要更少的网状物细丝或者更小的ePTFE管IDS。例如,在编织远侧牵引器区域的一些变型中,该装置可以包括具有远侧牵引器区域的0.072”ID导管,该远侧牵引器区域具有以90度编织角度编织在6mm心轴上的0.0008”至0.002”镍钛线材的24个至72个端部。在一些变型中,远侧牵引器区域由以90度编织角度编织在6mm心轴上的0.0008”至0.002PP单丝的24个至72个端部形成。在一些变型中,远侧牵引器区域由针织编织物(假定0.072”导管)形成,并且可以包括在3mm心轴上韧炼的16个端部或40D PET复丝自由经编针织物。在一些变型中,远侧牵引器区域由在3mm心轴上韧炼的经编针织的0.002”PP单丝的16个端部形成。在具有由ePTFe管形成的远侧牵引器区域(同样,假设0.072”导管)的变型中,远侧牵引器区域可以是0.002”厚的3mm的管。可替代地,远侧牵引器区域可以是0.002”厚的3mm的管激光器,其被开槽以收缩和抓取凝块。

[0169] 如所提及的,在一些变型中,该装置被配置成在远侧牵引器区域中包括抓持内网状表面。例如,该装置可以包括具有较大直径编织细丝和/或混合直径细丝的激光开槽

ePTFE管。在一些变型中，抓持内网状表面可以用作为经编针织成型管的针织编织物形成。此类结构可以具有自然的宏观结构以允许网状物滚动和抓持凝块，因为细丝不会平行于导管进入导管ID，而是它们相对于导管长轴线是垂直或环状的。对于其中远侧牵引器区域由ePTFE激光开槽材料(材料片)形成的示例，该结构可以包括切割成允许泊松比影响管直径同时产生抓持纹理以抓取凝块的狭缝。

[0170] 通常，通过使用自扩张的和/或较硬的远侧牵引器区域(例如，远侧牵引器区域的自扩张的和/或柔性第一端部区域)，可以增强远侧牵引器区域在抓取凝块中的有效性)。当远侧牵引器区域的第一端部区域由编织物形成时，较硬的细丝(例如，由较大直径的细丝、较硬的材料、较大数量的纤维等形成)可导致远侧牵引器的更扩张的第一端部区域，如图18A至图18C所示。在图18A中，较柔软的远侧牵引器区域不会扩张超出导管的OD相当大的距离。图18B示出了远侧牵引器区域的略微更硬/更可扩张的第一端部区域。图18C示出了最可扩张的远侧牵引器区域1801，其可以最佳地扩张至血管1803的内膜。

[0171] 如图18A至图18C所示，可扩张的牵引器区域的唇缘的嘴部可相对于导管OD的长轴线形成切向角度或滚动角度(Φ)。该角度可以在大约5°至60°的范围内(例如，10°至60°、10°至50°、10°至45°、10°至40°等，并且优选地至少为10度)。本发明人惊奇地发现，在一些变型中，当牵引器区域被收回到导管中时与管具有至少约10度(例如10°至60°、10°至50°、10°至45°、10°至40°)的滚动角度可防止导管尖端上的束缚或堵塞。网状管可以被修改(例如，在远侧尖端或端部区域处)，包括通过修改远侧尖端的刚度和/或形状，以确保滚动角度大于10度。可替代地或与保持最小滚动角度的组合，可能期望在导管最远侧尖端处保持管材料ID与导管的O.D之间的物理空间或间隙(参见例如图18A至图18C)。间隙可能需要大于0.1mm、0.2mm、0.3mm、0.4mm、0.5mm、0.7mm、0.8mm或1.0mm，以确保当管收回时，管围绕导管的远侧端部滚动。

[0172] 在这些变型中的任一个中，如上所述，远侧牵引器区域可以是润滑的(例如，亲水涂层、硅树脂涂层、薄氨基甲酸酯或其他薄弹性体涂层)。可以包括一个或多个聚合物编织物端部以增强润滑性(例如，聚丙烯、尼龙等)。进一步地，编织角可保持较小(例如，小于70度、50度、45度等)以允许更好的拉动。当远侧牵引器区域在导管的尖端周围/上方滚动时，可以测量该角度。增加机织物的端部的数量也可以防止第一端部区域在导管内的锁定，使得编织元件之间的间隙/空间更小并且当远侧牵引器区域在导管的端部上滚动时不太可能阻碍导管尖端。当形成为编织元件时，这些装置中的任一个还可以包括轴向元件，该轴向元件在拉动时不太可能收缩或直径减小，并且因此当在尖端上滚动时不太可能挂在导管开口上。当使用镍钛(例如>0.0001”直径)时使用稍大的编织细丝也是有利的；直径越大，编织物可变形以锁定到导管尖端的可能性就越小。如上所述，在一些变型中，远侧牵引器区域可被热定形以在向远侧推进时在导管的远侧端部上自动滚动。

[0173] 图19A和图19B示出了用于形成远侧牵引器区域的翻折回来配置的替代方法。在图19A中，管状远侧牵引器区域1903可以耦接到拉动器/推动器1901，然后如上所述在导管尖端上翻转。在图19B中，管状编织物1905穿过编织物向远侧附接到线材/拉动器1901并被拉动以在导管的远侧端部上使其翻转。

[0174] 通常，远侧牵引器区域的第一端部区域可具有任何适当的形状(参见图15A至图15D)。图20A和图20B示出了可以形成远侧牵引器区域的渐缩机织物的示例。在图20A中，编

织物具有锥形侧面轮廓，其可以附接到拉动器(柔性牵引器管的近侧端部)并且翻转。本文所述的编织物中的任何一种可以包括标记线材(例如，DFT、金、铂、铂铱等)以帮助可视化(例如，荧光镜)。在图20B中，网状物比图20A中更突然地渐缩。

[0175] 如上所述，通常，本文所描述的导管中的任一个可适用于这些装置。例如，合适的导管可以是高度柔性的，并具有良好的柱刚度(例如，当向远侧推进时其长度不会缩短)。导管可以具有高角度编织物加强元件。例如，导管可以具有穿过近侧端部至远侧端部的高角度编织物(70度至85度，小线材镍钛、不锈钢、钴铬、MP35N、扁平或圆形线材)，以及针对导管的远侧1cm至5cm的较小编织角度。这将允许当施加轴向压缩时和/或在内扩张力(例如血块)下导管的内径扩张。

[0176] 通常，这些导管中的任一个都可以包括改变的刚度/顺应性。例如，近侧三分之一(1/3)可能较硬；中间部分可能不太硬，而远侧20％(1/5)可能是最不硬的。进一步地，导管的远侧尖端可以具有如图1A和图1B中所描述的适当的半径(曲线)。通常，半径应该是平滑且圆形的，而不是方形的。另外，导管的远侧尖端可以由足够硬的材料(约72D或更硬)制成，以允许编织物滚动而不抓取尖端。例如，导管尖端可以具有硬质金属结构以减少摩擦(例如，不锈钢、Pt等)。当拉动远侧牵引器区域时导管尖端压缩/弯曲越少越好。在一些变型中，导管包括附加加强件，诸如编织增强件而不是线圈加强件，以防止导管最后5cm至10cm的编织物屈曲。因此，如本文所描述的，在一些变型中，导管的尖端可由润滑和/或硬质材料制成，以当编织物围绕导管尖端被拉动或被推动时帮助减少编织物与导管尖端的摩擦。润滑材料可以包括诸如PTFE、FEP和/或亲水涂层的粉状聚合物。如尼龙之类的硬质材料或不锈钢之类的金属材料、铂和PT铱合金可用于该尖端，并且向近侧熔合/附接到较柔软材料。如果硬质尖端被放置在导管尖端的远侧端部上，则其长度可能是短的(例如<5mm并且优选地<3mm)，因此它不会不利地影响导管追踪。

[0177] 图21A至图21D示出了用于去除凝块的装置的示例。在该示例中，远侧牵引器区域由拉下到0.071”的导管上的10mm(扩张)直径的大约72个端部的细旦尼尔PET网状物形成，如图21A和图21B所示。图21A示出了在耦接到导管之前的可扩张的第一端部区域的示例。图21B示出了通过拉动柔性(牵引器)管的近侧端部将血管(玻璃管)内的可扩张的第一端区域拉入导管中。图21C示出了装置的远侧端部区域，其包括在导管的远侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉入导管中的图21C的装置。

[0178] 另一个示例检查了由具有72个端部和0.001”直径细丝的6mm编织物形成的远侧牵引器区域，该细丝滚动进入0.071”ID导管并且在0.071”ID导管上翻折。成功去除20cm长的“中等硬度”5mm凝块。图22示出了在将其向近侧拉出导管之后具有所捕获的凝块的图21D的可扩张的第一端部区域。

[0179] 图23A至图23D示出了如本文所述的机械取栓装置，其捕获血凝块并将其拉入装置中。图23E示出了在柔性牵引器管已经从导管去除(例如向近侧)之后保持在柔性牵引器管内的凝块。

[0180] 在本文所描述的一些变型中，远侧牵引器区域不是由机织或针织材料形成，而是由纵向布置(例如，平行或近似平行布置)的条或束构成。例如，图24是包括柔性牵引器构件的装置的另一个示例，其中，远侧牵引器区域由多个细丝形成，该多个细丝布置位未机织或编织的材料条(纵向平行)。这些条可以是细丝或管等。

[0181] 图25A至图25F示出了柔性牵引器组件的远侧牵引器区域的另一变型，其中，可扩张的第一端部区域(例如，远侧牵引器区域的远侧端部区域)由多个细丝或条形成，类似于图24中所示的；如图25A至图24B所示，导管的远侧端部包括通道；这些条可以装配在这些通道内，如图25C至图25D所示。图25E和图25F示出了穿过图25C和图25D的截面图。图25A、图25C和图25E示出了侧视图并且图25B、图25D和图25F示出了轴向视图。在该示例中，导管尖端包括细丝/条2503在其中行进的通道2502。形成远侧牵引器区域的条附接到柔性牵引器管2505的更近侧的拉动器区域，如图25E所示。

[0182] 图26A和图26B示出了具有外套筒(例如，外导管或释放保护器导管或其他外套筒/保护器)的图25A至图25F的装置的变型

[0183] 图27A至图27B示出了穿过图26A至图26B的装置的截面图。

[0184] 图28是包括柔性牵引器组件的远侧牵引器区域的装置，柔性牵引器组件具有多个纵向平行的(非机织/编织)细丝或条，其中，细丝或条的远侧端部通过远侧连接件彼此连接。

[0185] 图29示出了装置中的柔性牵引器组件的远侧牵引器区域，其中，纵向平行的(非机织/编织)细丝或条包括抓取元件。

[0186] 图30A至图30C示出了具有抓取元件的细丝/条的示例。抓取元件(和/或包括它们的细丝)可以用作本文所描述的变型中的任一个的一部分，包括机织或编织的远侧牵引器区域。带有抓取元件的对于细丝/条的其他选择可以包括编织条、网状物/机织条和微线圈。

[0187] 在本文所描述的这些配置中的任一种中，该装置可以适于允许远侧牵引器区域的往复运动，从导管的远侧端部的外侧至内侧并回到外侧而循环。例如，图31示出了其中远侧牵引器区域适于往复运动(例如，推动和拉动)使得可扩张的第一端部区域可被拉入导管中并且从导管翻转出的变型。在该示例中，牵引器管(拉动器)3105附接到远侧牵引器区域3144，该远侧牵引器区域可以附接(并且在一些变型中不附接)到内导管3101上的第二导管3109。中间导管3109可以耦接到拉动器3105，并且两者一起往复运动，使得编织物在导管3101的内侧来回往复运动。这可以帮助破碎凝块，这可能特别是在与抽吸一起使用时。

[0188] 图32示出了如本文所述的装置的另一示例，其中，远侧牵引器区域的柔性第一端部区域的最远侧端部3205不可释放地固定到导管3201的外侧的远侧端部；可扩张的第一端部区域3209的其余部分具有足够的弹性/柔性以被拉入导管中(用其拉动凝块3255)。然后柔性牵引器组件可以被收回并且整个装置被取回。该示例可能包括可选的真空3260。

[0189] 图33是装置的另一个示例，其中，柔性牵引器组件的拉动器部分3305由与远侧牵引器区域3344相同的材料形成，但可以层压或以其他方式加强以具有比远侧牵引器区域更小的柔性/可拉伸性。

[0190] 图34示出了另一个示例，其中，远侧牵引器区域3444适于当拉入导管3401中时压缩凝块3455。图35A至图35C示出了如图34所示的装置的操作，其中，凝块3455通过将远侧牵引器区域的可扩张的第一端部区域取回到压缩凝块的导管中(例如在牵引器组件的牵引器区域3505上拉动)而被拉入导管中(图35A至图35B)；释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并且将其从远侧牵引器区域释放，使得它可以向近侧分段(图35C)。

[0191] 图36示出了一种装置和使用方法的示例，其中，向近侧拉柔性牵引器组件可以向

远侧推进装置穿过导丝上的主体(例如血管),该导丝可以被处理以接合远侧牵引器区域。在该示例中,该装置可以被配置成拉动具有形成远侧牵引器区域3644的网状物的内牵引器管(导管3605),该远侧牵引器区域附接到其远侧端部并且在导管3601的远侧端部上翻转。拉动柔性牵引器管3605使编织物在导管3601的开口上滚动。形成远侧牵引器区域(例如,远侧牵引器区域的第一端部区域)的网状物/编织物被构造成当拉伸负载施加到该结构上并且锁定/抓取内线材(导丝3677)时在直径上收缩。该内导丝可能具有抓取线材的粘性、粗糙或多变的表面辅助网状物/编织物。当网状物/编织物抓取在导丝上时,牵引器管由于反作用力而将在脉管中被向前驱动。可替代地,用户将能够在拉回牵引管的同时能够容易地将外导管3601向前推进穿过血管。

[0192] 图37A至图37C示出了另一种装置和使用方法,其中,向近侧拉柔性牵引器组件可以向远侧推进该装置。在图37A中,远侧牵引器区域3744附接至中间导管3703(可包括可选的外导管3705),并且远侧牵引器区域3744的相对端部结合至在该导管的内径内的内导管3701的远侧端部。在图37B中,向远侧推进内导管,从而使远侧牵引器区域在侧向和前方扩张。如图37C所示,然后可以向远侧推动外导管和内导管,以使装置向远侧移动。

[0193] 在一些变型中,远侧柔性牵引器区域可以被保持预先加载在导管的外侧,例如以卷或束的形式被保持预先加载在导管的远侧端部区域上,使得其可以被逐渐拉出外存储区域并且在导管的远侧端部上滚动和翻转。一个此类变型的示例示出在图38A和图38B中,该示例性装置可用于从血管内去除材料,如图38B所示,并且可以称为“无限(infinite)”牵引器机构,因为大量(例如,大于50cm、大于60cm、大于70cm、大于80cm、大于90cm、大于100cm、大于150cm、200cm、大于300cm、大于400cm、大于500cm等)的牵引器材料(例如,网状物)可存储在外保持区域中,其被卷起但在扩大使用上不是必要的。

[0194] 在图38A中,该装置可以包括导管(内导管)3811并且远侧牵引器区域3806由在导管的远侧端部附近的壳体区域3813中卷起的网状物3803形成。通过在导管内向近侧拉动远侧牵引器区域,凝块3805可被拉入导管中。由于大量远侧牵引器区域可能存储在近侧并且向近侧被取回,因此这种变化对于非常长的手术或者需要去除大量材料的情况可能是有用的。

[0195] 这种变型可以允许使用者展开较长长度的网状物,这对于更刚度的工具(诸如在手术期间的刚度海波管)可能是有利的,例如,在吸脂手术中去除脂肪、去除脑内出血或更大的外周血管凝块中的凝块。

[0196] 如上所述,在本文所描述的变型中的任一个中,远侧牵引器构件可以是机织(例如针织)或编织的网状材料。网状物可以是针织材料,包括例如纬编针织物、圆形针织物、经编针织物和/或编织针织物。

[0197] 当特征或元件在本文中被称为“在”另一特征或元件“上”时,其可以直接在另一特征或元件上,或者也可以存在中间特征和/或元件。相反,当特征或元件被称为“直接在”在另一特征或元件“上”时,不存在中间特征或元件。还将理解,当特征或元件被称为“连接”、“附接”或“耦接”到另一特征或元件时,其可直接连接、附接或耦接到另一特征或元件,或者可能存在中间特征或元件。相反,当特征或元件被称为“直接连接”、“直接附接”或“直接耦接”到另一特征或元件时,不存在中间特征或元件。虽然相对于一个实施例进行了描述或示出,但是所描述或示出的特征和元件可以应用于其他实施例。本领域的技术人员还将认识

到，对“邻近”另一个特征设置的结构或特征的提及可以具有与邻近特征重叠或位于其下面的部分。

[0198] 本文所使用的术语仅用于描述特定实施例的目的，而不意图限制本发明。例如，如本文所使用的，除非上下文另外明确指出，否则单数形式“一”，“一个”和“该”也旨在包括复数形式。将进一步理解，当在本说明书中使用时，术语“包括”和/或“包含”指定所述特征、步骤、操作、元件和/或部件的存在，但不排除一个或多个其他特征、步骤、操作、元件、部件和/或其组合的存在或添加。如本文所使用的，术语“和/或”包括相关所列项目中的一个或多个的任何和所有组合，并且可以缩写为“/”。

[0199] 为便于描述，本文可以使用诸如“在...之下”、“在...下方”、“下”、“在...上”、“上”等的空间相对术语以描述一个元件或特征与另一个元件或特征的关系，如图所示。将理解，空间相对术语旨在包括除了附图中所描绘的方位之外的装置在使用或操作中的不同方位。例如，如果附图中的设备是翻转的，则被描述为在其他元件或特征“之下”或“下方”的元件将被定向为“在”其他元件或特征“上”。因此，示例性术语“在...下面”可以包括上方和下方两种方向。设备可以以其他方式定向(旋转90度或以其他方位)并且相应地解释在本文所使用的空间相对描述符。类似地，除非另外特别指出，否则术语“向上”、“向下”、“竖直”、“水平”等仅用于解释的目的。

[0200] 虽然术语“第一”和“第二”在本文中可以用于描述各种特征/元件(包括步骤)，但除非上下文另有指示，否则这些特征/元件不应受这些术语限制。这些术语可以用于区分一个特征/元件与另一个特征/元件。因此，下面论述的第一特征/元件可以被称为第二特征/元件，并且类似地，在不脱离本发明的教导的情况下，下面所论述的第二特征/元件可以被称为第一特征/元件。

[0201] 在整个说明书和所附的权利要求书中，除非上下文另有要求，否则词语“包含”以及诸如“包含了”和“其包含”的变型意味着各种部件可以在方法和物品中共同采用(例如，包括设备和方法的组合物和装置)。例如，术语“其包含”将被理解为暗示包含任何陈述的元件或步骤，但不排除任何其他元件或步骤。

[0202] 如在本说明书和权利要求书中所使用的，包括在示例中所使用的并且除非另有明确说明，即使术语没有明确出现，所有的数字也可以读作像“约”或“大约”这样的词语开头。当描述幅度和/或位置以指示所描述的值和/或位置在值和/或位置的合理预期范围内时，可以使用短语“约”或“大约”。例如，数值可以具有所述值(或值的范围)的+/－0.1％的值、所述值(或值的范围)的+/－1％的值、所述值(或值的范围)的+/－2％的值、所述值(或值的范围)的+/－5％的值、所述值(或值的范围)的+/－10％的值等。本文给出的任何数值也应被理解为包括约或大约该值，除非上下文另有指示。例如，如果公开了值“10”，则“约10”也被公开。本文列举的任何数值范围旨在包括其中所包含的所有子范围。还应理解，当公开值时，“小于或等于”该值、“大于或等于该值”以及值之间的可能范围也被公开，如本领域技术人员所适当理解的。例如，如果公开了值“X”，则还公开了“小于或等于X”以及“大于或等于X”(例如，其中X是数值)。还应该理解，在整个申请中，数据以多种不同的格式提供，并且该数据表示端点和起点以及数据点的任何组合的范围。例如，如果公开了特定的数据点“10”和特定的数据点“15”，则可以理解，大于、大于或等于、小于、小于或等于并且等于10和15被认为是公开的以及在10和15之间。还应该理解，还公开了两个特定单元之间的每个单元。例

如，如果公开了10和15，则还公开了11、12、13和14。

[0203] 尽管以上描述了各种说明性实施例，但是在不脱离如权利要求所描述的本发明的范围的情况下可以对各种实施例进行多种改变中的任何一种。例如，其中执行各种所描述的方法步骤的顺序通常可以在替代实施例中改变，并且在其他替代实施例中，可以完全跳过一个或多个方法步骤。各种设备和系统实施例的可选特征可以包括在一些实施例中而不包括在其他实施例中。因此，前面的描述主要是为了示例性的目的而提供的，并且不应该被解释为限制如在权利要求中所阐述的本发明的范围。

[0204] 本文包括的示例和说明通过说明而非限制的方式示出了其中可以实践主题的特定实施例。如上所述，其他实施例可以被利用并从中导出，使得可以在不脱离本公开的范围的情况下进行结构和逻辑替换和改变。本发明主题的此类实施例在本文中可以单独地或共同地由术语“发明”引用，仅仅是为了方便，并且无意将本申请的范围自愿地限制到任何单个发明或发明构思，如果事实上公开了不止一个的话。因此，尽管本文已经说明和描述了具体实施例，但是为了实现相同目的而计算出的任何布置都可以替代所示的具体实施例。本公开旨在覆盖各种实施例的任何和所有修改或变型。上述实施例的组合以及本文中未具体描述的其它实施例对于本领域技术人员在查看以上描述时将是显而易见的。

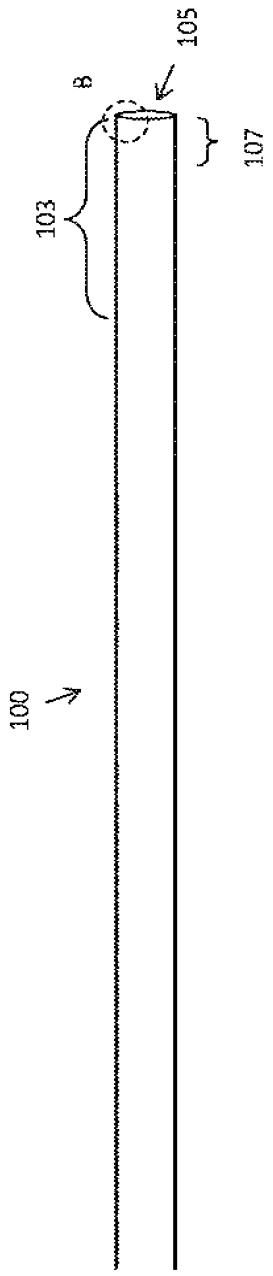


图1A

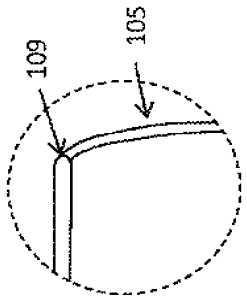


图1B

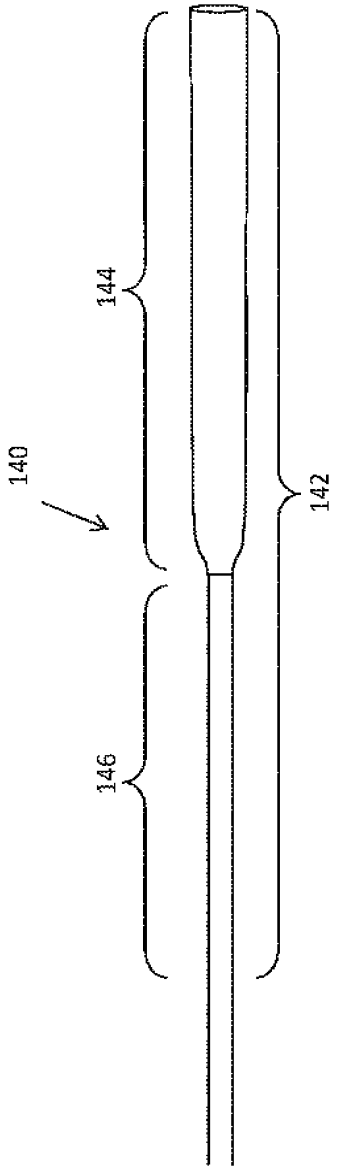


图1C

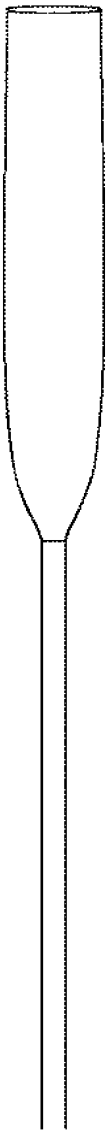


图1D

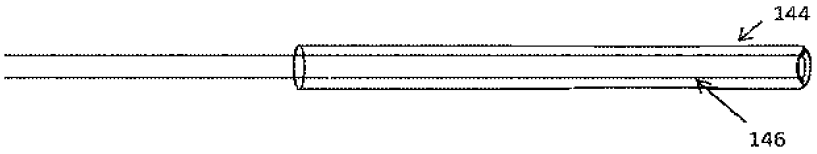


图1E

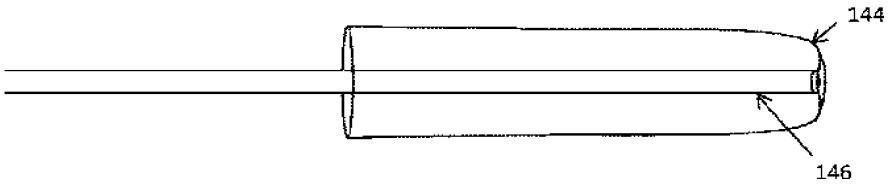


图1F

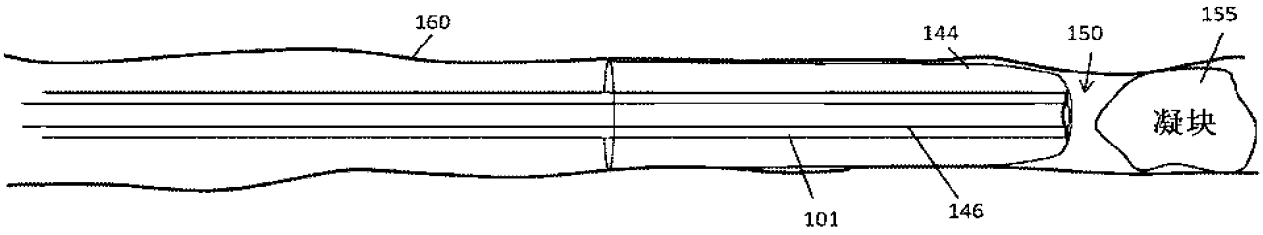


图1G

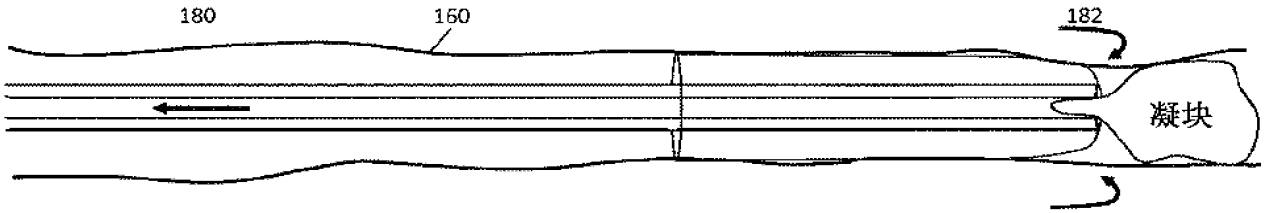


图1H

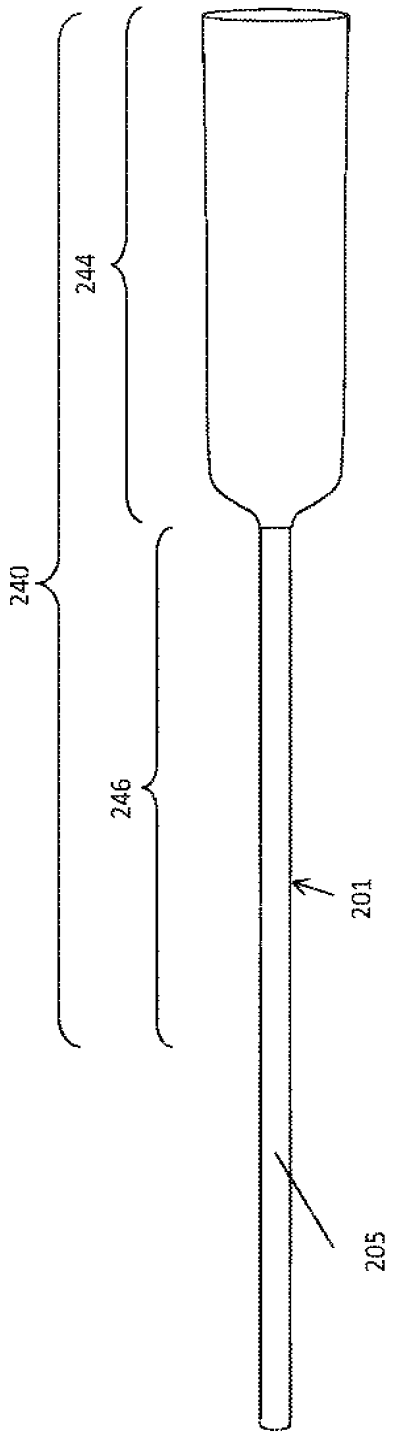


图2A

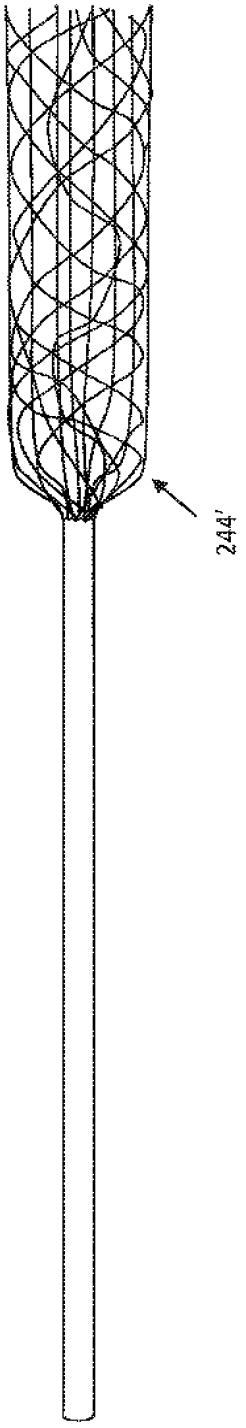


图2B

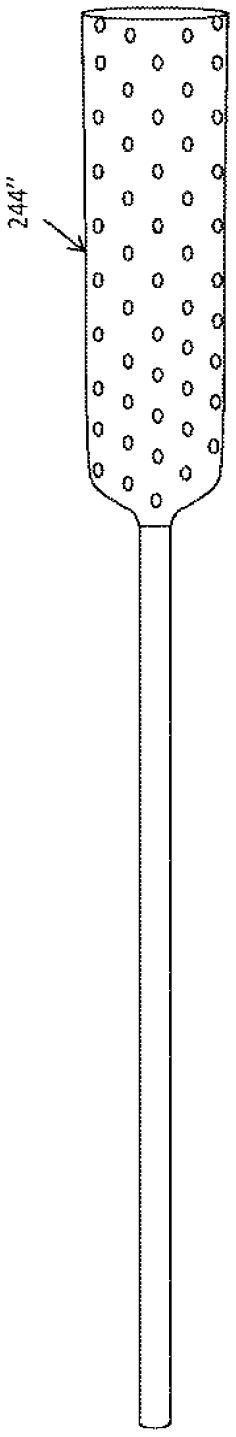


图2C

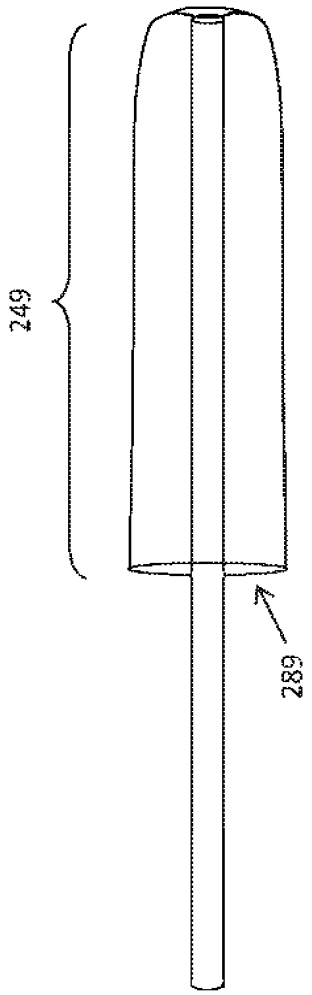


图2D

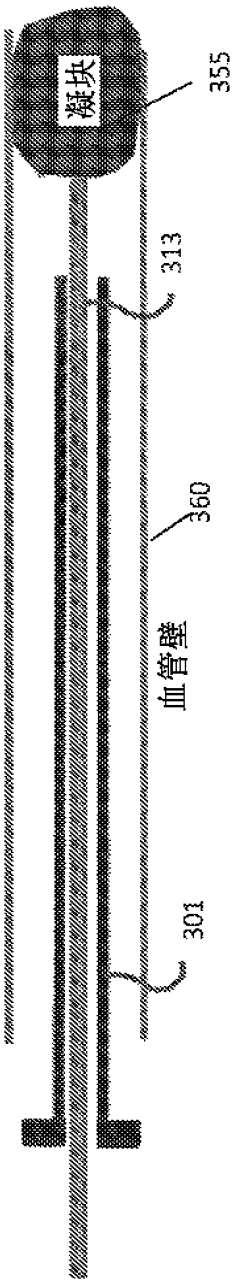


图3A

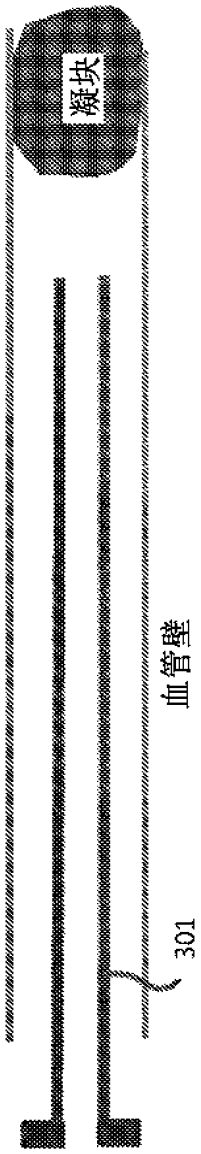


图3B

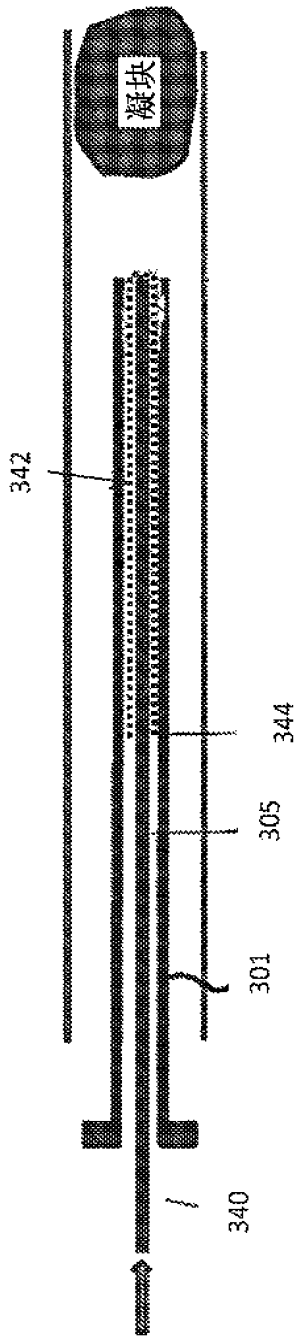


图3C

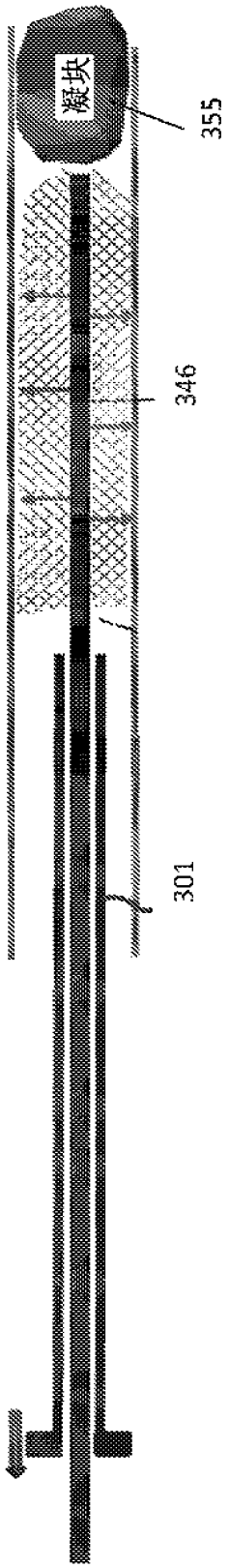


图3D

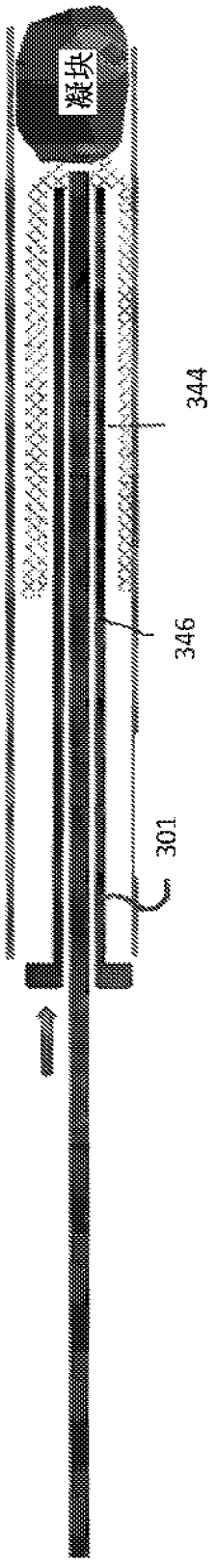


图3E

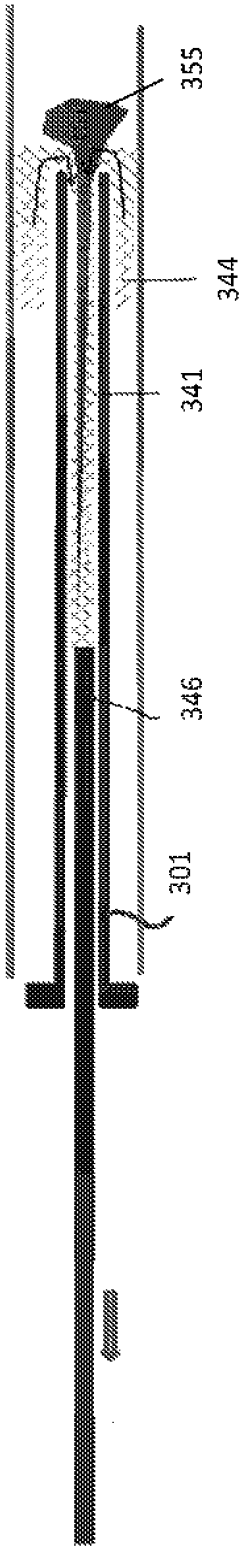


图3F

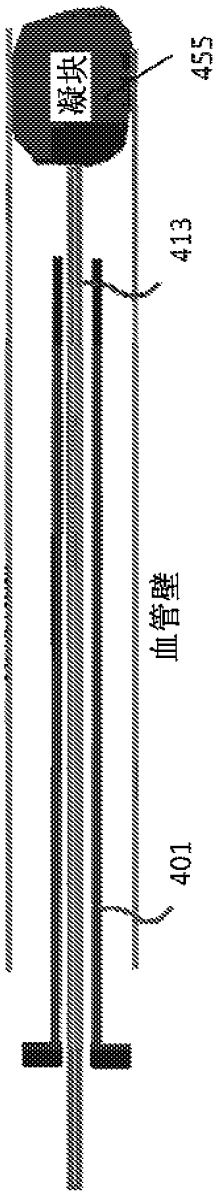


图4A

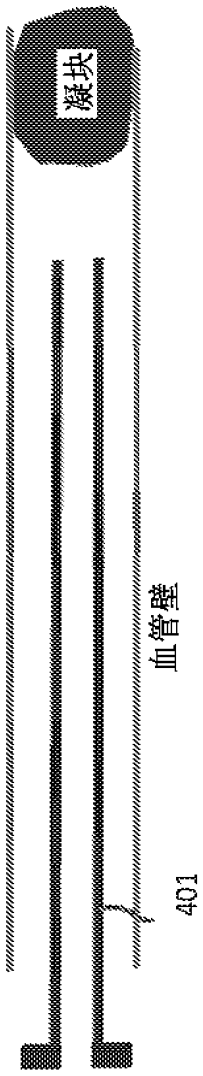


图4B

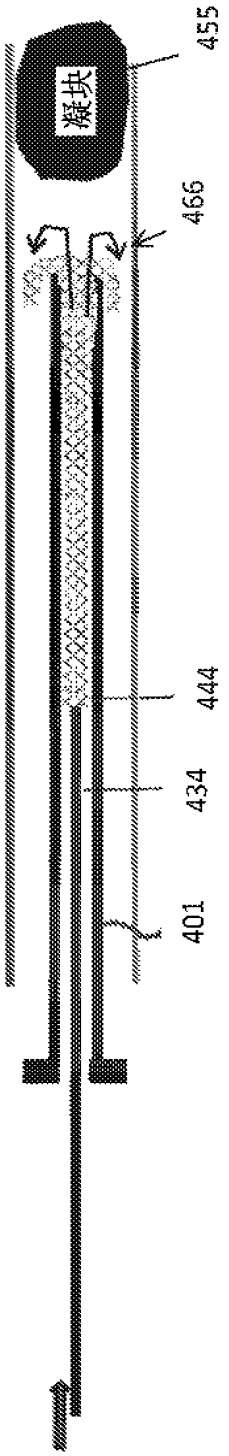


图4C

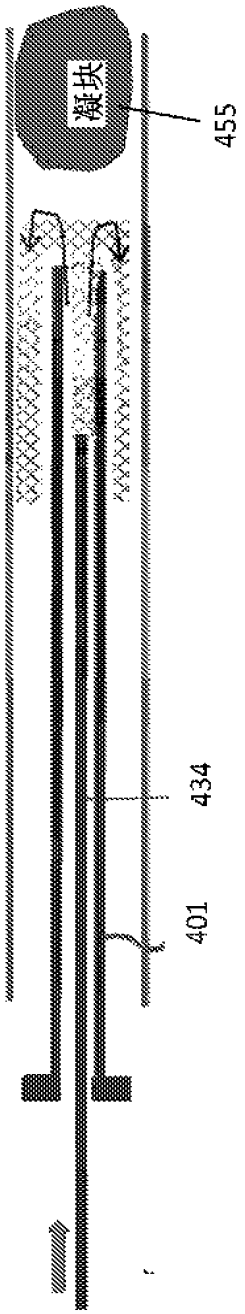


图4D

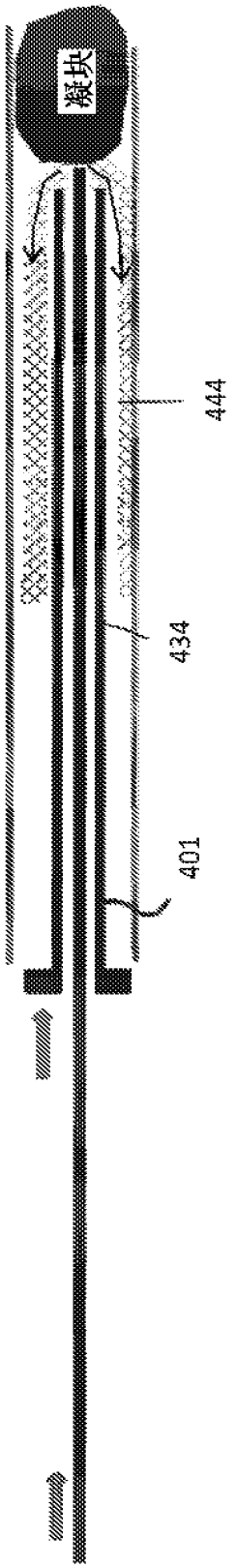


图4E

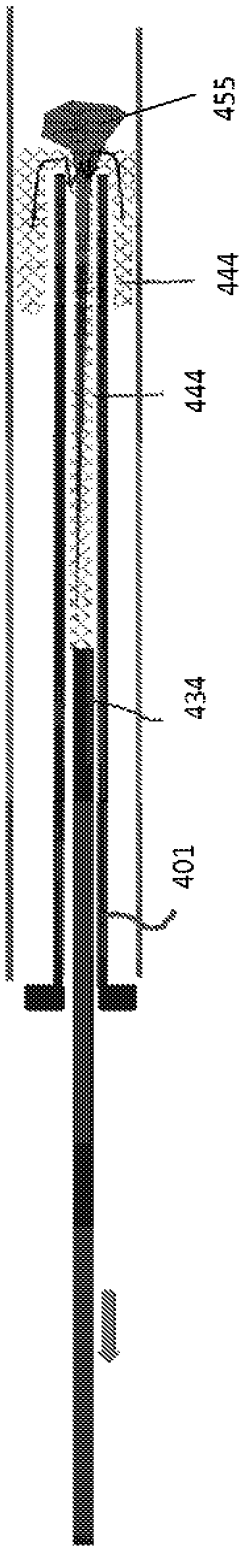


图4F

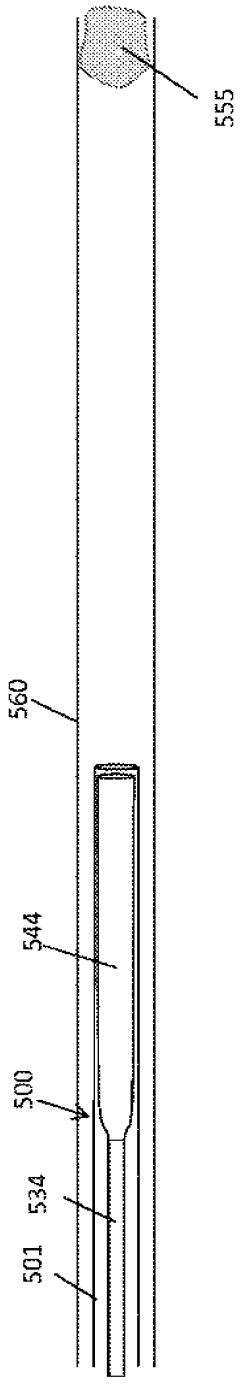


图5A

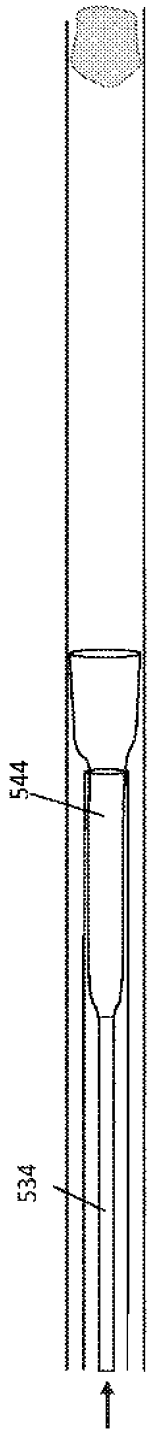


图5B

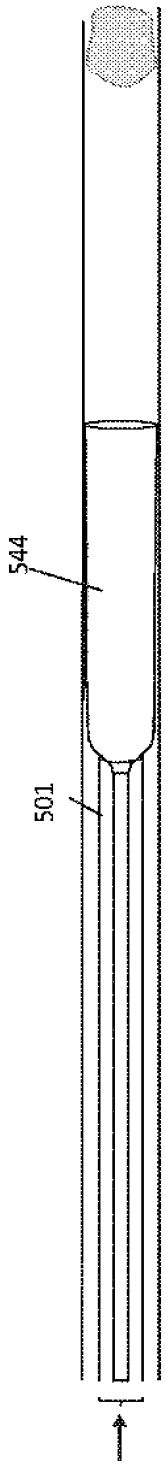


图5C

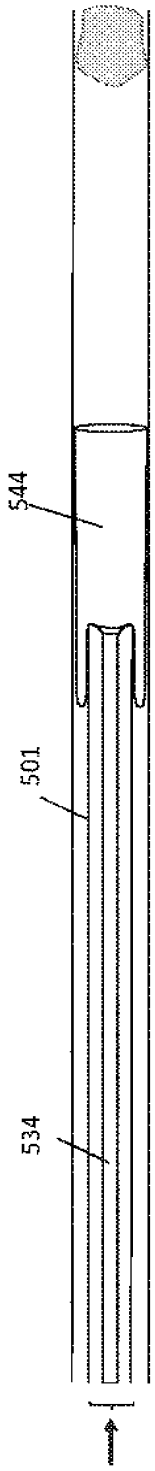


图5D

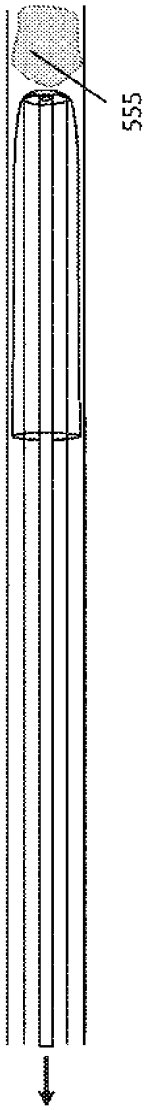


图5E

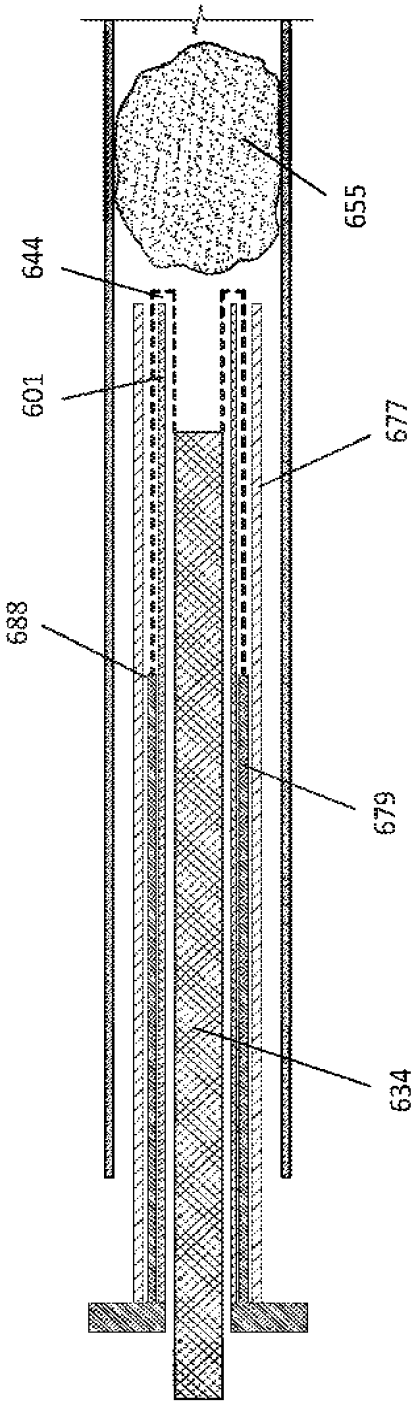


图6A

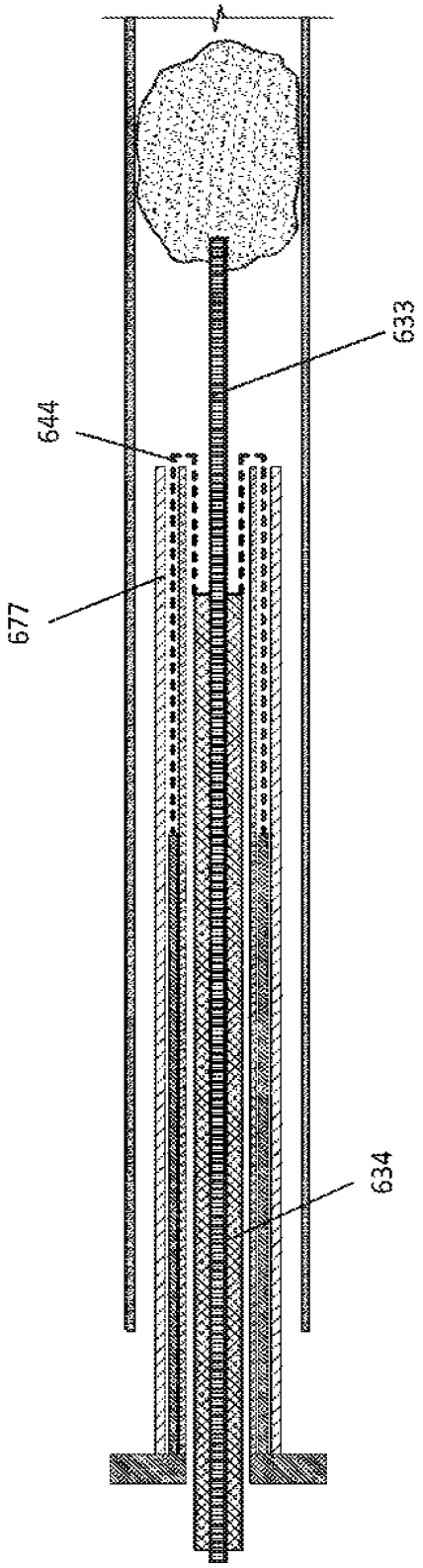


图6B

61

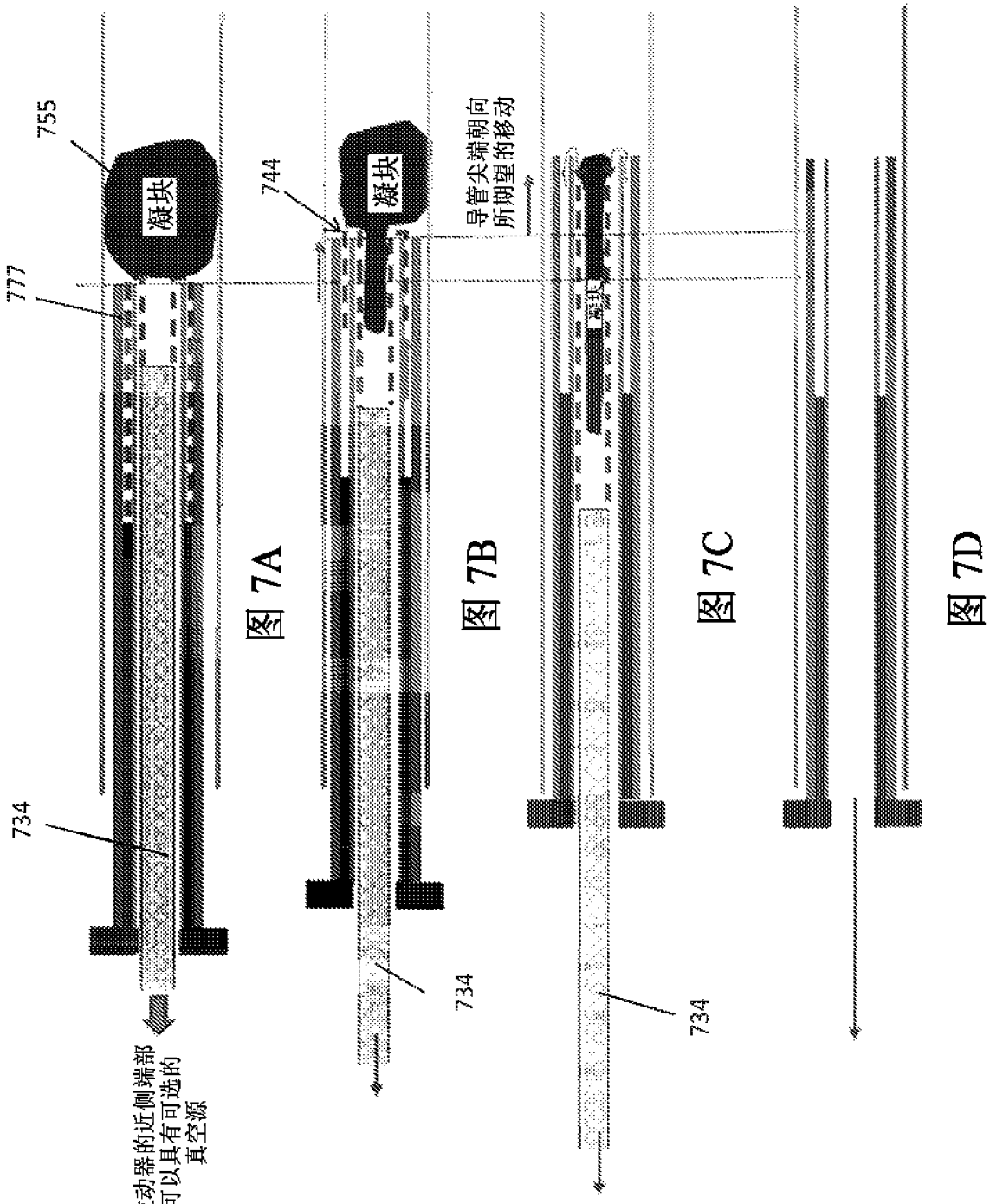


图 7A 图 7B 图 7C 图 7D

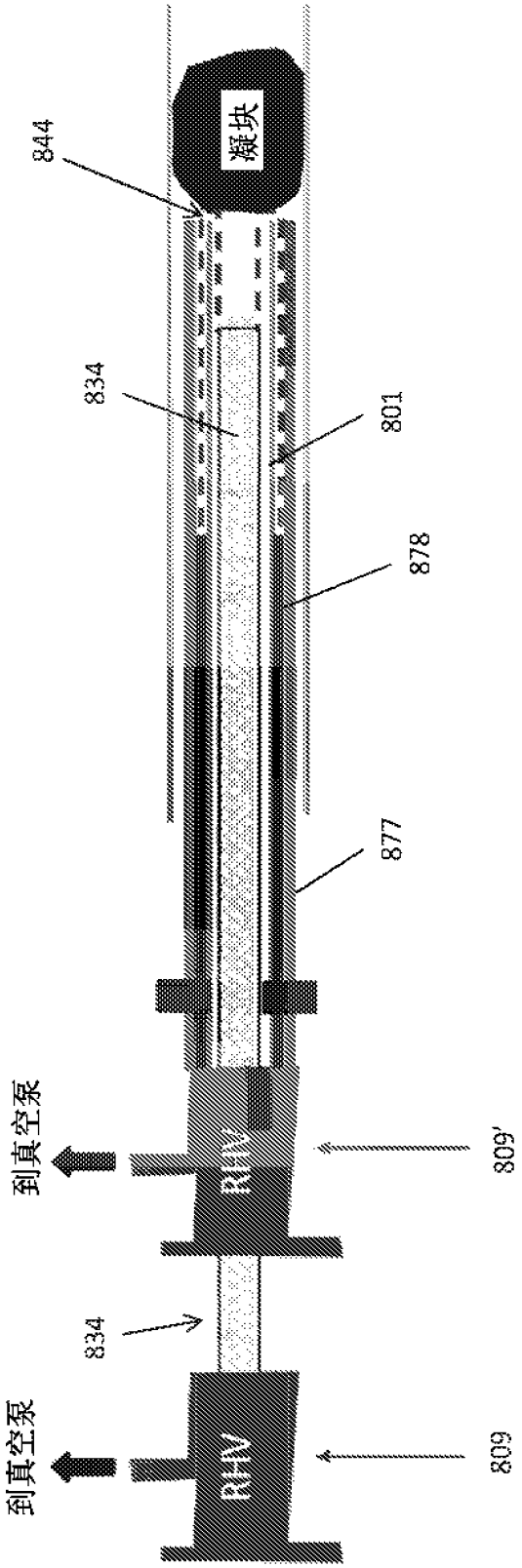


图8

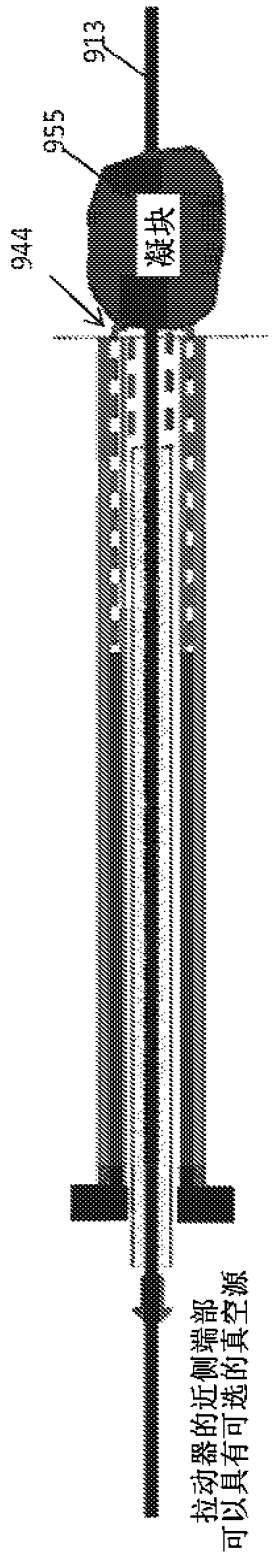


图9A

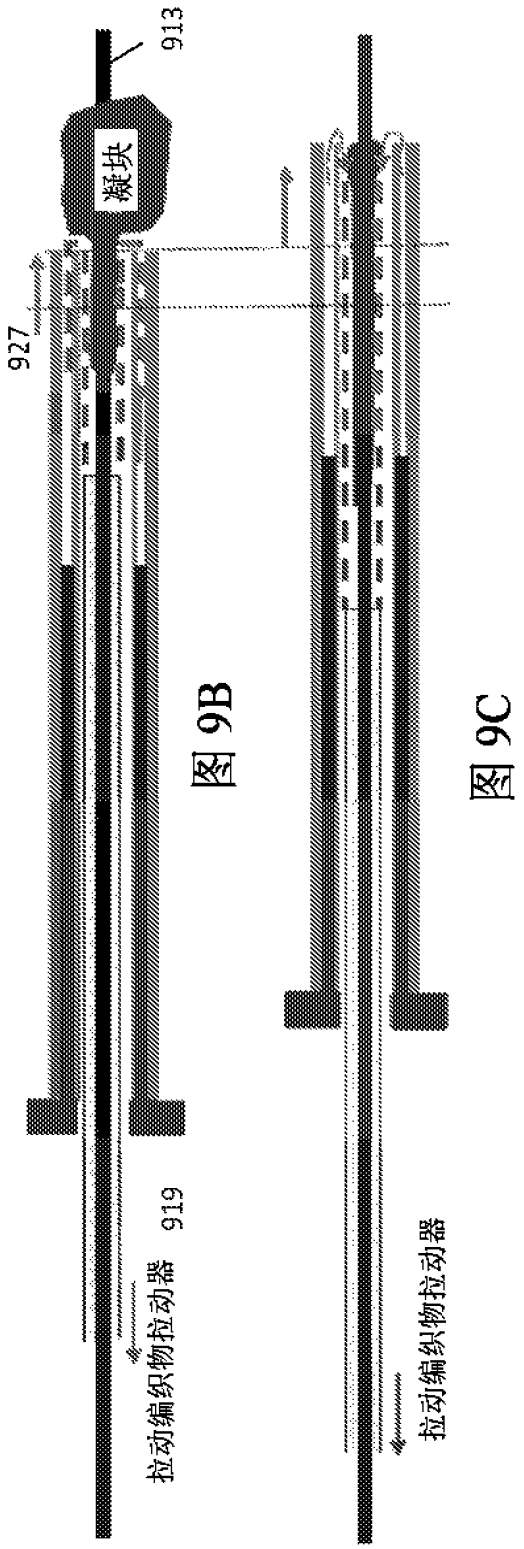


图 9B

图 9C

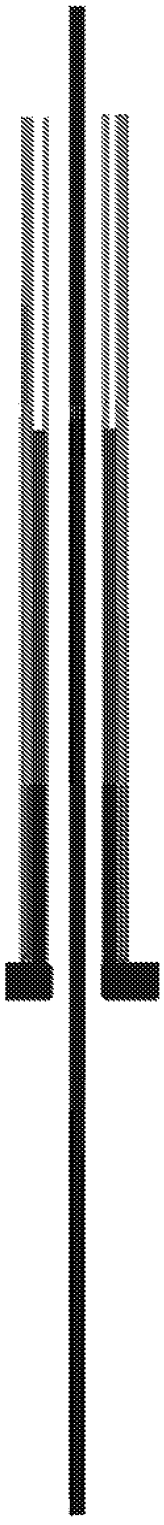


图9D

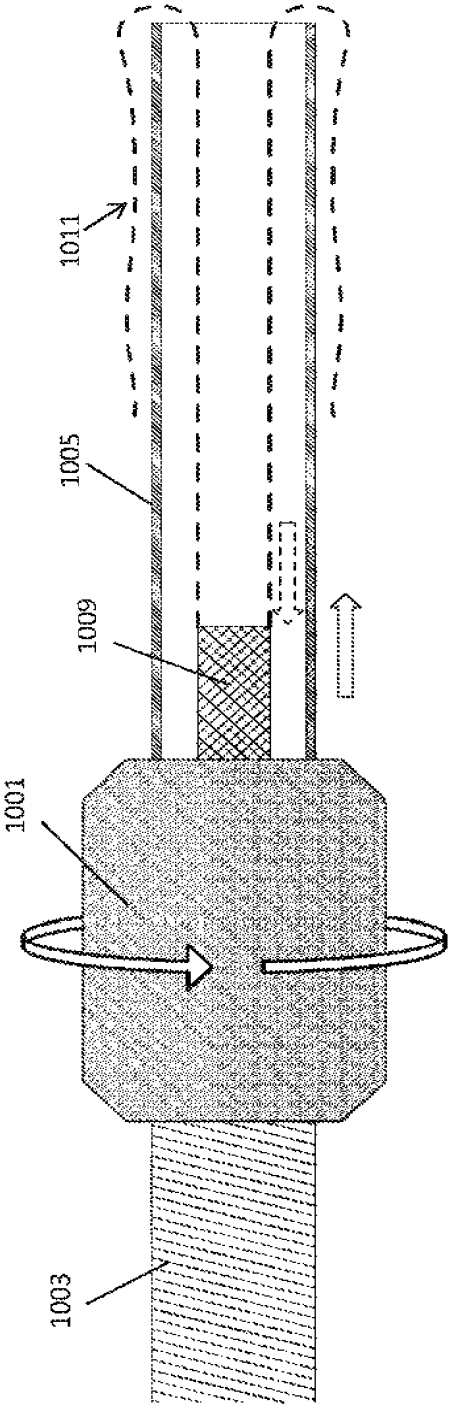


图10A

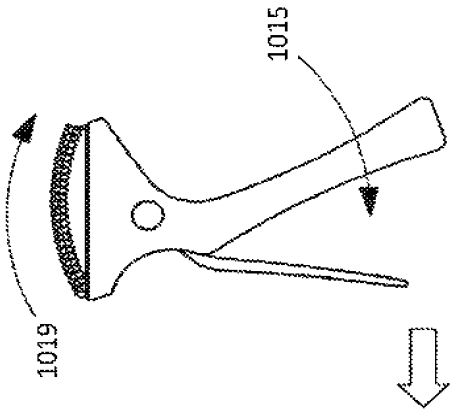


图10B

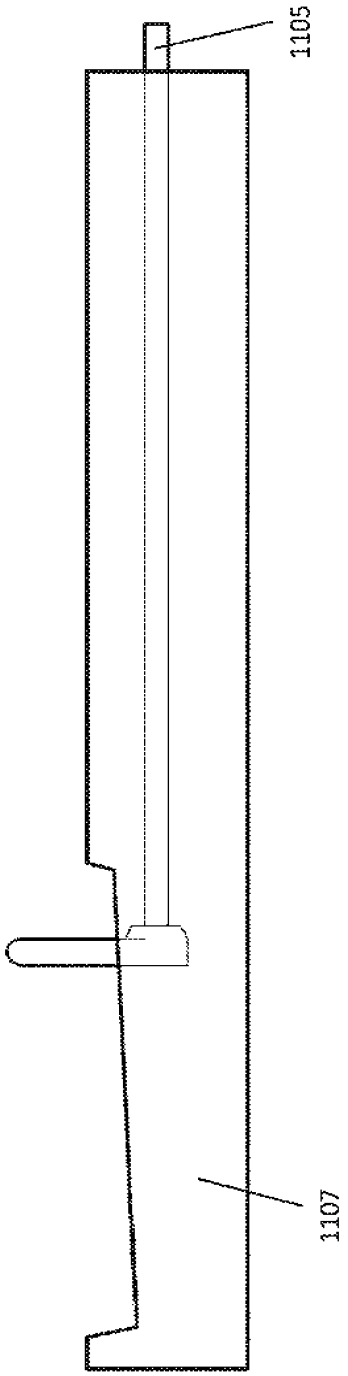


图11A

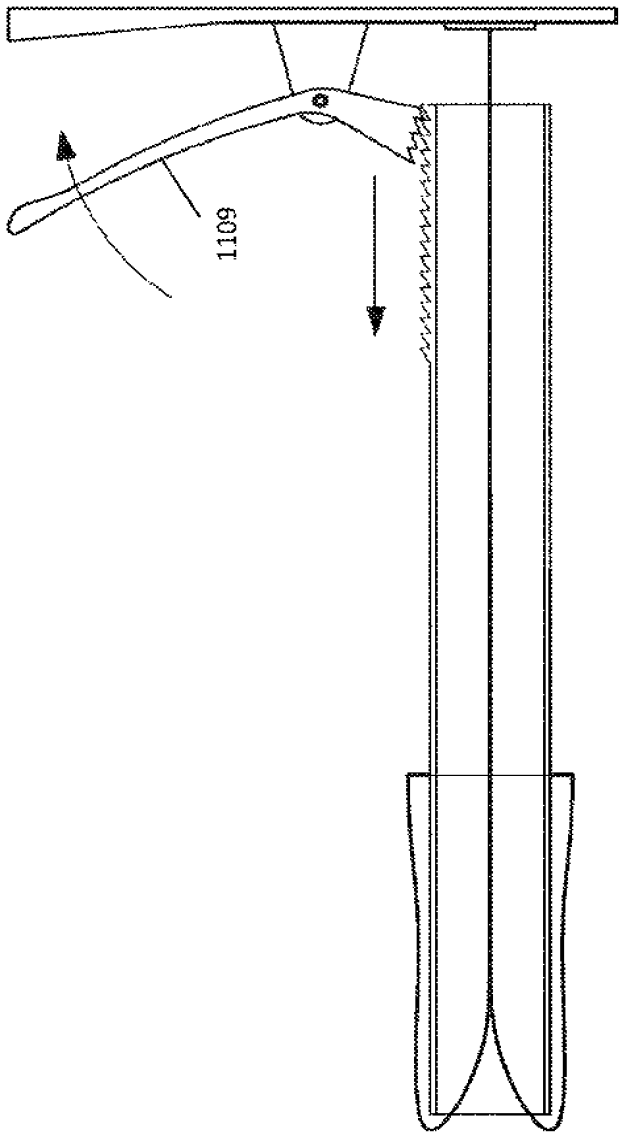


图11B

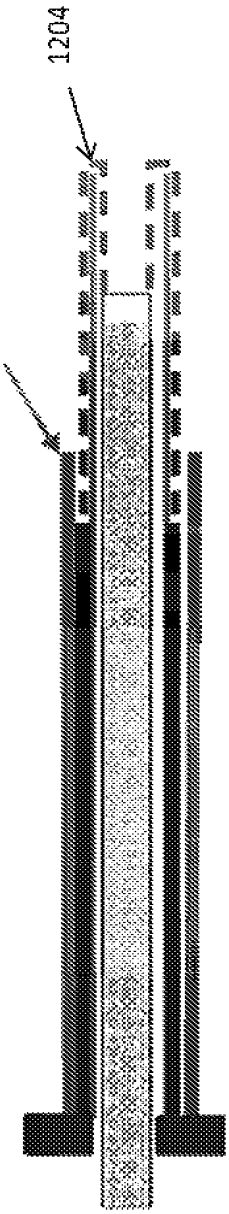


图12A

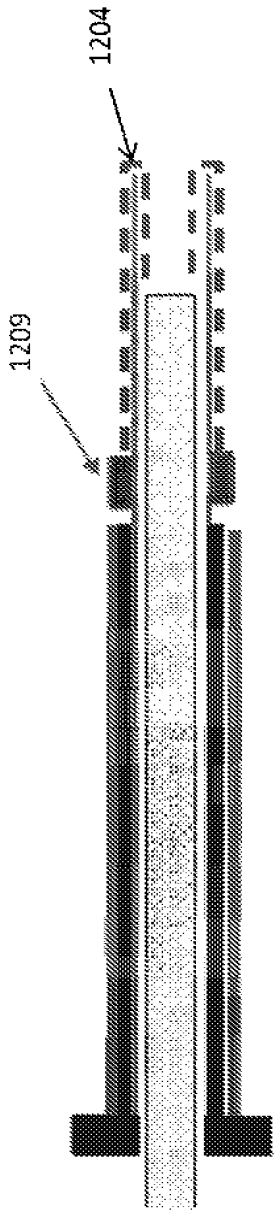


图12B

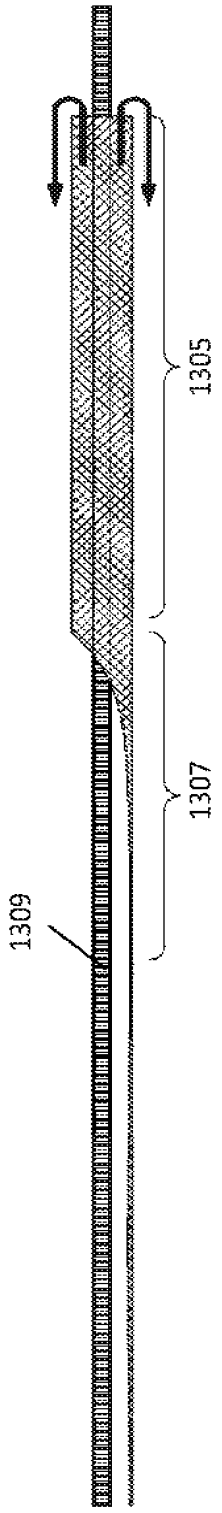


图13A

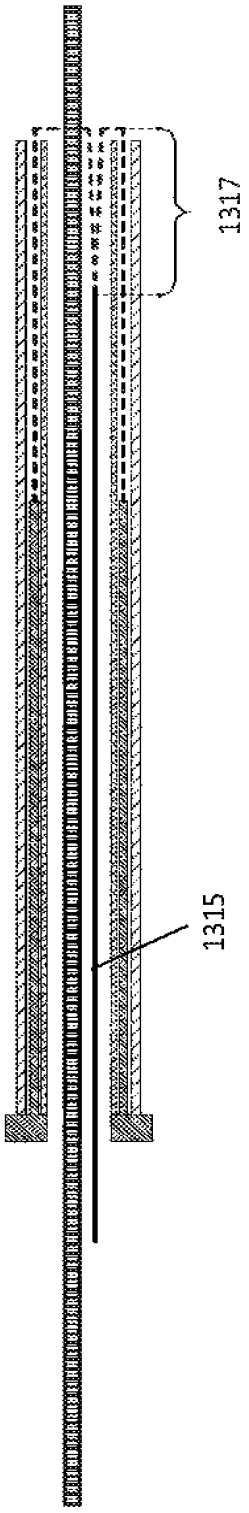


图13B

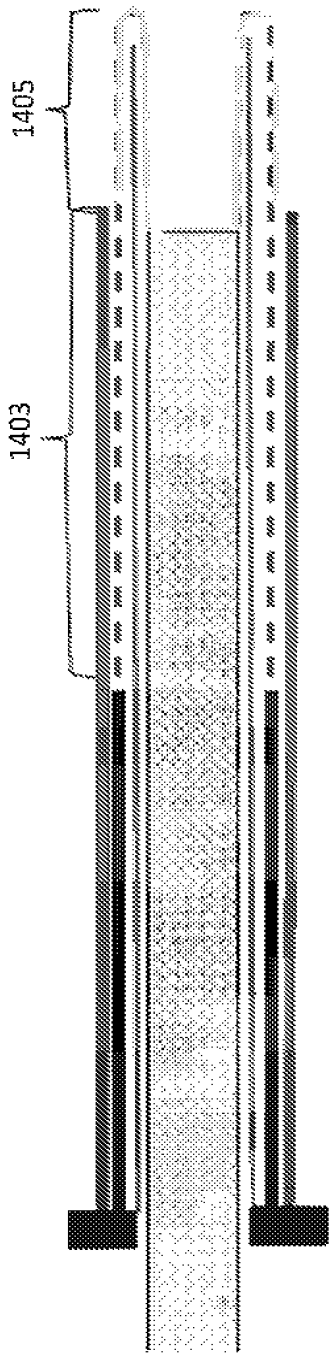


图14

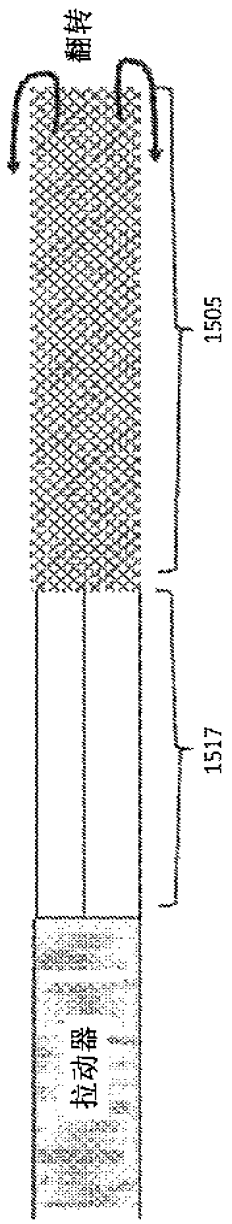


图15A

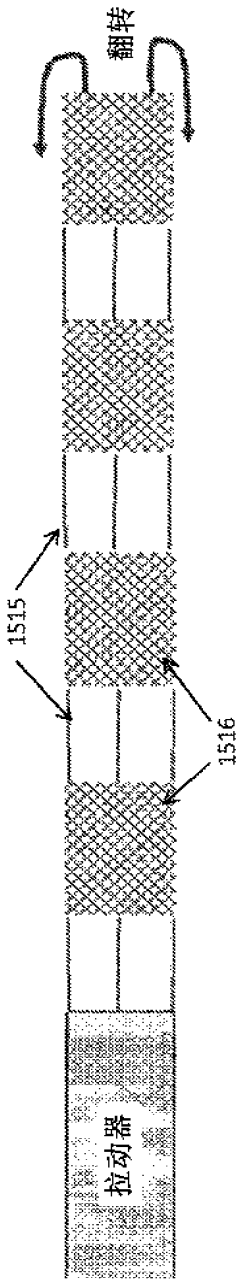


图15B

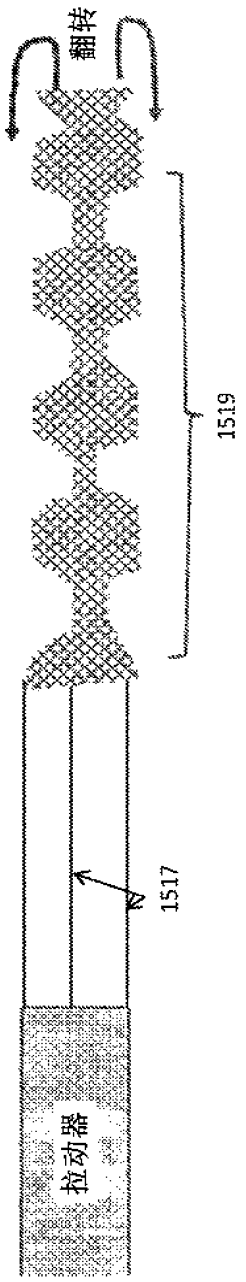


图15C

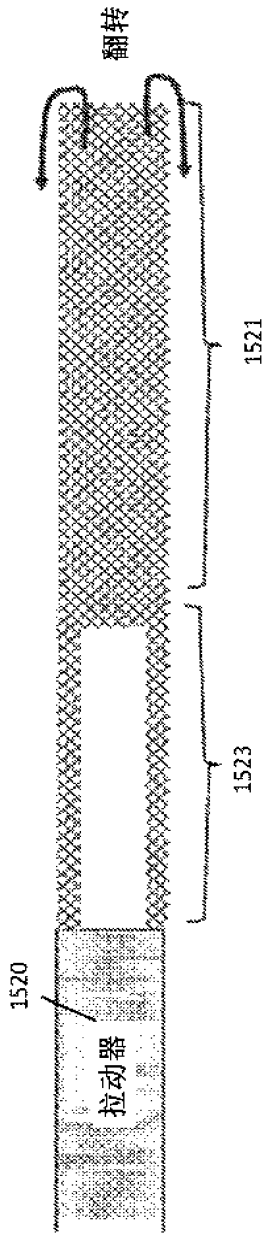


图15D

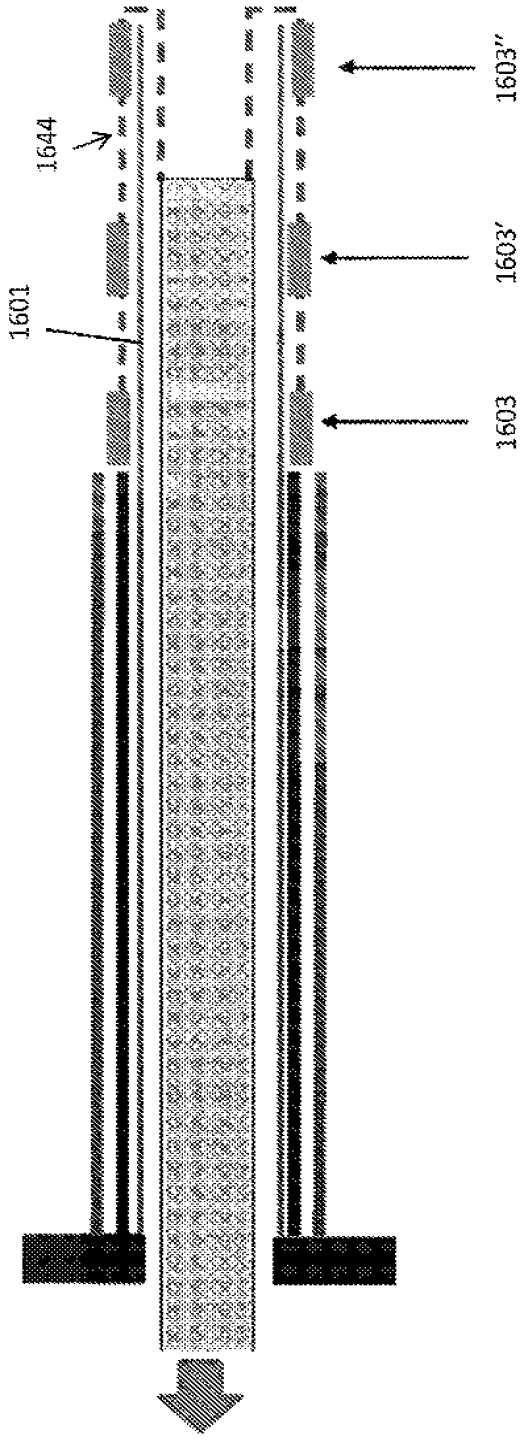


图16

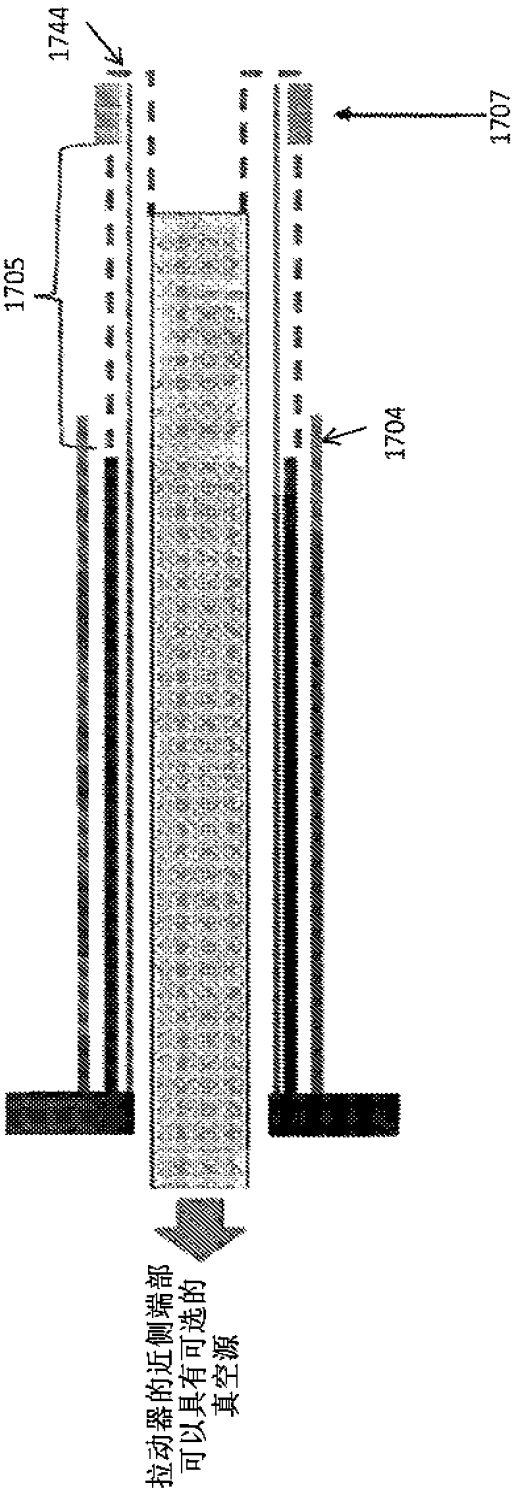


图17

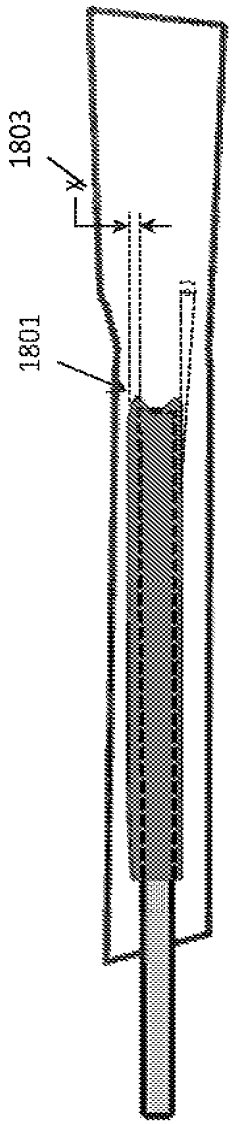


图18A

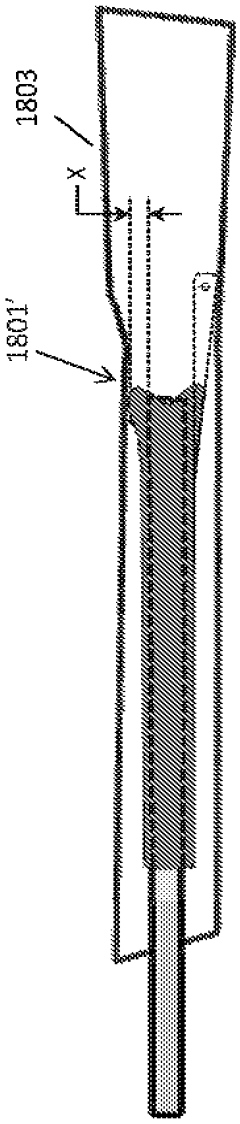


图18B

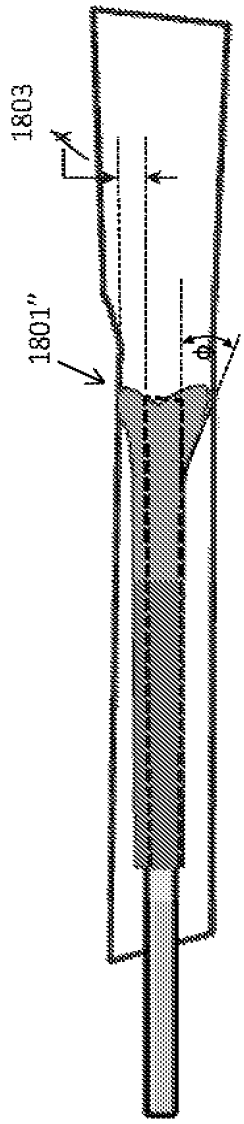


图18C

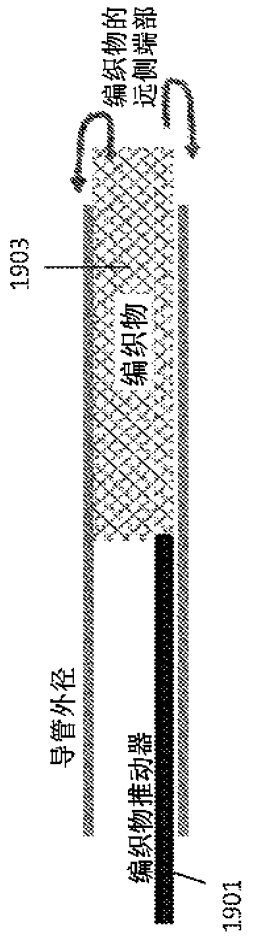


图19A

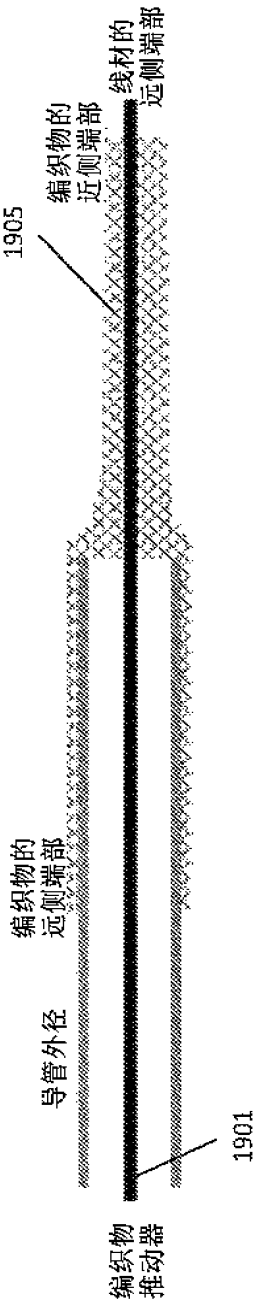


图19B

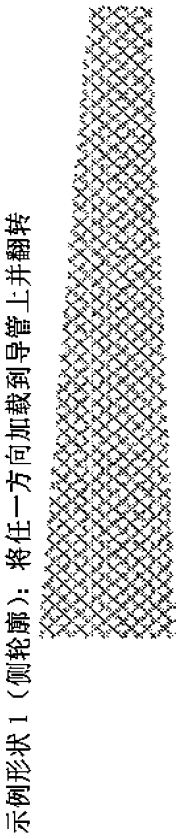


图20A

图20B

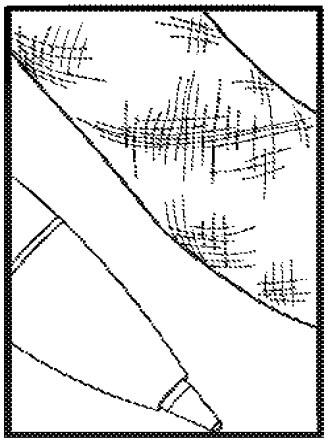


图21A

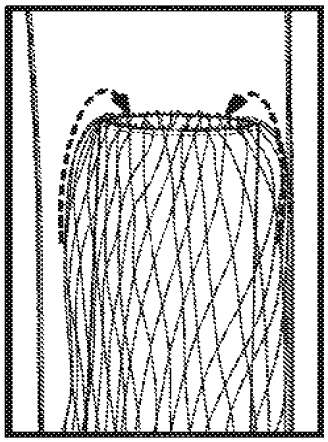


图21B

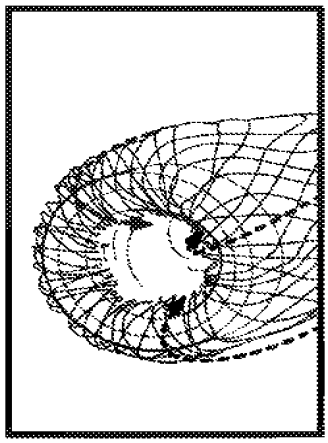


图21C

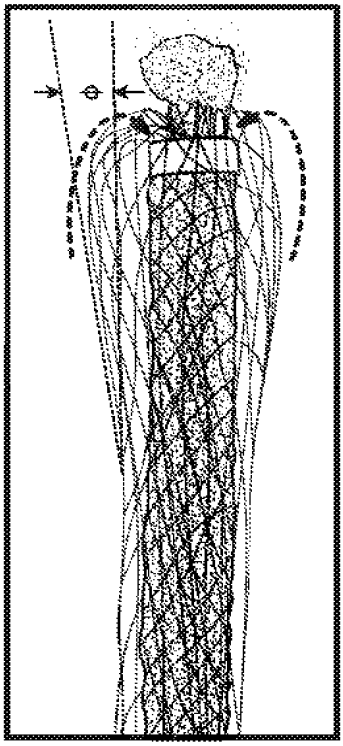


图21D

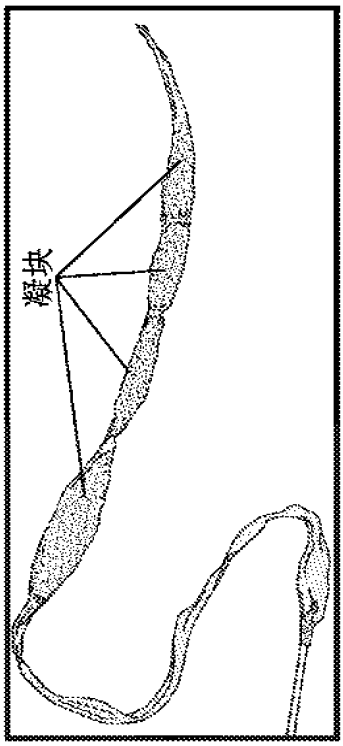


图22

90

图23A

图23B

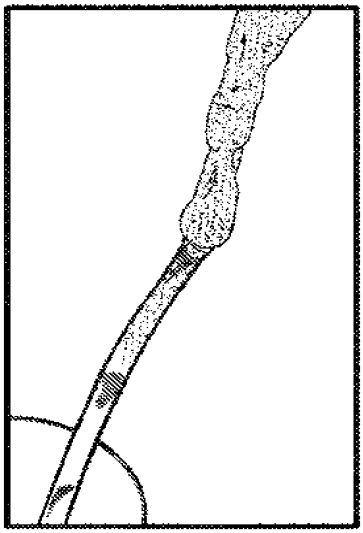


图23C

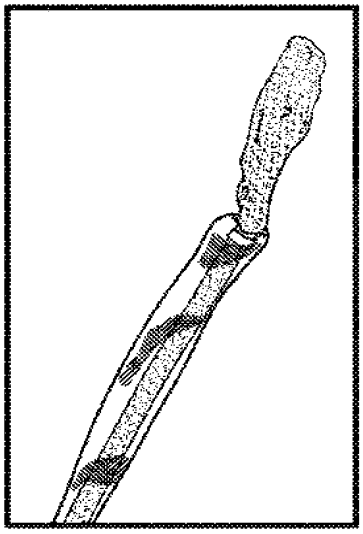


图23D

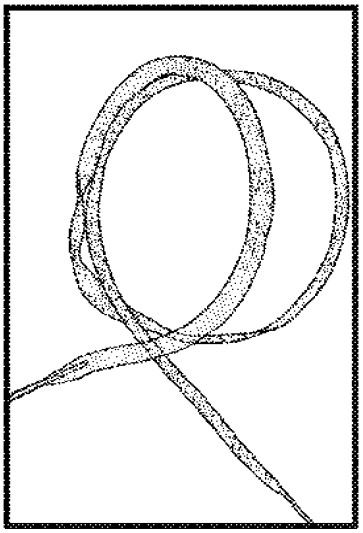


图23E

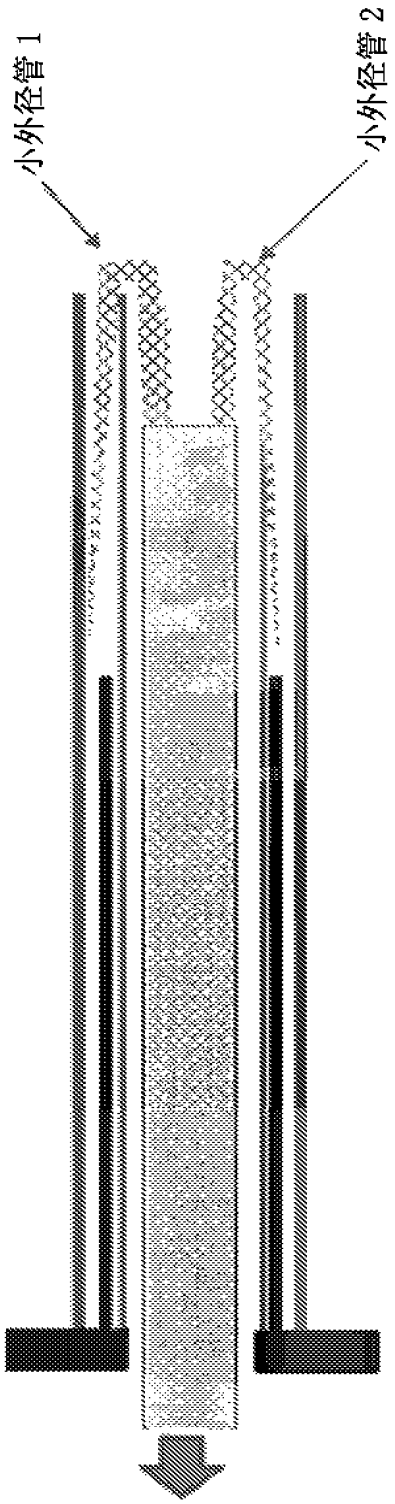


图24

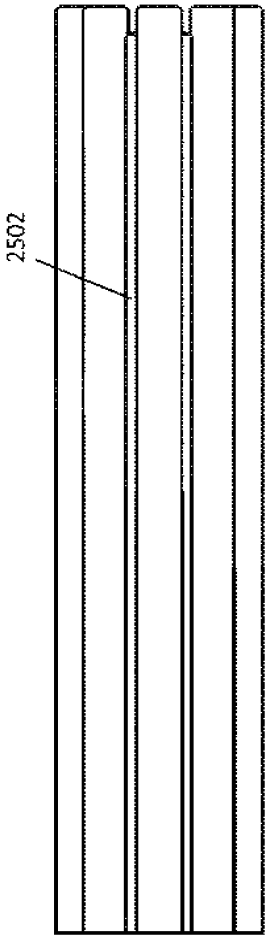


图25A

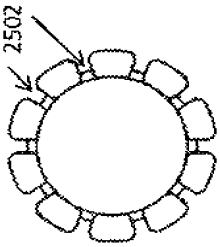


图25B

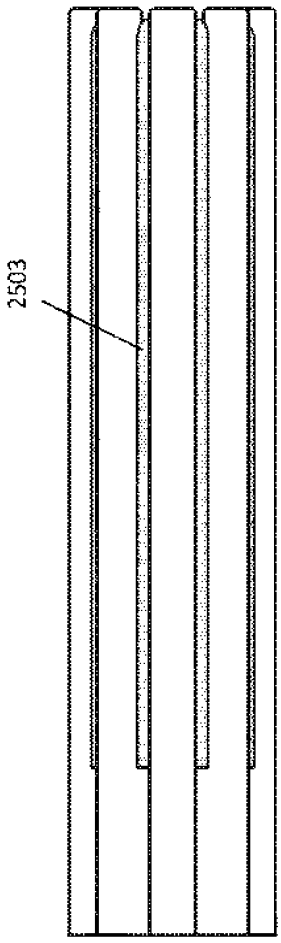


图25C

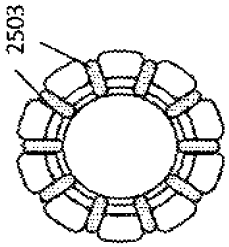


图25D

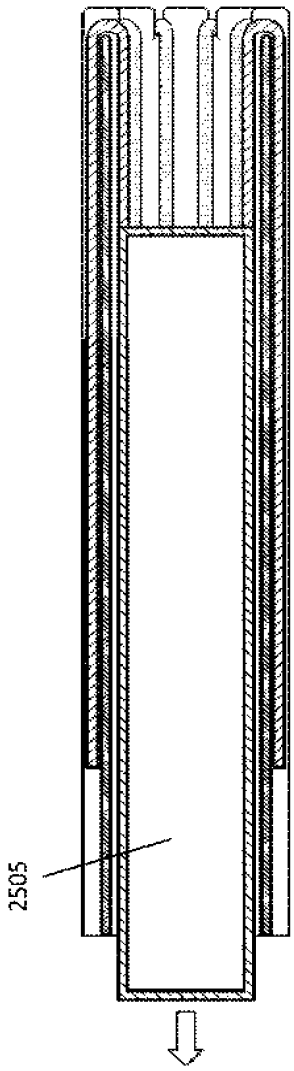


图25E

图25F

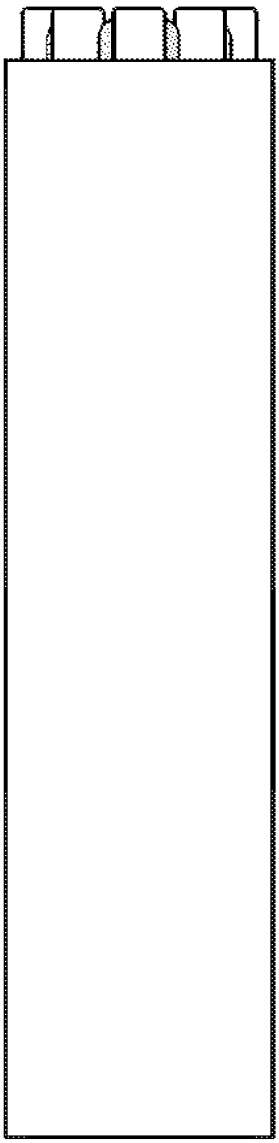


图26A

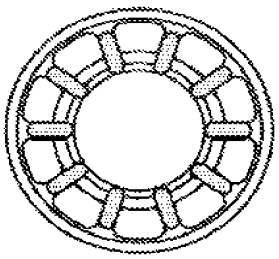


图26B

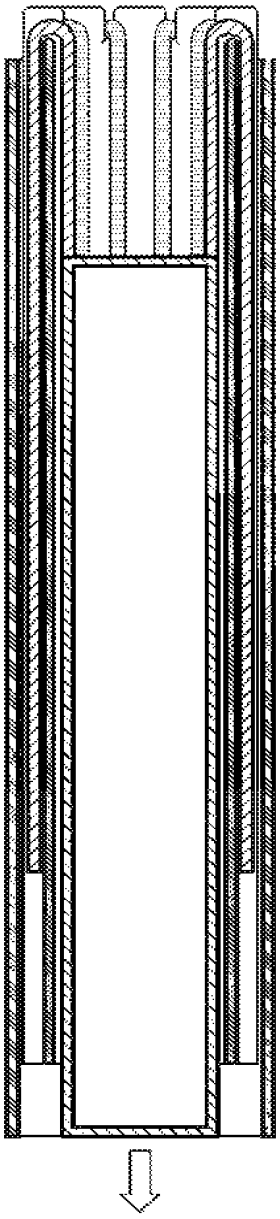


图27A

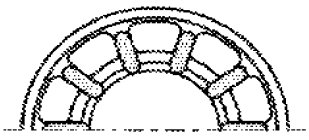


图27B

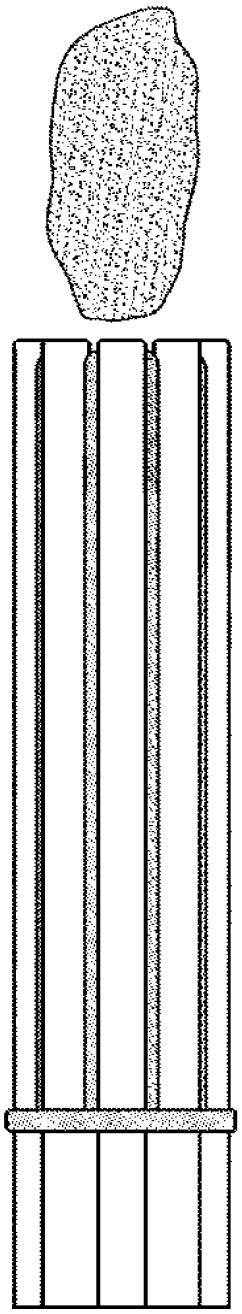


图28

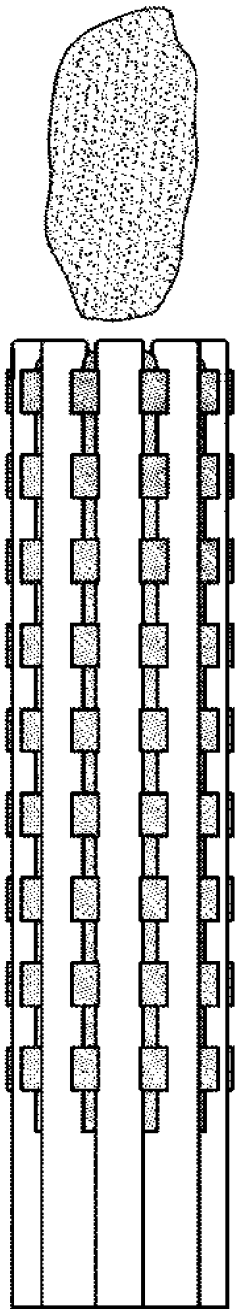


图29

图30A

图30B

图30C

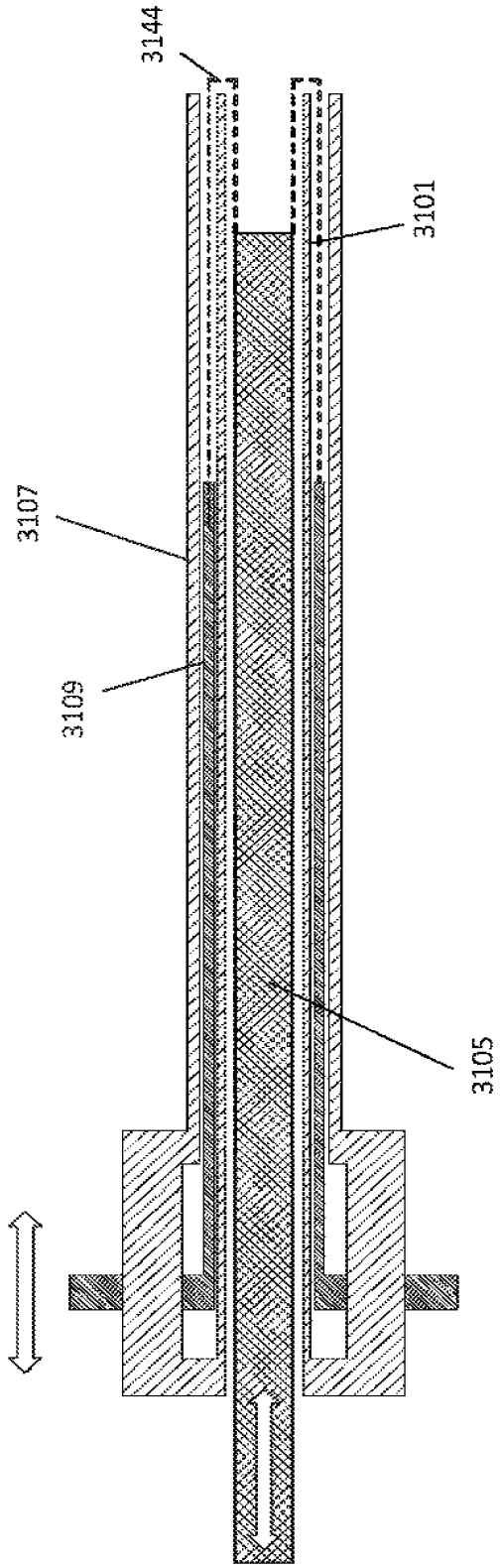


图31

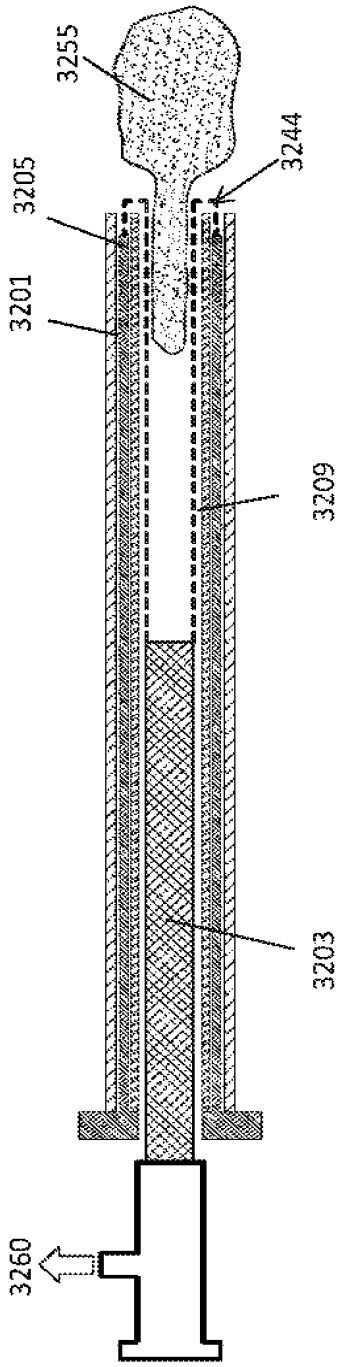


图32

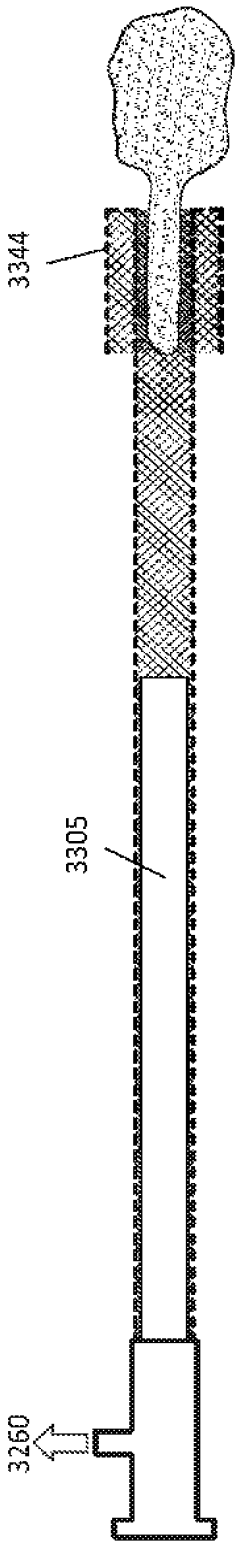


图33

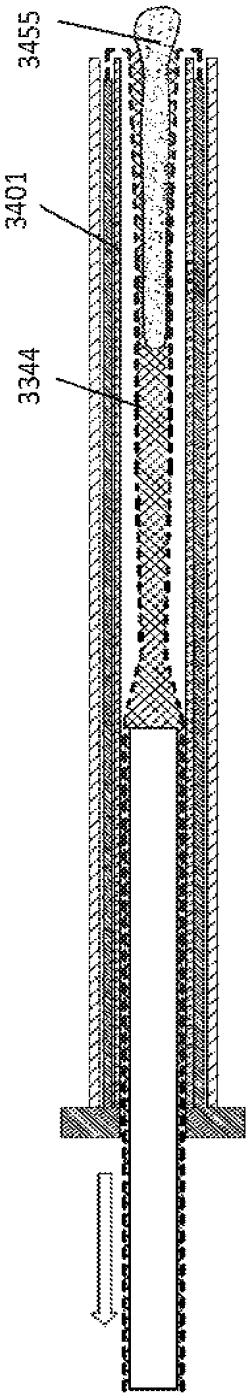


图34

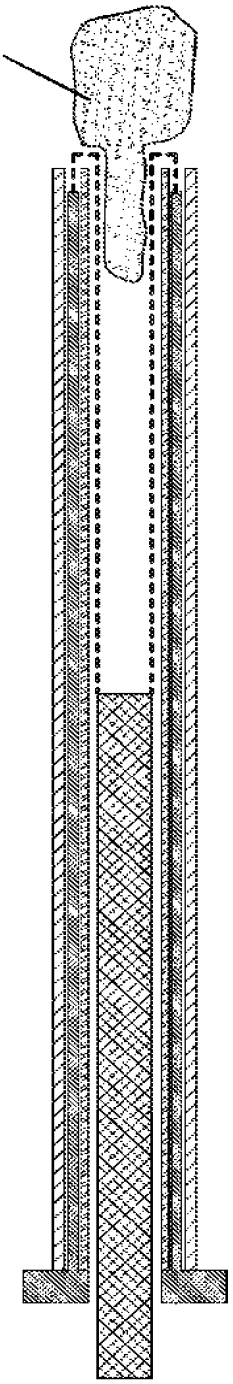


图35A

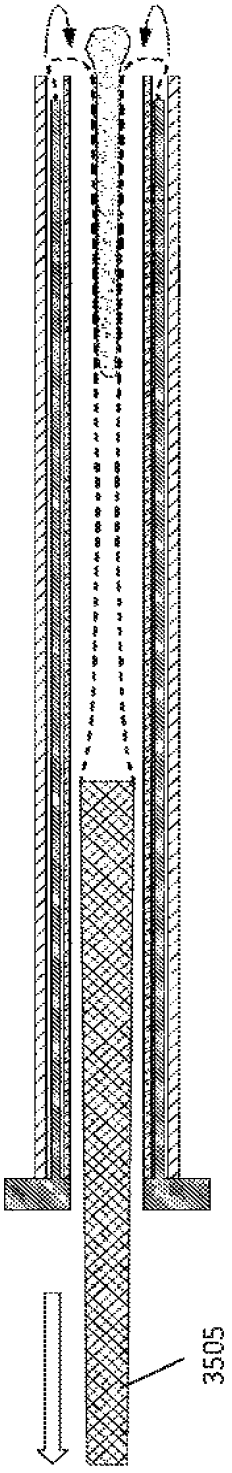


图35B

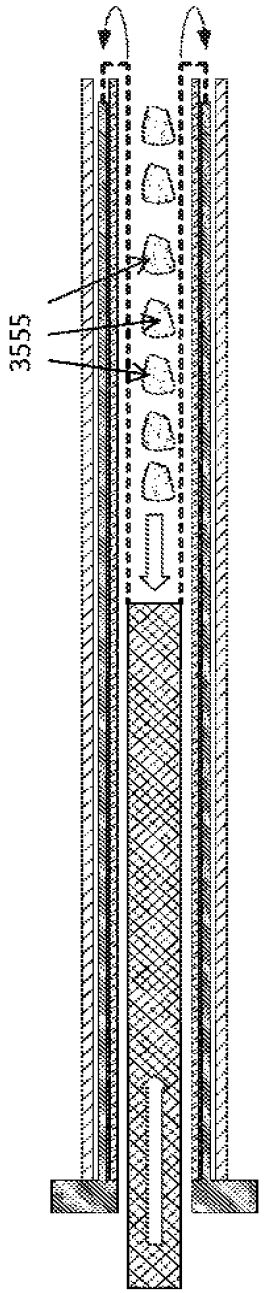


图35C

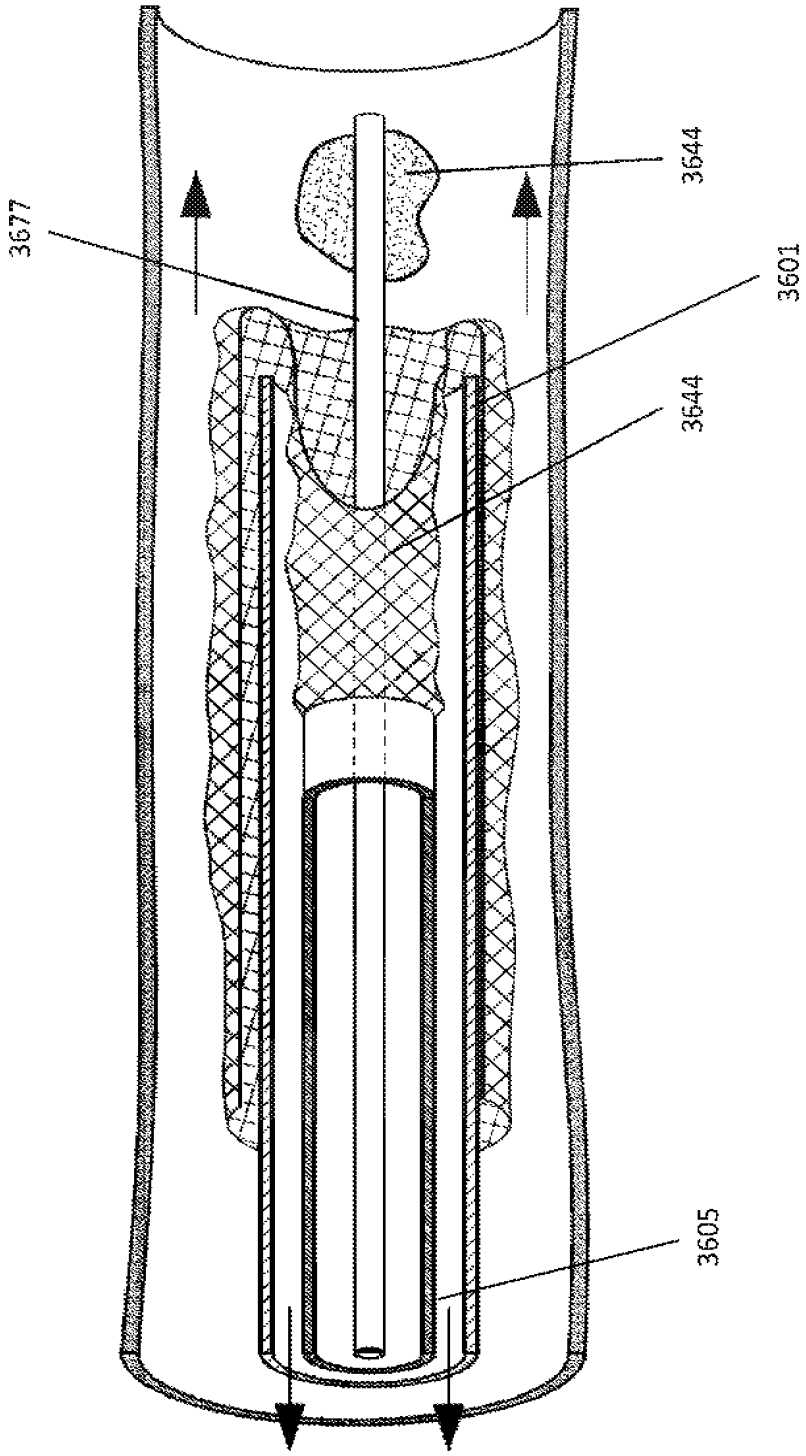


图36

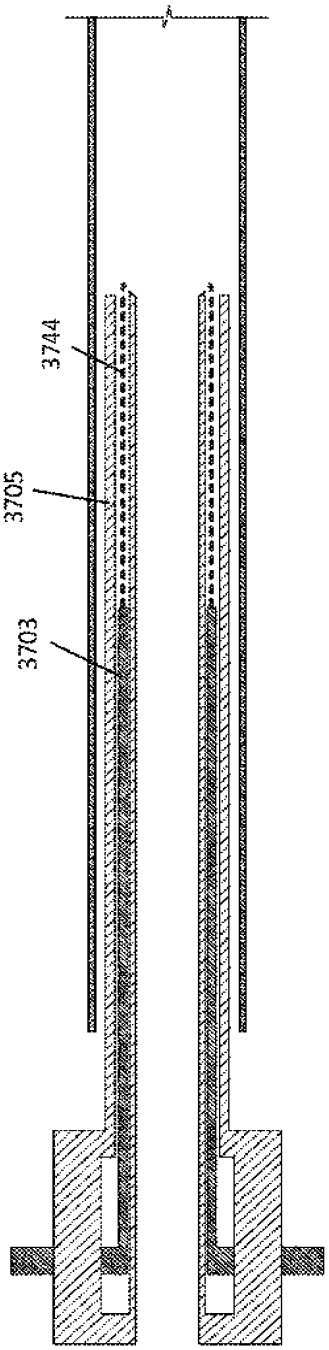


图37A

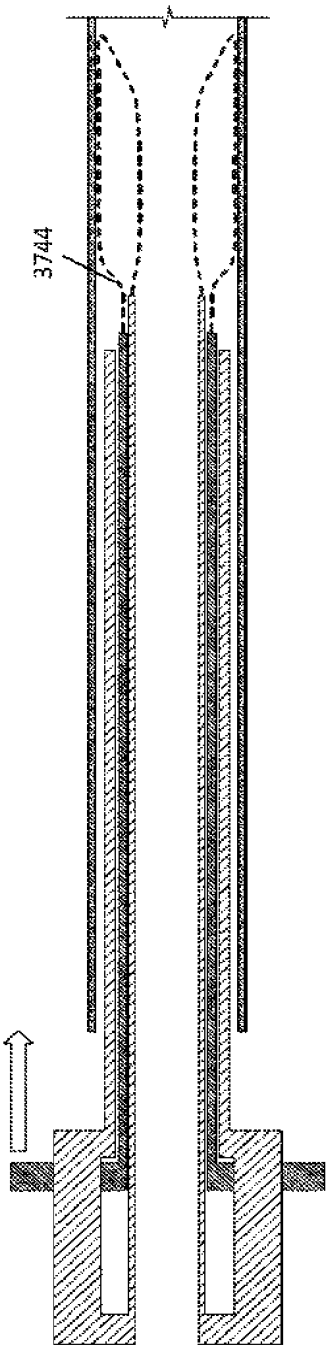


图37B

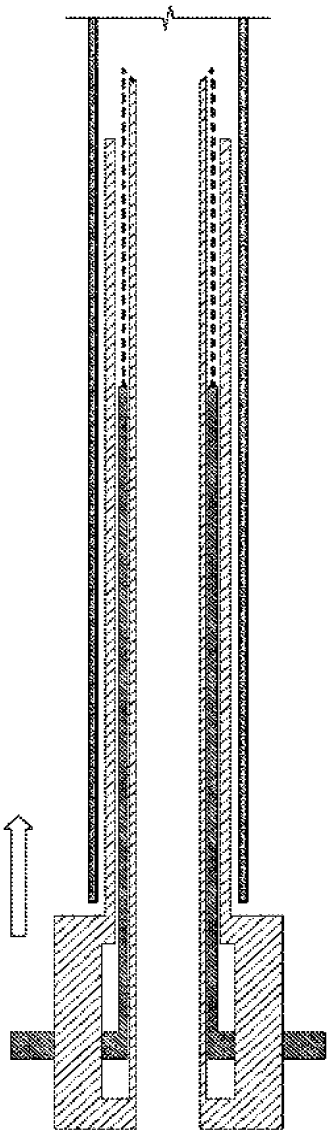


图37C

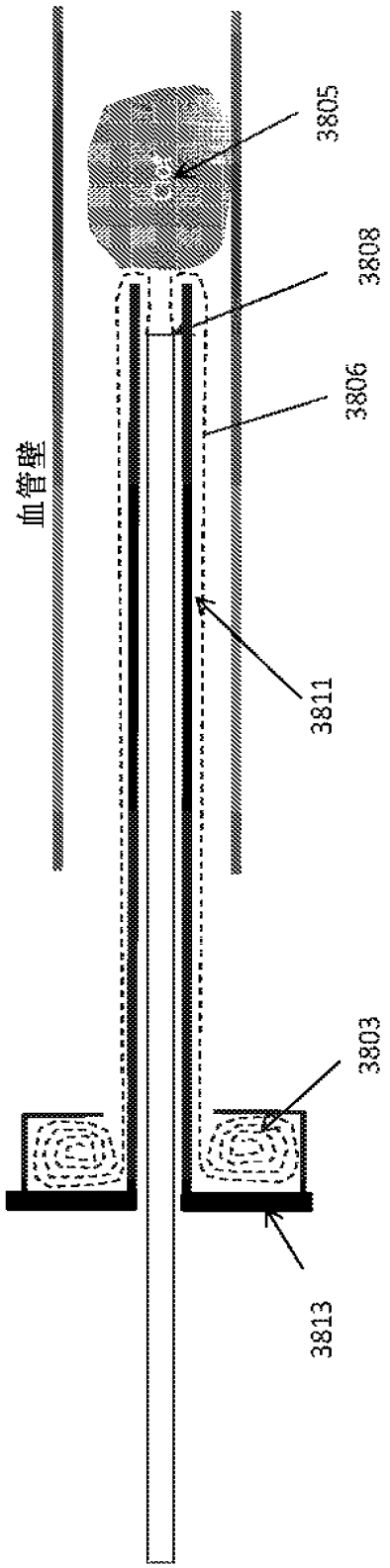


图38A

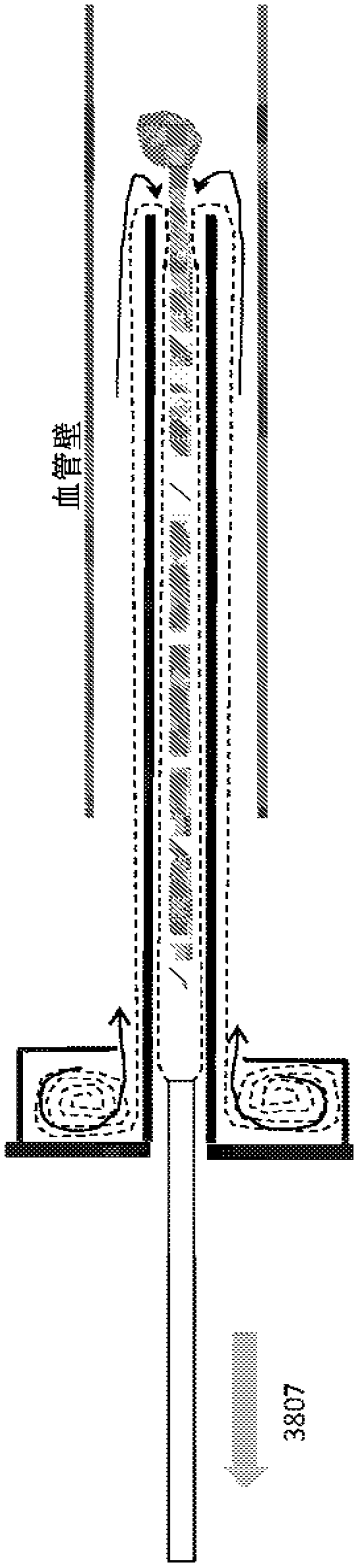


图38B

(19)中华人民共和国国家知识产权局

(12)发明专利申请

(10)申请公布号 CN 111281482 A
(43)申请公布日 2020.06.16

(21)申请号 202010148570.0

(22)申请日 2016.02.15

(30)优先权数据
62/284,300 2015.09.28 US
62/284,752 2015.10.08 US
62/245,560 2015.10.23 US

(62)分案原申请数据
201680056752.7 2016.02.15

(71)申请人 斯瑞克公司
地址 美国加利福尼亚州

(72)发明人 E·斯科特·格林哈尔希
迈克尔·P·华莱士

(74)专利代理机构 北京康信知识产权代理有限责任公司 11240
代理人 刘凤迪

(51)Int.Cl.
A61B 17/22(2006.01)
A61B 17/221(2006.01)
A61B 17/00(2006.01)

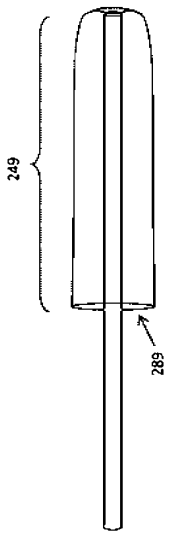
权利要求书2页 说明书31页 附图83页

(54)发明名称

机械取栓装置

(57)摘要

一种用于从血管去除凝块而没有堵塞的机械取栓装置，包括：导管，具有远侧端部区域和远侧端部开口，其中，远侧端部区域的在远侧端部开口处的硬度大于远侧端部区域的紧邻远侧端部开口的区域的硬度，进一步其中，远侧端部开口具有圆形唇缘轮廓；柔性管，在导管内延伸并且在导管的远侧端部上翻折回来，其中，柔性管被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上滑动并翻转；以及穿过导管和柔性管的导丝腔，被配置成使导丝通过。



CN 111281482 A

1.一种用于从血管去除凝块而不堵塞的机械取栓装置,所述装置包括:

导管,具有远侧端部区域和远侧端部开口,其中,所述远侧端部区域的在所述远侧端部开口处的硬度大于所述远侧端部区域的紧邻所述远侧端部开口的硬度,进一步其中,所述远侧端部开口具有圆形唇缘轮廓;

柔性管,在所述导管内延伸并且在所述导管的所述远侧端部上翻折回来,其中,所述柔性管被配置成当在所述导管内向近侧拉动所述柔性管的第一端部时在所述远侧端部开口上滑动并翻转;以及

穿过所述导管和所述柔性管的导丝腔,被配置成使导丝通过。

2.根据权利要求1所述的装置,其中,所述柔性管具有大于5cm的长度,并且所述柔性管被配置成使得通过向所述柔性管的远侧端部施加小于1000克的力,能将所述柔性管收回到所述导管中。

3.根据权利要求1所述的装置,其中,所述柔性管包括编织管。

4.根据权利要求1所述的装置,其中,所述柔性管的在所述导管的所述远侧端部上翻折回来的区域形成唇缘,所述唇缘相对于所述导管的长轴线具有5°至60°之间的滚动角度(Φ)。

5.根据权利要求1所述的装置,其中,延伸穿过所述导管并且在所述导管的所述远侧端部上翻折回来的所述柔性管使所述导管的远侧5cm的刚度增加小于所述导管的所述远侧5cm的所述刚度的15%,而不使所述柔性管延伸穿过所述导管和在所述导管的所述远侧端部上翻折回来。

6.根据权利要求1所述的装置,还包括位于所述柔性管上的可释放附件,所述可释放附件被配置成当以大于0.01N的预定力阈值的力拉动所述柔性管时释放。

7.根据权利要求1所述的装置,其中,所述柔性管被配置成当所述柔性管在所述导管中被轴向地且向近侧拉动时径向地压缩5%至20%之间。

8.根据权利要求1所述的装置,还包括在所述导管和所述柔性管上延伸的外导管。

9.根据权利要求1所述的装置,其中,所述柔性管被配置成当在所述导管内向近侧拉动所述柔性管的第一端部时在所述远侧端部开口上翻转,其中,所述柔性管具有低泊松比,使得网状的所述柔性管当被用足够的力在所述导管内向近侧拉动时的直径大于所述导管的内径的一半,以在所述远侧端部开口上翻转。

10.根据权利要求1所述的装置,还包括在所述导管内并耦接到所述柔性管的远侧端部的细长拉动器,其中,所述细长拉动器包括具有内腔的海波管,所述内腔与穿过所述柔性管的所述导丝腔连续。

11.根据权利要求1所述的装置,还包括围绕所述柔性管的远侧端部区域的保持环,所述保持环被配置成将所述柔性管保持抵靠在所述导管上。

12.根据权利要求1所述的装置,还包括真空连接件,所述真空连接件用于将所述导丝腔耦接到真空以通过所述导丝腔施加真空。

13.根据权利要求1所述的装置,还包括外导管真空泵,所述外导管真空泵耦接到所述导管与所述柔性管之间的空间并且被配置成在所述导管的位于所述导管的内壁与所述柔性管之间的腔内施加真空。

14.根据权利要求1所述的装置,还包括:拉动器,其中,所述柔性管的远侧端部耦接到

所述拉动器的远侧端部;以及外导管,所述外导管布置在所述导管上且邻近于所述柔性管的近侧端部,所述装置还包括具有控制器的手柄,所述控制器被配置成协调推进所述外导管以向远侧推动所述柔性管的所述近侧端部和向近侧拉动所述拉动器以将所述柔性管的所述近侧端部拉入所述导管。

15.根据权利要求1所述的装置,所述柔性管被能释放地保持,并且所述柔性管被配置成当用大于0.01N的预定力阈值的力拉动所述柔性管时释放。

机械取栓装置

[0001] 本申请是申请日为2016年2月15日、申请号为201680056752.7的中 国专利发明申请“机械取栓装置和方法”的分案申请。

[0002] 相关申请的交叉引用

[0003] 本专利申请要求以下临时专利申请中的每一个的优先权，其中的每一 个的全部内容通过引证结合于本文：2015年9月28日提交的美国临时专 利申请第62/284,300号；2015年10月8日提交的美国临时专利申请第 62/284,752号；以及2015年10月23日提交的美国临时专利申请第 62/245,560号。

[0004] 本说明书中提到的所有公开和专利申请的全部内容都通过引用结合 于本文，其程度如同每个单独的公开或专利申请被特定地和单独地指示通 过引用结合。

技术领域

[0005] 本文所描述的装置和方法涉及从身体内机械去除物体。具体地，本文 描述了机械取栓装置和方法。

背景技术

[0006] 通常希望尽可能以微创方式从身体中去除组织，以免损伤其他组织。 例如，从脉管系统去除组织(例如，血凝块)可改善患者状况和生活质量。

[0007] 许多脉管系统问题源于流过血管的血液不足。造成血液流量不足或不 规则的一个原因是血管内的阻塞，这被称为血凝块或血栓。出现血栓的原 因很多，包括诸如手术的创伤之后或由于其他原因。例如，在美国超过120 万的心脏病发作中很大一部分是由冠状动脉内形成的血凝块(血栓)引起 的。

[0008] 当形成血栓时，它可以有效地阻止血液流过形成区域。如果血栓横过 脉的内径延伸，则其可以切断通过动脉的血液流动。如果冠状动脉中的一 个是100％形成血栓，则血液流动在该动脉中停止，导致携带红血球的氧 气短缺，例如用于供应心脏壁的肌肉(心肌)。此类血栓形成对于防止血 液损失是不必要的，但是可能由于动脉粥样硬化疾病对动脉壁的损伤而在 动脉内被不期望地引发。因此，动脉粥样硬化的潜在疾病可能不会引起急 性缺氧(缺血)，但可经由诱导血栓形成引发急性缺血。类似地，颈动脉 中的一个的血栓形成可导致中风，这是因为颅内重要神经中枢的供氧不 足。缺氧会降低或禁止肌肉活动，会引起胸痛(心绞痛)，并可导致心肌 死亡，这在某种程度上会永久地使心脏失去活力。如果心肌细胞死亡很广 泛，则心脏将不能泵送足够的血液以供应人体的生命维持需求。局部缺血的程度受许多因素影响，包括可以提供必要氧气的侧支血管和血流的存 在。

[0009] 临床数据表明，去除凝块对于改善预后可能是有益的，甚至是必要的。 例如，在外周脉管系统中，发明和程序可以减少80％的截肢需求。治疗这 些动脉或静脉系统状况的任何方式的最终目标是快速、安全且经济有效地 去除堵塞或恢复通畅。这可以通过血栓溶解、碎裂、血栓抽吸或这些方法 的组合来实现。

[0010] 导管导向取栓术和溶栓治疗通常被认为创伤小，不太可能降低与常规 手术技术

相关的发病率和死亡率。近年来，将化学溶解剂直接给予冠状动 脉已经显示出对具有血栓形成冠状动脉的患者有益处。在此过程中，将导 管立即置于堵塞物的前方，并将链激酶滴定位成在血栓的上游侧定向。链 激酶是一种能够及时溶解纤维蛋白分子的酶。该程序可能需要几个小时， 并不总是成功地打破血栓。此外，其可能导致下游血栓碎片(栓子)，这 可能导致小直径分支的堵塞。美国专利第4,646,736号公开了一种取栓设 备，其可以快速去除阻塞性血栓。然而，该装置的特征在于小的导管尖端 尺寸，并因此不能对凝块施加显著的总力。而且，在旋转线材的“火线” 中，未处于在血管壁上取得的良好位置的凝块不会被纤维切除。对于血流 中游离的凝块尤其如此，这是因为在不存在诸如手指的限制的情况下，在 这些凝块内旋转几乎是不可能的。

[0011] 该取栓设备的其它缺点包括当在旋转期间线材侧向移动时难以在所 有旋转角度期间将凝块保持在线材上方的空间中，这对于扫动动脉腔有时 是需要的。实际上，除了最小的动脉(即直径小于1.5mm)之外，几乎 不可能用旋转线材扫出整个动脉腔。附加的严重的可能的缺点是凝块的碎 片可能在下游成为栓塞。

[0012] 美国专利申请2015/0005781中描述了用于捕获栓子的另一种方法。该 申请描述了具有从远侧端部延伸的篮状件的导管。可以向近侧拉动诸如杆 或线缆的致动器以将篮状件收回到导管中。不幸的是，篮状件阻塞腔的内 部，阻止与定位和/或支撑导丝同时使用，并且篮状件必须保持在导管的远 侧端部中或在其附近。取决于被去除的材料(例如凝块)的硬度，篮状件 的取回通常会使导管的远侧端部收缩，阻止其使用，并且篮状件可能难以 拉入导管中，特别是当保持凝块时。这可能会导致使凝块偏向。最后，在 插入血管中之前，篮状件必须被预加载到导管的远侧端部中，并且预加载 可能既困难又耗时，并且可能在展开之前破坏设备。

[0013] 因此，确实需要一种可以更有效地从身体内去除诸如凝块的组织的取 栓设备，特别是机械取栓设备。本文所描述的是可以解决上面论述的需要 和问题的装置(设备、系统和套件)以及使用它们的方法。

发明内容

[0014] 通常，本文描述了医疗装置，包括医疗设备和包括这些医疗设备的系 统，以及操作这些医疗设备以用于收集对象的方法，所述对象包括但不限 于血凝块(血栓)、组织(活组织检查、小肿瘤、息肉、钙化物、肾结石 等)。本文所描述的装置通常包括细长导管，其具有腔和远侧端部并具有 通向腔中的远侧端部开口。导管可以是具有任何适当直径(例如<1Fr、1Fr 至6Fr、1Fr至9Fr等)的低轮廓神经脉管导管(例如微导管、插入导管 等)。柔性牵引器组件或部分(例如，在本文中可被称为柔性牵引器管或 简单地为柔性管)通常定位在导管内并且可在导管内纵向滑动，并且布置 成使得远侧端部区域(“远侧牵引器区域”)在导管的远侧端部上翻折回来。柔性管(“牵引器管”)通常是细长和中空的，并且被配置成当在导管内向 近侧拉动柔性管的第一端部时在远侧端部开口上滑动和翻转。形成远侧牵 引器区域的远侧端部可以是管状的或不是管状的(例如，它可以由材料条 等形成)。组合式导管和柔性牵引器组件还形成穿过导管和柔性管的导丝 腔，该导丝腔被配置成使导丝穿过。

[0015] 在使用中，导丝可以被配置成滑动穿过该装置(并且可以形成装置的 一部分)以允许定位并且在一些变型中支撑，通常在不干扰牵引器管的操 作的情况下将诸如血凝块

的物体拉入导管的主体。

[0016] 除了具有布置在导管内并且在导管的远侧端部上翻转或翻折的柔性 牵引器管的导管之外，本文所描述的装置还可以包括一个或多个特征或元 件，其允许这些设备在脉管系统内操作而不收缩，特别是在其远侧端部处， 尽管在优选地相当柔软的远侧端部的远侧边缘/开口上施加拉力矩。进一步 地，这些装置可以适用于最小化将远侧牵引器区域取回到导管中并在导管 的远侧端部开口上翻转而不损坏或减弱远侧牵引器区域所需的力，从而防 止装置内的柔性牵引器管在其本身上或与导管一起破裂、束缚、堵塞或缠 结。例如，如下面将更详细描述的，这些装置中的任一个可以包括在导管 的远侧端部处或附近的选择性润滑区域。导管端部可以被成形为允许管的 远侧端部的柔性牵引器区域的翻转。另外，导管的端部轮廓(例如，最远 侧5mm、4mm、3mm、2mm、1mm等)可以具有防止导管的收缩/屈曲 的刚度(例如硬度)的布置。可替代地或附加地，柔性牵引器管可以适于 在导管周围“扫动”血管的尽可能大部分以从血管内收集物体，同时仍然 允许相对较低的力收回到导管中并且在导管的远侧端部上翻转。柔性管的 牵引器部分(可指代管的在导管内的远侧部分)通常可包括邻近于第二可 较少扩张(或不可扩张)的端部区域的远侧可扩张(第一)端区，其要么 紧邻要么由间隔区域分开。第二端部区域靠近于第一端部区域(当第一端 部区域和第二端部区域两者都被拉入导管时)。柔性牵引器管可以一直延 伸穿过导管到达近侧端部和/或近侧手柄，或者其可以在导管的近侧端部之 前终止并且连接到拉动器。拉动器可以是另一个可能较少柔性管，或者线 材、杆、绳等。柔性牵引器管通常被配置成具有穿过其的腔(例如，中心 腔或径向偏移的腔)，导丝可以穿过该腔通过，穿过包括导管和柔性牵引器管的装置。当导丝位于该腔内时，通常可以操作柔性牵引器管(例如， 向近侧拉动并且在一些变型中向远侧推动)。

[0017] 装置可预先加载以用于远侧牵引器区域的展开以及物体在脉管内的 捕获，或者在一些变型中，装置可以在将导丝和/或导管定位在血管内之后 或期间在体内加载。例如，在一些变型中，通过保持远侧牵引器区域收回 到导管中直到导管位于脉管内，并且优选地在待去除的物体附近，该装置 可以适于体内使用。一旦定位，柔性管的在导管内的远侧牵引器区域可以 从导管向远侧延伸，扩张以形成捕获形状，其可以在向远侧推进导管或不向远侧推进导管的情况下被拉入并且在导管的远侧端部上翻转。因此，远 侧牵引器部分可以被安全且可靠地输送至腔内的必要部位，而没有损坏装 置或身体的风险。

[0018] 例如，执行机械取栓以从血管去除凝块的方法可以包括：将导管的远 侧端部朝向凝块推进通过血管；将管的位于导管内的远侧牵引器区域从导 管的远侧端部暴露，其中，远侧牵引器区域包括可扩张的第一端部区域以 及靠近于可扩张的第一端部区域的可较少扩张的第二端部区域；允许可扩 张的第一端部区域在血管内扩张；将导管的远侧端部定位成使得导管的远 侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张的第一端部区域之间，同时可扩张的第一端部区域在可较少扩张的第二端 部区域上翻折；以及通过将可扩张的第一端部区域在导管的远侧端部上滚 动使得可扩张的第一端部区域在可扩张的第一端部区域被拉动到导管中 时翻转，将凝块拉入导管。

[0019] 如上所述，将导管的远侧端部朝向凝块推进通过血管的步骤可以包括 在导丝上推进。导管可以在导丝上向远侧滑动或者与导丝一起向远侧延伸 (或向近侧收回)。内(牵引器)管可以被保持在导管内(例如，在远侧 端部附近、中间区域或者在近侧端部附近)，或

者在一些变型中，可以在 将导管定位在脉管内之后插入。导管的远侧端部可以定位在待去除的物体 (例如，凝块)处、附近或邻近，或者它可以分开预定的距离，例如以允 许通过将远侧牵引器区域延伸出导管的远侧端部之外并且扩张以准备将 物体取回到导管中来设定用于装置的空间。

[0020] 因此，一旦定位，就可以通过暴露远侧牵引器区域并且定位导管的远 侧端部以及在一些变型中的导丝来展开该装置，以允许物体被捕获并被拉 入导管。通过向近侧拉动导管，同时保持包括远侧牵引器区域的柔性管静 止(例如相对于血管)和/或通过向远侧延伸柔性管，可以暴露远侧牵引器 区域。

[0021] 如上所述，柔性管可以包括远侧牵引器区域，该远侧牵引器区域包括 可扩张的第一端部区域。该端部区域通常是多孔的(例如，由网状物、针 织物、机织物或其他材料形成，包括具有穿设有多个开口的固体材料)并 且适于抓取待去除的物体(例如血块)。该第一端部区域通常可扩张至导 管的内径的约1.3倍至约10倍之间(例如，在约1.5倍至约7倍之间、约 1.5倍至约5倍之间、约1.5倍至约4倍之间、约1.5倍至约3倍等)。形 成牵引器部分的该第一远侧端部区域通常邻近于可较少扩张(或基本上不 可扩张的)的第二端部区域。第二区域可以使导管向近侧一直向下延伸， 或者使导管部分向下延伸。通常，牵引器部分的第一端部区域暴露于导管 之外并用于捕获凝块或其他物体；第二端部区域可在定位期间暴露，但在 操作期间可保持在导管内。

[0022] 因此，将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可 以包括将远侧牵引器区域延伸或推出导管的远侧端部之外。在一些变型 中，远侧牵引器区域被预先形成为使得第一可扩张的远侧端部区域在第二 远侧端部区域上翻折；在其他变型中，第一远侧端部区域与可较少扩张的 第二远侧端部区域在同一直线上且远离。然后可以向远侧移动导管，使得 导管的远侧端部区域(包括远侧端部)在远侧牵引器区域的扩张的可扩张的第一端部区域与可较少扩张的第二端部区域之间的径向间隙中延伸。

[0023] 在远侧牵引器区域被推出导管的远侧端部之外的任何变型中，例如在 该初始体内设置阶段期间，柔性管(特别是远侧牵引器区域)可以被配置 成或以其他方式适于允许推出导管之外而不束缚。如果可扩张的第一端部 区域特别地被捕获在导管的内壁上，则可能发生可扩张的管的导管内的束 缚，从而阻止展开。在一些变型中，可扩张的第一端部区域被配置成具有 细丝(例如镍钛诺、聚合物等)的网状管状构件，该网状管状构件在具有约24至144个股线，股线在直径上的厚度为0.0005英寸至0.005英寸， 其中，网状管状构件在纵向轴线上延伸，进一步其中，网状管状构件的长 度大于5cm，当围绕导管的远侧端部被拉动和翻转时，在纵向轴线的方向 上的交叉股线之间形成35度的编织角度，并且当不受约束时在导管的外 部扩张到大于导管的内径的1.5倍的直径。在该配置下，管状构件被发现是可推动的。

[0024] 在其他变型中，当可扩张的第一远侧端部区域被推出或延伸出导管的 远侧端部之外时，其可以被配置(例如，预成形、形状设定等)成在导管 的远侧端部上翻转并扩张。导管可以向远侧移动，帮助将远侧牵引器区域 的该可扩张的第一端部区域相对于导管的外侧向近侧推动。

[0025] 在这些方法中的任一种中，远侧牵引器区域可以包括可扩张的第一端 部区域以及靠近于可扩张的第一端部区域的可较少扩张的第二端部区域， 并且可扩张的第一端部

区域被允许在血管内扩张。

[0026] 因此，在展开阶段即将结束之际，导管的远侧端部通常被定位成使得 导管的远侧端部区域径向地位于远侧牵引器区域的可较少扩张的第二端 部区域和可扩张的第一端部区域之间，同时可扩张的第一端部区域在可较 少扩张的第二端部区域上翻折。

[0027] 此后，可以通过将可扩张的第一端部区域在导管的远侧端部上滚动来 将物体(例如凝块)拉入导管，使得当可扩张的第一端部区域被拉东东啊 导管中时，可扩张的第一端部区域翻转。

[0028] 如上所述，定位可以包括向远侧推进导管的远侧端部，使得导管的远 侧端部区域位于远侧牵引器区域的可较少扩张的第二端部区域和可扩张 的第一端部区域之间。

[0029] 导丝可以与本文所描述的任何方法一起使用。对于本文所描述的任何 方法而言，可以包括将血管内的导丝推进至凝块，其中，推进导管的远侧 端部包括在导丝上推进导管通过血管，直到导管的远侧端部靠近于凝块。导丝可以插入或穿过凝块，或者其可以刚好位于凝块之前。导丝可以在凝 块去除期间被留下，或者其首先可以部分或完全取回。例如，这些方法中 的任一种可以包括将血管内的导丝推进至凝块，其中，推进导管的远侧端 部包括在导丝上推进导管穿过血管，直到导管的远侧端部靠近于凝块。进 一步其中，将凝块拉入导管包括在将可扩张的第一端部区域在导管的远侧 端部上滚动的同时在导丝上朝向凝块推进导管。

[0030] 将凝块拉入导管通常包括将远侧牵引器区域(例如，可扩张的第一端 部区域)在导管的远侧端部上滚动。该装置也可以在远侧牵引器区域的致 动期间向远侧移动。例如，将血块拉入导管可以包括向近侧取回管(以将 远侧牵引器区域在远侧端部上滚动)和/或在向远侧推进导管的同时向近侧 取回管。

[0031] 在这些方法中的任一种中，将凝块拉入导管可包括在向远侧推进导管 的同时向近侧取回管，其中，以与推进导管不同的速率取回该管。在一些 配置中，比向近侧拉管(远侧牵引器区域)更迅速地向远侧推进导管可能 是有益的。在一些变型中，可以比向近侧取回管(远侧牵引器区域)更慢 地推进导管。可替代地在一些变型中，它们以相同的速率移动。通过观察 导管内的近侧运动(例如，第二端部区域的近侧运动)可以确定柔性管的 运动速率。

[0032] 通常，远侧牵引器区域的可扩张的第一端部区域是可扩张的并且可以 形成可以与诸如凝块的物体接合的面向远侧的嘴部或唇缘。可扩张的牵引 器区域的唇缘的嘴部可相对于导管外径(OD)的长轴线形成5度至60度、并且优选地至少为10度(例如10°至60°、10°至50°、10°至45° 等)范围内的切向角度或滚动角度(如下面参考图18A至图18C和图21D更详细描述的)。只要滚动角度至少为10度并且管收回到导管中，则管应 该不会束缚或阻塞导管尖端。网状管可以通过改变刚度以确保滚动角度大 于10度而构造。可替代地或与保持最小滚动角度组合，可能期望在导管 的最远侧尖端处保持导管材料ID和导管的O.D之间的物理空间或间隙(如 下面在图18A至图18C中更详细描述的)。该间隙可能需要大于例如0.1 mm、0.2mm、0.3mm、0.4mm、0.5mm、0.7mm、0.8mm、0.9mm、1.0 mm等，以确保当管被收回时管围绕导管的远侧端部滚动。扩张材料(例 如网状材料、机织材料、编织材料、针织材料、穿孔材料等)可以允许其 本身在血管内扩张。因此可扩张的第一区域可以是可自扩张的。远侧牵引 器区域的可扩张的第一端部区域可以被预先偏置以扩张。在一些变型中， 使用形

状记忆材料(例如,形状记忆合金)。在一些变型中,偏置元件被 包括在可扩张的第一端部区域中或与可扩张的第一端部区域成一体以扩 张使得远侧牵引器区域。可扩张的第一端部区域可以扩张至接触血管的内 膜。在一些变型中,装置可以被配置(例如,设定尺寸,包括确定可扩张 的第一端部区域的尺寸),使得远侧牵引器区域的最远侧端部与血管腔接触。因此,本文所描述的变型中的任一个可以附加地或可替代地包括偏置 元件,诸如圈、环、支架等以推动可扩张的远侧端部区域,使得其可以通 过施加增加的径向力将其扩张开来而与脉管接触。在一些变型中,该开口 偏置(圈、螺旋、环等)位于远侧牵引器区域的可扩张的第一端部区域的 远侧端部处或附近。

[0033] 本文所描述的变型中的任一个可以包括可扩张的导管尖端。例如,在 一些变型中,导管尖端的硬度可以足够柔软以当远侧牵引器区域被向近侧 拉入导管时向近侧压缩;轴向压缩远侧端部尖端可使其在远侧端部处略微 扩张(例如,使得其可扩张)。

[0034] 如上所述,将管的位于导管内的远侧牵引器区域从导管的远侧端部暴 露可以包括将远侧牵引器区域推出导管的远侧端部之外。可替代地或附加 地,将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外可以 包括向近侧拉动导管。例如,将管的导管内的远侧牵引器区域从导管的远 侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外以暴露 已经在可较少扩张的第二端部区域上翻转的可扩张的第一端部区域。

[0035] 在一些变型中,将管的位于导管内的远侧牵引器区域从导管的远侧端 部暴露包括将可扩张的第一端部区域延伸出导管的远侧端部之外,使得当 可扩张的第一端部区域延伸时,可扩张的第一端部区域在导管的远侧端部 上翻转。

[0036] 远侧牵引器区域的可扩张的第一端部区域可以是任何适当的长度,并 且该长度的任何部分(全部、90%、80%、70%、60%、50%、40%等)可 能在该设定时段期间暴露。例如,在一些变型中,暴露管的远侧牵引器区 域可以包括暴露至少5mm的可扩张的第一端部。可扩张的第一端部区域 可以是例如5mm或更大(例如,在约5mm至500mm之间的6mm、7mm、8mm、9mm、10mm、11mm、12mm、13mm、14mm、15mm、16mm、 17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、 50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、 120mm、130mm、140mm、150mm、200mm、300mm、400mm、500mm 等,在约5mm、6mm、7mm、8mm、9mm、10mm、11mm、12mm、13mm、14mm、15mm、16mm、17mm、18mm、19mm、20mm、25mm、 30mm、35mm、40mm、45mm、50mm、55mm、60mm、70mm、80mm、 90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm 的任何较小值与10mm、11mm、12mm、13mm、14mm、15mm、16mm、 17mm、18mm、19mm、20mm、25mm、30mm、35mm、40mm、45mm、 50mm、55mm、60mm、70mm、80mm、90mm、100mm、110mm、120mm、130mm、140mm、150mm、200mm、300mm、400mm、500mm 的任何较大值之间,其中较小值总是小于较大值)。在这些变型中的任一 个中,当暴露远侧牵引器区域时,仅可扩张的第一远侧端部区域可以暴露 出导管之外(例如,当将可扩张的远侧端部区域向远侧推出并且允许其在 导管的远侧端部上翻转),或者可扩张的第一远侧端部区域和可较少扩张 的第二远侧端部区域两者都可以全部或部分暴露。例如,暴露至少1cm 的可扩张的第一端部区域和至少1cm的可较少扩张的第二端部区域。可 扩张的第一端部区域可以在可较少扩张的第二端部区域上翻转(翻折回来)。

[0037] 如上所述,可扩张的第一端部区域可以包括既可扩张又能够抓取物体 (例如凝块)的任何适当材料。例如,远侧牵引器区域的可扩张的第一端 部区域可以包括邻近于可

较少扩张的第二端部区域耦接的网状物。例如，可扩张的第一端部区域可以是以下中的一种或多种：机织材料、网状编织 材料、针织材料或穿设有多个开口的膜材料。可较少扩张的第二端部区域 可以由相同的材料制成，或者其可以由不同的材料制成。可较少扩张的第二端部区域可以具有相同的结构(例如机织等)或者其可以具有不同的结 构，包括可扩张的第一端部区域的结构的可较少扩张变型。例如，可较少 扩张的第二端部区域可以是非多孔的(例如非机织的、非针织的等，或固 体材料)或较少多孔的(例如，紧密机织的小空隙针织孔、紧密编织物)。在一些变型中，可较少扩张的第二端部区域可包括位于可扩张的第一端部 区域(例如，具有中间可扩张性)与第二端部区域的不可扩张部分之间的 过渡区域。通常，远侧牵引器区域的可较少扩张的第二端部包括不可扩张 的结构和材料。

[0038] 执行机械取栓以从血管去除凝块的方法可以包括：将导管的远侧端部 朝向凝块推进通过血管；将管的位于导管内的远侧牵引器区域从导管的远 侧端部暴露，其中，远侧牵引器区域包括可扩张的第一端部区域和靠近于 可扩张的第一端部区域的可较少扩张的第二端部区域，并且被配置成使得 可扩张的第一端部区域在可较少扩张的第二端部区域上翻转；允许可扩张 的第一端部区域在血管内扩张，使得导管的远侧端部区域位于远侧牵引器 区域的可较少扩张的第二端部区域与可扩张的第一端部区域之间；以及通 过向远侧端部推进导管并在导管内向近侧取回导管使得可扩张的第一端 部区域在导管的远侧端部上滚动并在可扩张的第一端部区域被拉动到导 管中时翻转，将凝块拉入导管。

[0039] 如上所述，在暴露远侧牵引器区域之前，可扩张的第一端部区域可以 在可较少扩张的第二端部区域上翻转。可替代地，暴露远侧牵引器区域可 以包括当暴露远侧牵引器区域时使可扩张的远侧端部区域在可较少扩张 的第二端部区域上翻转。通常，将管的位于导管内的远侧牵引器区域从导 管的远侧端部暴露可以包括将远侧牵引器区域推出导管的远侧端部之外。将管的位于导管内的远侧牵引器区域暴露在导管的远侧端部之外可包括 向近侧牵拉动导管。

[0040] 执行机械取栓以从血管去除凝块的方法可包括：将导管的远侧端部朝 向凝块推进通过血管；将管的位于导管内的远侧牵引器区域暴露于导管的 远侧端部之外，其中，远侧牵引器区域包括可扩张的第一端部区域和可较 少扩张的第二端部区域，其中，暴露包括将可扩张的第一端部区域延伸导 管的远侧端部之外，使得当可扩张的第一端部区域延伸时，可扩张的第一 端部区域在导管的远侧端部上翻转；允许可扩张的第一端部区域当延伸出 导管的远侧端部之外时在血管内扩张，使得导管的远侧端部区域位于可较 少扩张的第二端部区域与可扩张的第一端部区域之间；以及通过在导管内 向近侧取回管使得当可扩张的远侧端部区域被拉入导管中时可扩张的远 侧端部区域在导管的远侧端部上滚动、收缩和翻转，将凝块拉动到导管中。将管的位于导管内的远侧牵引器区域从导管的远侧端部暴露可以包括将 远侧牵引器区域推出导管的远侧端部之外。可替代地或附加地，将管的位于导管内的远侧牵引器区域暴露于导管的远侧端部之外可以包括相对于 管的远侧牵引器区域向近侧取回导管。

[0041] 本文还描述了用于从血管去除凝块的机械取栓设备，该设备包括：导 管，其具有远侧端部和远侧端部开口，其中导管具有内径和外径；管的位 于导管内的远侧牵引器区域，其中，远侧牵引器区域包括可扩张的远侧端 部区域以及靠近于可扩张的远侧端部区域的可较少扩张的远侧端部区域， 远侧牵引器区域被配置成使得可扩张的远侧端部区域在

可较少扩张的远 侧端部区域上翻转;穿过导管和管的导丝腔,该导丝腔包括远侧牵引器区域,其中,导丝腔被配置成使导丝通过;以及近侧手柄,其耦接至管并且 被配置成引起导管与管之间的相对运动,使得从导管的内径内释放远侧牵 引器区域,使得可扩张的远侧端部区域可以扩张至大于外径的直径,使得 可以在可扩张的远侧端部区域与可较少扩张的远侧端部区域之间推进导 管,并且可以向近侧拉该管以在导管的远侧端部上拉动可扩张的远侧端部 区域,使得可扩张的远侧端部区域滚动到导管的远侧端部中、翻转、收缩 并被拉入导管。

[0042] 例如,用于从脉管去除凝块的机械取栓设备可以包括:导管,其具有 远侧端部和远侧端部开口,其中,导管具有内径和外径;管,其具有位于 导管内的远侧牵引器区域,其中,远侧牵引器区域包括可扩张的远侧端部 区域和靠近于可扩张的远侧端部区域的可较少扩张的远侧端部区域,进一 步其中,可扩张的远侧端部区域被偏置成当其从导管的远侧端部暴露时在 可较少扩张的远侧端部区域上翻转;穿过导管和管的导丝腔,该导丝腔包括远侧牵引器区域,其中,导丝腔被配置成使导丝通过;以及近侧手柄, 其耦接至管并且被配置成引起导管与管之间的相对运动,使得从导管的内 径内释放远侧牵引器区域,使得可扩张的远侧端部区域可以扩张至大于外 径的直径,并且可以向近侧拉该管以在导管的远侧端部上拉动可扩张的远 侧端部区域,使得可扩张的远侧端部区域滚动到导管的远侧端部中、翻转、收缩并被拉入导管中。

[0043] 本文还概括描述了机械取栓装置。例如,本文描述了用于从脉管去除 凝块的机械取栓装置,包括:导管,其具有远侧端部和远侧端部开口;柔 性管,其在导管内延伸并且在导管的远侧端部上翻折回来,其中,柔性管 被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上 滑动并翻转;以及穿过导管和柔性管的导丝腔,被配置成使导丝通过。

[0044] 用于从脉管中去除凝块的机械血栓装置可包括:导管,其具有远侧端 部和远侧端部开口,其中远侧开口的硬度大于紧邻远侧端部的区域的硬 度,进一步其中远侧端部开口具有圆形唇缘轮廓;柔性管,其在导管内延 伸并且在导管的远侧端部上翻折回来,其中柔性管被配置以当柔性管的第 一端部在导管内向近侧被拉动时在远侧端部开口上翻转;以及导丝腔,其 穿过导管以及被配置以通过导丝的柔性管。导管远侧端部硬度可以大于 60A肖氏硬度或大于40D肖氏硬度。

[0045] 用于从脉管去除凝块的机械取栓装置,其包括:内导管,其具有远侧 端部和远侧端部开口;柔性管,其延伸穿过导管并且在内导管的远侧端部 上翻折回来,其中,柔性管被配置成当在内导管内向近侧拉动柔性管的第 一端部时在远侧端部开口上翻转;外导管,其在内导管和柔性管上延伸; 柔性管的在外导管的远侧端部与内导管的远侧端部开口之间延伸的润滑 区域,其中,大部分柔性管是未润滑的;以及穿过导管和柔性管的导丝腔, 其被配置成使导丝通过。

[0046] 用于从脉管去除凝块的机械取栓装置可以包括:内导管,其具有远侧 端部和远侧端部开口;柔性管,其延伸穿过导管并且在内导管的远侧端部 上翻折回来,其中,柔性管被配置成当在内导管内向近侧拉动柔性管的第 一端部时在远侧端部开口上翻转;可释放附件,其位于柔性管和导管的外 表面之间,被配置成当以预定力(例如,大于0.01N)拉动柔性管时释放; 以及穿过导管和柔性管的导丝腔,其被配置成使导丝通过。

[0047] 用于从脉管去除凝块的机械取栓装置可包括:导管,其具有远侧端部、远侧端部开口和内径;柔性管,其延伸穿过导管并且在导管的远侧端部上 翻折回来,其中,柔性管被配置成当在导管内向近侧拉动柔性管的第一端 部时在远侧端部开口上翻转,柔性管具有低泊松比,使得柔性管当被用足 够的力在导管内向近侧拉动时的直径大于导管的内径的一半,以在远侧端 部开口上翻转;以及穿过导管和柔性管的导丝腔,被配置成使导丝通过。具有低泊松比的柔性管可以小于0.5或者在0.05至0.5或0.1至0.3的范围 内。

[0048] 如上清楚所述,柔性管通常包括远侧牵引器区域,远侧牵引器区域具 有可扩张的第一端部区域以及邻近于第一端部区域的可较少(或不可)扩 张的第二端部区域。因此,柔性管可以包括网状管。

[0049] 通常,形成本文所描述的装置的一部分的导管是高度灵活的,如适用 于所采取的侵害路径,例如,通过神经脉管导管。在一些变型中,组装装 置(具有缠绕在远侧端部上并准备好操作的柔性管)的总体刚度在不具有 柔性管的导管的原始刚度的预定百分比内(例如,在10%内、在12%内、 在15%内、在16%内,在17%内、在18%内、在19%内、在20%内、在 25%内、在30%内等)。例如,延伸穿过导管并且在导管的远侧端部上翻 折回来的柔性管可以将导管的远侧5cm的刚度增加小于导管的远侧5cm 的刚度的预定百分比(例如15%),而不使柔性管延伸穿过其中和在导管 的远侧端部上翻折回来。

[0050] 在本文所描述的变型中的任一个中,柔性管的远侧牵引器区域适于抓 取物体,例如凝块。特别地,柔性管可以是多孔的或者具有至少一个多孔 区段,所述多孔区段具有孔隙图案,所述孔隙图案在宽度小于预定距离(例 如,约0.005英寸)的孔隙之间具有纵向间隔。如在该示例中所使用的,“孔隙”包括网状物(机织物等)的股线之间的窗口、开口、间隙等以及 穿过固体片形成的孔隙。通常,对于机织(并且特别是编织)的可扩张的 第一端部区域材料,较小的细丝在抓取时可能更好,并且因此较小的孔隙 尺寸可能是优选的。最佳尺寸可以取决于材料,包括细丝尺寸、孔隙百分 比、孔隙间距的尺寸、孔径等。例如,在一些变型中,孔隙率大于>60% (大于70%、大于75%、大于80%、大于85%等,在60%至95%、65% 至95%、70%至95%等之间)以及纤维直径(对于机织材料)为<0.005 是有利的。确保凝块或异物被抓取所需的柔性管状构件的有效孔径可以在 50微米至1000微米(μm)的范围内,或者在100μm至200μm、100μm 至300μm、100μm至500μm或500μm至1000μm的范围内。柔性管状 构件可沿其长度具有各种孔径。

[0051] 通常,如本文所用,机织材料包括通过以交织图案(例如,交织股线、细丝、材料长度等)编织多股材料而形成的任何材料。网状物是一种机织 材料。取决于形成织物的材料的弹性,机织材料通常在某些方向上(在偏 置方向上)更可伸展/可扩张。机织材料通常以平行或几乎平行的路径行进。针织材料可以更柔性并且通常指的是曲折的单个路径或路线,从而形成可 以对称布置和互锁的环路。机织材料可以非常可拉伸/柔性的。针织结构区域可较少拉伸,但仍然非常柔性。

[0052] 在本文所描述的装置中的任一个中,并且特别是预加载或预成形的版 本中,该装置可以包括位于柔性管与导管的外表面之间的可释放附件,其 被配置成当用大于预定力阈值的力拉动柔性管时释放。例如,可释放力阈 值可以大于约0.001N、大于约0.005N、大于约0.01N、大于约0.03N、 大于约0.05N、大于约0.08N、大于约0.1N、大于约0.3N、大于约0.5N等)。

[0053] 在本文所描述的装置中的任一个中，柔性管可以包括多个柔性材料 条，其中，条被布置成与柔性管的长轴平行。可替代地或附加地，在这些 变型中的任一个中，远侧端部开口可以包括多个凹口或通道，当柔性管在 远侧端部开口上翻转时，形成柔性管的纤维或条被拉入该凹口或通道。

[0054] 在本文所描述的装置中的任一个中，柔性管可以包括具有穿设有多个 孔的聚合物管。例如，柔性管可以包括远侧端部、近侧端部以及在远侧端 部与近侧端部之间的主体区域，其中，主体区域从较柔性的远侧端部过渡 到较刚性的近侧端部。

[0055] 如上所述，在本文所描述的变型中的任一个中，导管的远侧端部(例 如，远侧端部开口区域)可以适于防止当在导管开口上翻转时收缩但仍然 足够柔软以为神经脉管应用提供合适的使用。例如，本文所述的装置中的 任一个在远侧端部(例如，在远侧端部开口/边缘处)处的硬度可大于紧邻 远侧端部的区域的硬度。这些远侧端部开口中的任一个都可以具有圆形唇 缘轮廓。通常，尽管远侧端部区域的硬度可能降低(变得“较软”)，但是 非常最远侧端部(开口)的硬度可能较高。这与圆形端部形状一起可以减 小在将远侧牵引器区域(例如，可扩张的第一端部区域)拉入导管时使其 翻转所需的力，同时防止导管的远侧端部区域收缩。

[0056] 本文所描述的装置中的任一个还可以包括适于相对于导管向近侧拉 入柔性管的手柄。手柄可以附接到或可附接到导管和/或柔性管，并且可以 包括用于独立地或者更优选地以协调的方式(或者在这两个模式之间切 换)而致动的单独的控制器。例如，这些装置中的任一个可以包括耦接到 导管的近侧端部区域的驱动手柄，其中，驱动手柄包括控制器，该控制器 被配置成在被致动时协调在向近侧收回柔性管的同时向远侧推进导管。

[0057] 这些装置中的任一个还可以包括在导管和柔性管上延伸的外导管。外 导管可以在导管和柔性管上延伸，并且可以保持远侧牵引器区域(导管外 部)的外部部分收缩，直到其已经被输送。这些装置中的任一个都可以包 括在外导管的远侧端部和远侧端部开口之间延伸的柔性管的润滑区域，其 中，大部分柔性管是未润滑的。该润滑区域可以减小致动该装置所需的初 始力。

[0058] 在本文所描述的装置中的任一个中，柔性管可被配置成当在导管内向 近侧拉动柔性管的第一端部时在远侧端部开口上翻转，并且柔性管可具有 低泊松比，使得柔性管(其可以是网状管)当被用足够的力在导管内向近 侧拉动时的直径大于导管的内径的一半，以在远侧端部开口上翻转。

[0059] 这些装置中的任一个可以包括位于导管内的拉动器(例如细长拉动 器)并且耦接到柔性管的远侧端部。拉动器通常被配置成向近侧拉入柔性 管，但是在一些变型中它可以向远侧移动柔性管。例如，这些装置中的任 一个还可包括位于导管内并耦接到柔性管的远侧端部的细长拉动器，其 中，细长拉动器包括具有内腔的海波管，该内腔与穿过柔性管的导丝腔连 续。

[0060] 如上所述，在一些变型中，柔性管包括可推动的柔软外部网状物。例 如，远侧牵引器区域(并且特别是可扩张的第一端部区域)可以由24至 144个股线形成，股线在直径上具有0.0020英寸或更小的厚度，其中，网 状管状构件在纵向轴线上延伸，进一步其中，网状物管状构件的长度大于 5cm，网状管状构件当围绕导管的远侧端部被拉动和翻转时在纵向轴线的 方向上的交叉股线之间形成约35度或更小的编织角度，并且当不受约束 时在导管的

外部扩张到大于导管的内径的1.5倍的直径。

[0061] 当柔性管由股线(例如机织、编织等)形成时,股线可以由以下中的 任一者形成:单丝聚合物、复丝聚合物、镍钛(NiTi)丝、具有不透射线 金属中心的镍钛管、钴铬合金丝、具有不透射线金属中心的钴铬合金管、 尼龙、聚酯、聚对苯二甲酸乙二醇酯和聚丙烯。

[0062] 如上所述,这些装置中的任一个都可以被配置成使得柔性管(例如可 扩张的远侧端部区域)可释放地保持在导管上。例如,这些装置中的任一 个可以包括围绕柔性管的远侧端部区域的保持环,该保持环被配置成将柔 性管可释放地保持抵靠在导管上。

[0063] 在这些变型中的任一个中,柔性管的形状可以被设定成当在导管内被 向近侧拉入导管之后时具有不同的直径。通常,柔性管可以包括多个机织 丝或一个(或多个)针织丝。在一些变型中,整个(或大部分)柔性管由 机织或针织细丝形成,并且柔性管的近侧端部可形成与形成拉线的细丝或 细丝束相反的渐缩开口。可替代地或附加地,柔性管可以由具有小于0.020 英寸的厚度的聚合物套筒形成,其中,套筒包括穿孔图案,其中,穿孔延 伸穿过聚合物。穿孔图案可以包括具有由以下一个或多个构成的形状的穿 孔:圆形孔、矩形孔和锯齿形状。

[0064] 这些装置中的任一个可以包括耦接到柔性管的近侧端部的一侧的拉 线,该拉线被配置成被向近侧拉以将柔性管拉动到导管内。

[0065] 通常,柔性管可以是任何适当的长度。例如,柔性管可以在3cm至 200cm之间(例如,3cm至150cm、3cm至100cm、3cm至50cm等)。

[0066] 在本文所描述的装置中的任一个中,装置的柔性管可被配置成使得可 通过向柔性管的远侧端部施加小于预定量的力(例如500克的力、450克 的力、400克的力、350克的力、300克的力、250克的力、200克的力、 150克的力等)将柔性管收回到导管中。

[0067] 在这些变型中的任一个中,柔性管可以包括位于柔性管的第一端部与 第二端部之间的渐缩部。在一些变型中,柔性管可以在导管的整个长度内 延伸,使得柔性管的近侧端部被配置成远离导管的近侧端部向近侧被拉动 以使柔性管在远侧端部开口上滑动并翻转。

[0068] 本文所描述的装置中的任一个还可以包括真空源。例如,这些装置中 的任一个可以包括导丝真空泵,该导丝真空泵耦接到导丝腔的近侧端部并 且被配置成通过其施加真空。例如,这些装置中的任一个可以包括外导管 真空泵,该外导管真空泵耦接到导管与柔性管之间的空间并且被配置成在 导管的位于导管的内壁与柔性管之间的腔内施加真空。

[0069] 如上所述,该装置可以包括拉动器,其中,柔性管的远侧端部耦接到 拉动器的远侧端部。外导管可以布置在导管上且邻近于柔性管的近侧端 部。这些装置中的任一个还可以包括具有控制器的手柄,该控制器被配置 成协调推进外导管以向远侧推动柔性管的近侧端部和向近侧拉动拉动器 以将柔性管的近侧端部拉入导管。例如,如本文所描述的装置可以包括: 拉动器,其中,柔性管的远侧端部耦接到拉动器的远侧端部;外导管,其 可滑动地布置在偶接到柔性管的近侧端部的导管上;以及手柄,其具有控 制器,该控制器被配置成协调在向近侧拉动拉动器以将柔性管的近侧端部 拉入导管的同时向远侧推进外导管以向远侧推动柔性管的近侧端部,或者 在向远侧推动拉动器以将柔性管的近侧端部推出导管之外的同时向近侧 拉动外导管以向近侧拉动柔性管的近侧端部。

[0070] 本文还描述了机械地去除取栓的方法,包括:将导丝至少推进到血管 中的凝块的

近侧端部;在导丝上向远侧推进取栓(例如凝块去除)装置,其中,取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的 外径且在导管的远侧端部上延伸的柔性管,使得导丝穿过导管的腔以及柔 性管;从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中,使得柔性管在远侧端部开口上滑动并翻转;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0071] 机械地去除取栓的方法可以包括:推进导丝邻近血管中的凝块;在导 丝上向远侧推进取栓装置,其中,取栓装置包括具有远侧端部和远侧端部 开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管,使 得导丝穿过导管的腔以及柔性管;从离开导管的外径向近侧拉动柔性管并 在导管的远侧端部开口的圆形唇缘上将柔性管拉动到导管腔中,使得柔性 管在远侧端部开口上滑动并翻转,其中,远侧端部开口的硬度大于紧邻远侧端部的区域的硬度;以及当柔性管被拉入导管时将凝块拉入翻转的柔性 管。

[0072] 机械地去除取栓术的方法可以包括:推进导丝邻近血管中的凝块;在 导丝上向远侧推进取栓装置,其中,取栓装置包括具有远侧端部和远侧端 部开口的内导管、沿着内导管的外径且在导管的远侧端部上延伸的柔性 管,以及将柔性管的远侧端部区域固定抵靠在内导管的外径上的外导管, 使得导丝穿过导管的腔和柔性管;从离开导管的外径向近侧拉动柔性管并 将柔性管拉动到导管腔中,使得柔性管的润滑近侧引导区域在远侧端开口上滑动并翻转,直到柔性管的未润滑远侧区域被拉入内导管;以及当柔性 管被拉入导管时将凝块拉入翻转的柔性管。

[0073] 机械地去除取栓术的方法可以包括:推进导丝邻近血管中的凝块;在 导丝上向远侧推进取栓装置,其中,取栓装置包括具有远侧端部和远侧端 部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管, 使得导丝穿过导管的腔和柔性管;从离开导管的外径向近侧拉动柔性管并 将柔性管拉动到导管腔中,使得柔性管在远侧端部开口上滑动并翻转;将 柔性管向远侧拉出或推出导管的远侧端部,使得柔性管在远侧端开口上滑动并翻转;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0074] 在本文所描述的方法中的任一个中,导丝可以至少部分地定位在血管 中的凝块内。

附图说明

[0075] 在所附权利要求中特别阐述了本发明的新颖特征。通过参考以下详细 描述来获得对本发明的特征和优点的更好理解,所述详细描述阐述了利用 本发明原理的说明性实施例以及附图,附图中:

[0076] 图1A至图1H示出了用于机械地去除诸如形成身体区域的凝块的物 体的装置的一个变型。图1A示出了该装置的导管部分;图1B示出了导 管的远侧端部(开口)的放大视图;图1C示出了柔性管(牵引器管)的 远侧牵引器区域的示例,其示出了处于收缩(未扩张)配置的柔性管的可 扩张的第一端部区域,而图1D示出了具有可扩张的第一端部区域的相同的远侧牵引器区域。图1E示出了组装的机械取栓装置,其中柔性管延伸 穿过导管并且在导管的远侧端部上翻折回来,使得柔性管的可扩张的第一 端部区域(形成远侧牵引器区域的一部分)至少部分地位于导管外侧并处 于非扩张状态。图1F示出了图1E的装置,其中可扩张的第一端部区域扩 张。图1G和图1H示出了图1E和图1F的装置的使用以通过向近侧拉柔

性管和/或向远侧朝向凝块推进导管而去除凝块，使得可扩张的第一端部区 域当其被拉入导管的远侧端部中时翻转，将凝块拉动到导管中。

[0077] 图2A至图2D示出了可以是本文所描述的装置的一部分的柔性管(牵 引器管)的变型。图2A示出了包括远侧牵引器区域的柔性管的远侧端部，远侧牵引器区域在远侧端部处包括可扩张的第一端部区域，其邻近于可较 少扩张的第二端部区域。在图2B中，可扩张的第一端部区域由多个机织 纤维形成。在图2C中，可扩张的第一端部区域由整个具有多个小孔的材 料片形成。在图2D中，可扩张的第一端部区域在可较少扩张的第二端部 区域上翻折(doubled over，对折)。

[0078] 图3A至图3F示出了机械取栓装置的一个示例的体内展开和操作。在 该示例中，在将导管定位在凝块附近之后，远侧牵引器区域被推动穿过导 管，直到远侧牵引器区域从凝块的远侧端部暴露(图3A至图3D)，使得 可扩张的第一端部区域扩张至血管的内膜；然后在可扩张的第一端部区域 与可较少扩张的第二端部区域之间推进导管(图3D至图3E)，并且可扩 张的第一端部区域被拉入导管中，使得其翻转并将凝块拉入导管中(图3E 至图3F)。

[0079] 图4A至图4F示出了机械取栓装置的另一个示例的体内展开和操作。在该示例中，柔性(牵引器)管的可扩张的第一端部区域在通过将可扩张 的第一端部区域延伸出导管的远侧端部而定位导管部分(图4A至图4B) 之后被展开，使得可扩张的第一端部区域在导管的远侧端部区域上翻折回 来(图4C至图4D)。一旦暴露和展开，可扩张的第一端部区域可以在向 远侧推进导管或不向远侧推进导管的情况下被拉回到导管中以将凝块拉 动到导管中(图4F)。

[0080] 图5A至图5E示出了机械取栓装置的另一个示例的体内展开和操作，其中可扩张的第一端部区域在定位在凝块附近的血管内之后向远侧延伸 出导管的端部(图5A至图5C)。一旦可扩张的第一端部区域已经延伸并 允许在脉管内扩张，则可以向远侧推进导管和导管内的柔性管的其余部分(图5D)，使得可扩张的第一端部区域在远侧端部上翻折，如图所示。此 后，在向远侧推进导管或不向远侧推进导管的情况下，可扩张的第一端部 区域可以被拉回到导管中，以将凝块拉动到导管中(图5E)。

[0081] 图6A和图6B示出了一种机械取栓装置，其包括导管以及延伸穿过 导管并在导管的远侧端部(形成远侧牵引器区域)上翻折回来的柔性管(牵 引器管)，以及在远侧牵引器区域上的外导管或释放保护器导管。图6A示 出了定位在凝块附近的装置；图6B示出了与导丝一起使用的装置，该导 丝穿过装置的导丝腔以用于定位和操作该装置。

[0082] 图7A至图7D示出了如图6A至图6B所示的取栓装置的操作，其示 出了邻近凝块定位远侧端部/远侧牵引器区域(图7A)，然后将凝块拉动到 导管中(图7B至图7C)并且最终去除凝块和柔性牵引器管(图7D)。

[0083] 图8示出了包括可选真空源的取栓装置。

[0084] 图9A至图9D示出了本文所描述的取栓装置与导丝结合的操作。导 丝可以完全或部分地经过凝块，并且该装置可以在导丝上被致动，从而提 供增强的稳定性和功效。

[0085] 图10A示出了用于致动诸如本文所描述的取栓装置的装置的手柄(近 侧)手柄的一个变型。手柄可以被耦接并且可以单独地或以协调的方式致 动导管和柔性(牵引器)管(包括远端侧牵引器区域)的运动。

[0086] 图10B示出了用于如本文所描述的装置的近侧手柄的另一示例，其包 括用于控制

(单独或一起)导管和/或内柔性牵引器管的致动的控制器。

[0087] 图11A示出了用于包括如本文所描述的取栓装置的装置的近侧手柄 的另一示例。

[0088] 图11B是示出用于如本文所描述的装置的手柄的操作的机械示意图。

[0089] 图12A和图12B示出了变型,其中装置的柔性牵引器管的可扩张的 第一端部区域可释放地固定到导管的外表面;在装置的致动使得远侧牵引 器区域可以被拉入导管的远侧端部中之前,可以分离可释放附件。在图 12A中,外管(例如,远侧牵引器区域上的外导管或释放保护器导管)至 少覆盖可扩张的远侧端部区域的端部。在图12B中,远侧牵引器区域的可 扩张的第一端部区域可包括可释放地将可扩张的第一端部区域固定到导 管的外径的带、粘合剂、焊接件(例如,脆的粘合剂或其他附件)、卡扣 配合件、抓持件等。

[0090] 图13A和图13B示出了本文所描述的装置的柔性(例如牵引器)管 的近侧端部区域(牵引器区域)的示例。图13A示出了其中牵引器管的近 侧端部形成与管的腔径向偏离的拉线的示例;如图所示,导丝仍然可以经 过管(和导管)的腔以用于该装置的操作。图13B示出了其中拉线(或杆、 构件等)由与柔性牵引器管的其余部分不同的材料形成的示例。

[0091] 图14示出了远侧牵引器区域,其包括远侧牵引器区域的可扩张的第 一端部区域的近侧端部区域附近的有限润滑区域;可扩张的第一端部区域 的其他部分可能不是润滑的,远侧牵引器区域的其余部分也可能不是润滑 的。

[0092] 图15A至图15D示出了具有成形的可扩张的第一端部区域的柔性(牵 引器)管。特别地,这些不同的可扩张的第一端部区域可以被预先设定为 不同的直径,这可以帮助拉入和/或破坏导管内的凝块。图15A示出了第 一示例,其中可扩张的第一端部区域通过多个拉线耦接到拉动器部分。在 这些示例中,可扩张的第一端部区域被示出未在柔性管状构件(牵引器管) 的较近侧部分上翻转。图15B示出了由不可径向扩张的多个拉线连接的多 个可扩张的端部区域。图15C示出了具有多个预先设定直径的可扩张的第 一端部区域。图15D示出了通过形成可扩张的第一端部区域的两束或多束 细丝耦接到牵引器管的较近侧拉动器部分的可扩张的第一端部区域。

[0093] 图16示出了可扩张的第一端部区域的另一示例,其包括到导管的外 径的多个可释放附件;这些可释放附件(其可以是脆的、弹性的等)可以 通过施加足够的力而被释放,以允许将远侧牵引器区域拉动到导管中以用 于致动该装置。

[0094] 图17示出了其中可扩张的第一端部区域在导管的远侧端部区域的外 径上被加载(例如弹簧加载,压缩等)并且被可释放地锁定或以其他方式 (例如,通过可靠的附件)保持在位(in place,在适当位置)的示例;该 可释放附件可以防止装置在致动之前的展开,并且可扩张的第一端部区域 的加载可以使得远侧牵引器区域更容易在导管的远侧端部上翻转以将凝 块拉入装置中。

[0095] 图18A至图18C示出了具有不同刚度的可扩张的第一端部区域的示 例。

[0096] 图19A和图19B示出了用于组装如本文所述的装置的组装方法。

[0097] 图20A和图20B示出了可用作本文所描述的装置的远侧牵引器区域 的一部分的可扩张的第一端部区域的示例性轮廓。

[0098] 图21A至图21D示出了用于去除凝块的装置的示例。图21A示出了 在耦接到导管之前的可扩张的第一端部区域的示例。图21B示出了通过拉 动柔性(牵引器)管的近侧端部而将血管(玻璃管)内的可扩张的第一端 区域拉入导管中。图21C示出了装置的远侧端部区

域，其包括在导管的远 侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉入导 管中的图21C的装置。

[0099] 图22示出了图21D的可扩张的第一端部区域，其在将其向近侧拉出 导管之后具有所捕获的凝块。

[0100] 图23A至图23D示出了如本文所描述的机械取栓装置，其捕获血凝 块并将其拉入装置中。

[0101] 图23E示出了柔性牵引器管已经从导管去除(例如近侧)之后保持在 柔性牵引器管内的凝块。

[0102] 图24是包括柔性牵引器构件的装置的另一个示例，其中，远侧牵引 器区域由多个细丝形成，多个细丝布置成未机织或编织材料的条(纵向平 行)。这些条(strip)可以是细丝或管等。

[0103] 图25A至图25F示出了柔性牵引器组件的远侧牵引器区域的另一变 型，其中，可扩张的第一端部区域(例如，远侧牵引器区域的远侧端部区 域)由多个细丝或条形成，类似于在图24中所示的；导管的远侧端部包 括通道，如图25A至图24所示；这些条可以装配在这些通道内，如25C 至图25D所示。图25E和图25F示出了穿过25C和图25D的截面图。。

[0104] 图26A和图26B示出了具有外套筒(例如，外导管或释放保护器导 管或其他外套筒/保护器)的图25A至图25F的装置的变型

[0105] 图27A和图27B示出了穿过26A至图26B的装置的截面图。

[0106] 图28是包括柔性牵引器组件的远侧牵引器区域的装置，该柔性牵引 器组件具有多个纵向平行的(非机织/编织的)细丝或条，其中细丝或条的 远侧端部通过远侧连接件彼此连接。

[0107] 图29示出了装置中的柔性牵引器组件的远侧牵引器区域，其中纵向 平行的(非机织/编织的)细丝或条包括抓取元件。

[0108] 图30A至图30C示出了具有抓取元件的细丝/条的示例。抓取元件(和 /或包括它们的细丝)可以用作本文所描述的变型中的任一个的一部分，包 括机织或编织的远侧牵引器区域。

[0109] 图31示出了一种变型，其中远侧牵引器区域适于往复运动(例如， 推动和拉动)使得可扩张的第一端部区域可被拉入导管中并从导管翻转 出。

[0110] 图32示出了如本文所述的装置的另一示例，其中可扩张的第一端部 区域的最远侧端部固定到导管的远侧端部的一部分；可扩张的第一端部区 域的其余部分具有足够的弹性/柔性以被拉入导管中(用其拉动凝块)。然 后柔性牵引器组件可以被收回并且整个装置被拉出。该示例可能包括可选 的真空。

[0111] 图33是装置的另一个示例，其中柔性牵引器组件的拉动器部分由与 远侧牵引器区域相同的材料形成，但可以被层压或以其他方式被增强以具 有比远侧牵引器区域更小的柔性/可拉伸性。

[0112] 图34示出了其中远侧牵引器区域适于在被拉入导管中时压缩凝块的 另一个示例。

[0113] 图35A至图35C示出了如图34所示的装置的操作，其中通过将远侧 牵引器区域的可扩张的第一端部区域拉回到压缩凝块(图35A至图35B) 的导管中(例如，在牵引器组件的

拉动器区域上拉动)而将凝块拉入导管；释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并将其 从远侧牵引器区域释放，使得其可以利用手动或动力真空源向近侧抽吸 (图35C)。

[0114] 图36示出了一种使用装置和方法的示例，其中向近侧拉入柔性牵引 器组件可以使装置向远侧行进通过导丝上的主体(例如血管)，该导丝可 以被处理以接合远侧牵引器区域。

[0115] 图37A至图37C示出了一种使用装置和方法，其中向近侧拉柔性牵 引器组件可以使装置向远侧行进。

[0116] 图38A和图38B示出了装置和使用该装置从血管中去除材料的方法 的另一变型，其中该装置是“无限”牵引机构，其中大量的牵引器材料(例 如，网状物)储存在一个外保持区域中，其被卷起但在扩充使用上不是必 须的。

具体实施方式

[0117] 通常，本文描述了用于从身体机械地去除物体的方法和装置。虽然这 些方法和装置可以适用于从身体的各种区域去除各种物体，但它们可能特 别适合于从血管的腔内去除血凝块。因此本文所描述的是机械取栓装置 (例如设备和系统)。

[0118] 本文所描述的装置(例如，用于从血管去除凝块的机械取栓装置)可 以是包括具有远侧端部和远侧端部开口的细长导管的组件以及至少部分 位于导管内的柔性牵引器组件，其中，牵引器组件的远侧端部区域被配置 为远侧牵引器区域，远侧牵引器区域至少部分地在导管内延伸并且在导管 的远侧端部上翻折回来。牵引器组件可以包括连接到远侧牵引器区域的近 侧推动器区域。柔性牵引器组件包括配置成允许导丝通过的细长腔。柔性牵引器组件还被配置成在近侧端部区域被向近侧拉动时沿着导管腔内的 长轴线滑动并且在导管的远侧端部开口上翻转。牵引器组件在本文可被称 为柔性牵引器组件、柔性牵引器部分、柔性牵引器管或简单的柔性管，并 且典型地定位在导管内并且可在导管内纵向可滑动，并且布置成使得远侧 端部区域(“远侧牵引器区域”)在导管的远侧端部上翻折回来。

[0119] 例如，图1A示出了可形成本文所描述的装置的一部分的导管的一种 变型。在该示例中，导管100包括远侧端部区域103，远侧端部区域包括 远侧端部105。除了非常远侧尖端(远侧端部105)可以实质上比紧邻其 的区域较不柔软之外，远侧端部区域可以具有增加的柔软度(通过硬度计 测量，例如肖氏硬度计)。因此，虽然远侧尖端区域(例如，最远侧的x线性尺寸，其中x为10cm、7cm、5cm、4cm、3cm、2cm、1cm、9mm、 8mm、7mm、6mm、5mm、4mm、3mm)具有从近侧端部到远侧端部 延伸的增加的柔软度/减小的硬度，非常远侧端部区域107(例如，测量为 最远侧的z线性尺寸，其中z为1cm、9mm、8mm、7mm、6mm、5mm、 4mm、3mm、2mm、1mm、0.8mm、0.5mm、0.3mm、0.2mm等，并 且z总是比x小至少三倍)的硬度大于紧邻其的区域的硬度，并且可以与 远侧尖端区域的最近侧区域一样硬或比其更硬。

[0120] 导管100也可以被称为内导管或牵引器导管。可以使用任何适当类型 的导管，包括适用于神经血管使用的微导管。

[0121] 在一些变型中，导管的远侧端部105适于使得远侧牵引器区域可以在 导管的远侧端部上滑动并翻转而不被捕获(束缚)或没有实质摩擦。例如， 在一些变型中，远侧尖端(端部)可以是弯曲的或倒圆的109，如图1B 所示。特别是在外表面上(例如从外径到内径的过

渡)。在一些变型中，远侧尖端包括一个或多个通道，如图25A至图28所示和所述的，包括围绕面向远侧的边缘的通道，以引导远侧牵引器区域的滑动。

[0122] 图1C示出了柔性牵引器管140的示例。在图1C中，管是柔性的并 且细长(具有通常比导管101大的长度)，并且包括远侧牵引器区域142，该远侧牵引器区域包括配置成紧邻近侧区域146上折叠的最远侧可扩张的 第一端部区域144，其可以是可较少扩张的第二端部区域。通常，可扩张 的远侧端部区域被配置成在不受约束时扩张至介于导管的内径的直径的 1.3倍至10倍之间的径向直径。图1D示出了处于扩张配置的图1C的可 扩张的远侧端部区域。因此可扩张的远侧端部区域可以被偏置以扩张打 开。可扩张的远侧端部区域可以形成为网状物、机织物或材料片，并且通 常适于抓取待去除的物体(例如血凝块)。

[0123] 图1C中一般性示出的柔性牵引器管被示出为图1E中的可扩张的远侧 端部区域在其本身上(例如在更近侧的可较少扩张的第二端部区域上)翻 折回来。在图1E中，可扩张的远侧端部区域收缩，而在图1F中，可扩张 的远侧端部区域扩张。通常，可扩张的远侧端部区域可以与近侧的可较少 扩张的第二端部区域区分开，然而在一些变型中，整个柔性牵引器管可以 包括在导管内被推动和/或拉动且不包括近侧的可较少扩张的远侧端部区 域的可扩张的材料(例如，网状物、机织物等)。

[0124] 图1G和图1H示出了使用诸如由图1A和图1E的部件组装的装置的 装置去除凝块。在该示例中，该装置被配置为包括导管101和柔性牵引器 管的取栓装置，该柔性牵引器管包括可扩张的远侧端部区域144，该可扩 张的远侧端部区域在导管的远侧端部区域上延伸并且在导管的远侧端部 上翻折，使得可扩张的远侧端部区域与内近侧的可较少扩张的(在该示例 中，可较少扩张的包括不可扩张的)第二远侧端部区域146连续，该第二 远侧端部区域在导管内向近侧延伸并形成可使导丝通过的内腔。柔性牵引 器管(未示出)的近侧端部可以包括推动器/拉动器构件，该推动器/拉动 器构件可以是与远侧端部区域(远侧牵引器区域140)连续的杆或其它构 件。在图1G中，装置被示出在凝块155附近的血管160内定位并展开。 通过将远侧牵引器区域140取回到导管101中，可以将凝块拉入导管中， 如箭头180所示，其示出了柔性牵引器管的内部部分的拉动(例如，使用 手柄，未示出)，从而导致将可扩张的远侧端部区域拉动到导管远侧端部 中并翻转可扩张的远侧端部区域，使得其被拉动到导管中，如箭头182所 示。可扩张的远侧端部区域的远侧端部可相对于导管的外壁“松动”，或 者其可被去除附接或在一些变型中永久附接。

[0125] 通常，定位这些装置并致动它们可能是具有挑战性的，这是因为它们 在致动之前和操作期间都必须是高度柔性的。例如，一般来说，柔性牵引 器管必须不能增加导管的刚度/柔性，并且特别是导管的远侧端部区域过 多，或者对于操纵来说过于困难和/或危险，特别是在神经血管系统的侵蚀 血管内。本文所描述的是柔性牵引器管部分，其增加了小于预定百分比(例 如，小于10％、12％、15％、18％、20％、25％、30％等)的导管的最后y cm(例如，最远侧的20cm、18cm、15cm、12cm、10cm、9cm、8cm、 7cm、6cm、5cm、4cm、3cm、2cm、1cm等)的刚度。例如，本文所 描述的是柔性牵引器管部分，其穿过导管并且在导管的远侧端部上翻折回 来，但是在没有柔性管延伸穿过其中并且在导管的远侧端部上翻折回来的 情况下，将导管的远侧5cm的刚度增加小于导管的远侧5cm的刚度的 15％。

[0126] 例如，图2A示出了柔性牵引器管201。在该示例中，柔性牵引器管 包括在近侧推动器区域201的远侧的远侧牵引器区域242，该远侧牵引器 区域具有可扩张的第一端部区域

244以及可较少扩张的第二端部区域 246。整个柔性牵引器管是中空的并且可以使导丝通过(未示出)。柔性牵 引器管的各个区域可以由相同的材料(例如,机织的、编织的等细丝(filament)或多个细丝)制成,或者它们可以由不同的材料制成。

[0127] 图2B示出了具有远侧牵引器区域的柔性牵引器管,或者至少由多个 机织纤维形成的可扩张的第一端部区域244'。可替代地,可扩张的第一端 部区域可由一个(或多个)针织纤维或机织和针织纤维的组合形成。可扩 张的第一端部区域可以通过纤维或机织/针织图案的形状设定特性或通过 包含一个或多个偏置构件(例如,环、弹簧、带、细丝等)而被偏置地打 开(如图所示),其倾向于至少将可扩张的第一端部区域的远侧端部区域 偏置打开。

[0128] 图2C示出了由包括多个开口(例如,孔、穿孔、通道、窗口等)的 材料片形成的可扩张的第一端部区域的另一变型。这些开口可以是任何尺 寸,包括不均匀尺寸(例如尺寸的范围)或均匀尺寸。穿过片的这些开口 的尺寸可取决于所使用的材料,例如聚合物材料(PTFE)、硅树脂材料、 聚氨酯、形状记忆合金等。在一些变型中,片的孔隙率大于>60%(大于 70%、大于75%、大于80%、大于85%等、在60%至95%之间、在65% 至95%之间、在70%至95%之间等)是有益的。

[0129] 在这些变型中的任一个中,远侧牵引器区域被配置成使得其可以在其 本身上被翻转(例如,翻折),如图2D所示。在一些变型中,该装置可被 执行为使得可扩张的第一端部区域在其本身上和/或在导管的远侧端部区 域上翻转,或者其可以被配置成使得其可以在体内(例如在血管内)在 导管的远侧端部展开和翻转。通常,在装置可被致动之前,导管可以插入 可扩张的第一端部区域与柔性牵引器管上的可扩张的第一端部区域的近 侧的区域之间,在一些变型中,其可以是可较少扩张的第二远侧端部区域。 该空间289可以通过在可扩张的第一端部区域的远侧端部处或附近的偏置 构件而保持打开。如所提到的,该可扩张的第一端部区域开口偏置构件可 以是环、带、弹簧、线圈等,并且可以由偏置元件(例如,形状设定材料, 诸如形状记忆合金)、橡胶或其他聚合物材料等制成。

[0130] 尽管存在相关的挑战,但是本文所描述的装置的体内展开可以为操作 装置的用户提供许多优点。图3A至图3F示出了配置用于体内展开的取栓 装置的一个示例。在该示例中,该装置包括导管301,该导管可以使用导 丝313定位(如同本文所描述的变型中的任一个)。导丝可以延伸到或进 入(或穿过)待去除的物体,其示出为在血管360内的图3A中的凝块355。装置的导管可以与导丝一起插入或在导丝之后插入,并且在有或没有柔性 牵引器管在导管的远侧端部处或附近的情况下,可以将导管定位在凝块附 近(例如,邻近或紧邻)。在图3A中,在导丝已经定位之后,定位导管, 并且如图3B所示,从血管中取出导管。导丝可以是线材,较小的导管或 可以定位(例如,操纵)到凝块和/或穿过凝块的装置的组合。在定位导管 之后,包括远侧牵引器区域342的内柔性牵引器管340被推动穿过导管至 导管的远侧端部区域,如图3C所示。在该示例中,形成远侧牵引器区域 的柔性牵引器管的远侧端部包括示出为网状物344的可扩张的第一端部区 域,该网状物在近侧端部处(推动器区域305)连接到与柔性牵引器管的 其余部分连续的近侧的不可扩张的第二端部区域。可扩张的第一端部区域 的机织网状物344在收缩(非扩张)配置中在管状第二端部区域/推动器区 域的外侧上预先翻转,并且可以滑动穿过导管的腔,并且(当导丝留在适 当的位置或用于调节该位置时)在导丝(未示出)上滑动。如图3D所示, 柔性牵引器管的远侧牵引器区域

然后可以通过延伸(在该示例中,向远侧 推动柔性牵引器管和/或向近侧拉动导管)而暴露于导管的外侧,从而允许 远侧牵引器区域(示为网状物)344的可扩张的第一端部区域沿着第一端 部区域的长度扩张。在图3D中,这显示为可以完全扩张至血管的内膜的 支架状结构,在可扩张的第一端部区域与可较少扩张的(在此情况下是不 可扩张的)第二端区域346之间形成分离。特别地,第一端部区域的扩张 可以大于导管的内腔的直径的1.3倍(例如,大于1.5倍、大于2倍、大 于2.2倍、大于2.5倍、大于3倍、大于3.5倍、大于4倍、大于5倍、大于6倍、大于7倍、大于8倍、大于9倍、大于10倍等)。

[0131] 在图3D中,导管在远侧牵引器区域的第一端部区域与第二端部区域 之间向远侧滑动。然后可以通过向近侧拉动柔性牵引器管(例如,近侧牵 引器区域)和/或向远侧推进导管中的一者或两者,而可以通过将可扩张的 第一端部区域向近侧取回到导管中来移除凝块。在一些变型中,既推进该 装置(特别是导管),同时又取回可扩张的第一端部区域并将其翻转到导 管中可能是有益的。可以比取回柔性牵引器管更快地推进导管。

[0132] 如图3F所示,凝块355可以被拉入到具有可扩张的第一端部区域的 导管中。

[0133] 体内展开方法和装置的另一种变型示于图4A至图4F中。在该示例中, 柔性牵引器管的自扩张的第一端部区域被配置成当其被推出导管时在导 管的端部上自扩张,使得它将在导管的远侧端部上滑动。如以上对于图3A 至图3B所描述,可以使用导丝413等来定位该装置。在图4A中,将导 管401定位在邻近待去除的凝块455的导丝413上。在图4B中,导丝可 以(可选地)被去除,或者(优选地)保留在位。包括远侧牵引器区域的 柔性牵引器管434然后可以在导管内向远侧移动并且以可扩张的第一端部 区域444延伸出远侧端部,使得其在远侧端部上翻转466并且在远侧端部 区域上向近侧滑动,如图4C所示。该过程可以通过在脉管的腔内向远侧 推动装置来辅助,因为第一端部区域444的扩张可以帮助将其抵靠血管的 壁固定,如图4D至图4E所示。一旦暴露,通过向近侧拉动柔性牵引器 管434和/或向远侧端部推进组件(或至少导管),可扩张的第一端部区域 可以取回到装置中,如图4F所示。凝块455然后可以被拉入装置中。

[0134] 图5A至图5E示出了使用机械取栓装置的体内展开和取栓(凝块去 除)方法的另一变型。在图5A中,包括导管501和内柔性牵引器管534 的装置500(例如,在导丝上,未示出)被推进至凝块555附近。在该示 例中(其可以与本文所描述的方法中的任一个相关),该装置与柔性牵引 器构件一起定位,该柔性牵引器构件具有未展开的远侧牵引器区域,该远侧牵引器区域已经在远侧定位在装置的远侧端部区域附近。如图5B所示, 处于图5A中导管501内的收缩配置的可扩张的第一端部区域544被推出 导管的远侧端部并扩张至腔的壁,如图5B和图5C所示。一旦推出并扩 张,可向远侧推进导管和导管内的柔性牵引器管的部分,如图5D所示, 导致可扩张的第一端部区域544翻转,在导管501的远侧端部区域上翻折。通过图5E,装置已经在凝块555附近展开并且可以如已经描述的那样被 致动以去除凝块,但是将远侧牵引器区域的可扩张的第一端部区域拉动到 导管中,使得它翻转并将凝块拉入导管中。导管可以可选地同时被推进。 注意,上述体内展开的方法也可以用于加载用于插入体内的装置,以便将 导管径向地定位在柔性牵引器管的可扩张的第一端部区域与较近侧部分 之间。

[0135] 图6A示出了具有柔性牵引器管634的取栓装置的另一变型的示例, 该柔性牵引器管634具有形成于编织(例如机织)或针织材料的该示例中 的柔性第一(远侧)端部区域

644，其中，柔性第一端部区域(牵引器区 域)在导管601的远侧端部上翻转并且附接到柔性牵引器管634的近侧端 部区域。如在本文所描述的装置中的任一个中，柔性牵引器管的该近侧端 部区域可以是海波管、导管或者在导管内可推动/可拉动并且在其远侧端部 附接到柔性牵引器区域(例如，远侧牵引器区域)(包括在一些变型中的 可扩张的第一端部区域)的层压机织物/网状物或机织材料。注意，在一些 变型中，远侧牵引器区域(第一端部区域)可以是不可扩张的，但是可以 只是柔性的。

[0136] 在图6A中，附接到柔性牵引器管的远侧牵引器区域的第一端部区域 被外导管或套筒(保护器)677覆盖。在该示例中，该装置还包括在内导 管601与保护器导管或套筒677之间的中间导管679。在一些变型中，柔 性第一端部区域644可以附接到该中间导管，包括可拆卸地附接使得向近 侧拉动柔性牵引器管634将使其脱离并允许网状物(柔性第一端部区域 644)在血管中展开。在图6A所示的变型中，柔性第一端部区域644未附 接至中间导管679。

[0137] 本文所描述的装置中的任一个，包括图6A中所示的装置，可以与如 图6B所示的导丝633一起使用(并且可以包括导丝)。图7A至7D示出 了图6A至图6B中所示的设备的操作以去除凝块755。在该装置中，柔性 牵引器管734的近侧端部可以耦接到真空源(未示出)，该真空源当向近 侧取回牵引器管734以在导管的端部上翻转远侧牵引器区域时可以被致动。在图7A中，装置位于凝块755附近。在图7B中，通过如箭头所示 拉动柔性牵引器管734而翻转远侧牵引器区域并将其拉动到导管中。在该 示例中，远侧牵引器区域不被扩张，这是因为它仍然被外套筒777覆盖， 如图7B和图7C所示。可以通过推动或通过向近侧拉动远侧牵引器端部 区域(在该示例中示为网状物744)的动作以使其在导管的远侧端部上翻 转中的一者或两者，向远侧朝向凝块或者在凝块上推进该装置。一旦凝块 被去除，装置可以被取回并从血管中被拉出，如图7D所示。

[0138] 如上所述，这些变型中的任一个可以包括一个或多个真空源。图8示 出了包括真空源的一个示例，其示出了耦接到柔性牵引器管834的腔的近 侧端部处的第一可选真空源。例如，与真空和牵引器管834耦接的可以是 旋转止血阀(RHV)，如图所示。在图8中，在(可选)外导管877和内 导管801或(可选)中间导管878之间形成第二(可选)真空连接。可以在该方法的任何适当部分处施加真空，包括在柔性牵引器管834的收回期 间去除凝块。

[0139] 如上所述，本文所描述的装置中的任一个可以包括导丝并且可以在手 术期间将导丝留在适当的位置。图9A至9D示出了当导丝913留在适当 的位置时去除物体(例如凝块)的方法。在该示例中，该装置类似于图6A 至图6B中所示的装置，并且可以包括可选的真空源。在图9A中，包括 远侧牵引器区域944的柔性第一端部区域944的翻转部分的导管的远侧端 部定位成邻近凝块，并且通过向近侧拉动而被致动以将凝块拉入导管中， 如图9B所示。在该示例中，凝块已经被导丝913穿透，因此具有翻转的 牵引器区域的导管尖端可以通过推动导管927和/或通过向近侧拉动牵引 器管919而在导丝上被向前推进。这可以继续直到整个凝块在导管内，如 图9C所示。

[0140] 在本文所描述的变型中的任一个中，该装置可以包括一个或多个标 记，或者可以被配置成与一种或多种对比剂一起使用以帮助使所描述的方 法可视化。进一步地，这些方法中的任一种都可以包括可视化。可视化可 以是间接的(例如，使用荧光镜检查或等效技术)，或者可以是直接的， 例如使用一个光纤用于直接使该装置可视化(例如，通过装置的

腔)。

[0141] 在图9D中,具有捕获物体(例如凝块)的牵引器管可以从装置的近 侧去除并且可以检查所去除的材料(例如,通过组织学/细胞学检查)。随 后或同时去除导管。如上所述,当去除物体(例如凝块)时,可能期望在 柔性牵引器管向近侧拉回(未示出)的同时(向近侧)拉回导丝。在一些 变型中,远侧牵引器区域(例如,编织/机织或针织区域)可以抓取导管内 的导丝并且还可以帮助在凝块上或朝向凝块向远侧推进该装置,如下面在 图36以及图37A至图37C中更详细地描述的。

[0142] 通常,抓取器(远侧牵引器区域)的滚动效果通过导管相对于远侧牵 引器区域的运动而被致动。如果远侧牵引器区域向近侧固定并且导管被推 进,则远侧牵引器区域可以具有1:1的抓取比。如果远侧牵引器区域被 拉动通过导管,则抓取效果可能被放大。例如,当远侧牵引器区域被拉回 (通过拉动牵引器管)并且当内导管被向远侧推动1个单元时翻转进入内 导管中在导管内的近侧的1个单元,抓取效果大约是2倍。如果当内导管 向远侧推进一个单元时,远侧牵引器区域被取回到导管中向近侧两个单 元,则抓取效果可以是大约3倍。远侧牵引器区域和导管的同时运动可以 通过手柄来协调。

[0143] 通常,本文所描述的装置中的任一个可以包括手柄。手柄可以与柔性 牵引器管和/或导管(例如内导管)和/或任何外导管(例如保护器、套筒 等)耦接。手柄可被配置成允许柔性牵引器管和/或导管的选择性的分开致 动和/或这些部件的协调运动。图10A和图10B示出了可以使用的手柄的 示例。在图10A中,手柄包括驱动机构以拉回牵引器管,并且因此在导管 的远侧端部上翻转远侧牵引器区域和/或相对于远侧牵引器区域推进导管。在图10A中,手柄包括可旋转手柄1001,该可旋转手柄与导管驱动器1003 耦接。手柄连接到导管1005和具有远侧牵引器区域1011的内部柔性牵引 器管1009两者。手柄可以被配置成使得导管的推进(向远侧)与牵引器 管的拉动(向近侧)的比率可以被选择和/或可以取决于导管驱动螺纹的螺 距或其他机械机构。

[0144] 手柄的另一个变型在图10B中示出。在该示例中,手柄可以附接到牵 引器管以拉动(或推动)牵引器管1017,并且因此在导管的远侧端部上翻 转远侧牵引器区域,并且手柄的另一部分可以耦接到导管以推动/拉动导管 1015。

[0145] 图11A示出了手柄机构1107的另一个变型,该手柄机构被配置成通 过在附件部位1105处耦接到牵引器管的近侧端部来拉动本文所述的装置 中的任一个的抓取器(远侧牵引器区域),和/或通过耦接到导管的近侧端 部来推进导管。手柄机构的另一个示例在图11B中示意性地示出,其示出 了杠杆机构1109和与可以固定或可调节的内牵引器管耦接的耦接件。

[0146] 在本文所描述的装置中的任一个(例如,机械取栓装置)中,远侧牵 引器区域可以被预加载在导管中/上,使得它可以通过向近侧拉动耦接到远 侧牵引器区域的牵引器管和/或向远侧推进导管而被致动。在其中远侧牵引 器区域包括在导管的远侧端部上翻折的柔性和/或可扩张的第一端部区域 (例如,由网状物和/或机织物材料形成)的预加载变型中,装置可以是适 于防止第一端部区域在已经被定位在凝块处或凝块附近之前无意地移位 和/或扩张。

[0147] 图12A和图12B示出了附接到导管外侧的远侧牵引器区域的可释放 附件的示例。通过施加应用于柔性牵引器管的近侧端部的适当量的力(例 如拉力)可以释放这些附件中

的任一个。例如，如图12A所示，远侧牵引 器区域(示为网状物1204)的外远侧端部被从外导管或管1203延伸的肩 部或衬垫覆盖)。类似地，在图12B中，远侧牵引器区域(示为网状物1204) 的外远侧端部被单独的带、环或衬垫1209覆盖。通过添加细丝(例如在 编织或机织变型中，附加编织细丝)、通过添加涂层、通过热定形至较大 直径，和/或通过添加轴向编织间拉线，当张紧(例如在牵引器管上向近侧 拉动)时，可以防止远侧牵引器区域收缩或直径减小。

[0148] 本文所描述的变型中的任一个可包括作为柔性牵引器管的一部分的 近侧拉杆或拉线。进一步地，牵引器管的近侧端部区域可能比远侧端部(远 侧牵引器区域)柔性更小。图13A和图13B示出了柔性牵引器管的示例。 在图13A中，管包括近侧锥形区域，其中，远侧牵引器区域1305由向近 侧1307渐缩(tapered，锥化)到拉线的材料(例如，网状物/机织材料) 形成，为导丝1309留出空间并允许远侧牵引器区域在导管上翻转。近侧 拉线部分可由形成远侧牵引器区域的细丝形成，例如，在其中机织或编织 远侧牵引器区域的变型中。这些细丝可以通过例如其他材料(诸如有助于 使其更硬或更柔顺的聚合物)来增强。图13B示出了另一个示例，其中， 柔性牵引器管的近侧端部由拉线1315形成，该拉线可以是单独的材料或 附接到拉线的远侧端部并形成远侧牵引器区域1317的编织线束的延伸部。

[0149] 本文所描述的装置中的任一个可以被处理或适应为减少在导管端部 上翻转远侧牵引器区域所需的力。例如，在一些变型中，远侧端部可以被 处理为润滑的，或者远侧牵引器区域的全部或一部分可以被处理以提高费 力性。例如，在一些变型中，仅远侧牵引器区域的一部分(例如最初在导 管的远侧端部上相互作用/翻转的部分)被处理；远侧牵引器区域的其余部 分不被处理。图14示出了此类装置的一个示例。在图14中，可扩张和/ 或柔性第一端部区域(其定位于导管外侧)的最近侧端部1405用润滑涂 层处理或由润滑材料形成。第一端部区域的剩余部分(未按比例示出)不 是润滑的1403。由于较近侧区域1405暴露于血管和导管的远侧端部，所 以它可以更有效地追踪目标或者允许装置追踪目标以及更有效地开始在 远侧端部上翻转。该区域可以以任何适当的方式制成润滑的，包括但不限于涂层，诸如疏水/亲水涂层，并且形成或包括更润滑的聚合物材料(例如 PTFE)。

[0150] 通常，本文所描述的远侧牵引器区域中的任一个可以适于包括不同的 轮廓，包括预先设定以具有(例如，形状设定)可以更容易地在远侧端部 上滑动/移动和/或抓取凝块或其他目标物体以用于去除的轮廓。例如，图 15A至图15D示出了具有形成不同远侧牵引器区域的不同远侧端部轮廓 的牵引器管。例如，在图15A中，远侧牵引器区域包括由通过多个拉线连 接到牵引器管的近侧端部的由编织/网状或机织材料形成的最远侧可扩张 和/或柔性第一端部区域1505。这些拉线1517可以由形成编织/网状或机 织的远侧端部区域的相同线材或细丝形成。图15B示出了另一种变型，其 中，多个离散的编织/网状或机织的远侧端部区域通过拉线1515连接；这 些拉线区域1515可以是比编织/网状或机织区域1516更少可扩张的和/或 柔性的。在图15C中，远侧端部区域被编织/网状或机织，但预先设定为 具有不同的直径。因此这些区域沿其长度可以具有不同的形状；当这些形 状被拉入导管中时，这些形状可被热定形以更好地抓取或破碎凝块。图 15D示出了编织或支架状第一端部区域1521的示例，其通过形成编织/网 状或机织的远侧牵引器的相同细丝的相同细丝或束连接到牵引器管1520 的海波管或其他更近侧端部区域1523。

[0151] 本文所描述的装置中的任一个还可以或可替代地包括附接到导管的 外表面上的

多个可释放附件，从而将远侧牵引器区域(并且特别是远侧端 部部分)固定到外表面。在图16中，示出了形成可释放附件的三个环1603、16.3'、1603"，其将远侧牵引器区域1644的远侧端部固定到导管1601的外 侧。在该示例中，聚合物涂层/膜与编织物附接或成一体，形成远侧牵引器 区域以帮助防止其过早地滑出或滑离导管(例如，直到由使用者拉动)。 该装置可以包括沿着导管的长度径向定位的多个附件，如图所示，以帮助 其保持固定到导管输送系统的外径。在一些变型中，这些可释放附件是弹 性构件(例如聚氨酯环)，但可以是脆的，并且允许破坏以释放远侧牵引 器区域。

[0152] 图17示出了另一种变型，其中，可释放附件定位成使得远侧牵引器 区域的一部分被弹簧加载(偏置)以驱动它在导管远侧端部上滚动并进入 导管腔中。在图17中，远侧牵引器区域1704的远侧端部可被固定(固定、附接或松动但受约束)，并且在导管的远侧端部附近的较近侧端部区域可 被可释放地固定到导管1707。例如，聚合物涂层或膜可以附接到远侧牵引 器区域(在图17中示出为编织物1744)并且被耦接以使远侧牵引器区域 1705的在远侧端部1704与可释放附接部位1707之间的一部分保持张紧 (例如，压缩)。然后释放可释放附件1707可以施加驱动围绕导管远侧端 部的远侧牵引器区域的力，以帮助将凝块拉入装置中，并减小翻转远侧牵 引器区域所需的力。

[0153] 如上所述，形成远侧牵引器区域(并且特别是最远侧柔性和/或可扩张 的第一端部区域)的材料可以由任何适当的材料形成。例如，该材料可以 包括织物、机织物、针织物、编织物、缝合物、管和/或平片。该材料可以 具有任何合适的厚度，例如在0.0005"至0.015"的壁厚之间，并且可以具 有从低至高孔隙率的任何合适间隔/尺寸(孔隙率)的孔。远侧牵引器区域 的全部或一部分可以是不透射线的或无线电透明的。在机织、针织、编织 或缝制的变型中，材料可以由多丝或单丝形成。不同尺寸的细丝可以混合 在一起(例如，大和/或小)以通过增加或减少织物表面纹理来改变抓取效 果。在一些变型中，材料(包括形成材料的细丝)可以是基于聚合物的(例 如PET、尼龙、聚丙烯、PTFE、ePTFE)、弹性和非弹性的(例如PU、硅 酮、橡胶、莱卡)、金属细丝(例如镍钛、包括DFT的拉伸充填的镍钛， 即带Pt内芯的镍钛、钢、不锈钢、钴铬合金等)以及金属和聚合物细丝 的混合物。织物的端部可以是激光切割/焊接或自由切割。在一些变型中， 远侧牵引器区域的全部或部分包括膜或片。该膜可以在0.0005"至0.008" 厚度之间。该膜可以通过管挤出或片形成并且卷成管。在一些变型中，膜 是纱线增强的。膜可以是开槽的(例如，可以包括被切割的孔和/或狭缝以 改进抓持或滑入导管)。在一些变型中，膜具有纹理化表面(例如，翻转 时暴露的纹理化内表面)。膜可形成具有沿长度具有脊和/或环(径向环) 和/或线和/或具有锯齿形图案的管。纹理化内表面可以包括大丝和小丝的 混合物，和/或可以由更多孔的较密度的织物形成。

[0154] 在一些变型中，抓取器元件的可视性是期望的，但并非始终需要。例 如，如上所述，标记可以位于设备上。在一些变型中，可能期望看到结构 的整个结构或近侧端部和远侧端部。例如，材料可以是镍钛诺或在铂材料 (DFT)上拉制的镍钛诺以增强可视性。

[0155] 变型中的任一个可以包括位于编织结构中的任一个的内侧的旋转螺 旋钻元件以协助将凝块拉回到毂。如上所述，这些装置中的任一个都可以 包括真空源。向系统添加真空可能有助于远侧牵引器区域将凝块/栓塞拉入 导管中的能力。所施加的真空可以是稳定的/恒定的、倾斜的或脉动的。

[0156] 在一些变型中，使用它们的装置和方法可以包括阻流近侧球囊(例如， 定位在凝

块附近)，其可以在手术期间减少凝块上的压力。

[0157] 本文所描述的装置和方法可以用于捕获活检样品(例如，来自乳房或 任何其他器官)。例如，当执行腹腔镜手术时，可以使用这些装置去除较 大的组织段(例如，癌症、胆囊等)。

[0158] 当形成远侧牵引器区域的材料是机织/编织材料时，所得到的网状结构 可具有范围从1cm到100cm长以围绕导管的外径(OD)的编织物长度，优选地长度为在约3cm至30cm之间。

[0159] 在这些变型中的任一种中，牵引器管和/或导管(包括远侧牵引器区域) 可以被构造成使得可以拉动远侧牵引器区域，使得远侧牵引器区域以最小 的力在导管远侧端部的外径周围被拉入(翻转)，使得导管尖端不会在血 管中弯曲或显著变形(例如，蛇形扭动)，其中，拉力小于约：50克、100 克、300克、500克、800克、1000克、2千克、3千克、5千克、8千克、10千克、15千克、20千克等。

[0160] 在其中抓取器(远侧牵引器区域)至少在远侧端部(例如，可扩张的 和/或柔性第一端部区域)上构造为机织(例如编织)结构的变型中，形成 机织结构的细丝的示例可以包括：镍钛、镍钛-PT DFT线材(Pt内部的镍 钛管)、PET、PP、尼龙、Algiloy、SS、混合材料。当使用时，镍钛可能 被蚀刻以使其非常平滑。细丝端部的数量可以是约：16、24、36、48、77、 96、144或这些整数之间的任何数量。任何编织结构都可以使用。例如， 示例性编织结构可以包括1×1(1×1)、1×2、2×2等。在一些变型中， 形成机织和/或针织材料的细丝包括单丝，例如所具有的外径(O.D.)尺寸 约为：0.0005”、0.00075”、0.001”、0.0015”、0.002”、0.003”或在本文列 出的整数之间的尺寸或直径尺寸的组合。如上所述，这些装置可以适用于 使用的神经脉管系统，例如假设2mm至3mm脉管内径(ID)。例如，如 本文所描述的适于神经脉管应用的装置可以包括韧炼至3mm至7mm OD 的0.001”至0.002”聚合物编织物的36个至72个端部。在一些变型中， 远侧牵引器区域包括24个编织线材，其具有以45度角度编织的在2mm心轴上韧炼的0.0005”至0.0015”或0.002”的扁平镍钛线材。可替代地， 在一个变型中，远侧牵引器区域包括编织材料，该编织材料由以45度角 度编织的在2mm心轴上韧炼的0.002”厚度的镍钛线材的24个线材形成。 在一个示例中，远侧牵引器区域包括编织材料，该编织材料包括以45度 角度编织的在2mm心轴上韧炼的0.002”DFT镍钛线材的24个线材。在 一个示例中，远侧牵引器区域包括机织材料，该机织材料包括与在2mm 心轴上的0.002”镍钛线材的8个附加端部混合的0.003”线材的8个端部。 在一个示例中，远侧牵引器区域包括编织材料，该编织材料包括在2mm 心轴上韧炼的0.002”铂铱线材的16个端部。在一个示例中，远侧牵引器 区域包括编织材料，该编织材料包括具有0.002”直径的外径的PP单丝的 24个端部。在一个示例中，远侧牵引器区域包括编织材料，该编织材料包 括0.003”PP单丝的12个端部。在一个示例中，远侧牵引器区域包括编 织材料，该编织材料包括0.003”PP单丝的16个端部。在一个示例中， 远侧牵引器区域包括编织材料，该编织材料包括1x1、90度编织角度、8 mm心轴的0.001”PET或PP的72个端部。在一个示例中，远侧牵引器 区域包括编织材料，该编织材料包括1x1、75度编织角度、6mm心轴的 0.001”PET或PP的36个端部。在一个示例中，远侧牵引器区域包括编 织材料，该编织材料包括1x1、90度编织角度、8mm心轴的0.002”PET 或PP的48个端部。在一个示例中，远侧牵引器区域包括编织材料，该 编织材料包括1x1、70度编织角度、6mm心轴的0.002”PET或PP的48 个端部。

[0161] 在其中远侧牵引器区域包括网状物的变型中，管状网状物可由针织或 替代结构形成，该针织或替代结构被构造成使得当网状牵引器被轴向拉动 并且围绕导管尖端的外侧并进入导管ID中时，径向压缩(管状网状物内 径ID的变化)经受直径减小5％至20％。这种5％至20％网状物直径的减 小可以有助于在将网状物拉动到导管中时抓取凝块或异物，而不会产生很 大的径向压缩力使得在拉动时管状网状物结合在导管尖端上并且不容易围绕导管尖端滚动。相反，当向近侧拉入时，机织的网状物可在导管内收 缩20％至60％之间，这可提供其他所去除材料的凝块的大量压缩。

[0162] 在其中该装置被配置用于外围血管(例如，具有4mm至8mm血管 ID)的变型中，远侧牵引器区域可以被配置用于该应用。例如，远侧牵引 器区域可以包括具有形成在4mm心轴上并被韧炼的0.009”PP单丝的24 个端部的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的 0.008”PP单丝的编织材料。远侧牵引器区域可以包括具有4mm心轴韧 炼的0.006”PP单丝的72个端部的编织材料。远侧牵引器区域可以包括 具有4mm心轴韧炼的36个端部的编织材料。远侧牵引器区域可以包括 具有心轴韧炼的0.004”DFT镍钛的48个端部的编织材料。

[0163] 在其中装置被配置为活检装置(例如，具有4mm至12mm样本大小) 的变型中，该装置可以是机织材料，其包括在10mm心轴上形成的PP 007” 单丝的72个端部。在一些变型中，装置(例如，远侧牵引器区域)可以 包括在1mm心轴上形成的0.004”镍钛的48个端部。在一些变型中，装 置(例如，远侧牵引器区域)可以包括在12mm心轴上的PP 0.008”单丝 的48个端部。

[0164] 在本文所描述的变型中的任一个中，所述装置可以被配置成具有相对 低的摩擦。特别地，远侧牵引器区域可以具有低摩擦力以允许在收回凝块 时更容易和/或可靠地拉动穿过导管。如上所述，这些变型中的任一个可以 包括润滑材料和/或涂层，包括在抓取器(远侧牵引器区域)上使用或涂覆 一种或多种以下材料：PET、PP、PTFE、ePTFE。当形成装置的材料是小 直径细丝金属结构时，细丝的直径可以在0.0005”至0.003”之间。材料 可以是镍钛、不锈钢、MP35n、Ti、铂、铂铱、钴铬合金等。

[0165] 在远侧牵引器区域是网状物(例如，机织和/或针织材料)的变型中， 远侧牵引器区域相对于导管直径的直径可以取决于机织/针织结构。例如， 当编织时，比率可以在2至1之间或更大；当经编时，比率在1.5至1之 间或更大。当形成为激光管时，比例在1.1至1之间或更大。类似地，对 于编织管或带结构，导管内部的编织角度应该在导管内侧在编织角度的0 度至45度之间，并且在导管外侧在编织角度的约20度至90度之间。在 远侧牵引器区域包括针织编织(例如，经编)管的变型中，该装置可以包 括每英寸12个至16个端部。对于具有0.0035”ID导管的装置：可以使 用20至40D PET复丝的12个至16个端部，或者可以使用0.0007”至0.003” PET或聚丙烯(Polypro)或PTFE单丝的12个至16个端部，或者可以使 用0.0007”至0.002”镍钛、不锈钢、MP35n等的12个至16个端部。

[0166] 如上所述，在一些变型中，远侧牵引器区域由ePTFE形成为片(例如， 形成为管或带)。这种材料可以是薄壁的(例如厚度在0.0005”至0.003” 之间)，被认为是有壁厚的(在0.0005”至0.002”之间)，并且可以在导 管尖端上折叠/起作用。该材料可能包括0.001”至0.004”，带有支架状的 激光图案。

[0167] 包括不同形状的远侧牵引器区域的装置的设计的其他示例可以是导 管ID的功

能。例如，在一些变型中，装置可以选择导管ID、细丝的数量、细丝的直径/长度、弯曲/滚动刚度的刚度、泊松比、抓取器的内表面的摩 擦(和/或纹理)等。较小直径的导管比较大直径的导管可能需要更少的网 状物细丝或者更小的ePTFE管IDS。例如，在编织远侧牵引器区域的一些 变型中，该装置可以包括具有远侧牵引器区域的0.072”ID导管，该远侧 牵引器区域具有以90度编织角度编织在6mm心轴上的0.0008”至0.002” 镍钛线材的24个至72个端部。在一些变型中，远侧牵引器区域由以90 度编织角度编织在6mm心轴上的0.0008”至0.002PP单丝的24个至72 个端部形成。在一些变型中，远侧牵引器区域由针织编织物(假定0.072” 导管)形成，并且可以包括在3mm心轴上韧炼的16个端部或40D PET 复丝自由经编针织物。在一些变型中，远侧牵引器区域由在3mm心轴上 韧炼的经编针织的0.002”PP单丝的16个端部形成。在具有由ePTFe管 形成的远侧牵引器区域(同样，假设0.072”导管)的变型中，远侧牵引 器区域可以是0.002”厚的3mm的管。可替代地，远侧牵引器区域可以 是0.002”厚的3mm的管激光器，其被开槽以收缩和抓取凝块。

[0168] 如所提及的，在一些变型中，该装置被配置成在远侧牵引器区域中包 括抓持内网状表面。例如，该装置可以包括具有较大直径编织细丝和/或混 合直径细丝的激光开槽ePTFE管。在一些变型中，抓持内网状表面可以用 作为经编针织成型管的针织编织物形成。此类结构可以具有自然的宏观结 构以允许网状物滚动和抓持凝块，因为细丝不会平行于导管进入导管ID， 而是它们相对于导管长轴线是垂直或环状的。对于其中远侧牵引器区域由 ePTFE激光开槽材料(材料片)形成的示例，该结构可以包括切割成允许 泊松比影响管直径同时产生抓持纹理以抓取凝块的狭缝。

[0169] 通常，通过使用自扩张的和/或较硬的远侧牵引器区域(例如，远侧牵 引器区域的自扩张的和/或柔性第一端部区域)，可以增强远侧牵引器区域 在抓取凝块中的有效性)。当远侧牵引器区域的第一端部区域由编织物形 成时，较硬的细丝(例如，由较大直径的细丝、较硬的材料、较大数量的 纤维等形成)可导致远侧牵引器的更扩张的第一端部区域，如图18A至图 18C所示。在图18A中，较柔软的远侧牵引器区域不会扩张超出导管的 OD相当大的距离。图18B示出了远侧牵引器区域的略微更硬/更可扩张的 第一端部区域。图18C示出了最可扩张的远侧牵引器区域1801，其可以 最佳地扩张至血管1803的内膜。

[0170] 如图18A至图18C所示，可扩张的牵引器区域的唇缘的嘴部可相对 于导管OD的长轴线形成切向角度或滚动角度(Φ)。该角度可以在大约 5°至60°的范围内(例如，10°至60°、10°至50°、10°至45°、 10°至40°等，并且优选地至少为10度)。本发明人惊奇地发现，在一些 变型中，当牵引器区域被收回到导管中时与管具有至少约10度(例如10° 至60°、10°至50°、10°至45°、10°至40°)的滚动角度可防止导 管尖端上的束缚或堵塞。网状管可以被修改(例如，在远侧尖端或端部区 域处)，包括通过修改远侧尖端的刚度和/或形状，以确保滚动角度大于10 度。可替代地或与保持最小滚动角度的组合，可能期望在导管最远侧尖端处保持管材料ID与导管的O.D之间的物理空间或间隙(参见例如图18A 至图18C)。间隙可能需要大于0.1mm、0.2mm、0.3mm、0.4mm、0.5mm、 0.7mm、0.8mm或1.0mm，以确保当管收回时，管围绕导管的远侧端部 滚动。

[0171] 在这些变型中的任一个中，如上所述，远侧牵引器区域可以是润滑的 (例如，亲水涂层、硅树脂涂层、薄氨基甲酸酯或其他薄弹性体涂层)。 可以包括一个或多个聚合物编织物端部以增强润滑性(例如，聚丙烯、尼 龙等)。进一步地，编织角可保持较小(例如，小于70

度、50度、45度 等)以允许更好的拉动。当远侧牵引器区域在导管的尖端周围/上方滚动时，可以测量该角度。增加机织物的端部的数量也可以防止第一端部区域在导 管内的锁定，使得编织元件之间的间隙/空间更小并且当远侧牵引器区域在 导管的端部上滚动时不太可能阻碍导管尖端。当形成为编织元件时，这些 装置中的任一个还可以包括轴向元件，该轴向元件在拉动时不太可能收缩 或直径减小，并且因此当在尖端上滚动时不太可能挂在导管开口上。当使 用镍钛(例如>0.0001”直径)时使用稍大的编织细丝也是有利的；直径 越大，编织物可变形以锁定到导管尖端的可能性就越小。如上所述，在一 些变型中，远侧牵引器区域可被热定形以在向远侧推进时在导管的远侧端 部上自动滚动。

[0172] 图19A和图19B示出了用于形成远侧牵引器区域的翻折回来配置的 替代方法。在图19A中，管状远侧牵引器区域1903可以耦接到拉动器/ 推动器1901，然后如上所述在导管尖端上翻转。在图19B中，管状编织 物1905穿过编织物向远侧附接到线材/拉动器1901并被拉动以在导管的远 侧端部上使其翻转。

[0173] 通常，远侧牵引器区域的第一端部区域可具有任何适当的形状(参见 图15A至图15D)。图20A和图20B示出了可以形成远侧牵引器区域的渐 缩机织物的示例。在图20A中，编织物具有锥形侧面轮廓，其可以附接到 拉动器(柔性牵引器管的近侧端部)并且翻转。本文所述的编织物中的任 何一种可以包括标记线材(例如，DFT、金、铂、铂铱等)以帮助可视化(例如，荧光镜)。在图20B中，网状物比图20A中更突然地渐缩。

[0174] 如上所述，通常，本文所描述的导管中的任一个可适用于这些装置。 例如，合适的导管可以是高度柔性的，并具有良好的柱刚度(例如，当向 远侧推进时其长度不会缩短)。导管可以具有高角度编织物加强元件。例 如，导管可以具有穿过近侧端部至远侧端部的高角度编织物(70度至85 度，小线材镍钛、不锈钢、钴铬、MP35N、扁平或圆形线材)，以及针对导管的远侧1cm至5cm的较小编织角度。这将允许当施加轴向压缩时和 /或在内扩张力(例如血块)下导管的内径扩张。

[0175] 通常，这些导管中的任一个都可以包括改变的刚度/顺应性。例如，近 侧三分之一(1/3)可能较硬；中间部分可能不太硬，而远侧20％(1/5) 可能是最不硬的。进一步地，导管的远侧尖端可以具有如图1A和图1B 中所描述的适当的半径(曲线)。通常，半径应该是平滑且圆形的，而不 是方形的。另外，导管的远侧尖端可以由足够硬的材料(约72D或更硬) 制成，以允许编织物滚动而不抓取尖端。例如，导管尖端可以具有硬质金 属结构以减少摩擦(例如，不锈钢、Pt等)。当拉动远侧牵引器区域时导 管尖端压缩/弯曲越少越好。在一些变型中，导管包括附加加强件，诸如编 织增强件而不是线圈加强件，以防止导管最后5cm至10cm的编织物屈 曲。因此，如本文所描述的，在一些变型中，导管的尖端可由润滑和/或硬质材料制成，以当编织物围绕导管尖端被拉动或被推动时帮助减少编织物 与导管尖端的摩擦。润滑材料可以包括诸如PTFE、FEP和/或亲水涂层的 粉状聚合物。如尼龙之类的硬质材料或不锈钢之类的金属材料、铂和PT 铱合金可用于该尖端，并且向近侧熔合/附接到较柔软材料。如果硬质尖端 被放置在导管尖端的远侧端部上，则其长度可能是短的(例如<5mm并且 优选地<3mm)，因此它不会不利地影响导管追踪。

[0176] 图21A至图21D示出了用于去除凝块的装置的示例。在该示例中， 远侧牵引器区域由拉下到0.071”的导管上的10mm(扩张)直径的大约 72个端部的细旦尼尔PET网状物形成，如图21A和图21B所示。图21A 示出了在耦接到导管之前的可扩张的第一端部区域的示例。

图21B示出了 通过拉动柔性(牵引器)管的近侧端部将血管(玻璃管)内的可扩张的第 一端区域拉入导管中。图21C示出了装置的远侧端部区域,其包括在导管 的远侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉 入导管中的图21C的装置。

[0177] 另一个示例检查了由具有72个端部和0.001”直径细丝的6mm编织 物形成的远侧牵引器区域,该细丝滚动进入0.071”ID导管并且在0.071”ID导管上翻折。成功去除20cm长的“中等硬度”5mm凝块。图22示 出了在将其向近侧拉出导管之后具有所捕获的凝块的图21D的可扩张的 第一端部区域。

[0178] 图23A至图23D示出了如本文所述的机械取栓装置,其捕获血凝块 并将其拉入装置中。图23E示出了在柔性牵引器管已经从导管去除(例如 向近侧)之后保持在柔性牵引器管内的凝块。

[0179] 在本文所描述的一些变型中,远侧牵引器区域不是由机织或针织材料 形成,而是由纵向布置(例如,平行或近似平行布置)的条或束构成。例 如,图24是包括柔性牵引器构件的装置的另一个示例,其中,远侧牵引 器区域由多个细丝形成,该多个细丝布置位未机织或编织的材料条(纵向 平行)。这些条可以是细丝或管等。

[0180] 图25A至图25F示出了柔性牵引器组件的远侧牵引器区域的另一变 型,其中,可扩张的第一端部区域(例如,远侧牵引器区域的远侧端部区 域)由多个细丝或条形成,类似于图24中所示的;如图25A至图24所示, 导管的远侧端部包括通道;这些条可以装配在这些通道内,如图25C至图 25D所示。图25E和图25F示出了穿过图25C和图25D的截面图。图25A、图25C和图25E示出了侧视图并且图25B、图25D和图25F示出了轴向 视图。在该示例中,导管尖端包括细丝/条2503在其中行进的通道2502。形成远侧牵引器区域的条附接到柔性牵引器管2505的更近侧的拉动器区 域,如图25E所示。

[0181] 图26A和图26B示出了具有外套筒(例如,外导管或释放保护器导 管或其他外套筒/保护器)的图25A至图25F的装置的变型

[0182] 图27A至图27B示出了穿过图26A至图26B的装置的截面图。

[0183] 图28是包括柔性牵引器组件的远侧牵引器区域的装置,柔性牵引器 组件具有多个纵向平行的(非机织/编织)细丝或条,其中,细丝或条的远 侧端部通过远侧连接件彼此连接。

[0184] 图29示出了装置中的柔性牵引器组件的远侧牵引器区域,其中,纵 向平行的(非机织/编织)细丝或条包括抓取元件。

[0185] 图30A至图30C示出了具有抓取元件的细丝/条的示例。抓取元件(和 /或包括它们的细丝)可以用作本文所描述的变型中的任一个的一部分,包 括机织或编织的远侧牵引器区域。带有抓取元件的对于细丝/条的其他选择 可以包括编织条、网状物/机织条和微线圈。

[0186] 在本文所描述的这些配置中的任一种中,该装置可以适于允许远侧牵 引器区域的往复运动,从导管的远侧端部的外侧至内侧并回到外侧而循 环。例如,图31示出了其中远侧牵引器区域适于往复运动(例如,推动 和拉动)使得可扩张的第一端部区域可被拉入导管中并且从导管翻转出的 变型。在该示例中,牵引器管(拉动器)3105附接到远侧牵引器区域3144, 该远侧牵引器区域可以附接(并且在一些变型中不附接)到内导管3101 上的第二导管3109。中间导管3109可以耦接到拉动器3105,并且两者一 起往复运动,使得编织物

在导管3101的内侧来回往复运动。这可以帮助 破碎凝块，这可能特别是在与抽吸一起使用时。

[0187] 图32示出了如本文所述的装置的另一示例，其中，远侧牵引器区域 的柔性第一端部区域的最远侧端部3205不可释放地固定到导管3201的外 侧的远侧端部；可扩张的第一端部区域3209的其余部分具有足够的弹性/ 柔性以被拉入导管中(用其拉动凝块3255)。然后柔性牵引器组件可以被 收回并且整个装置被取回。该示例可能包括可选的真空3260。

[0188] 图33是装置的另一个示例，其中，柔性牵引器组件的拉动器部分3305 由与远侧牵引器区域3344相同的材料形成，但可以层压或以其他方式加 强以具有比远侧牵引器区域更小的柔性/可拉伸性。

[0189] 图34示出了另一个示例，其中，远侧牵引器区域3444适于当拉入导 管3401中时压缩凝块3455。图35A至图35C示出了如图34所示的装置 的操作，其中，凝块3455通过将远侧牵引器区域的可扩张的第一端部区 域取回到压缩凝块的导管中(例如在牵引器组件的牵引器区域3505上拉 动)而被拉入导管中(图35A至图35B)；释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并且将其从远侧牵引器区域释放，使得 它可以向近侧分段(图35C)。

[0190] 图36示出了一种装置和使用方法的示例，其中，向近侧拉柔性牵引 器组件可以向远侧推进装置穿过导丝上的主体(例如血管)，该导丝可以 被处理以接合远侧牵引器区域。在该示例中，该装置可以被配置成拉动具 有形成远侧牵引器区域3644的网状物的内牵引器管(导管3605)，该远侧 牵引器区域附接到其远侧端部并且在导管3601的远侧端部上翻转。拉动 柔性牵引器管3605使编织物在导管3601的开口上滚动。形成远侧牵引器 区域(例如，远侧牵引器区域的第一端部区域)的网状物/编织物被构造成 当拉伸负载施加到该结构上并且锁定/抓取内线材(导丝3677)时在直径 上收缩。该内导丝可能具有抓取线材的粘性、粗糙或多变的表面辅助网状 物/编织物。当网状物/编织物抓取在导丝上时，牵引器管由于反作用力而 将在脉管中被向前驱动。可替代地，用户将能够在拉回牵引管的同时能够容易地将外导管3601向前推进穿过血管。

[0191] 图37A至图37C示出了另一种装置和使用方法，其中，向近侧拉柔 性牵引器组件可以向远侧推进该装置。在图37A中，远侧牵引器区域3744 附接至中间导管3703(可包括可选的外导管3705)，并且远侧牵引器区域3744的相对端部结合至在该导管的内径内的内导管3701的远侧端部。在 图37B中，向远侧推进内导管，从而使远侧牵引器区域在侧向和前方扩张。如图37C所示，然后可以向远侧推动外导管和内导管，以使装置向远侧移 动。

[0192] 在一些变型中，远侧柔性牵引器区域可以被保持预先加载在导管的外 侧，例如以卷或束的形式被保持预先加载在导管的远侧端部区域上，使得 其可以被逐渐拉出外存储区域并且在导管的远侧端部上滚动和翻转。一个 此类变型的示例示出在图38A和图38B中，该示例性装置可用于从血管 内去除材料，如图38B所示，并且可以称为“无限(infinite)”牵引器机 构，因为大量(例如，大于50cm、大于60cm、大于70cm、大于80cm、 大于90cm、大于100cm、大于150cm、200cm、大于300cm、大于400 cm、大于500cm等)的牵引器材料(例如，网状物)可存储在外保持区 域中，其被卷起但在扩大使用上不是必要的。

[0193] 在图38A中，该装置可以包括导管(内导管)3811并且远侧牵引器 区域3806由在导管的远侧端部附近的壳体区域3813中卷起的网状物3803 形成。通过在导管内向近侧拉动

远侧牵引器区域，凝块3805可被拉入导 管中。由于大量远侧牵引器区域可能存储在近侧并且向近侧被取回，因此 这种变化对于非常长的手术或者需要去除大量材料的情况可能是有用的。

[0194] 这种变型可以允许使用者展开较长长度的网状物，这对于更刚度的工 具(诸如在手术期间的刚度海波管)可能是有利的，例如，在吸脂手术中 去除脂肪、去除脑内出血或更大的外周血管凝块中的凝块。

[0195] 如上所述，在本文所描述的变型中的任一个中，远侧牵引器构件可以 是机织(例如针织)或编织的网状材料。网状物可以是针织材料，包括例 如纬编针织物、圆形针织物、经编针织物和/或编织针织物。

[0196] 当特征或元件在本文中被称为“在”另一特征或元件“上”时，其可 以直接在另一特征或元件上，或者也可以存在中间特征和/或元件。相反， 当特征或元件被称为“直接在”在另一特征或元件“上”时，不存在中间 特征或元件。还将理解，当特征或元件被称为“连接”、“附接”或“耦接” 到另一特征或元件时，其可直接连接、附接或耦接到另一特征或元件，或 者可能存在中间特征或元件。相反，当特征或元件被称为“直接连接”、“直 接附接”或“直接耦接”到另一特征或元件时，不存在中间特征或元件。 虽然相对于一个实施例进行了描述或示出，但是所描述或示出的特征和元 件可以应用于其他实施例。本领域的技术人员还将认识到，对“邻近”另 一个特征设置的结构或特征的提及可以具有与邻近特征重叠或位于其下 面的部分。

[0197] 本文所使用的术语仅用于描述特定实施例的目的，而不意图限制本发 明。例如，如本文所使用的，除非上下文另外明确指出，否则单数形式“一”， “一个”和“该”也旨在包括复数形式。将进一步理解，当在本说明书中 使用时，术语“包括”和/或“包含”指定所述特征、步骤、操作、元件和 /或部件的存在，但不排除一个或多个其他特征、步骤、操作、元件、部件 和/或其组合的存在或添加。如本文所使用的，术语“和/或”包括相关所 列项目中的一个或多个的任何和所有组合，并且可以缩写为“/”。

[0198] 为便于描述，本文可以使用诸如“在...之下”、“在...下方”、“下”、“在... 上”、“上”等的空间相对术语以描述一个元件或特征与另一个元件或特征 的关系，如图所示。将理解，空间相对术语旨在包括除了附图中所描绘的 方位之外的装置在使用或操作中的不同方位。例如，如果附图中的设备是 翻转的，则被描述为在其他元件或特征“之下”或“下方”的元件将被定 向为“在”其他元件或特征“上”。因此，示例性术语“在...下面”可以包括上方和下方两种方向。设备可以以其他方式定向(旋转90度或以其他 方位)并且相应地解释在本文所使用的空间相对描述符。类似地，除非另 外特别指出，否则术语“向上”、“向下”、“竖直”、“水平”等仅用于解释 的目的。

[0199] 虽然术语“第一”和“第二”在本文中可以用于描述各种特征/元件(包 括步骤)，但除非上下文另有指示，否则这些特征/元件不应受这些术语限 制。这些术语可以用于区分一个特征/元件与另一个特征/元件。因此，下 面论述的第一特征/元件可以被称为第二特征/元件，并且类似地，在不脱 离本发明的教导的情况下，下面所论述的第二特征/元件可以被称为第一特 征/元件。

[0200] 在整个说明书和所附的权利要求书中，除非上下文另有要求，否则词 语“包含”以及诸如“包含了”和“其包含”的变型意味着各种部件可以 在方法和物品中共同采用(例如，

包括设备和方法的组合物和装置)。例 如,术语“其包含”将被理解为暗示包含任何陈述的元件或步骤,但不排 除任何其他元件或步骤。

[0201] 如在本说明书和权利要求书中所使用的,包括在示例中所使用的并且 除非另有明确说明,即使术语没有明确出现,所有的数字也可以读作像 “约”或“大约”这样的词语开头。当描述幅度和/或位置以指示所描述的 值和/或位置在值和/或位置的合理预期范围内时,可以使用短语“约”或 “大约”。例如,数值可以具有所述值(或值的范围)的+/－0.1%的值、 所述值(或值的范围)的+/－1%的值、所述值(或值的范围)的+/－2% 的值、所述值(或值的范围)的+/－5%的值、所述值(或值的范围)的+/ －10%的值等。本文给出的任何数值也应被理解为包括约或大约该值,除 非上下文另有指示。例如,如果公开了值“10”,则“约10”也被公开。 本文列举的任何数值范围旨在包括其中所包含的所有子范围。还应理解, 当公开值时,“小于或等于”该值、“大于或等于该值”以及值之间的可能 范围也被公开,如本领域技术人员所适当理解的。例如,如果公开了值“X”, 则还公开了“小于或等于X”以及“大于或等于X”(例如,其中X是数 值)。还应该理解,在整个申请中,数据以多种不同的格式提供,并且该 数据表示端点和起点以及数据点的任何组合的范围。例如,如果公开了特 定的数据点“10”和特定的数据点“15”,则可以理解,大于、大于或等 于、小于、小于或等于并且等于10和15被认为是公开的以及在10和15 之间。还应该理解,还公开了两个特定单元之间的每个单元。例如,如果 公开了10和15,则还公开了11、12、13和14。

[0202] 尽管以上描述了各种说明性实施例,但是在不脱离如权利要求所描述 的本发明的范围的情况下可以对各种实施例进行多种改变中的任何一种。例如,其中执行各种所描述的方法步骤的顺序通常可以在替代实施例中改 变,并且在其他替代实施例中,可以完全跳过一个或多个方法步骤。各种 设备和系统实施例的可选特征可以包括在一些实施例中而不包括在其他 实施例中。因此,前面的描述主要是为了示例性的目的而提供的,并且不应该被解释为限制如在权利要求中所阐述的本发明的范围。

[0203] 本文包括的示例和说明通过说明而非限制的方式示出了其中可以实 践主题的特定实施例。如上所述,其他实施例可以被利用并从中导出,使 得可以在不脱离本公开的范围的情况下进行结构和逻辑替换和改变。本发 明主题的此类实施例在本文中可以单独地或共同地由术语“发明”引用, 仅仅是为了方便,并且无意将本申请的范围自愿地限制到任何单个发明或 发明构思,如果事实上公开了不止一个的话。因此,尽管本文已经说明和 描述了具体实施例,但是为了实现相同目的而计算出的任何布置都可以替 代所示的具体实施例。本公开旨在覆盖各种实施例的任何和所有修改或变 型。上述实施例的组合以及本文中未具体描述的其它实施例对于本领域技 术人员在查看以上描述时将是显而易见的。

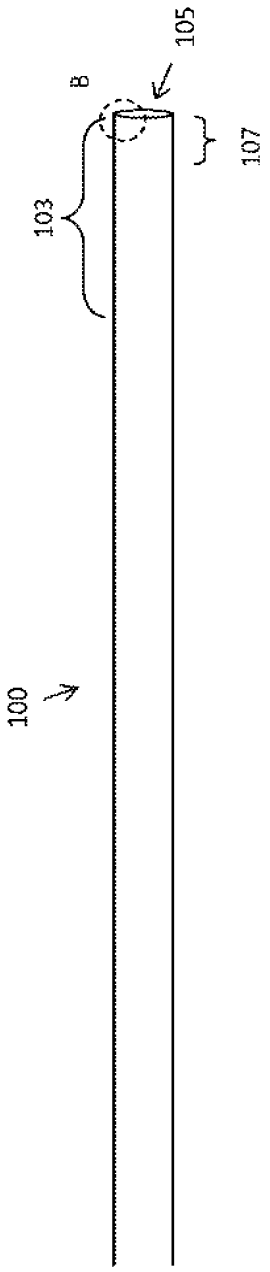


图1A

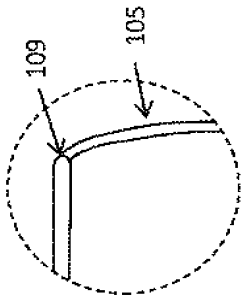


图1B

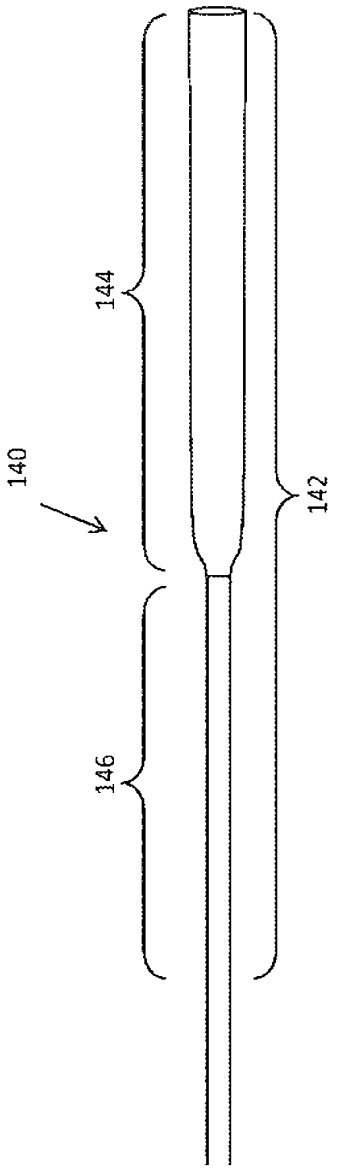


图1C

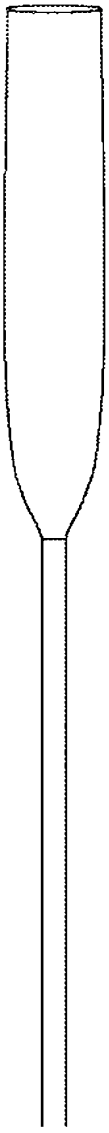


图1D

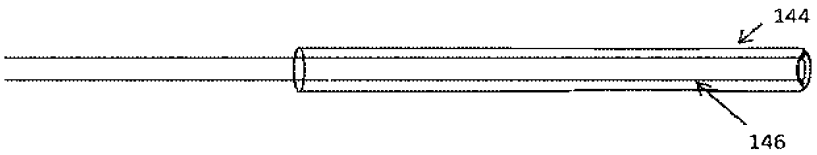


图1E

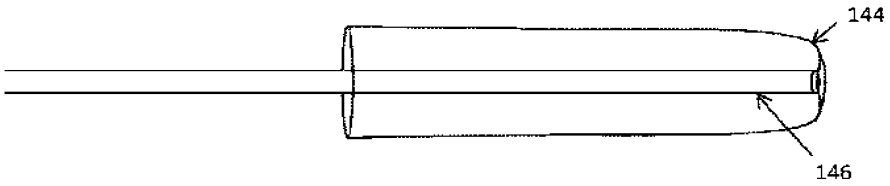


图1F

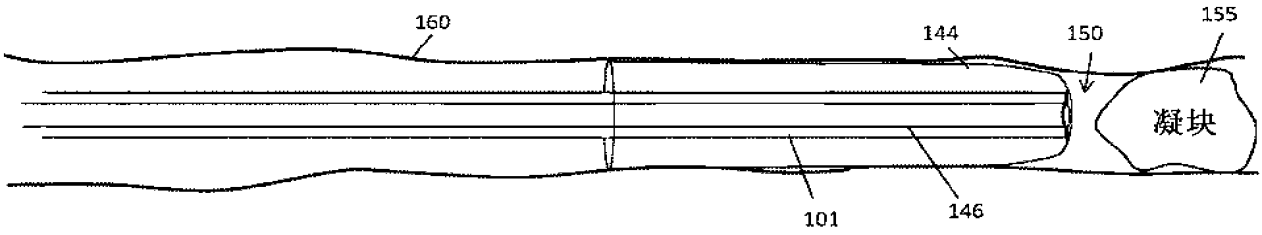


图1G

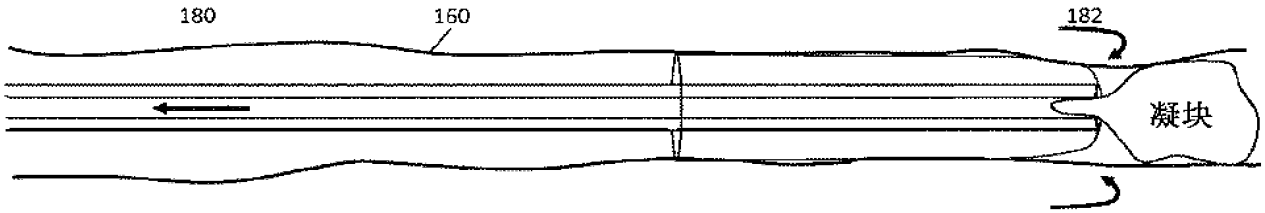


图1H

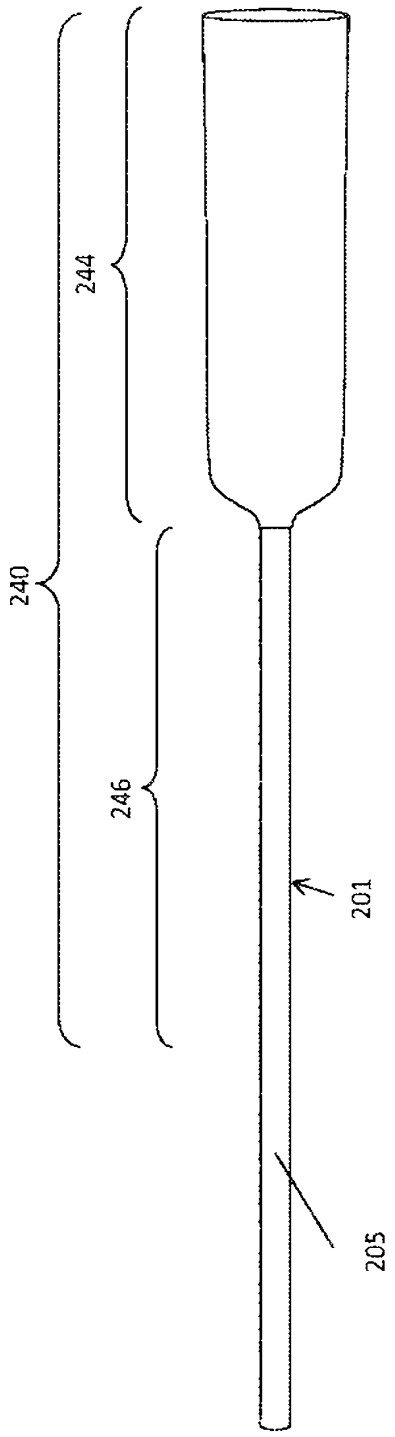


图2A

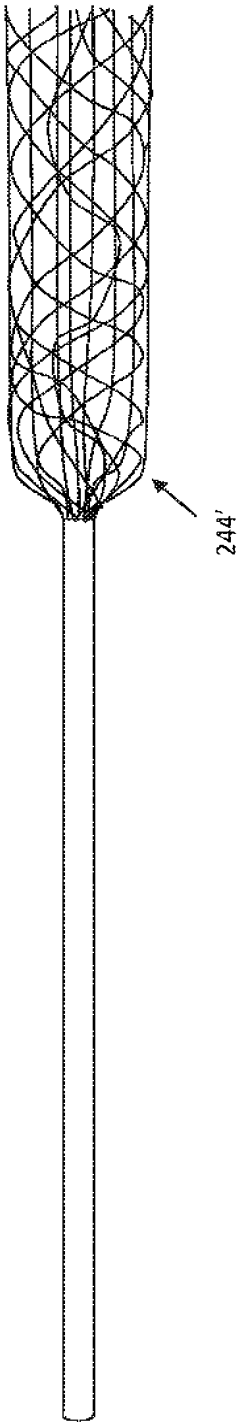


图2B

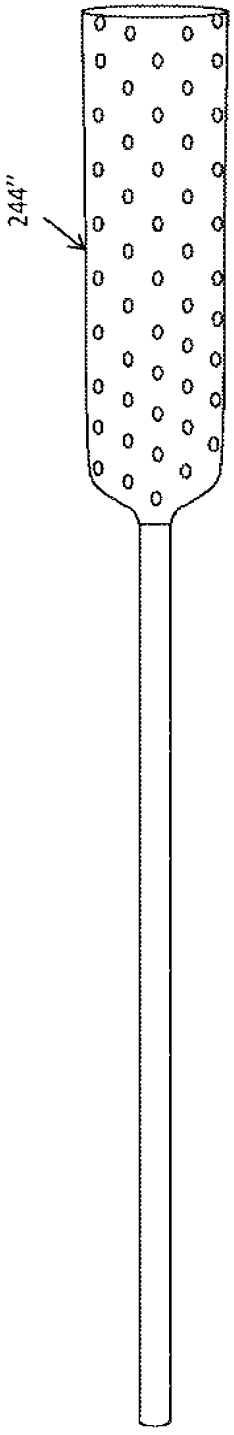


图2C

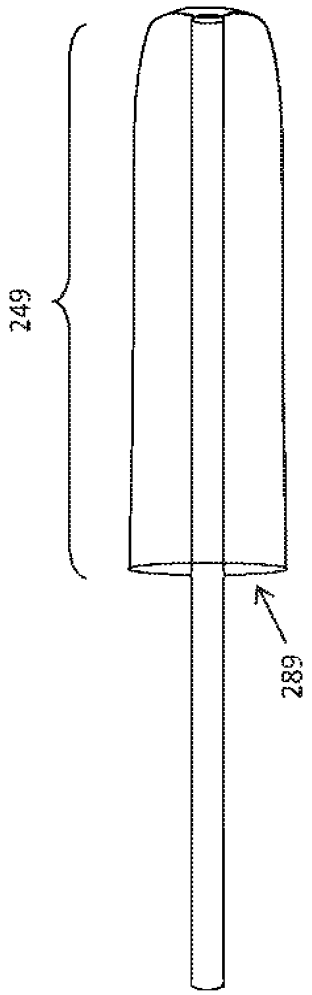


图2D

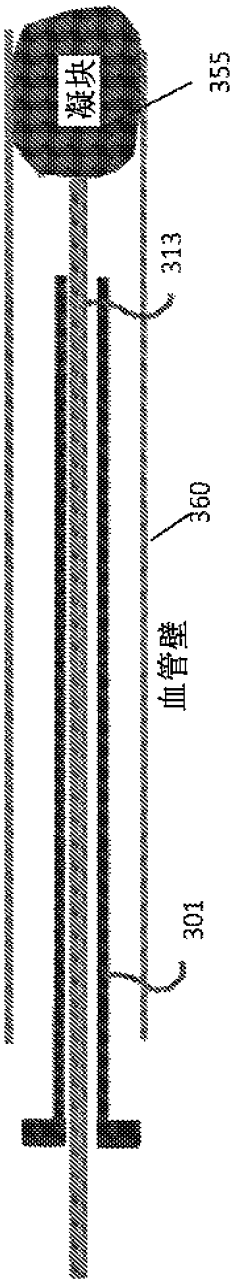


图3A

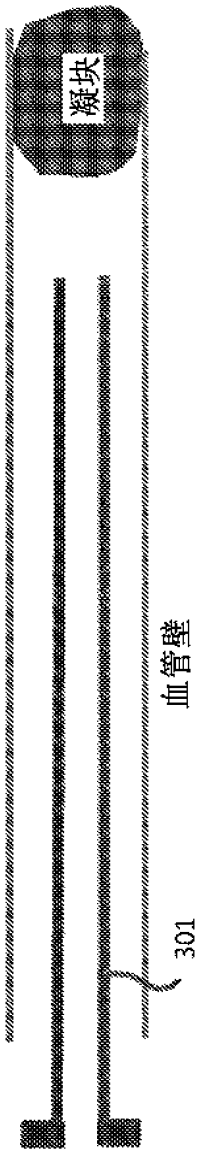


图3B

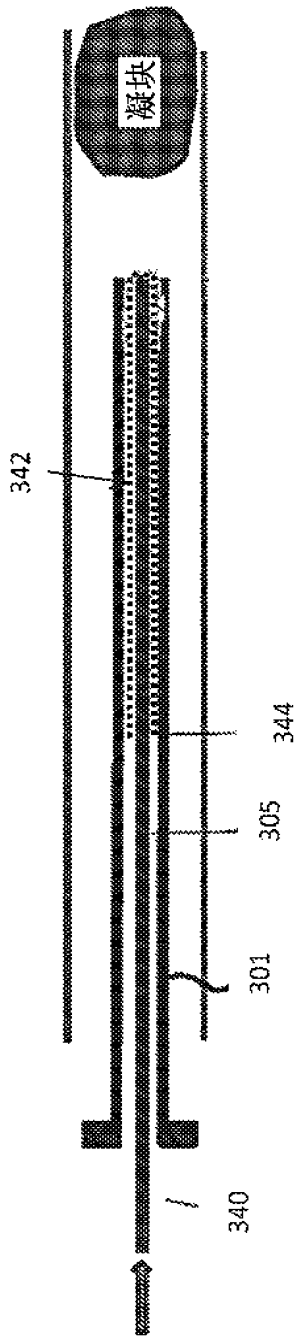


图3C

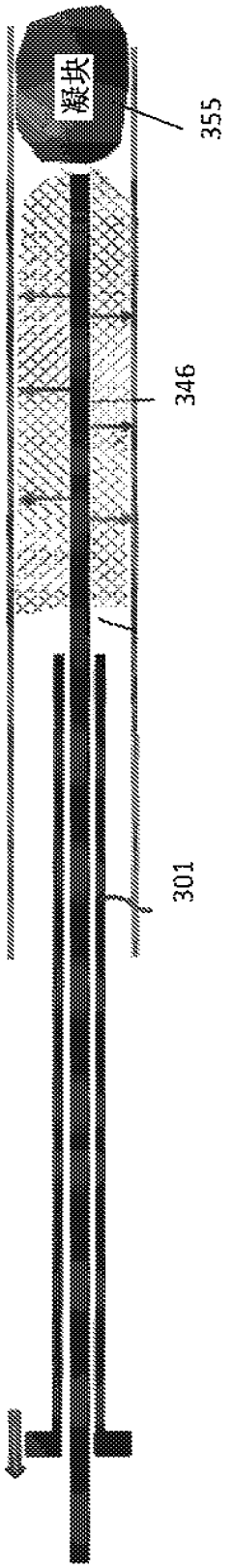


图3D

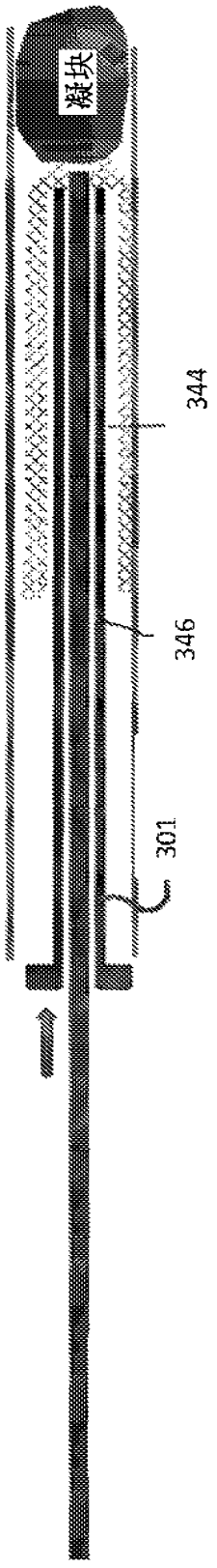


图3E

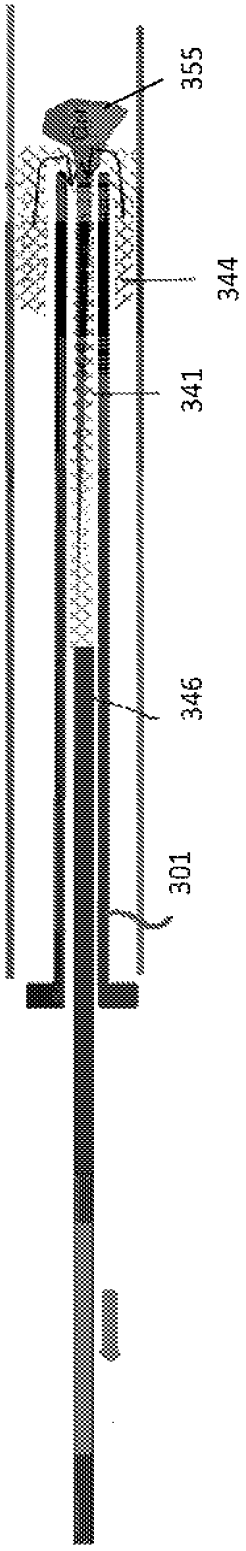


图3F

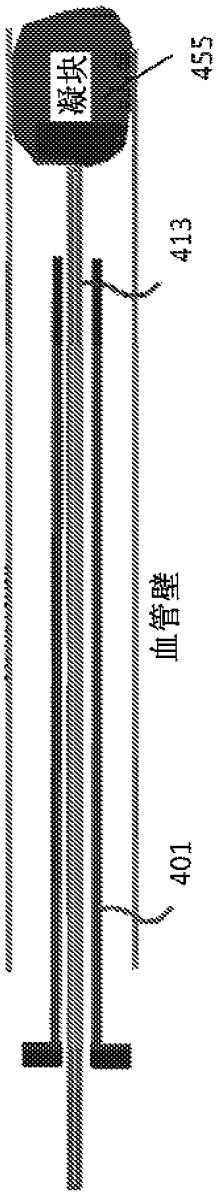


图4A

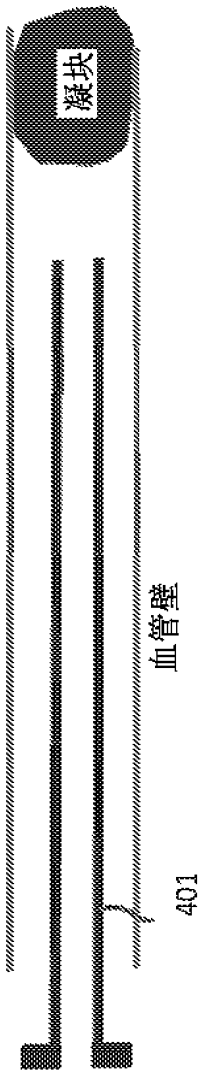


图4B

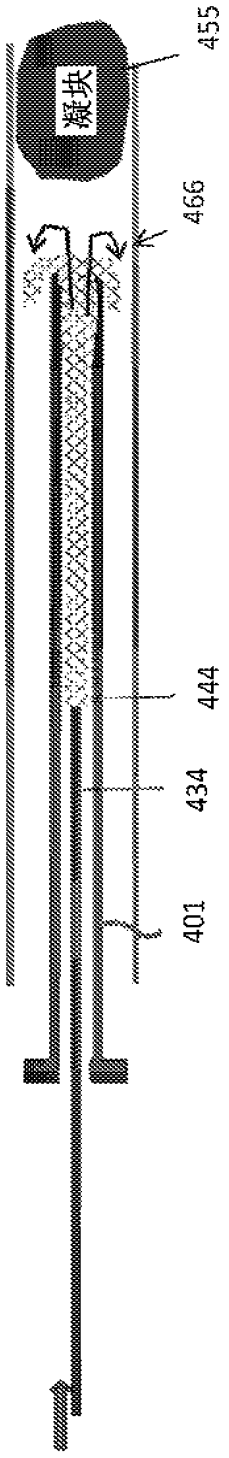


图4C

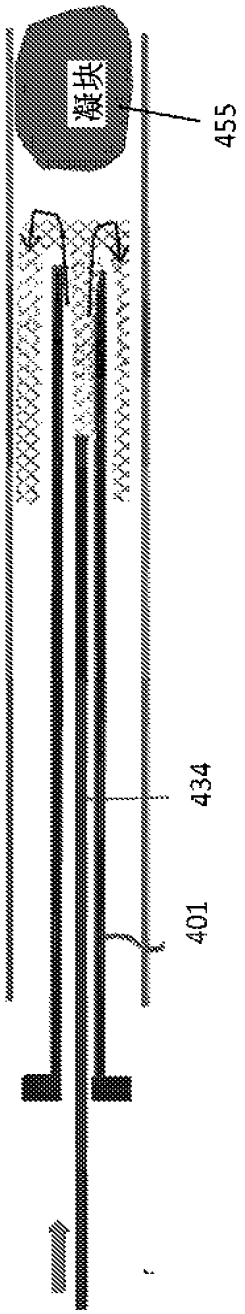


图4D

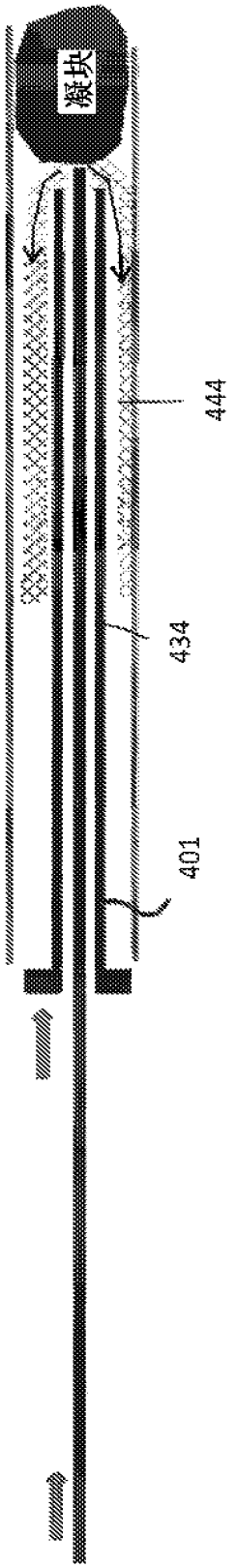


图4E

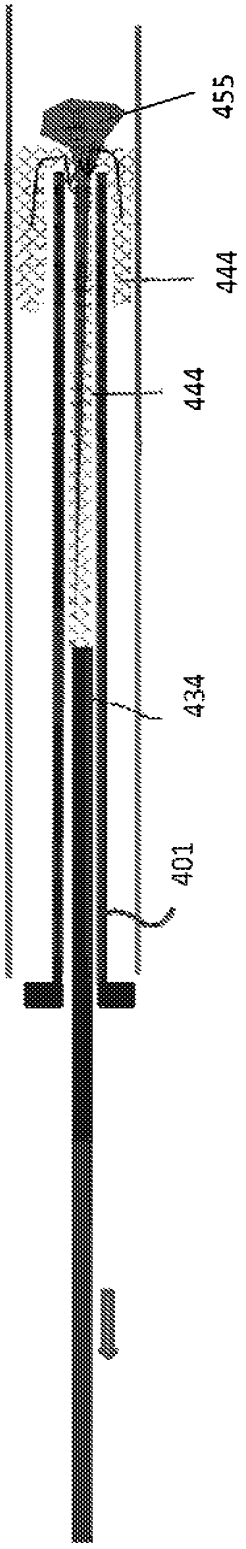


图4F

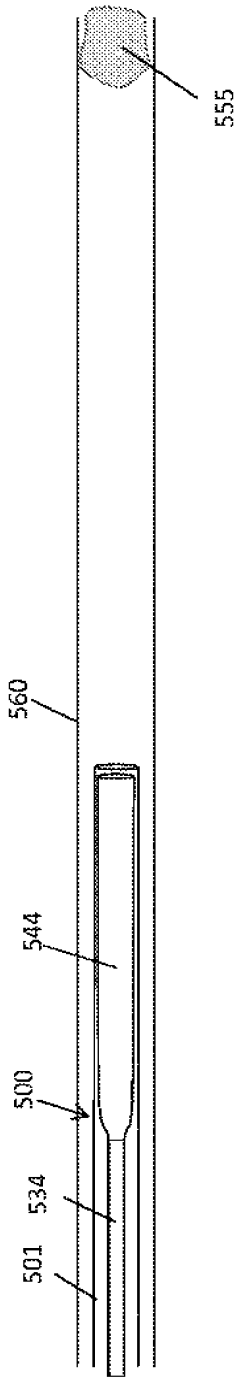


图5A

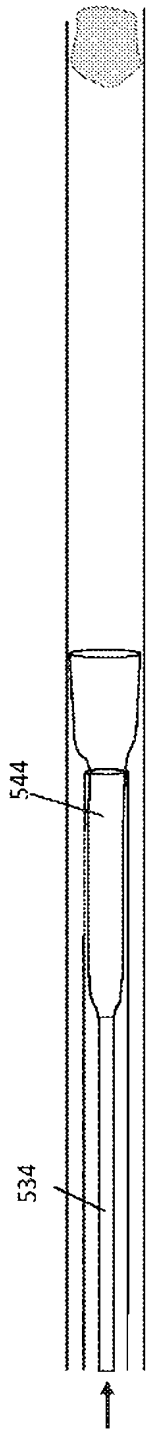


图5B

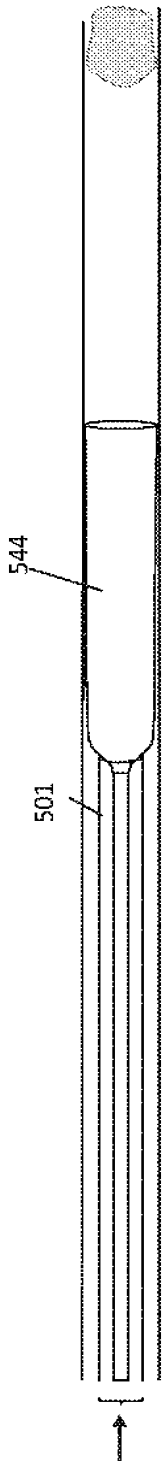


图5C

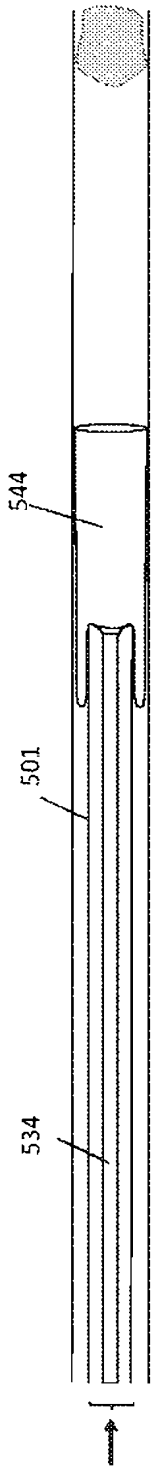


图5D

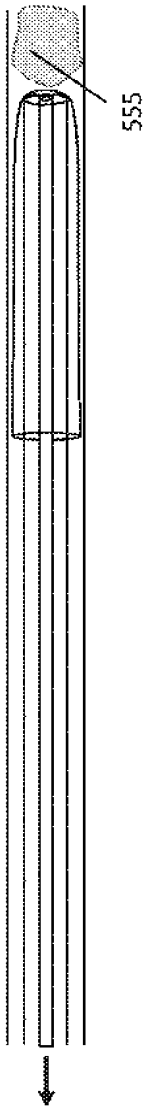


图5E

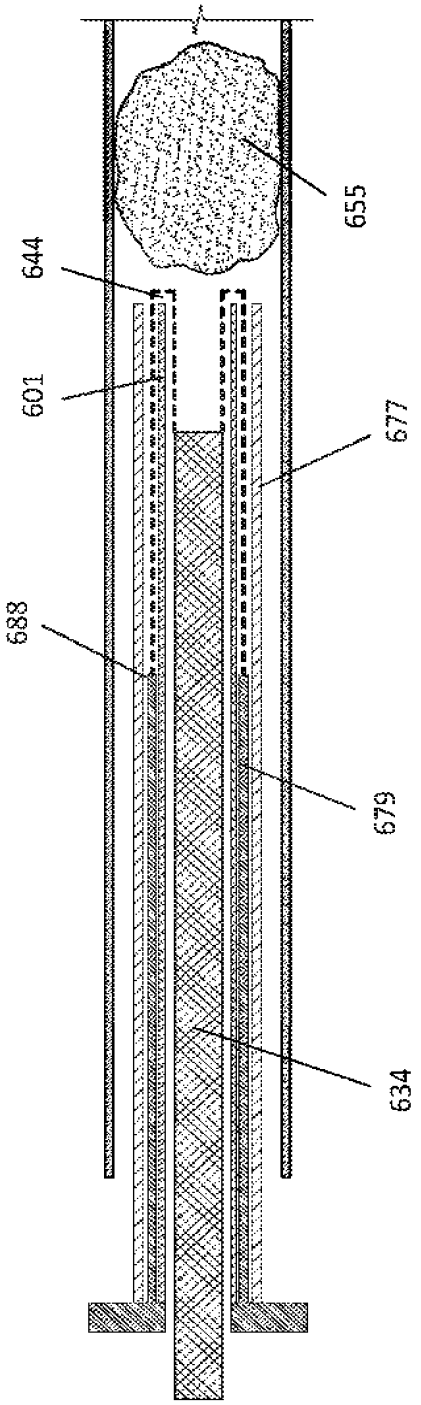


图6A

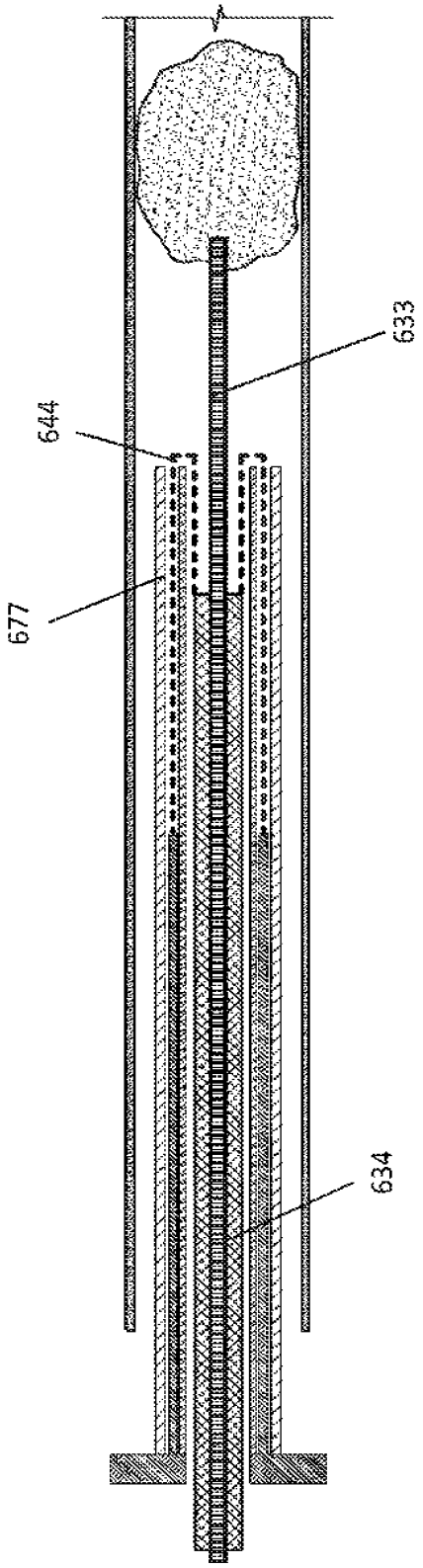


图6B

61

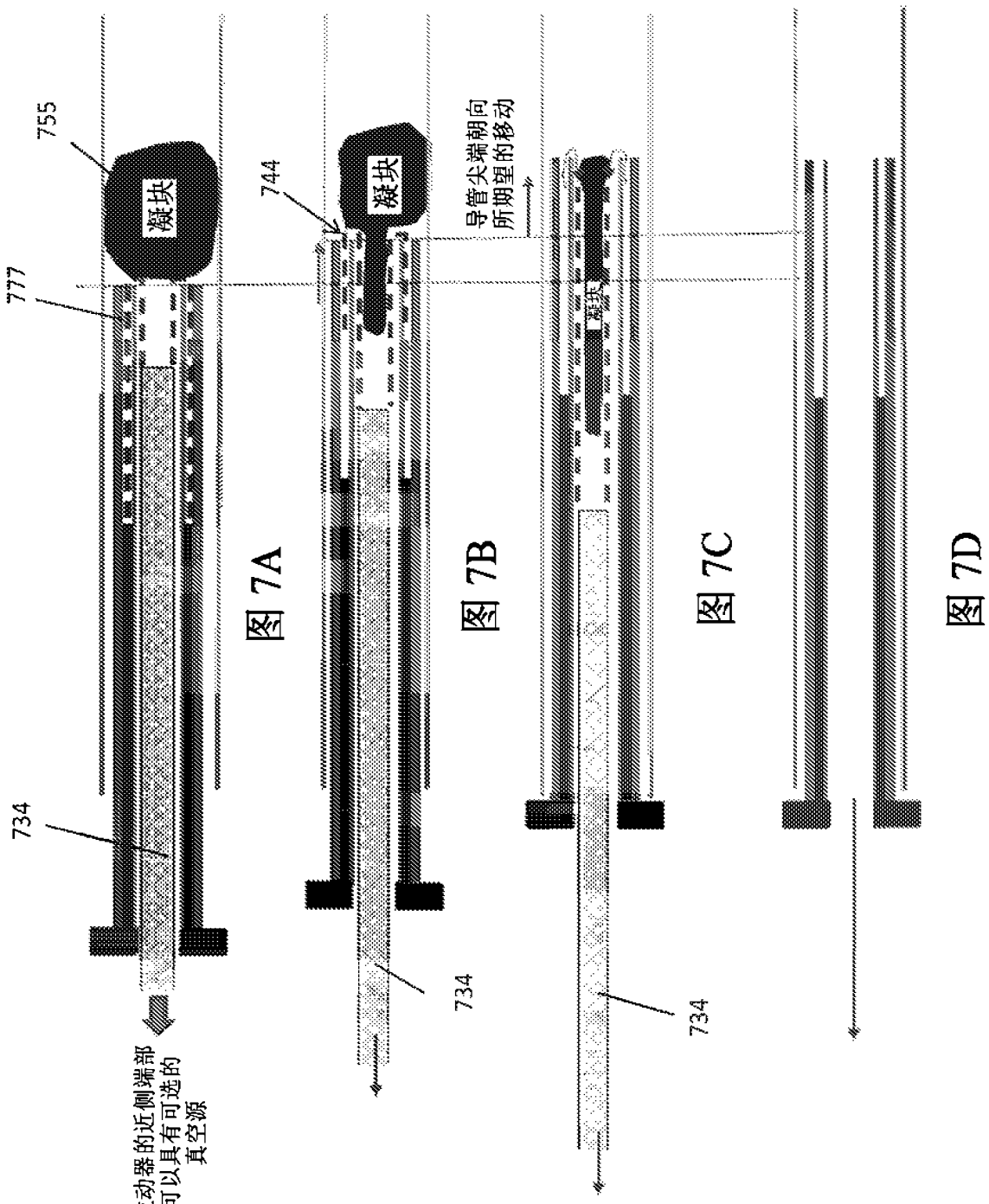


图 7A 图 7B 图 7C 图 7D

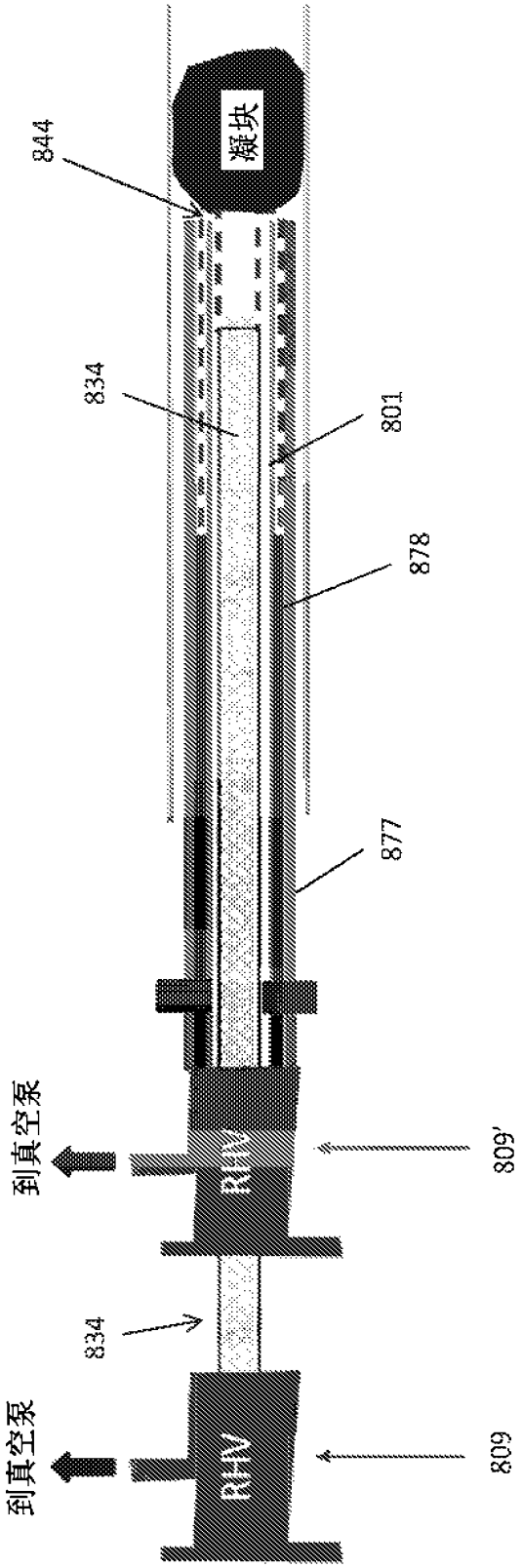


图8

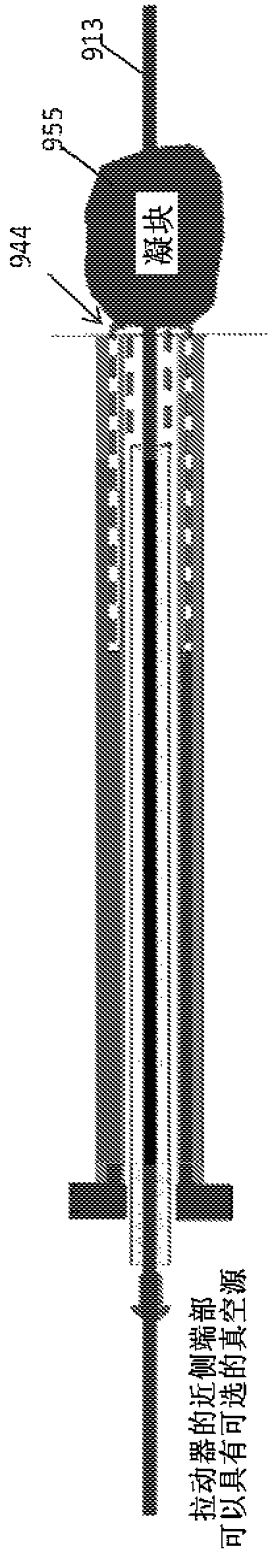


图9A

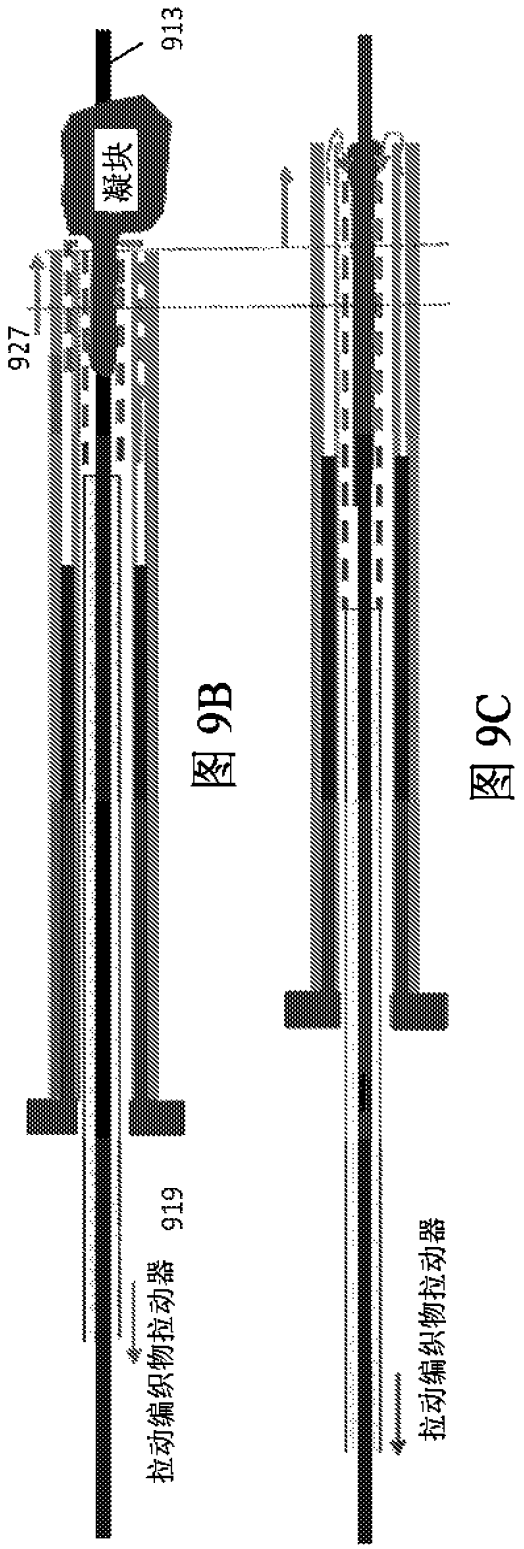


图 9B

图 9C

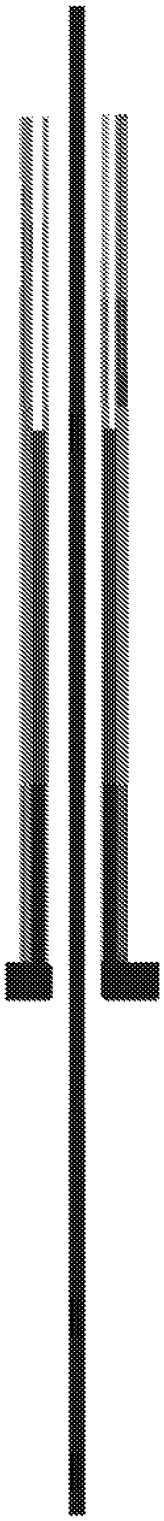


图9D

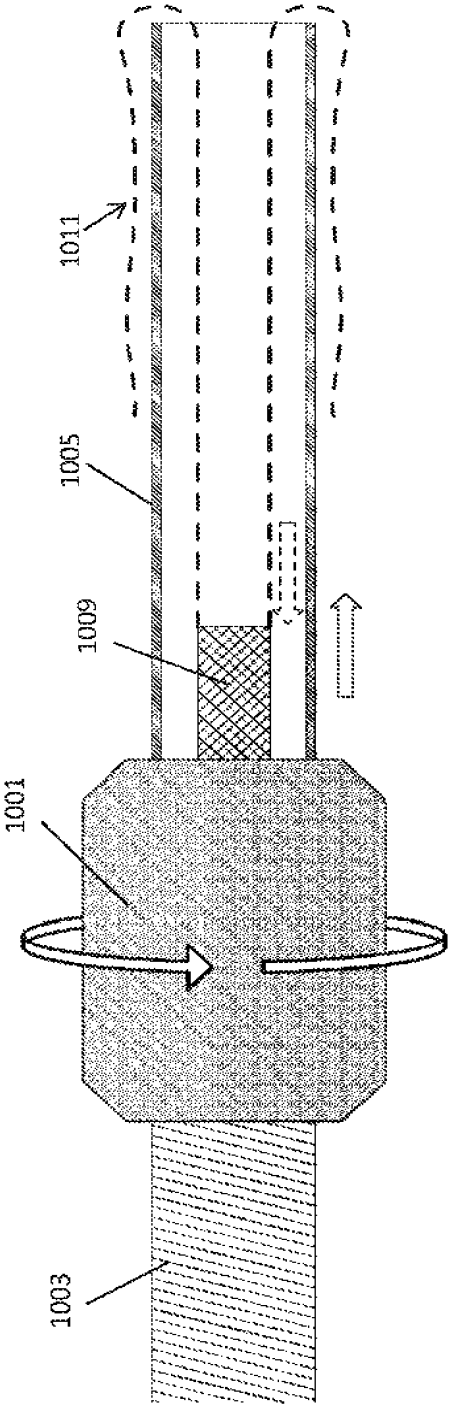


图10A

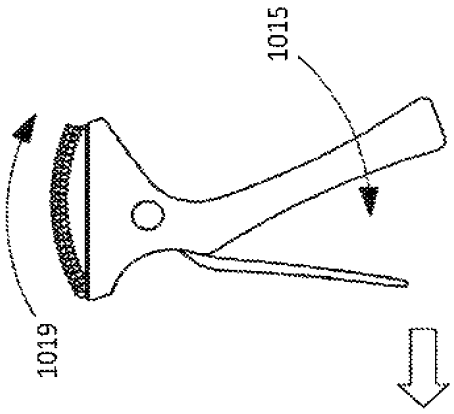


图10B

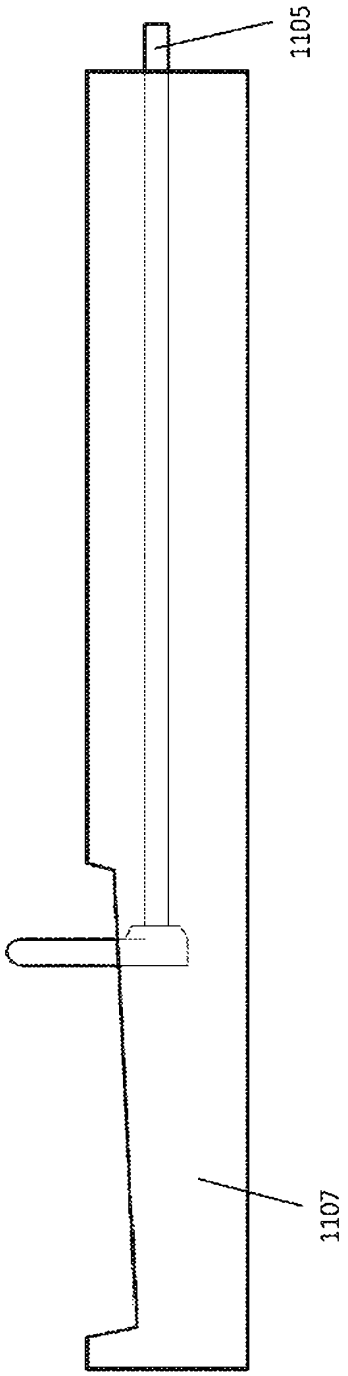


图11A

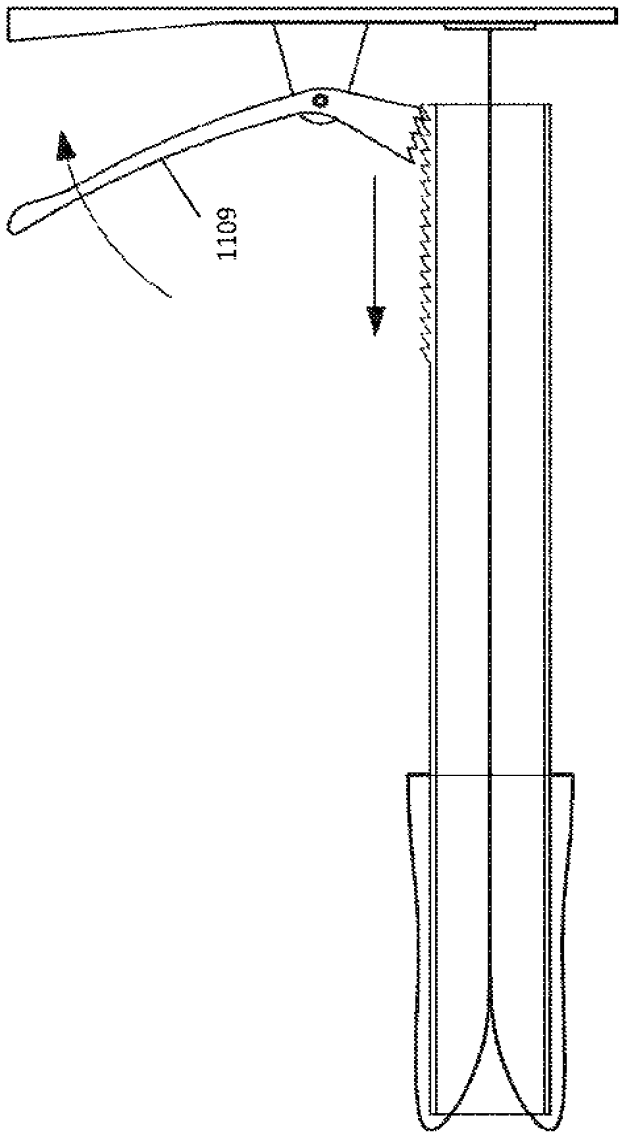


图11B

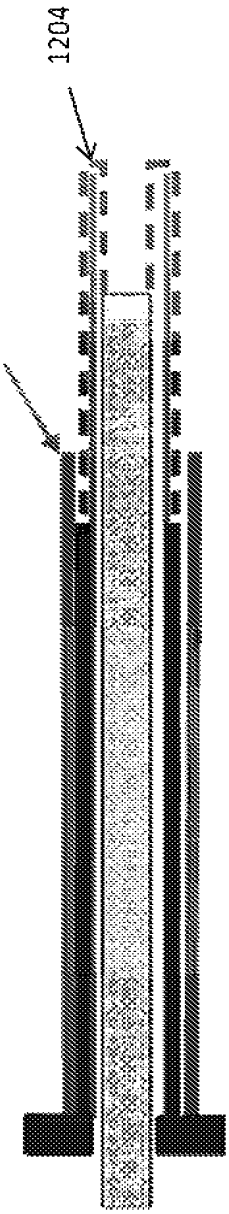


图12A

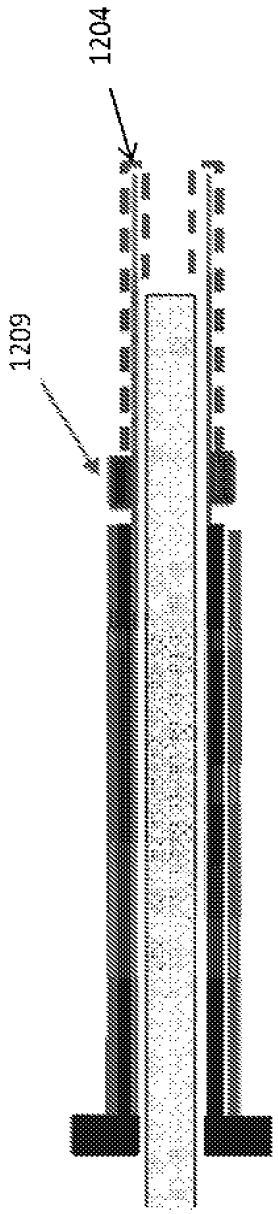


图12B

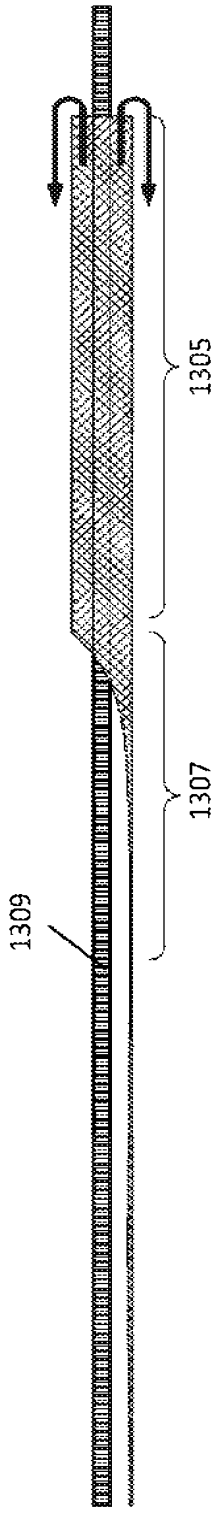


图13A

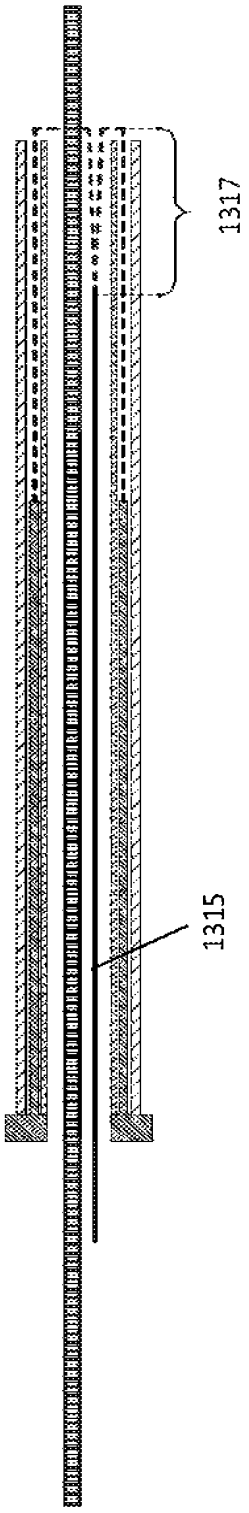


图13B

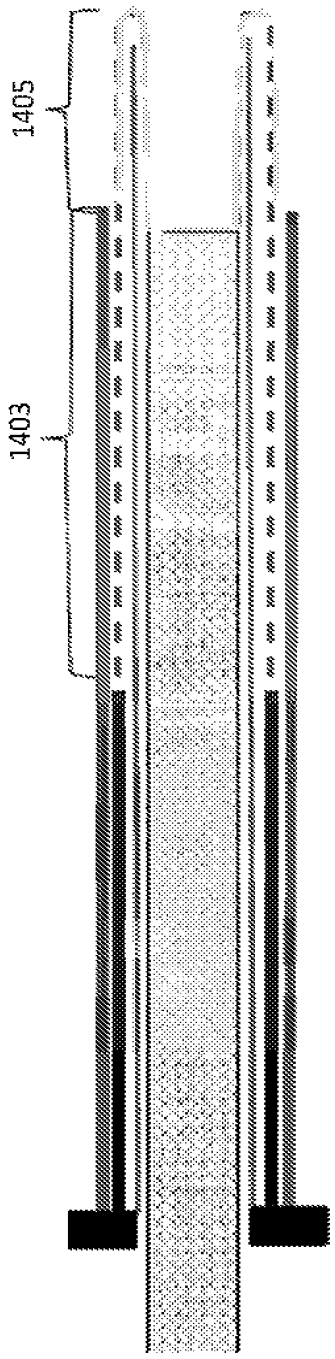


图14

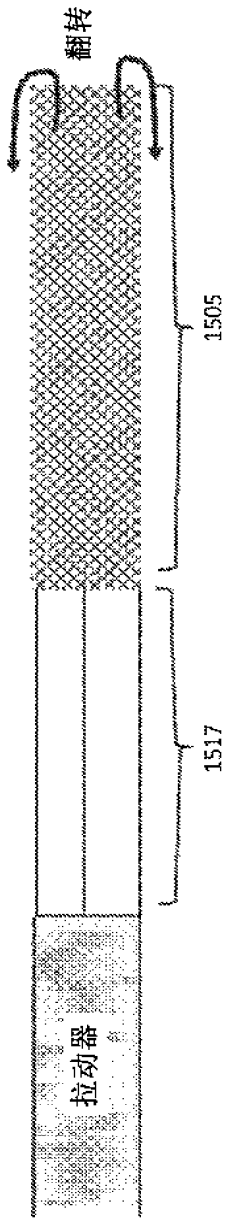


图15A

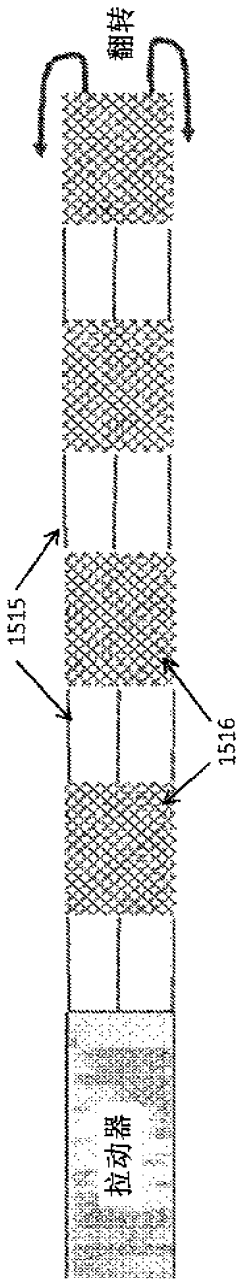


图15B

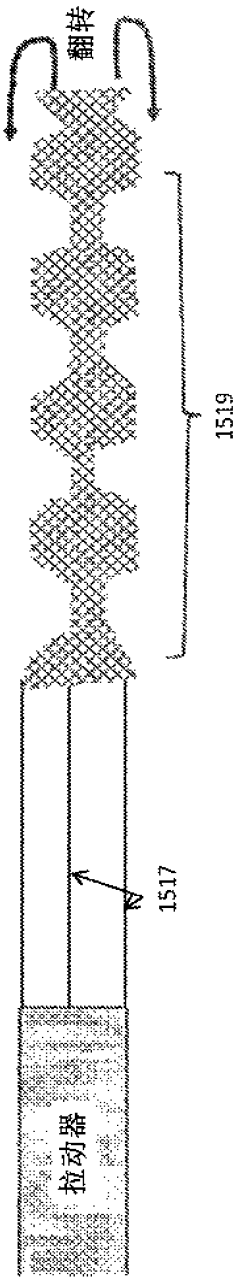


图15C

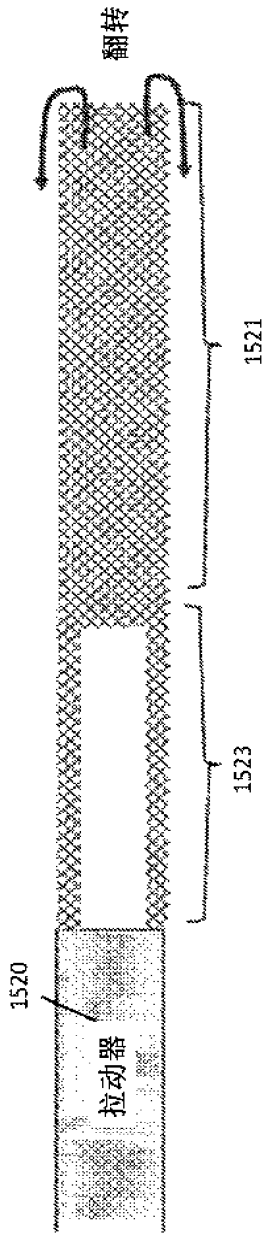


图15D

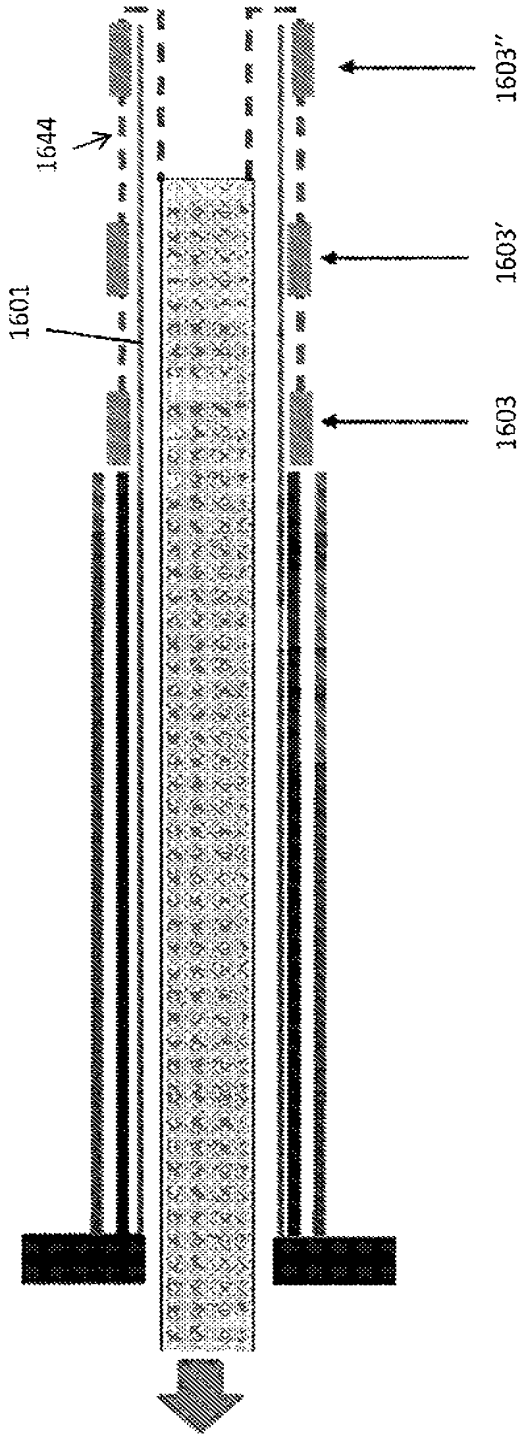


图16

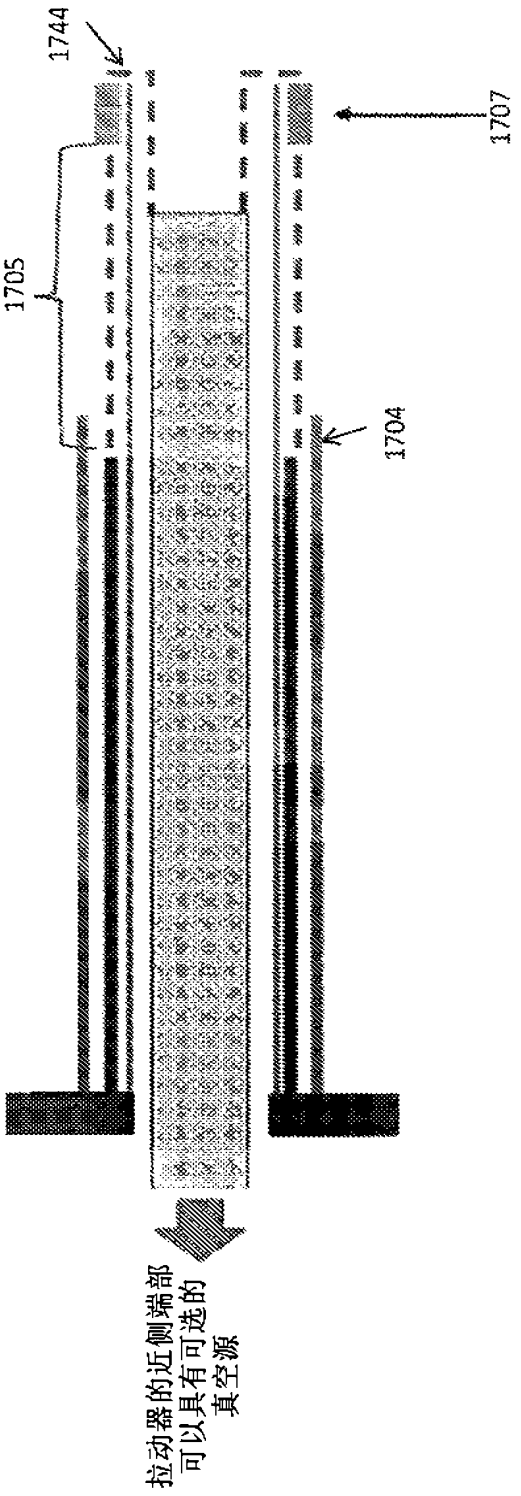


图17

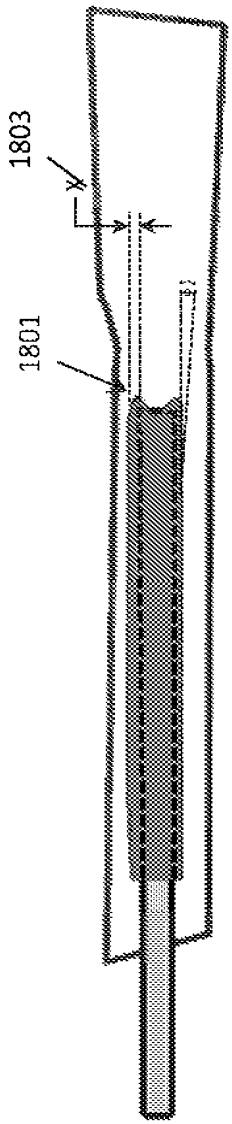


图18A

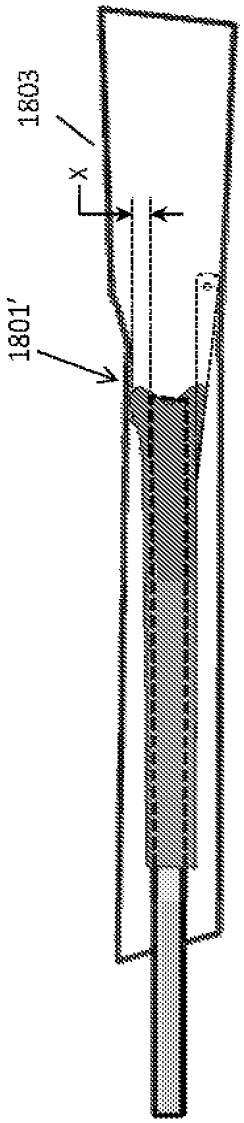


图18B

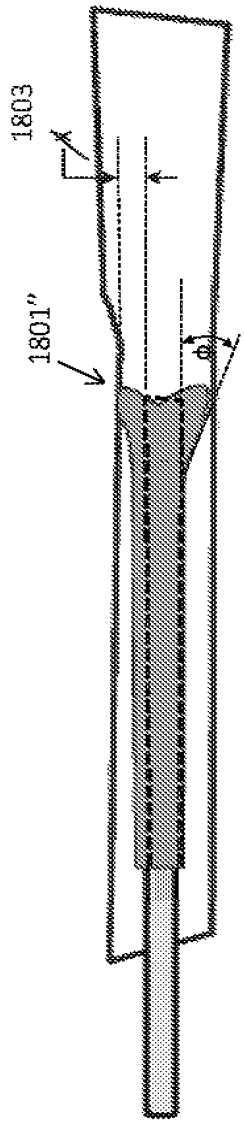


图18C

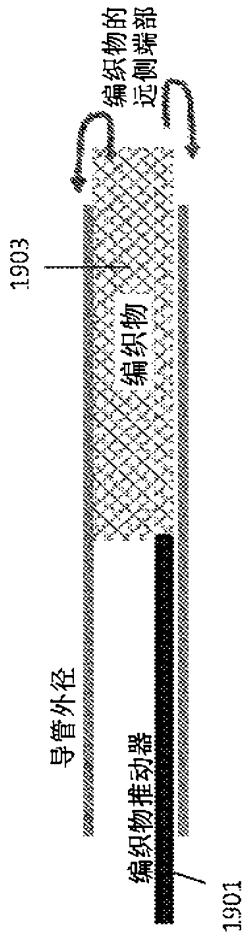


图19A

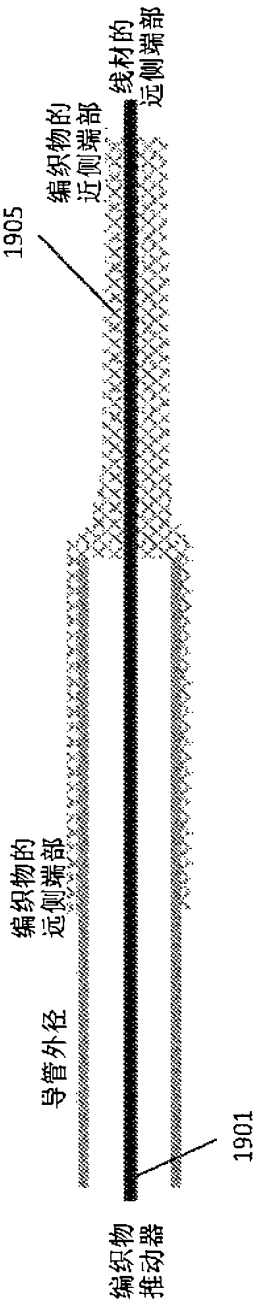


图19B

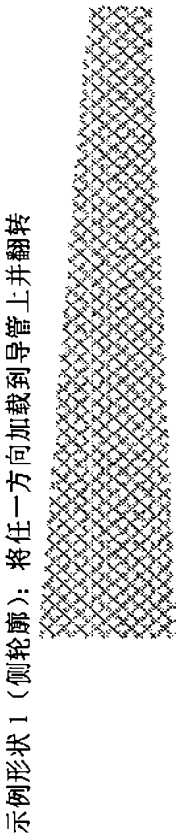


图20A

图20B

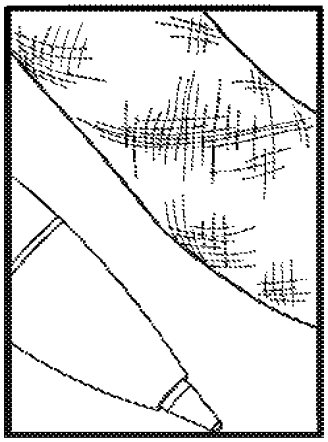


图21A

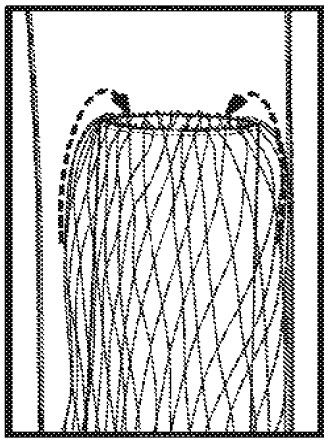


图21B

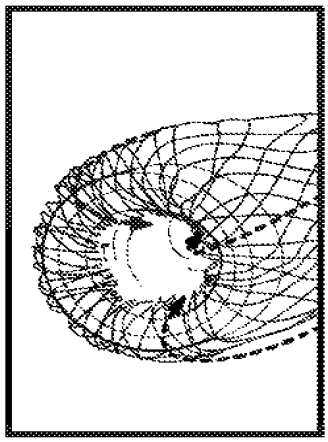


图21C

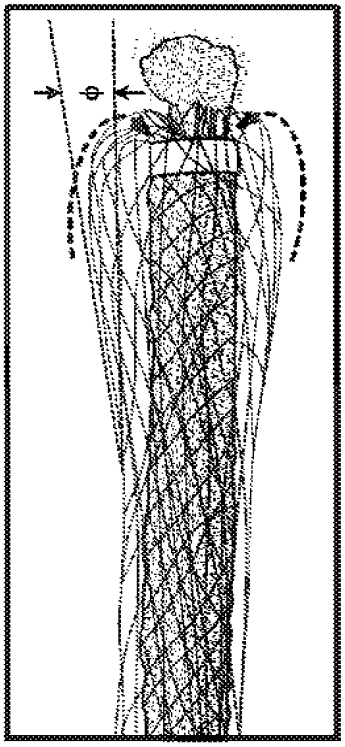


图21D

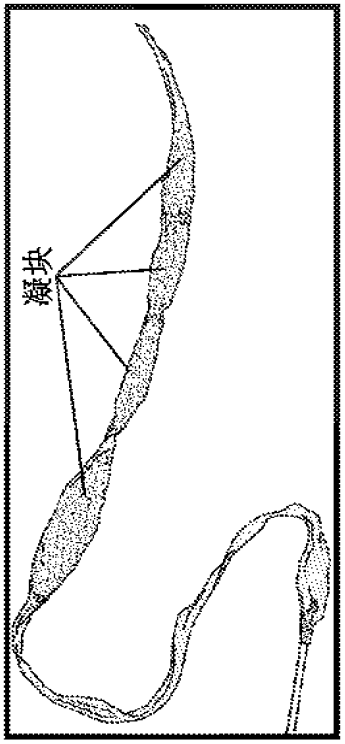


图22

90

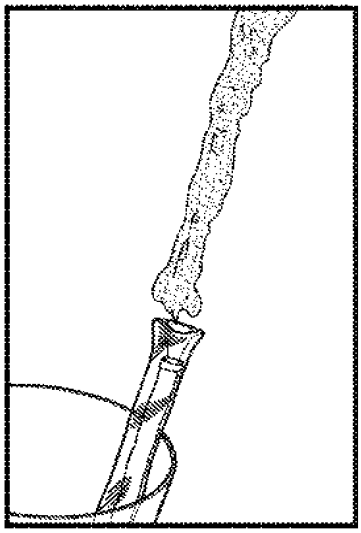


图23A

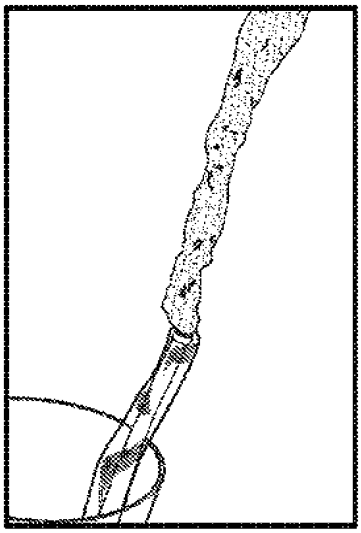


图23B

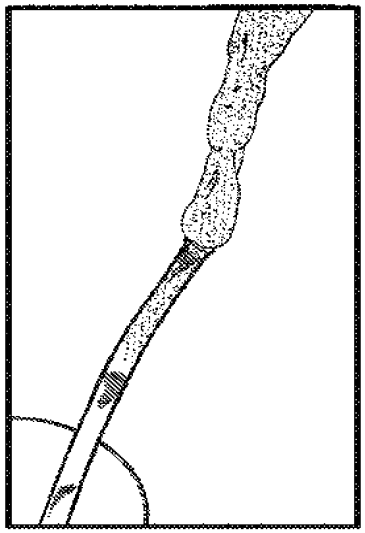


图23C

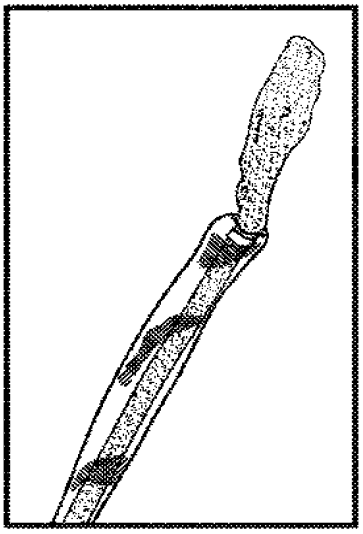


图23D

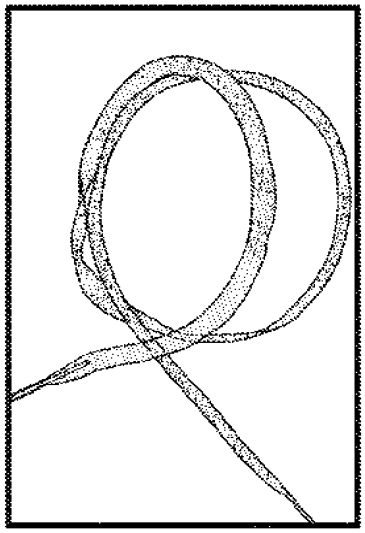


图23E

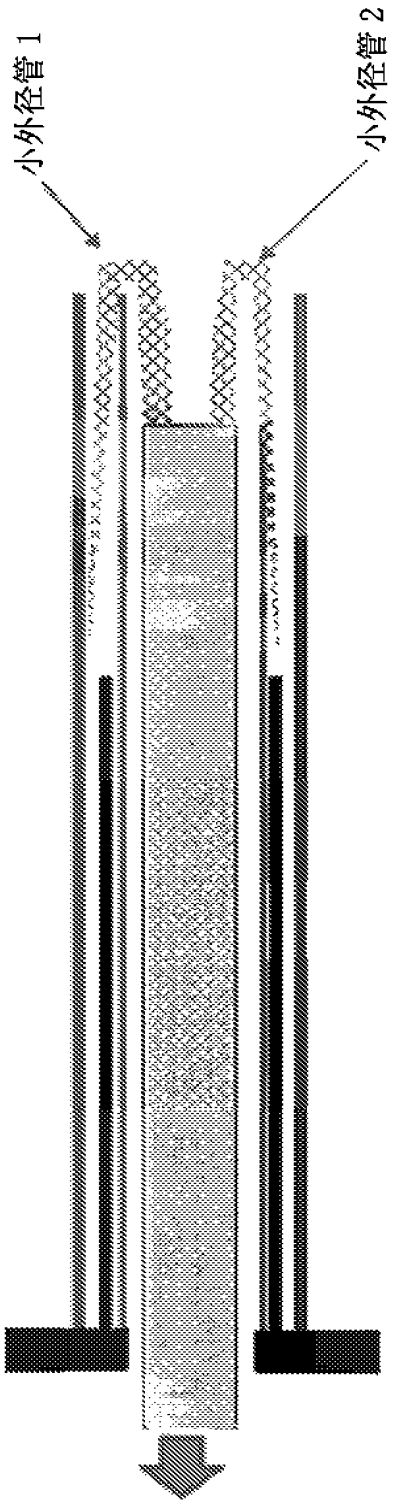


图24

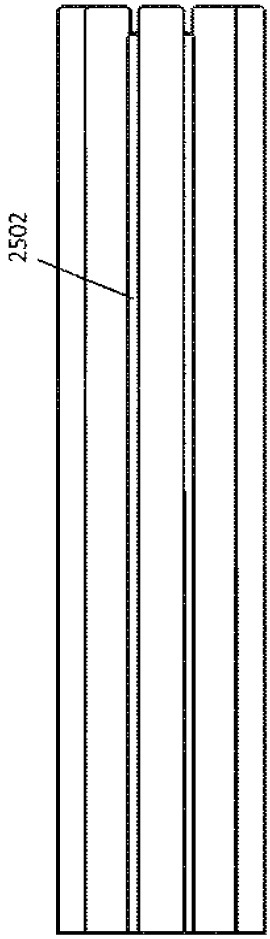


图25A

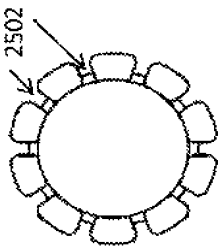


图25B

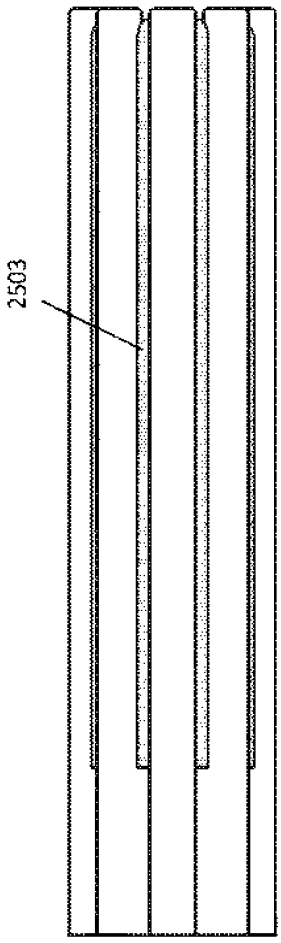


图25C

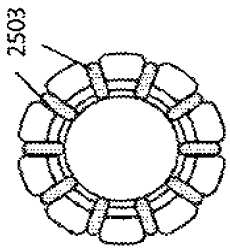


图25D

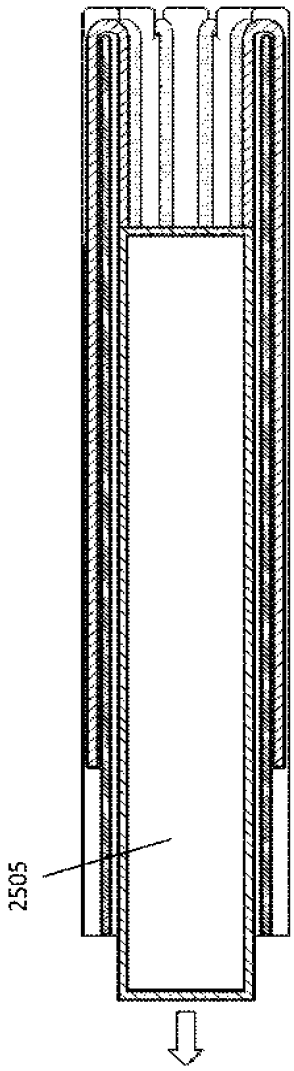


图25E

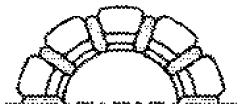


图25F

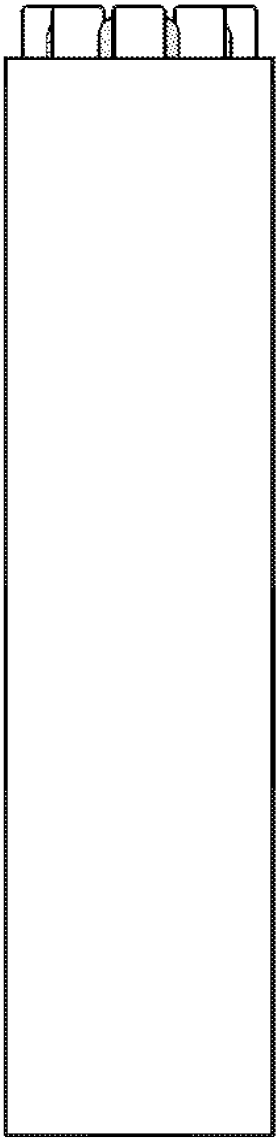


图26A

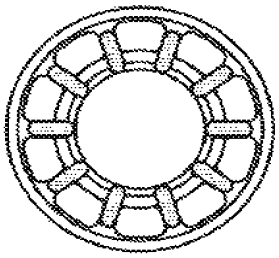


图26B

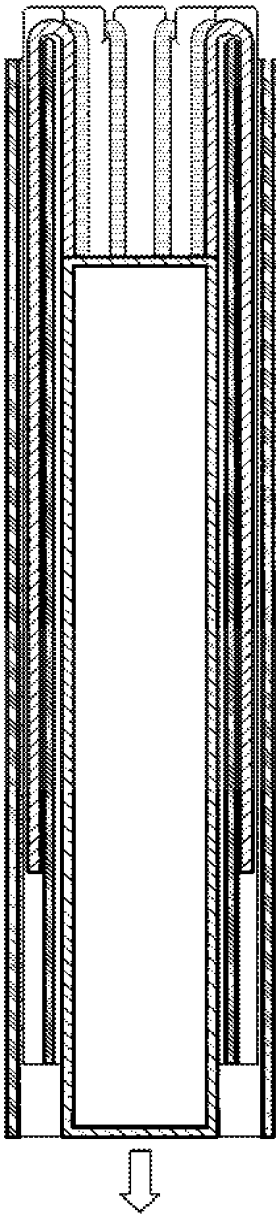


图27A

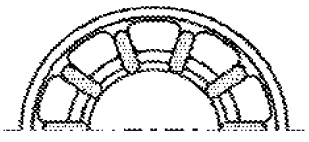


图27B

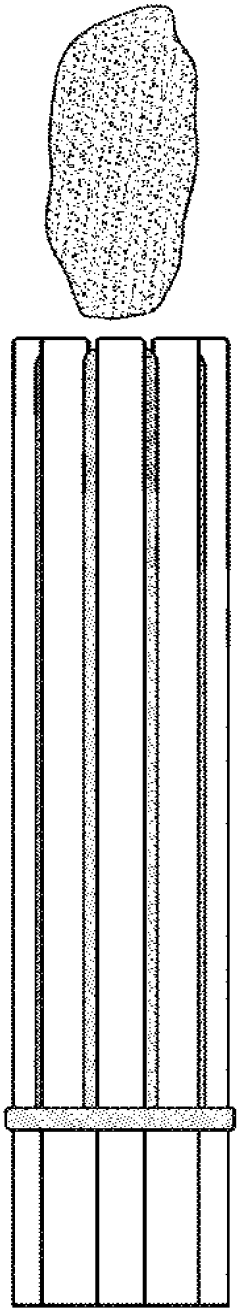


图28

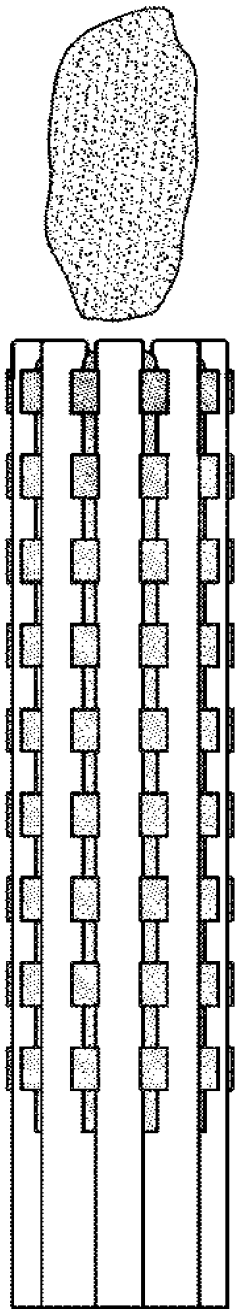


图29

图30A

图30B

图30C

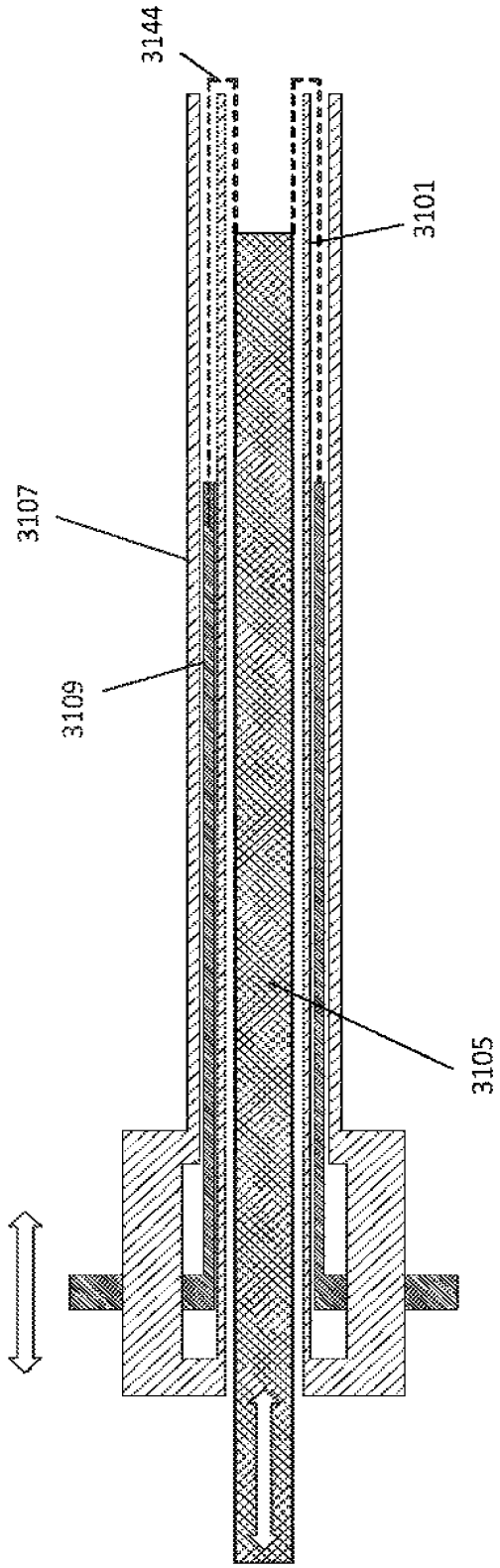


图31

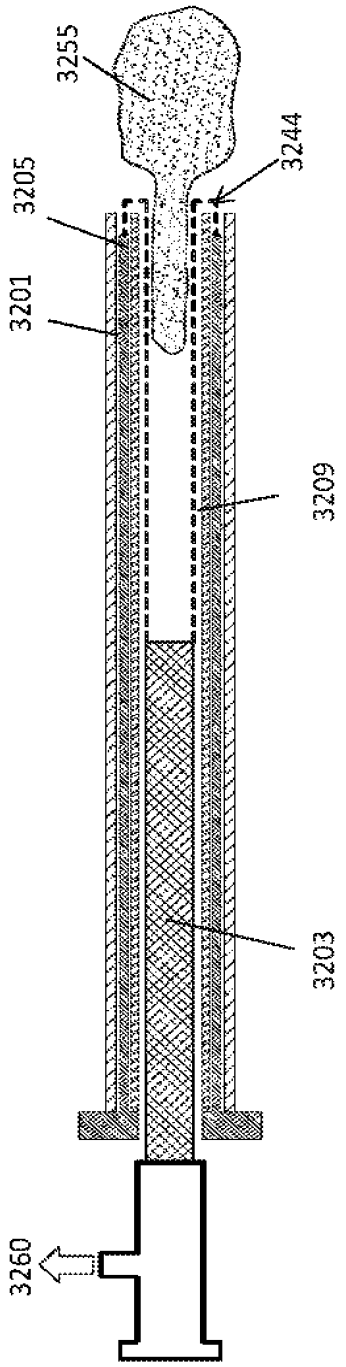


图32

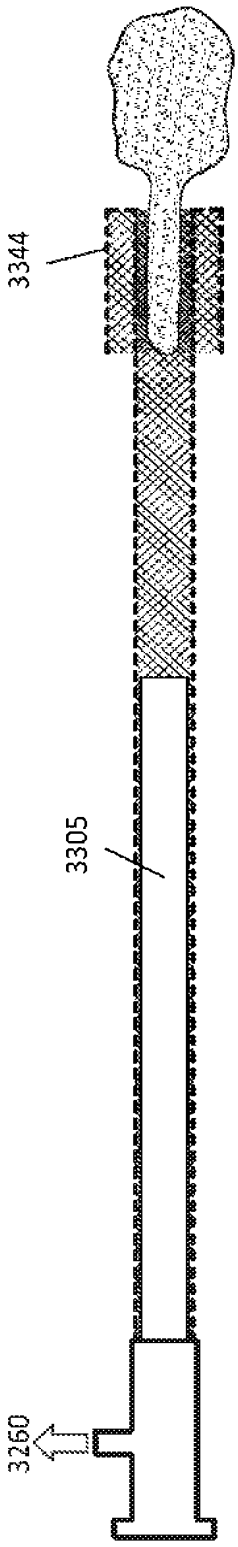


图33

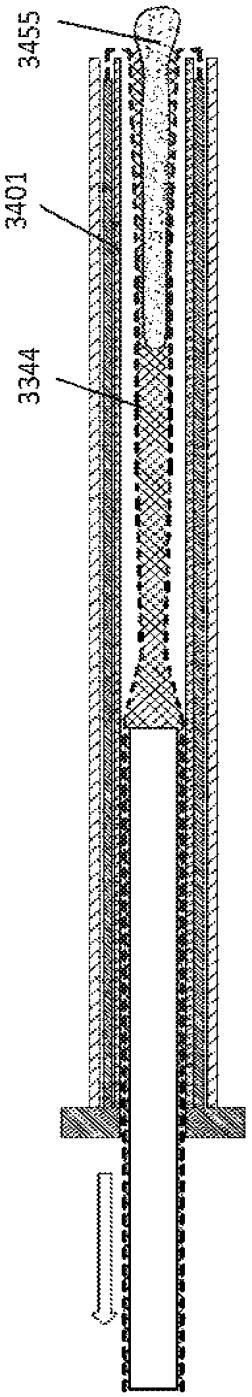


图34

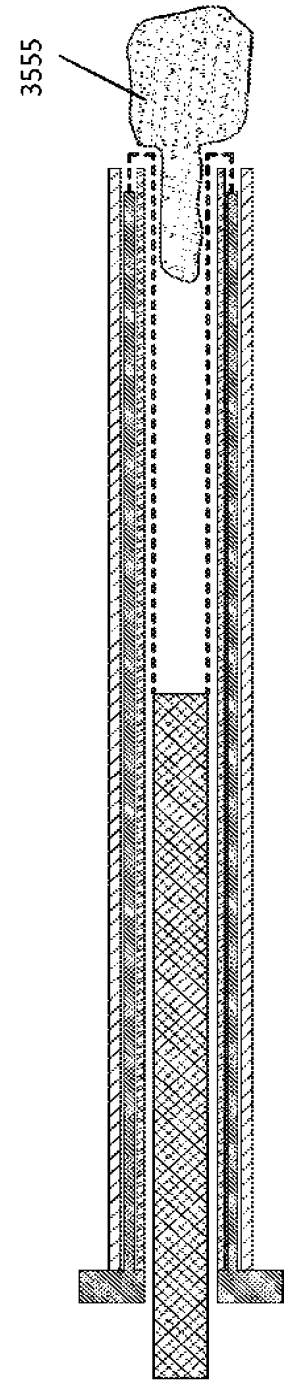


图35A

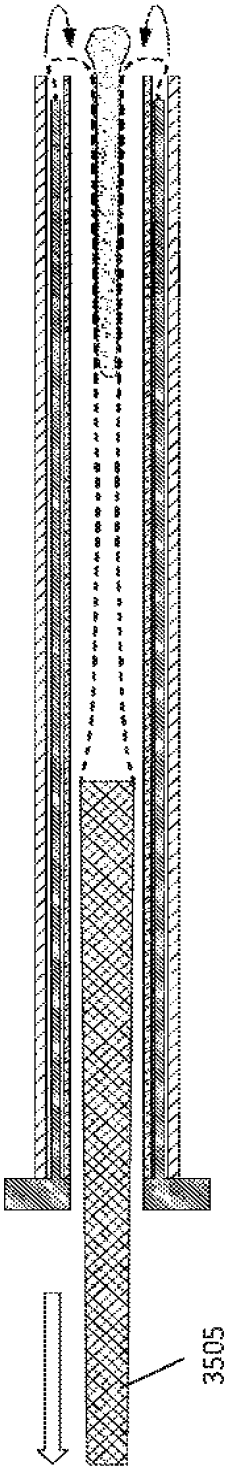


图35B

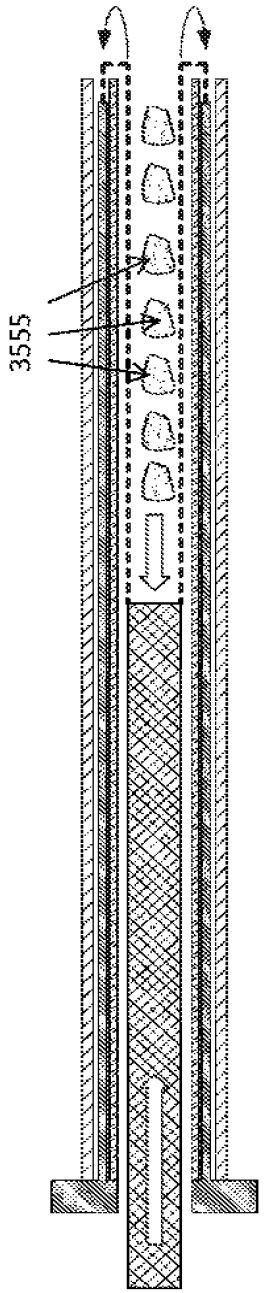


图35C

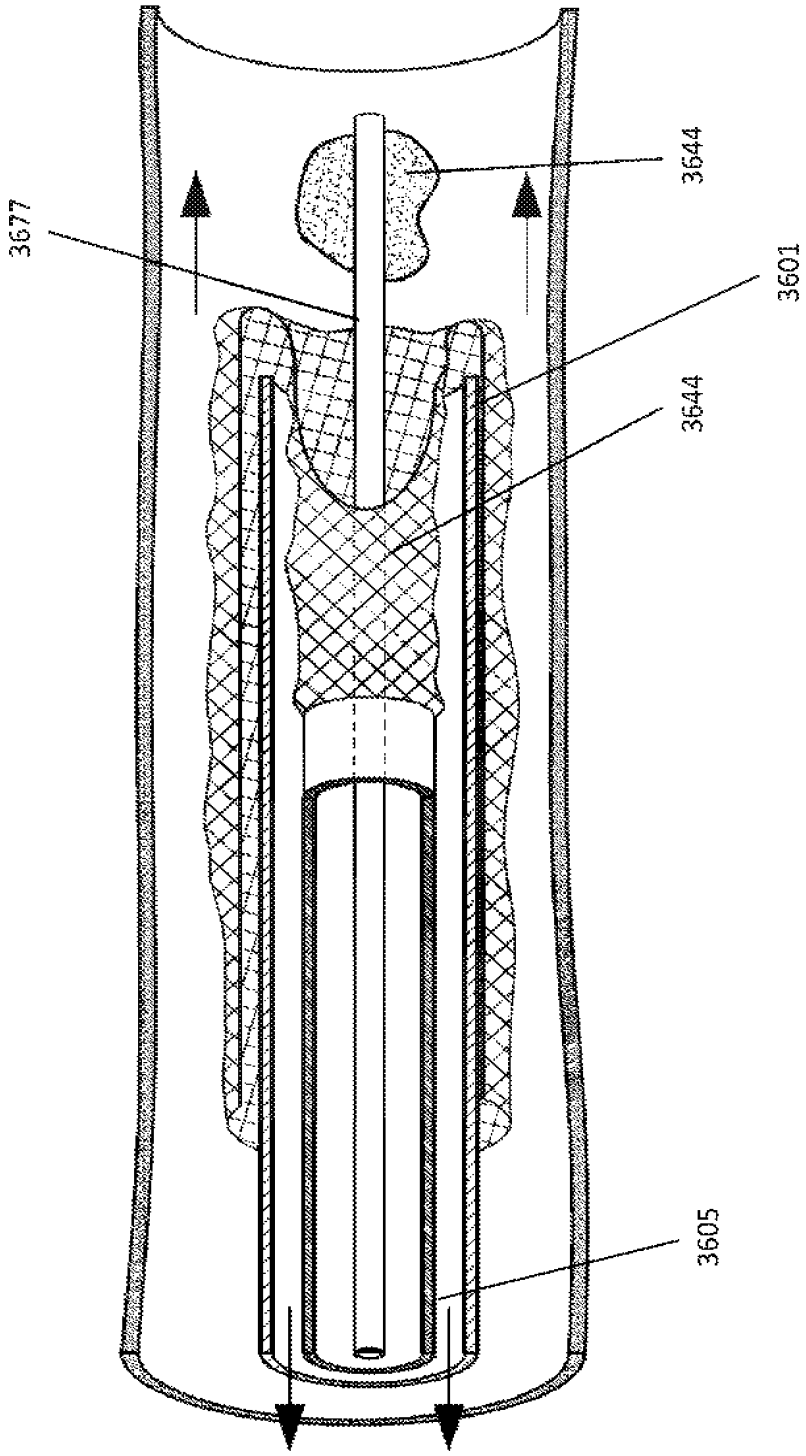


图36

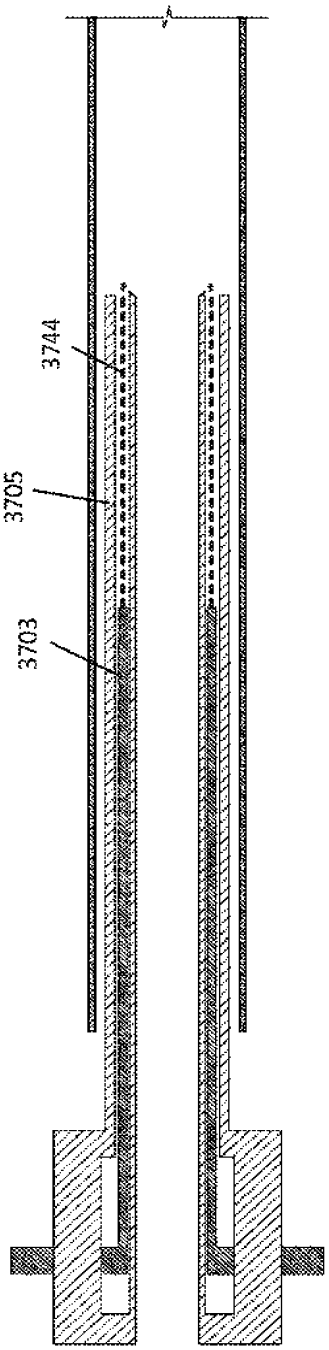


图37A

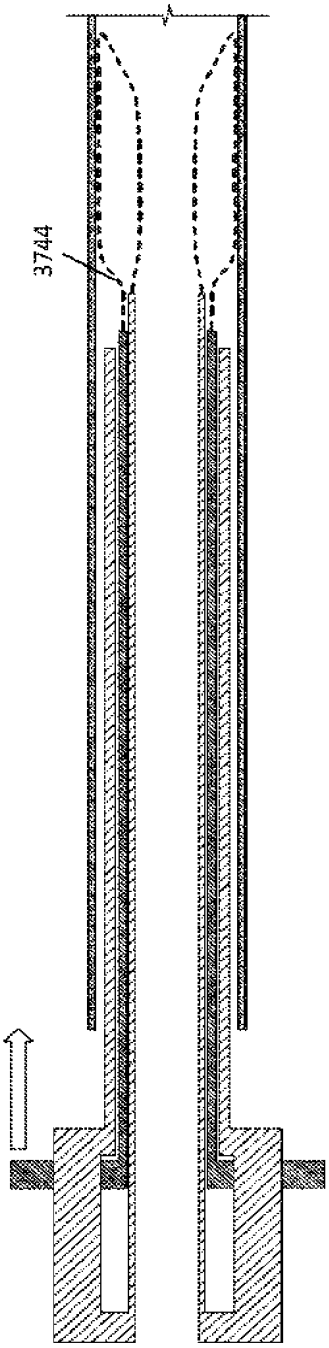


图37B

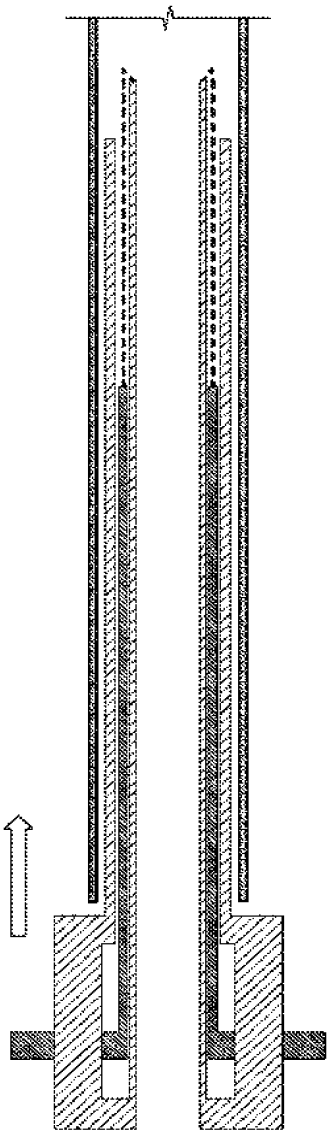


图37C

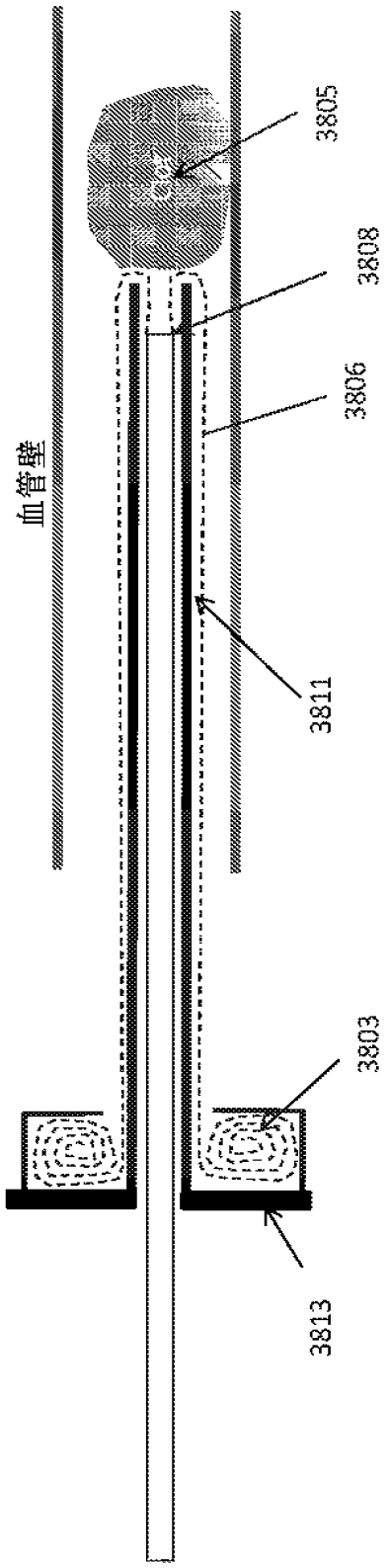


图38A

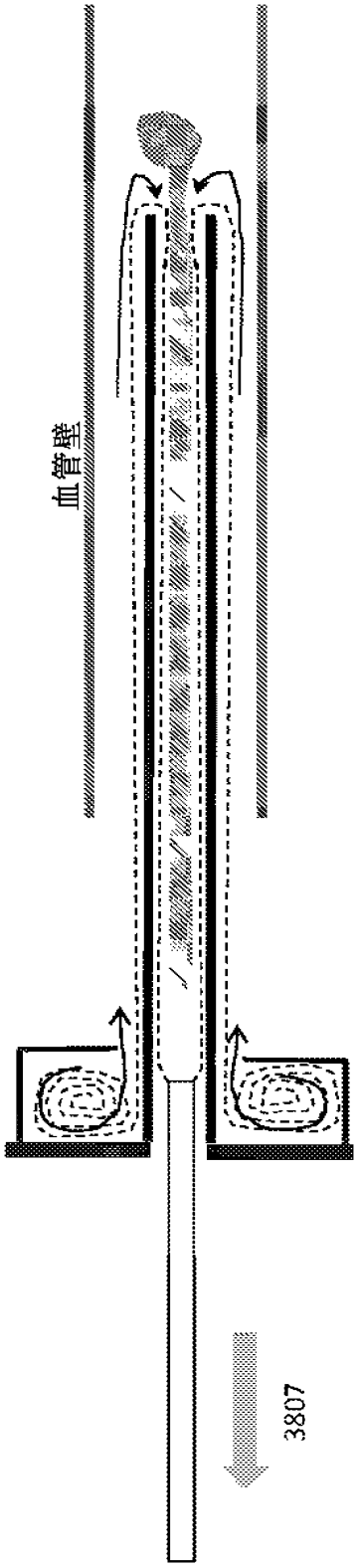


图38B

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 May 2014 (30.05.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/081892 A1

(51) International Patent Classification:
A61M 25/01 (2006.01) *A61M 25/09* (2006.01)
A61M 25/08 (2006.01)

(21) International Application Number:
PCT/US2013/071101

(22) International Filing Date:
20 November 2013 (20.11.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/728,775 20 November 2012 (20.11.2012) US
61/750,277 8 January 2013 (08.01.2013) US
13/843,742 15 March 2013 (15.03.2013) US

(72) Inventors; and
(71) Applicants : **ROSENBLUTH, Robert** [US/US]; 24161 Cherry Hills Place, Laguna Niguel, CA 92677 (US). **COX, Brian, J.** [US/US]; 3 Novilla, Laguna Niguel, CA 92677 (US). **LUBOCK, Paul** [US/US]; 11 Santa Lucia, Monarch Beach, CA 92629 (US). **QUICK, Richard** [US/US]; 22970 Bouquet Canyon, Mission Viejo, CA 92692 (US).

(74) Agents: **FOX, Mary L.** et al.; Perkins Coie LLP, P.O. Box 1247, Seattle, WA 98111-1247 (US).

(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, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, 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, 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, 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).

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))*

(54) **Title**: METHODS AND APPARATUS FOR TREATING EMBOLISM

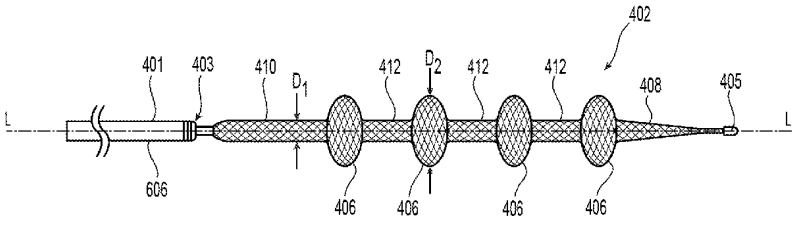


Fig. 5B

(57) **Abstract**: A method and apparatus for treating a clot in the blood vessel of a patient, and particularly the treatment of a pulmonary embolism is disclosed. The treatment includes restoring flow through the clot followed by clot removal, either partially or substantially completely. The clot treatment device is expandable into the blood vessel and may contain radial extensions that assist in restoring flow as well as in removing clot material.

WO 2014/081892 A1

METHODS AND APPARATUS FOR TREATING EMBOLISM

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Patent Application No. 13/843,742, filed on March 15, 2013, and entitled Methods and Apparatus for Treating Embolism, which examples priority to U.S. Provisional Application Serial No. 61/750,277 filed January 8, 2013 entitled Devices and Methods for Treatment of Vascular Occlusion and U.S. Provisional Application Serial No. 61/728,775 filed November 20, 2012 entitled Devices and Methods for Treatment of Vascular Occlusion, all of which are hereby incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

[0002] This invention relates to the apparatus and methods of endovascular treatment of blood clots obstructing passageways in the circulatory system and particularly the endovascular treatment of pulmonary embolism.

BACKGROUND OF THE INVENTION

[0003] Thromboembolism is the formation in a blood vessel of a clot (thrombus) that breaks loose (embolizes) and is carried by the blood stream to another location in the circulatory system resulting in a clot or obstruction at that new location. For example, a clot may embolize and plug a vessel in the lungs (pulmonary embolism), the brain (stroke), the gastrointestinal tract, the kidneys, or the legs. Thromboembolism is a significant cause of morbidity (disease) and mortality (death), especially in adults. A thromboembolism can be sudden and massive or it may be small and multiple. A thromboembolism can be any size and a thromboembolic event can happen at any time.

[0004] When a thrombus forms in the venous circulation of the body it often embolizes to the lungs. Such a thrombus typically embolizes from the veins of the legs, pelvis, or inferior vena cava and travels to the right heart cavities and then into the pulmonary arteries thus resulting in a pulmonary embolism.

[0005] A pulmonary embolism results in right heart failure and decreased blood flow through the lungs with subsequent decreased oxygenation of the lungs, heart and the rest of the body. More specifically, when such a thrombus enters the pulmonary arteries, obstruction and spasm of the different arteries of the lung occurs which further decreases blood flow and gaseous exchange through the lung tissue resulting in pulmonary edema. All of these factors decrease the oxygen in the blood in the left heart. As a result, the oxygenated blood supplied by the coronary arteries to the musculature of both the left and right heart is insufficient for proper contractions of the muscle which further decreases the entire oxygenated blood flow to the rest of the body. This often leads to heart dysfunction and specifically right ventricle dysfunction.

[0006] This condition is relatively common and has many causes. Some of the more common causes are prolonged inactivity such as bed rest, extended sitting (e.g., lengthy aircraft travel), dehydration, extensive surgery or protracted disease. Almost all of these causes are characterized by the blood of the inferior peripheral major circulatory system coagulating to varying degrees and resulting in permanent drainage problems.

[0007] There exist a number of approaches to treating thromboembolism and particularly pulmonary embolism. Some of those approaches include the use of anticoagulants, thrombolytics and endovascular attempts at removal of the emboli from the pulmonary artery. The endovascular attempts often rely on catheterization of the affected vessels and application of chemical or mechanical agents or both to disintegrate the clot. Invasive surgical intervention in which the emboli is removed by accessing the chest cavity, opening the embolized pulmonary artery and/or its branches and removing the clot is also possible.

[0008] The prior approaches to treatment, however, are lacking. For example, the use of agents such as anticoagulants and/or thrombolytics to reduce or remove a pulmonary embolism typically takes a prolonged period of time, e.g., hours and even days, before the treatment is effective. In some instances, such agents can cause hemorrhage in a patient. Moreover, the known mechanical devices for removing an

embolism are typically highly complex, prone to cause undue trauma to the vessel, and can be difficult and expensive to manufacture.

[0009] Lastly, the known treatment methods do not emphasize sufficiently the goal of urgently restoring blood flow through the thrombus once the thrombus has been identified. In other words, the known methods focus primarily and firstly on overall clot reduction and removal instead of first focusing on relief of the acute blockage condition followed then by the goal of clot reduction and removal. Hence, known methods are not providing optimal patient care, particularly as such care relates to treatment of a pulmonary embolism.

SUMMARY OF THE PRESENT TECHNOLOGY

[0010] In view of the foregoing, several embodiments of the present technology to provide a method and system that initially restores an acceptable level of oxygenated blood to the patient's circulatory system followed by safe and effective removal of the thrombus.

[0011] Several embodiments of the present technology treat pulmonary embolism in a minimally invasive manner.

[0012] Several embodiments of the present technology can also provide a system that does not cause undue trauma to the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] These and other objects, aspects, features and advantages of which the present technology is capable will be apparent from the following description of embodiments of the present technology, reference being made to the accompanying drawings, in which

[0014] Fig. 1A is a schematic view of a patient with a pulmonary embolism;

[0015] Fig. 1B is an enlarged view of the lung area of the patient depicted in Fig. 1A;

[0016] Fig. 1C is an enlarged view of the introducer device depicted being used in the femoral vein of the patient in Fig. 1A;

[0017] Fig. 2 is a cross-sectional view of a patient's heart;

[0018] Fig. 3 is a perspective view of a patients main pulmonary artery and right and left pulmonary arteries with a clot located in the left pulmonary artery;

[0019] Fig. 4 is a cross-sectional view of an embodiment of a clot treatment device in accordance with the present technology in a compressed, undeployed state;

[0020] Fig. 5A is a side cross-sectional view of a clot treatment device in a compressed, undeployed state within a delivery catheter in accordance with the present technology;

[0021] Fig. 5B is a top view of the a clot treatment device in a deployed state in accordance with the present technology;

[0022] Figs. 6A-6F are a series of cross-sectional views of embodiments of the method and device of the present technology;

[0023] Figs. 7A-7B are a series of cross-sectional views of embodiments of the method and device of the present technology;

[0024] Fig. 8 is a cross-sectional view of another embodiment of the method and device of the present technology; and,

[0025] Figs. 9A-9G show cross-sectional views of embodiments of a clot treatment device in accordance with the present technology.

[0026] Fig. 10 is a cross-sectional view of a clot treatment device in accordance with another embodiment of the present technology.

[0027] Figs. 11 and 12 are detailed cross-sectional views of a distal portion and a proximal portion, respectively, of an expandable member of a clot treatment device in accordance with an embodiment of the present technology.

[0028] Figs. 13 and 14 are detailed cross-sectional views of a proximal portion and a distal portion, respectively, of an expandable member of a clot treatment device in accordance with another embodiment of the technology.

[0029] Figs. 15-18 are side views of guide catheters for use with clot treatment devices and methods in accordance with embodiments of the present technology.

[0030] Fig, 19 is a side view of a clot treatment device including arcuate clot engagement members configured in accordance with an embodiment of the present technology.

[0031] Figs. 20-23 show embodiments of arcuate clot engagement members configured in accordance with the present technology.

[0032] Figs. 24-25 are side views of clot treatment devices configured in accordance with embodiments of the present technology.

[0033] Fig. 26 is a circumferential structure including arcuate clot engagement members in accordance with embodiments of the present technology.

[0034] Fig. 27 is a side view of a clot treatment device having a distal radially extending member configured in accordance with another embodiment of the present technology.

DESCRIPTION OF EMBODIMENTS

[0035] Specific embodiments of the present technology will now be described with reference to the accompanying drawings. This present technology may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the present technology to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the present technology. In the drawings, like numbers refer to like elements.

[0036] Referring to Figures 1A-1C, these drawings show the typical locations in a human patient where clots 100, such as pulmonary embolisms, thromboses, or other obstructions, occur in the pulmonary arteries and further discloses the pathway through which access to such clots 100 is achieved. In particular, an introducer device (e.g., a hemostatic valve) 102 which supports relatively large diameter devices is inserted into the patient into the femoral vein FV in the pelvic area of the patient. The tools and devices needed to treat the pulmonary embolism are then inserted through the introducer 102 into the femoral vein FV through the inferior vena cava IVC to the patient's heart.

[0037] It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and which are consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to right atrium RA of the patient's heart may be attractive as this will reduce the length of the instruments needed to reach the pulmonary embolism.

[0038] Referring to Figs. 2 and 3, the tools/devices are then guided through the right atrium RA through the tricuspid valve TV, into the right ventricle RV, through the pulmonary valve PV into the main pulmonary artery (MPA). Depending on the location of the embolism 100, the tools/devices are then guided to one or more of the branches of the right pulmonary artery RPA or the left pulmonary artery LPA, including deeper branches thereof, to the location of the pulmonary embolism 100.

[0039] Referring to Figure 4, an embodiment of a clot treatment device 402 for restoring blood flow through the clot 100 and for removing at least a portion of the clot is depicted in its undeployed, or compressed state. The device 402 is constrained by a delivery catheter 606. In many embodiments, the device 402 comprises a braided material having ends that are captured distally by a tip 405 and proximally by an attachment member 403 that connects to a wire 401 configured to push and/or pull the clot treatment device 402.

[0040] In alternative embodiments, the clot treatment device 402 may be an "over the wire" device, in which case, the wire 401 is a tube or coil having a lumen, and the attachment member 403 and the tip 405 have a hollow central lumen for receiving a guide wire.

[0041] In yet a further embodiment, the distal end of the clot treatment device shall have a flexible, atraumatic extension from the device. In an alternative embodiment, the tip 405 is tapered to better penetrate the clot material in the vessel.

[0042] In preferred embodiments the clot treatment device 402 of the present technology has a generally cylindrical shape that, during use, creates a flow lumen through the clot material that restores significant blood flow across a clot. The treatment device 402 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 such that the clot treatment device 402 creates a lumen for restoring the blood flow.

[0043] Fig. 5A shows one embodiment of the treatment device 402 in a low-profile, undeployed state in which the clot treatment device is configured to fit within a delivery catheter, and Fig. 5B shows the clot treatment device 402 of Fig. 5A in a deployed state configured to restore blood flow and capture clot material for removal. Referring to Fig. 5A, the clot treatment device 402 is compressed to fit within the diameter D_L of a lumen 607 of the delivery catheter 606 in the undeployed state. In the deployed state shown in Fig. 5B, the clot treatment device 402 has a plurality of capture elements, such as a series of radially extending capture portions 406 which are separated from each other by flow restoration portions 412. The flow restoration portions 412 are configured to expand outwardly from the low-profile undeployed state within the delivery catheter lumen 607 to a first cross-sectional dimension D_1 (e.g., diameter) in the deployed state. For example, the flow restoration portions 412 can be generally cylindrical braided sections that expand radially outward from the undeployed stated to the deployed state. In many applications, the first cross-sectional dimension D_1 is greater than the diameter D_L of the delivery catheter lumen 607. The capture portions 406 are configured to expand outwardly from the low-profile undeployed state to a second cross-sectional dimension D_2 greater than the first cross-sectional dimension D_1 in the deployed state.

As explained in more detail below, the capture portions 406 can project into the clot such that they extend transverse to a longitudinal axis L-L of the clot treatment device 402, while the flow restoration portions 412 expand radially outward into the clot to open a passage through which blood can quickly resume flow through the vessel. The clot treatment device 402 can be porous so blood flows therethrough. In this regard, many embodiments of the clot treatment device 402 are made from a mesh or braided material. The material can be a super-elastic material such as Nitinol or an alternative material such as cobalt chrome alloy. The device can be made from a wire lattice, wire braid or stent. Specific preferred embodiments are discussed throughout this specification.

[0044] Referring again to Fig. 5B, the clot treatment device 402 can comprise a single mesh structure that is generally cylindrical in the low-profile undeployed state (shown in Fig. 5A). The series of radially extending capture portions 406 accordingly extend from the same mesh as the corresponding series of flow restoration portions 412. The flow restoration portions 412 can be generally cylindrical sections in the deployed state, or in other embodiments the flow restoration portions 412 may taper in the distal direction individually and/or collectively to form a conical lumen (not shown). Each of the capture portions 406 can be a radial or otherwise transversely projecting disk that projects outward relative to the flow restoration portions 412.

[0045] The clot treatment device 402 can self-expand from the undeployed state to the deployed state. For example, the clot treatment device 402 can be a shape-memory material, such as Nitinol, and may be formed as a braid or a stent that is set to have the expanded configuration of the deployed state shown in Fig. 5B unless it is otherwise deformed or constrained, such as being elongated along the longitudinal axis L-L to fit within the delivery catheter 606 as shown in Fig. 5A. In other embodiments, the clot treatment device 402 can be actuated by a push/pull wire, tube or coil to move from the low-profile undeployed state to the expanded deployed state as explained in more detail below with reference to Figs. 10-12.

[0046] Figs. 1-6F show embodiments of methods for restoring blood flow and retrieving/removing clot material with the clot treatment device 402 in a body lumen L.

[0047] Referring to Figs. 1A, 1B and 6A, a guide wire 602 is inserted into the patient via an introducer 102 and maneuvered through the femoral vein FV into the inferior vena cava IVC to the heart. As stated above, access can also be achieved through one of the veins leading to the superior vena cava SVC. The guide wire 602 is then urged through the right atrium RA, through the tricuspid valve TV, through the right ventricle RV, through the pulmonary valve PV to the main pulmonary artery MPA and then to a location of the clot 100 in one of the branches or lumens L of either the right or left pulmonary artery RPA, LPA. In several embodiments, the guide wire 602 is extended through the clot 100 in the body lumen L as shown in Fig. 6A.

[0048] Referring to Fig. 6B, a guide catheter 604 is placed over the guide wire 602 and moved to a location where a distal end of the guide catheter 604 is positioned proximal to the clot 100. At this point, the guide wire can optionally be withdrawn. However, in the embodiment shown in Fig. 6C, the guide wire 602 remains positioned through the clot 100 and a delivery catheter 606 is then moved through the guide catheter 604 over the guide wire 602 and pushed through the clot 100.

[0049] Referring to Figure 6D, the guide wire 602 is then withdrawn and the clot treatment device 402 in its undeployed (i.e., compressed) state is then moved through the delivery catheter 606 until it is positioned at the distal end of the delivery catheter 606. Alternatively, if an over-the-wire device configuration (as shown in Figure 10) is used, the guide wire 602 may be left in place while the treatment device 402 is deployed and retracted. Referring to Fig. 6E, the delivery catheter 606 is then retracted in a proximal direction while maintaining forward pressure on the clot retrieval device 402 via the pusher wire 401 so that the clot treatment device 402 is exposed and released from the delivery catheter 606. The clot treatment device 402 radially expands into the clot 100 and, in some embodiments, at least a portion of the clot treatment device 402 expands distal of the clot 100. For example, at least one of the radially extending capture portions 406 of the clot treatment device 402 is located distal to the clot 100 upon expansion of the clot treatment device 402. Additionally, the flow restoration portions 412 between the capture portions 406 also expand outwardly against a portion of the clot 100 to form a flow passage 430 though the clot treatment device 402.

[0050] The clot treatment device 402 accordingly restores blood flow through the clot 100 immediately or at least quickly after expanding to the deployed state as shown by arrows 407 in Fig. 6E. More specifically, the blood freely moves through the mesh of the clot treatment device 402, travels through the device lumen and exits the clot treatment device 402 distal to the clot 100. As a result, the acute condition of blockage is mediated thus immediately improving the circulation of oxygenated blood in the patient.

[0051] The restoration of blood flow is anticipated to equate with restoration of a substantial portion of the normal blood flow rate for the patient. In less severe. e.g., "sub-massive," pulmonary embolism patients, the clot treatment device 402 may increase blood flow rate by at least about 50 ml/min, at least about 150 ml/min or between about 100 to 250 ml/min. In severe, e.g., "massive," pulmonary embolism patients, a larger amount of the pulmonary artery flow is compromised. Hence, in some embodiments, at least about 500 ml/min of blood flow rate may be restored. Moreover, at least a portion of the flow restoration is expected to occur prior to the removal of the clot 100, or any portion thereof.

[0052] The restoration of blood flow by the clot treatment device 402 can be achieved in a low pressure environment. For example, the pressure in the target vessel can be less than 60 mmHg and the blood can be venous blood, substantially non-oxygenated blood or low oxygenated blood.

[0053] In addition to restoring blood flow, the expansion of the clot treatment device 402 also deforms the clot material by pushing, penetrating and/or otherwise cutting into the clot material. This enhances the subsequent removal of the clot 100 since portions of the clot 100 may be captured and retained (1) between the radially extending portions 406; (2) through the pores of the mesh forming the radially extending portions 406; (3) along the longitudinal cylindrical sections 412 between the radially extending portions 406 of the removal device 402; and (4) within the clot treatment device 402 itself.

[0054] As can be understood from the above description and figures, the deployment of the clot treatment device 402 results in an outwardly expanding generally cylindrical

force being urged against an inner surface of the clot 100 because the flow restoration portions 412 expand to the first cross-sectional dimension D_1 greater than the diameter D_L of the delivery catheter lumen 607. This force pushes the clot material outwardly and creates a lumen through which blood flow is restored. As can also be appreciated, the presence of the radially extending capture portions 406 on the clot treatment device 402 causes the outwardly expanding generally cylindrical force to vary in magnitude along the axis of the clot treatment device 402. The force on the clot material may be greater at the locations of the radially extending capture portions 406.

[0055] In braided embodiments of the clot treatment device 402, deployment/expansion of the device leads the filaments of the braid to change their angular orientation with respect to the axis of the device. This angular change may improve or enhance adherence of clot material to the clot treatment device 402.

[0056] After the clot treatment device 402 has been expanded and blood flow restored, the user then retracts the clot treatment device 402 in a proximal direction as shown in Fig. 6F. Since the capture portions 406 extend transverse to the longitudinal dimension of the vessel, the capture portions 406 form transverse surfaces relative to the force exerted against the clot 100 as the clot treatment device 402 is pulled in the proximal direction. The capture portions 406 accordingly enhance the ability of the clot treatment device 402 to securely dislodge and retain the clot 100 as the clot treatment device 402 is moved axially along the vessel to retrieve the clot 100 from the patient. In one embodiment, the clot treatment device 402 and the delivery catheter 606 are pulled back simultaneously into the guide catheter 604. This is followed by the entire apparatus (e.g., clot treatment device 402, delivery catheter 606 and guide catheter 604) being withdrawn through the heart and the venous circulation and out from the body.

[0057] As further shown in Fig. 6F, the clot treatment device 402 may elongate as it is being withdrawn into the guide catheter 604 due to the resistance it encounters from the presence of clot material of the clot 100. The presence of the radially extending portions 406 may allow elongation that enhances the capability of the device 402 to capture the maximum amount of clot material. This is further discussed below with

respect to the surface area and expansion ratio of preferred embodiments of the clot treatment device 402.

[0058] It will be appreciated that variations in the above-described method are contemplated. For example, in certain circumstances a guide catheter 604 may not be necessary or desirable and the user may choose to use only the delivery catheter 606 for placing and manipulation of the clot treatment device 402. As a further example, the clot may be of such a nature that the user may desire repeat the above-described process, or at least portions of it, in order to more fully remove the clot 100 or clot material.

[0059] Referring next to Figs. 7A-7B, it may be advantageous to include the use of a collection or funnel catheter 612 to assist in the removal of the clot 100. Such a funnel catheter 612 has an expandable portion 614 at its distal end and may be situated between the guide catheter 604 and the delivery catheter 608 or may be part of the guide catheter 604. In the presence of the collection catheter 612, the clot treatment device 402 is pulled proximally into the collection catheter 612 such that the clot or portions of it are captured within the collection catheter 612. In an alternative embodiment, the collection catheter 612 can be pushed distally over the clot treatment device 402 such that the collection catheter 612 captures the clot or portions thereof. If the collection catheter 612 is separate from the guide catheter 606, the collection catheter with the clot treatment device 402 is then pulled into the guide catheter for ultimate removal of all devices (and the clot) from the patient.

[0060] In certain circumstances, it may be advisable to remove the clot 100 without capturing it in the guide catheter 606 or the collection catheter 612 (if used) and remove the clot 100 by withdrawing the entire system, e.g., guide catheter 605, delivery catheter 604, clot treatment device 402 and collection catheter 612 (if used) simultaneously.

[0061] In several embodiments, the expandable portion 614 of the collection catheter 612 is a conical funnel or other tapered member constructed from a mesh, braid or stent structure. Such structure assists in retrieving and containing the clot material in the withdrawal process. In yet further preferred embodiments, the collection catheter 612

contains structural features to assist in the expansion of the expandable portion 614 and to hold the expandable portion 614 open towards the wall of the blood vessel. Such features (not shown) include interwoven support struts, self expanding material (e.g., Nitinol), longitudinal wire supports, stent supports, polymeric webbing, etc.

[0062] In another embodiment of the present invention, a vacuum apparatus may be used to aid in the removal of the clot material. Referring to Fig. 8, a syringe 802 is shown connected to a vacuum manifold 806 that is in fluid communication with the proximal end of the guide catheter 604. At the time the clot treatment device 402 (and clot material) is being withdrawn into the guide catheter 604 (or the collection catheter 612), vacuum is applied by pulling on the syringe. Alternative sources of vacuum 804 are also acceptable, e.g., a vacuum pump. A system is also contemplated whereby vacuum is actuated automatically when the clot treatment device 402 (and the clot material) is being withdrawn. A representation of the effect of the use of vacuum can be seen with reference to Fig. 7B which shows how vacuum causes flow 701 into the catheter 612.

[0063] Referring now to Figs. 9A-9H, alternative preferred embodiments of the clot treatment device 402 are disclosed.

[0064] Referring to Fig. 9A, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a cylindrical disk shape with a rounded triangular cross-section.

[0065] Referring to Fig. 9B, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 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 device 402 thus forming a conical exterior extent.

[0066] Referring to Fig. 9C, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a cylindrical disk shape with a rectangular cross-section.

[0067] Referring to Fig. 9D, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a cylindrical disk shape with a linear (non-rounded) triangular cross-section.

[0068] Referring to Fig. 9E, some of the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a cylindrical disk shape with a rounded cross-section and others have a rectangular cross section.

[0069] Referring to Fig. 9F, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 alternate between cylindrical disk shape with a T-shaped cross-section and a flare-shaped cross-section.

[0070] Referring to Fig. 9G, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a partial cylindrical disk shapes.

[0071] Referring to Fig. 9H, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by tabs and bumps or protuberances arising from the cylindrical surface of the device 402.

[0072] Fig. 10 is a cross-sectional view of another embodiment of the clot treatment device 402 in accordance with the technology having an expandable member 1010, an elongated inner member 1020, and an elongated outer member 1022. The expandable member 1010 is configured to have an undeployed state in which the expandable member 1010 is elongated axially to have a low profile that fits within a delivery catheter as shown in Fig. 4. The expandable member 1010 is further configurable into a deployed state in which the expandable member 1010 forms a flow channel 1012 for restoring blood flow through the region obstructed by the clot. The expandable member 1010, for example, can be a mesh, braid, stent-type device, or other suitable member through which blood flows in the deployed state. In one embodiment, the expandable member 1010 is a continuous braid formed from a shape-memory material that has been heat set such that, in the deployed state, the expandable member 1010 has a

plurality of flow restoration portions 412 that expand to the first cross-sectional dimension D_1 to form the flow channel 1012 and a plurality of capture portions 406 that expand to the second cross-section dimension D_2 greater than the first cross-sectional dimension D_1. The flow restoration members 412 accordingly exert an outward force (arrows O) against clot material (not shown) to create the flow channel 1012, and the capture portions 406 accordingly exert a longitudinal force L (arrows L) against the clot material as the clot treatment device 402 is moved proximally.

[0073] The elongated inner member 1020 can be a tube or coil having inner lumen configured to receive the guidewire 602 for over-the-wire or rapid exchange delivery of the expandable member 1010 to the clot. The outer elongated member 1022 can be a tube or coil having a lumen configured to receive the inner elongated member 1020 such that the inner elongated member 1020 and/or the outer elongated member 1022 can move relative to each other along the longitudinal dimension of the clot treatment device 402.

[0074] Figs. 11 and 12 are detailed views of a distal portion 1011a (Fig. 11) and a proximal portion 1011b (Fig. 12) of the expandable member 1010 of the clot treatment device 402 shown in Fig. 10. Referring to Fig. 11, the distal portion 1011a is attached to a distal end of the inner elongated member 1020 by the tip 405. The tip 405 can be blunt as described above with reference to the embodiment of the clot treatment device 402 shown in Fig. 4, or the tip 405 can have a tapered distal portion 1040 configured to pass through the clot as shown in Fig. 11. Additionally, the tip 405 can have a proximal opening 1042 configured to receive the distal end of the inner elongated member 1020 and the distal end of the expandable member 1010. Referring to Fig. 12, the proximal portion 1011b is attached to the distal end of the outer elongated member 1022 by a proximal hub 1030. For example, the distal and proximal portions 1011a and 1011b can be attached to the inner elongated member 1020 and the outer elongated member 1022, respectively, using welds, adhesives, crimping or clamping forces, and/or other suitable attachment mechanisms.

[0075] In the operation of the clot treatment device 402 shown in Figs. 10-12, the expandable member 1010 can self-expand from the undeployed state to the deployed

state without an actuator. For example, as a delivery catheter is drawn proximally to release the expandable member 1010, the inner elongated member 1020 can be held in place to hold the distal portion 1011a of the expandable member 1010 distally of the clot. As the distal end of the delivery catheter moves proximally, the outer elongated member 1022 will slide distally as the expandable member 1010 expands until the expandable member 1010 reaches its predetermined deployed size or otherwise reaches equilibrium with the clot. In other embodiments, the inner elongated member 1020 and/or the outer elongated member 1022 can be actuators that are moved proximally and/or distally to control the radial expansion and/or the radial contraction of the expandable member 1010.

[0076] Figs. 13 and 14 are detailed views of the proximal and distal portions 1011b and 1011a, respectively, of an expandable member 1010 and other components of a clot treatment device 402 in accordance with another embodiment of the technology. In this embodiment, the clot treatment device 402 has a proximal tube 1410 (Fig. 13) and an expansion element 1420 having one end attached to the proximal tube 1410 and another end attached to the distal portion 1011a (Fig. 14) of the expandable member 1010. The expansion element 1420, for example, can be a coil or spring that is stretched from its normal state when the expandable member 1010 is the low-profile, undeployed state inside the delivery catheter. As the distal portion 1011a and then the proximal portion 1011b of the expandable member 1010 are released from the delivery catheter, the expansion element 1420 contracts axially under its own stored spring force causing the expandable member 1010 to contract axially and expand radially outward. In the embodiments where the expandable member 1010 is self-expanding, the expansion element 1420 assists the expansion of the expandable member 1010. In other embodiments, the expandable member 1010 may not be self-expanding or may be inherently spring-biased into the low-profile undeployed state, and the expansion element 1420 can have enough stored energy when it is stretched in the low-profile undeployed state to pull the distal portion 1011a and the proximal portion 1011b of the expandable member 1010 toward each other and thereby radially expand the expandable member 1010.

[0077] In the foregoing embodiments, the radially extending capture portions 406 provide more surface area along the device than a device that is uniformly cylindrical. Moreover, the radially extending capture portions 406 extend transversely to the longitudinal dimension of the device to more effectively transfer the axial force as the device is moved axially along the vessel after deployment. Such increased surface area facilitates the treatment and/or retrieval of a much larger portion of the clot 100 than is generally feasible with a uniformly cylindrical device. For example, in a preferred embodiment of the clot treatment device 402, the device will have an external surface area between 1.5x and 6x the surface area of a uniformly cylindrical device of the same general diameter of the cylindrical sections 412. In other preferred embodiments the ratio will be 2x to 4x.

[0078] This is advantageous particularly during retraction of the clot treatment device 402 through the clot 100. As shown in Fig. 6F, the clot treatment device 402 may become elongated as it is being withdrawn through the clot 100. Such elongation causes the clot material to encounter greater surface area of the clot treatment device 402 than would otherwise occur with a device that was only generally cylindrical, i.e., that did not incorporate radially extending portions 406. Accordingly the clot treatment device 402 is particularly adept at capturing the maximum amount of clot material during withdrawal.

[0079] The clot treatment device 402 is intended for use in large vessels, i.e., vessels with a diameter greater than 8mm. For example, the diameter of the pulmonary arteries typically range from 15 to 30mm whereas the first branches of the pulmonary arteries typically range from 10 to 15mm and the secondary and tertiary branches typically range from 5 to 10mm. At the same time, however, it is important to minimize the size of catheter providing access to the clot 100. Accordingly, the clot treatment device 402 has a large expansion ratio. In a preferred embodiment the expansion ratio from the diameter of the cylindrical sections 412 in the collapsed state to the expanded state will be between 4 and 8. In another preferred embodiment the ratio will be between 5 and 7. The large expansion ratio also enables the formation of a flow channel in the clot 100 that is large, e.g., on the order of 4-8mm.

[0080] The radially extending portions 406, in their fully expanded position are intended to have a size that matches the diameter of the target blood vessel. However, the diameters may be slightly larger than the vessel diameter so to apply greater radial force against the blood vessel (without causing trauma) in those circumstances when it is desirable to improve clot collection. Similarly, in those circumstances where there is a concern of creating trauma on delicate blood vessels, the radially extending portions 406 may have a diameter that is smaller than the vessel diameter. It is contemplated that different sizes of the device 402 will be available for selection by the user for a particular presentation of the patient.

[0081] As for the length of the clot treatment device 402, it is known that a typical pulmonary embolism will have a length within the range between about 2 cm and 10 cm and sometimes between about 1 cm and 20 cm. Accordingly, in a preferred embodiment, the clot treatment device 402 will have a length that exceeds the length of the embolism so that a portion of the clot treatment device is positioned distal of the clot 100 during expansion.

[0082] With regard to the delivery catheter 606, in a preferred embodiment for use with a pulmonary embolism, the size will be around 1F-6F. Smaller diameters will pass through the clot 100 more easily. In addition, the delivery catheter 606 may have stiffness characteristics to assist in making sure the delivery catheter 606 passes through the clot in a smooth manner. Such stiffness characteristics include self expanding Nitinol wire braids or stent structures that are contained within the structure of the delivery catheter 606. The delivery catheter 606 also has sufficient flexibility so that it may carry the clot treatment device 402 and still pass through a tortuous vessel path as described above starting with insertion of the delivery catheter 606 in the femoral vein FV.

[0083] In some preferred embodiments, the method and device in accordance with the present invention may reduce the Mean Resting Pulmonary Artery Pressure (MRPAP). Upon at least partial relief from the clot 100, MRPAP may be reduced by about 20-50mmHg to a normal range of 8-20 mmHg. In some embodiments, the reduction in MRPAP may be about 25-50%. In some embodiments, the reduction in

MRPAP may be about 15% to 40% and in other embodiments between about 30% and 75%.

[0084] Such a reduction in MRPAP can occur in two steps. A first step is when the clot treatment device 402 is first deployed and blood flow is at least partially restored. A second step may be when the clot treatment device 402 is retracted and at least some of the clot 100 is removed from the vessel. A third step may be after the clot treatment device 402 has been removed and the effect of the body's own processes and/or thrombolytic drugs that may have been used before, during or after the procedure take effect upon clot that has been disrupted by the clot treatment device.

[0085] Fig. 15 is a side view of an embodiment of a guide catheter 1500 for use with any of the foregoing embodiments of the clot treatment devices 402 (not shown in Fig. 15). The guide catheter 1500 can include a shaft 1502 having a sufficiently large lumen to accommodate the delivery catheter 606 (Figs. 4 and 5A). The guide catheter 1500 can further include an expandable guide member 1510 at the distal end of the shaft 1502 configured to expand radially outward to contact or nearly contact the vessel wall VW. The guide member can be formed from a permeable, radially expanding material, such as a mesh or other macroporous structure (e.g., a braid of wires or filaments). The guide member 1510, for example, may be formed from a tubular braid of elastic or super-elastic filaments such as Nitinol that has been heat set into the desired expanded shape. The permeable, radially expanding guide member 1510 may have advantages over an occlusive member such as a balloon or impermeable funnel. For example, the guide member 1510 allows a substantial amount of blood flow BF to continue flowing through the blood vessel where therapy is being directed. In addition, the guide member 1510 positions the shaft 1502 and delivery catheter 606 at or near the center of the vessel. The clot treatment device 402 (not shown in Fig. 15) may also be substantially self-centering upon deployment, and the guide member 1510 may further guide the clot material captured by the clot treatment device 402 into the shaft 1502 as the clot treatment device 402 moves into proximity of the distal end of the shaft 1502. This is expected to enhance aspiration of the clot material. For example, in the embodiment shown in Fig. 15, the radially expanding guide member 1510 has a funnel

shape adjacent the distal end of the shaft 1502 to guide thrombus material into the distal opening of the shaft 1502 where it can be more readily aspirated.

[0086] The radially expanding guide member 1510 may also be formed by conventional machining, laser cutting, electrical discharge machining (EDM) or other means known in the art to make a fenestrated, mesh or porous structure that can be affixed near the distal end of the shaft 1502. In some embodiments the radially expanding guide member 1510 may self-expand, but in other embodiments it may be actuated by an operator using, for example, electrical or electromechanical means. By having a porous radially expanding guide member 1510, the guide catheter 1500 may be substantially centered within a vessel without blocking a large portion of the flow around the catheter. In some embodiments, the radially expanding guide member 1510 may block less than about 50% of the flow about the catheter and in other embodiments less than about 25% of the flow. When the guide member 1510 is made with a braid of filaments (e.g. wires), it may be formed from a tubular braid. In some embodiments, the tubular braid may be formed with approximately 12 to approximately 144 filaments, or in other embodiments from about 36 to about 96 filaments. The pores as measured by the largest circle that can be inscribed within an opening of the mesh may be between about 0.5 mm and 5 mm.

[0087] Figs. 16 and 17 show additional embodiments of guide members 1610 and 1710, respectively, that can be used instead of or in addition to the guide member 1510. Referring to Figs. 15 and 16, one or both ends of the tubular braid of the guide members 1510 and 1610 may be inverted and attached to the catheter body. Referring to Fig. 17, neither end of the guide member 1710 is inverted. With the distal end inverted, it advantageously may form a funnel adjacent the distal opening of the catheter that may enhance clot capture and aspiration.

[0088] Fig. 18 shows an embodiment of a guide catheter 1900 having a shaft 1902 and a guide member 1910 in accordance with another embodiment of the technology. In the embodiment shown in Fig. 18, the guide member 1910 has a tapered or funnel shape, and includes a non-permeable portion 1912 and a permeable portion 1914. The permeable portion 1914 can comprise a flared radially expanding mesh that has, at least

in part, a tapered or funnel shape, and the non-permeable portion 1912 may have a substantially non-porous or otherwise non-permeable material or coating over the mesh. Preferably, the non-permeable material is a highly elastic material such as polyurethane, silicone, latex rubber and the like so that it can flex with the expansion of the mesh. In some embodiments, the non-permeable material covers a proximal portion of the mesh as shown in Fig. 18. The non-permeable portion 1912 may divert some flow away from the distal end of the catheter. The covering may cover a portion of the mesh to a diameter "d". In some embodiments, the diameter d of the covering is less than about 75% of the diameter "D" of the mesh funnel. In some embodiments, the diameter d may be less than about 50% of diameter D. The concept of a non-permeable material can also be applied to the guide catheter 1500 shown above in Fig. 15. For example, the expandable member 1510 of the guide catheter 1500 can have a non-permeable portion 1512 at the proximal portion of the expandable guide member 1510 similar to the non-permeable portion 1912 shown and described with reference to Fig. 18.

[0089] Figs. 19-27 show additional embodiments of clot treatment devices 402 in accordance with the present technology. The embodiments of the clot treatment devices 402 shown in Figs. 19-27 can restore blood flow and capture clot material in a manner similar to the embodiments of the clot treatment devices 402 described above with respect to Figs. 4-18. The embodiments of the clot treatment devices 402 related to Figs. 19-27 can also be made from the same materials and be deployed in the same manner as described above with respect to Figs. 4-18. As such, many of the features, materials and benefits of the clot treatment devices 402 shown in Figs. 4-18 are applicable to the clot treatment devices shown in Figs. 19-27.

[0090] Fig. 19 shows an embodiment of the clot treatment device 402 that includes a plurality of capture elements, such as clot engagement ("CE") members 1952. The CE members 1952 can be (a) arcuate as shown in Fig. 19, (b) bent at one or more angles (e.g., 30°, 45°, 60°, 90°, 135°, etc.), and/or (c) straight (e.g., project outward along a straight line). In some embodiments, the clot treatment device 402 can include a combination of arcuate, angled and/or straight CE members. In other embodiments, the

clot treatment device 402 can include a single CE member 1952. The CE members 1952 can be interwoven into the mesh structure of the device 402 (see Fig. 21). The CE members 1952 can also be bonded, soldered, welded, tied or otherwise secured to the mesh structure or mechanically interlocked with the mesh structure. As the clot treatment device 402 is unsheathed during deployment, the CE members 1952 can radially extend and form a heat-set shape configured to penetrate and fasten the clot to the treatment device 402. The CE members 1952 can accordingly define hook-like capture elements in several embodiments of the present technology.

[0091] The CE members 1952 can be disposed about an exterior surface of the device 402. For example, as shown in Fig. 19, the CE members 1952 can be arranged in one or more circumferential rows 1954 that are evenly positioned along a longitudinal axis of the device 402. In other embodiments, the CE members 1952 can have any suitable arrangement and/or positioning about the device (e.g., arranged in a helical pattern, off-set rows, random, or irregular or otherwise uneven/non-uniform spacing, etc.).

[0092] As shown in Fig. 19, the CE members 1952 can curve proximally such that a concave portion 1956 of the CE members 1952 face a proximal region 402b of the device 402. In some embodiments, the CE members 1952 can curve distally such that a concave portion of the CE members 1952 face a distal region 402a of the device 402 (not shown). In particular embodiments, the clot treatment device 402 includes both distally-curving and proximally-curving CE members.

[0093] The CE members can have a single radius of curvature or have regions with different radii or have a complex or changing radius of curvature. For example, as shown in Fig. 20, one or more of the CE members 1952 can have a first portion 1958 that has a first radius R and a second portion 1960 (e.g., the distal region of the CE member 1952) that has a second radius r that is smaller than the first radius R. In some embodiments, the first radius R may range from about 2 mm to about 15 mm, and the second radius r may range from about 0.25 mm to about 5 mm. Additionally, the CE members 1952 can have a range of arc lengths. For example, in some embodiments

the CE members 1952 can have an arc length greater than 180 degrees. In certain embodiments, the arc length can be between 180 degrees and 330 degrees.

[0094] Fig. 22 shows another embodiment of a CE member 2202 having a V-shaped base 2204 that branches into a first arm 2206a and a second arm 2206b. The V-shaped base 2204 and/or any portion of the first and/or second arms 2206a, 2206b can be interwoven into the mesh structure of the clot treatment device 402, as shown in Figs. 24 and 25. In some embodiments, the angle α between the first and second arms 2206a, 2206b may be between about 40 degrees and about 100 degrees. Although Fig. 24 shows a plurality of such CE members 2202 disposed about a clot treatment device 402, in other embodiments the device 402 can only include a single CE member 2202.

[0095] As shown in Fig. 25, the first arm 2206a and the second arm 2206b can extend into a first distal portion 2208a and a second distal portion 2208b, respectively, where the first distal portion 2208a and the second distal portion 2208b are generally arcuate. As shown in Fig. 24, in some embodiments the first distal portion 2208a and the second distal portion 2208b can be generally linear.

[0096] Referring to Fig. 26, two or more CE members can be connected to form a circumferential structure 2602 that extends around at least a portion of a circumference of a clot treatment device 402. The device 402 can include one or more circumferential structures 2602 spaced along a longitudinal axis of the device. These circumferential structures 2602 can allow for the CE members to flex with the mesh structure as it expands and contracts. In some embodiments, the angle θ formed by the circumferential structure 2602 can be between about 40 degrees and about 100 degrees.

[0097] Fig. 23 shows one embodiment of an CE member 2302 having a double-wire arcuate portion 2306. Referring to Fig. 27, in some embodiments, the clot treatment device 402 can include a plurality of CE member 1952 and a radially extended member 406 at a distal end. The radially extended member 406 could be a disc, balloon, screen or other clot capture member.

Examples

[0098] Several examples of the present technology are as follows:

1. A device for treating a pulmonary embolism, comprising:
an expandable flow restoration portion; and
a plurality of capture elements including at least a first capture element and a second capture element, wherein the flow restoration portion is between the first and second capture elements, and wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which the flow restoration portion has a first cross-sectional dimension greater than that of the low-profile state such that the flow restoration portion forms a flow channel through the device and the capture elements project outwardly from the flow restoration portion.

2. The device of example 1 wherein the flow restoration portion and the capture elements comprise an expandable braided material that is heat set to have the deployed state.

3. The device of any of examples 1 and 2 wherein the flow restoration portion and the capture elements are integrally formed from a common braided material.

4. The device of any of examples 1-3, further comprising a plurality of flow restoration portions and the capture elements comprise a series of radially extending capture portions, and wherein the radially extending capture portions are separated from each other by individual flow restoration portions.

5. The device of example 4 wherein the flow restoration portions comprise expandable cylindrical sections and the capture elements comprise radially expandable disk-like capture portions of the braided material.

6. The device of example 1 wherein the flow restoration portion comprises a radially expandable cylindrical braided material and the capture elements comprise protuberances projecting from the flow restoration portion.

7. The device of any of examples 1-6 wherein the flow restoration portion has an expansion ratio from the undeployed state to the deployed state of approximately 1:4 to 1:8.

8. The device of any of examples 1-6 wherein the flow restoration portion has an expansion ratio from the undeployed state to the deployed state of approximately 1:5 to 1:7.

9. The device of any of examples 1-8 wherein the flow restoration portion has a diameter of approximately 4-8 mm in the deployed state to restore blood flow through a pulmonary embolism.

10. The device of any of examples 1-9 wherein the flow restoration portions and the capture elements comprises a self-expanding braided material, and the capture elements comprise capture portions that have a second diameter greater than the first cross-sectional dimension of the flow restoration portions in the deployed state.

11. The device of any of examples 1-3 and 6-9 wherein the flow restoration portion comprises a single expandable braided tube, and the capture elements comprise clot engagement members configured to project from the flow restoration portion in the deployed state.

12. The device of example 11 wherein the clot engagement members comprise arcuate members that form hook-like elements projecting from the flow restoration portion.

13. The device of example 11 wherein the clot engagement members are formed from wires of the expandable braided tube that defines the flow restoration portion.

14. The device of example 11 wherein the clot engagement members are formed from separate wires that project through interstices of the expandable braided tube that defines the flow restoration portion.

15. A pulmonary embolism treatment device, comprising:

an outer elongated member having a distal end;

an inner elongated member within the outer elongated member, wherein the inner elongated member and/or the outer elongated member slides relative to the other, and wherein the inner elongated member has a distal end; and

an expandable member having a proximal portion attached to the distal end of the outer elongated member and a distal portion attached to the distal end of the inner elongated member, the expandable member having a flow restoration portion and a plurality of capture elements arranged along the flow restoration portion, wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which the flow restoration portion has a first cross-sectional dimension greater than that of the low-profile state that defines a flow channel through the device and the capture elements project outwardly from the flow restoration portion.

16. The pulmonary embolism treatment device of example 15 wherein the expandable member comprises a braided material.

17. The pulmonary embolism treatment device of example 15 wherein the device has a plurality of flow restoration portions and the capture elements are separated by individual flow restoration portions, and wherein (a) the capture elements comprise capture portions formed from a continuous shape-memory braided material heat-set to the deployed state and (b) the capture portions project from the flow restoration portions to a second cross-sectional dimension in the deployed state.

18. The pulmonary embolism treatment device of example 17 wherein the flow restoration portions comprise cylindrical portions and the first cross-sectional dimension comprises a first diameter in the deployed state, and the capture portions comprise disk-like projections having a second diameter greater than the first diameter in the deployed state.

19. The pulmonary embolism treatment device of any of examples 11-18 wherein the flow restoration portion(s) have an expansion ratio from the undeployed state to the deployed state from 1:4 to 1:8.

20. The pulmonary embolism treatment device of any of examples 11-18 wherein the flow restoration portion(s) have an expansion ratio from the undeployed state to the deployed state from 1:5 to 1:7.

21. The pulmonary embolism treatment device of any of examples 11-20 wherein the first elongated member comprises an outer tube and the second elongated member comprises an inner tube within the outer tube.

22. The pulmonary embolism treatment device of any of examples 11-20 wherein the first elongated member comprises an outer tube and the second elongated member comprises a coil within the outer tube.

23. The pulmonary embolism device of any of examples 11-20 wherein the first elongated member comprises an outer coil and the second elongated member comprises an inner coil.

24. The pulmonary embolism treatment device of any of examples 11-23 wherein the flow restoration portion(s) and the capture elements comprise a self-expanding braided material.

25. The pulmonary embolism treatment device of any of examples 11-24 wherein the outer elongated member is configured to slide distally with respect to the inner

elongated member to move the expansion member from the undeployed state to the deployed state.

26. The pulmonary embolism treatment device of any of examples 11-25, further comprising a guide catheter having a shaft with a distal end and an expandable guide member at the distal end of the shaft, wherein the shaft has a lumen configured to receive the expandable member in the undeployed state.

27. The pulmonary embolism treatment device of example 26 wherein the expandable guide member comprises radially expandable mesh.

28. The pulmonary embolism treatment device of example 27 wherein the radially expandable mesh comprises a braided material.

29. The pulmonary embolism treatment device of any of examples 26-28 wherein the expandable guide member has a funnel shape.

30. The pulmonary embolism treatment device of any of examples 26-29 wherein at least a portion of the expandable guide member is permeable to allow blood to flow through the expandable guide member when the expandable guide member is expanded.

31. The pulmonary embolism treatment device of any of examples 26-29 wherein the expandable guide member has a non-permeable portion at the distal end of the shaft and a permeable portion extending distally from the non-permeable portion.

32. A pulmonary embolism treatment device, comprising:
an elongated member having a distal end;
an expansion portion having a proximal end attached to the distal end of the elongated member, and the expansion portion having a distal end; and
an expandable member having a proximal portion attached to the distal end of the elongated member and a distal portion attached to the distal end of the

expansion portion, the expandable member having at least one of flow restoration portion and a plurality of capture elements arranged such that the capture elements are separated by individual flow restoration portion, wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which (a) the flow restoration portion has a first cross-sectional dimension greater than that of the low-profile state that defines a flow channel through the device and (b) the capture elements project outwardly from the flow restoration portion, and wherein the expansion portion is stretched from a normal state when the expandable member is in the undeployed state such that the expansion portion is configured to axially contract the expandable member from the undeployed state to the deployed state.

33. A method of treating a pulmonary embolism, comprising:

delivering an embolectomy device through the heart to a pulmonary embolism that at least partially restricts blood flow through a pulmonary vessel, wherein the embolectomy device has a plurality of capture elements separated by an expandable cylindrical section;

deploying the embolectomy device within the pulmonary embolism by expanding the cylindrical section into the pulmonary embolism so that the cylindrical section forms an expanded flow channel through the pulmonary embolism and thereby restores blood flow through the pulmonary embolism and by expanding the capture elements to a greater extent than the cylindrical section so that at least a portion of the pulmonary embolism is captured the capture elements;

moving the embolectomy device and at least a portion of the pulmonary embolism along the pulmonary vessel; and

withdrawing the embolectomy device and at least a portion of the pulmonary embolism from the pulmonary vessel.

34. The method of example 33 wherein deploying the embolectomy device comprises expanding a plurality of radial extendable capture elements of the embolectomy device.

35. The method of example 34, wherein at least one of the plurality of radial extendable capture elements is expanded distal relative to the pulmonary embolism.

36. The method of example 33, further comprising applying vacuum while withdrawing the embolectomy device.

37. The method of example 36, wherein withdrawing the embolectomy device includes urging the portion of the pulmonary embolism into a funnel catheter.

38. The method of example 37, wherein deploying the embolectomy device comprises expanding the device such that a surface area of the embolectomy device expands within a range of at least 200% to 400% of the surface area of a uniformly cylindrical device.

39. The method of example 33 wherein deploying the embolectomy device comprises expanding the generally cylindrical section by 400% to 800% of its diameter in the undeployed state.

40. The method according to and of examples 33-39 wherein deploying the embolectomy device comprises expanding a braided material into a preset shape having a plurality of radially extending disk-like capture portions that define the capture elements.

[0099] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the exampleed invention. Accordingly, it is to be understood

that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A device for treating a pulmonary embolism, comprising:
an expandable flow restoration portion; and
a plurality of capture elements including at least a first capture element and a second capture element, wherein the flow restoration portion is between the first and second capture elements, and wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which the flow restoration portion has a first cross-sectional dimension greater than that of the low-profile state such that the flow restoration portion forms a flow channel through the device and the capture elements project outwardly from the flow restoration portion.

2. The device of claim 1 wherein the flow restoration portion and the capture elements comprise an expandable braided material that is heat set to have the deployed state.

3. The device of any of claims 1 and 2 wherein the flow restoration portion and the capture elements are integrally formed from a common braided material.

4. The device of any of claims 1-3, further comprising a plurality of flow restoration portions and the capture elements comprise a series of radially extending capture portions, and wherein the radially extending capture portions are separated from each other by individual flow restoration portions.

5. The device of claim 4 wherein the flow restoration portions comprise expandable cylindrical sections and the capture elements comprise radially expandable disk-like capture portions of the braided material.

6. The device of claim 1 wherein the flow restoration portion comprises a radially expandable cylindrical braided material and the capture elements comprise protuberances projecting from the flow restoration portion.

7. The device of any of claims 1-6 wherein the flow restoration portion has an expansion ratio from the undeployed state to the deployed state of approximately 1:4 to 1:8.

8. The device of any of claims 1-6 wherein the flow restoration portion has an expansion ratio from the undeployed state to the deployed state of approximately 1:5 to 1:7.

9. The device of any of claims 1-8 wherein the flow restoration portion has a diameter of approximately 4-8 mm in the deployed state to restore blood flow through a pulmonary embolism.

10. The device of any of claims 1-9 wherein the flow restoration portions and the capture elements comprises a self-expanding braided material, and the capture elements comprise capture portions that have a second diameter greater than the first cross-sectional dimension of the flow restoration portions in the deployed state.

11. The device of any of claims 1-3 and 6-9 wherein the flow restoration portion comprises a single expandable braided tube, and the capture elements comprise clot engagement members configured to project from the flow restoration portion in the deployed state.

12. The device of claim 11 wherein the clot engagement members comprise arcuate members that form hook-like members projecting from the flow restoration portion.

13. The device of claim 11 wherein the clot engagement members are formed from wires of the expandable braided tube that defines the flow restoration portion.

14. The device of claim 11 wherein the clot engagement members are formed from separate wires that project through interstices of the expandable braided tube that defines the flow restoration portion.

15. A pulmonary embolism treatment device, comprising:

an outer elongated member having a distal end;

an inner elongated member within the outer elongated member, wherein the inner elongated member and/or the outer elongated member slides relative to the other, and wherein the inner elongated member has a distal end; and

an expandable member having a proximal portion attached to the distal end of the outer elongated member and a distal portion attached to the distal end of the inner elongated member, the expandable member having a flow restoration portion and a plurality of capture elements arranged along the flow restoration portion, wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which the flow restoration portion have a first cross-sectional dimension greater than that of the low-profile state that defines a flow channel through the device and the capture elements project outwardly from the flow restoration portion.

16. The pulmonary embolism treatment device of claim 15 wherein the expandable member comprises a braided material.

17. The pulmonary embolism treatment device of claim 15 wherein the device has a plurality of flow restoration portions and the capture elements are separated by individual flow restoration portions, and wherein (a) the capture elements comprise capture portions formed from a continuous shape-memory braided material heat-set to the deployed state and (b) the capture portions project from the flow restoration portions to a second cross-sectional dimension in the deployed state.

18. The pulmonary embolism treatment device of claim 17 wherein the flow restoration portions comprise cylindrical portions and the first cross-sectional dimension comprises a first diameter in the deployed state, and the capture portions comprise disk-like projections having a second diameter greater than the first diameter in the deployed state.

19. The pulmonary embolism treatment device of any of claims 11-18 wherein the flow restoration portion(s) have an expansion ratio from the undeployed state to the deployed state from 1:4 to 1:8.

20. The pulmonary embolism treatment device of any of claims 11-18 wherein the flow restoration portion(s) have an expansion ratio from the undeployed state to the deployed state from 1:5 to 1:7.

21. The pulmonary embolism treatment device of any of claims 11-20 wherein the first elongated member comprises an outer tube and the second elongated member comprises an inner tube within the outer tube.

22. The pulmonary embolism treatment device of any of claims 11-20 wherein the first elongated member comprises an outer tube and the second elongated member comprises a coil within the outer tube.

23. The pulmonary embolism device of any of claims 11-20 wherein the first elongated member comprises an outer coil and the second elongated member comprises an inner coil.

24. The pulmonary embolism treatment device of any of claims 11-23 wherein the flow restoration portion(s) and the capture elements comprise a self-expanding braided material.

25. The pulmonary embolism treatment device of any of claims 11-24 wherein the outer elongated member is configured to slide distally with respect to the inner

elongated member to move the expansion member from the undeployed state to the deployed state.

26. The pulmonary embolism treatment device of any of claims 11-25, further comprising a guide catheter having a shaft with a distal end and an expandable guide member at the distal end of the shaft, wherein the shaft has a lumen configured to receive the expandable member in the undeployed state.

27. The pulmonary embolism treatment device of claim 26 wherein the expandable guide member comprises radially expandable mesh.

28. The pulmonary embolism treatment device of claim 27 wherein the radially expandable mesh comprises a braided material.

29. The pulmonary embolism treatment device of any of claims 26-28 wherein the expandable guide member has a funnel shape.

30. The pulmonary embolism treatment device of any of claims 26-29 wherein at least a portion of the expandable guide member is permeable to allow blood to flow through the expandable guide member when the expandable guide member is expanded.

31. The pulmonary embolism treatment device of any of claims 26-29 wherein the expandable guide member has a non-permeable portion at the distal end of the shaft and a permeable portion extending distally from the non-permeable portion.

32. A pulmonary embolism treatment device, comprising:
an elongated member having a distal end;
an expansion portion having a proximal end attached to the distal end of the elongated member, and the expansion portion having a distal end; and
an expandable member having a proximal portion attached to the distal end of the elongated member and a distal portion attached to the distal end of the

expansion portion, the expandable member having at least one of flow restoration portion and a plurality of capture elements arranged such that the capture elements are separated by individual flow restoration portion, wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which (a) the flow restoration portion has a first cross-sectional dimension greater than that of the low-profile state that defines a flow channel through the device and (b) the capture elements project outwardly from the flow restoration portion, and wherein the expansion portion is stretched from a normal state when the expandable member is in the undeployed state such that the expansion portion is configured to axially contract the expandable member from the undeployed state to the deployed state.

33. A method of treating a pulmonary embolism, comprising:

delivering an embolectomy device through the heart to a pulmonary embolism that at least partially restricts blood flow through a pulmonary vessel, wherein the embolectomy device has a plurality of capture elements separated by an expandable cylindrical section;

deploying the embolectomy device within the pulmonary embolism by expanding the cylindrical section into the pulmonary embolism so that the cylindrical section forms an expanded flow channel through the pulmonary embolism and thereby restores blood flow through the pulmonary embolism and by expanding the capture elements to a greater extent than the cylindrical section so that at least a portion of the pulmonary embolism is captured the capture elements;

moving the embolectomy device and at least a portion of the pulmonary embolism along the pulmonary vessel; and

withdrawing the embolectomy device and at least a portion of the pulmonary embolism from the pulmonary vessel.

34. The method of claim 33 wherein deploying the embolectomy device comprises expanding a plurality of radial extendable capture elements of the embolectomy device.

35. The method of claim 34, wherein at least one of the plurality of radial extendable capture elements is expanded distal relative to the pulmonary embolism.

36. The method of claim 33, further comprising applying vacuum while withdrawing the embolectomy device.

37. The method of claim 36, wherein withdrawing the embolectomy device includes urging the portion of the pulmonary embolism into a funnel catheter.

38. The method of claim 37, wherein deploying the embolectomy device comprises expanding the device such that a surface area of the embolectomy device expands within a range of at least 200% to 400% of the surface area of a uniformly cylindrical device.

39. The method of claim 33 wherein deploying the embolectomy device comprises expanding the generally cylindrical section by 400% to 800% of its diameter in the undeployed state.

40. The method according to and of claims 33-39 wherein deploying the embolectomy device comprises expanding a braided material into a preset shape having a plurality of radially extending disk-like capture portions that define the capture elements.

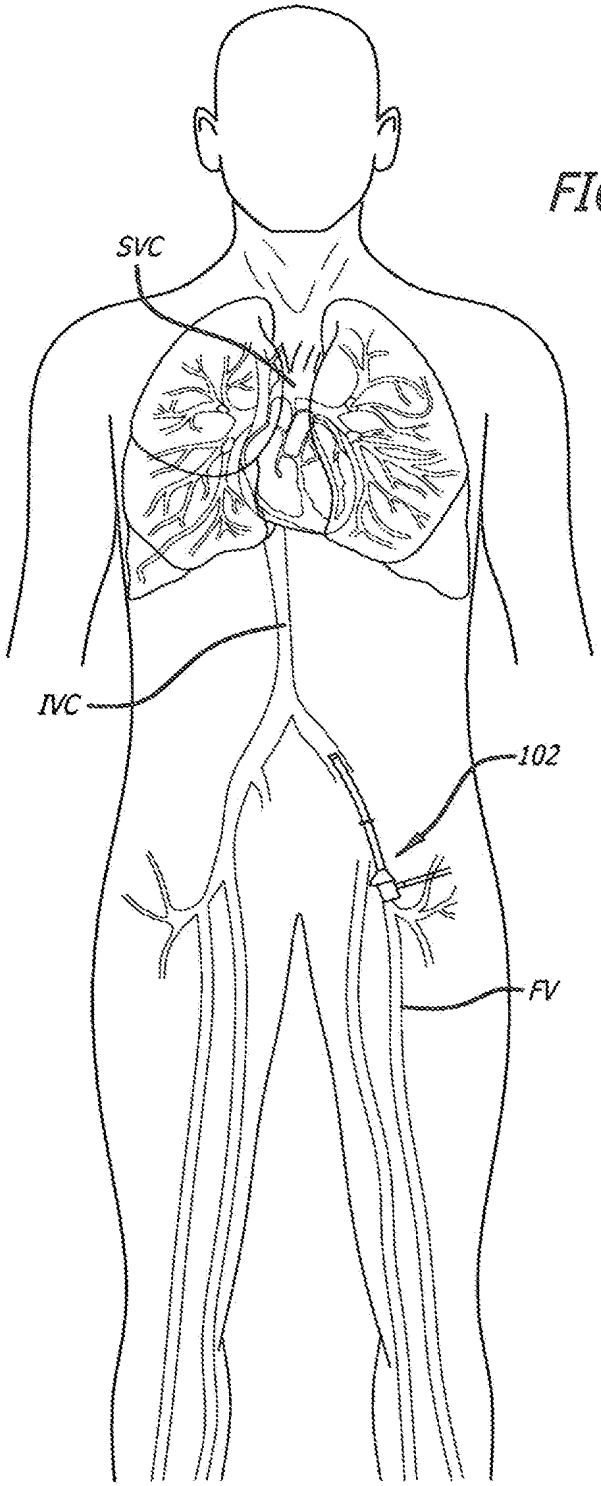


FIG. 1A

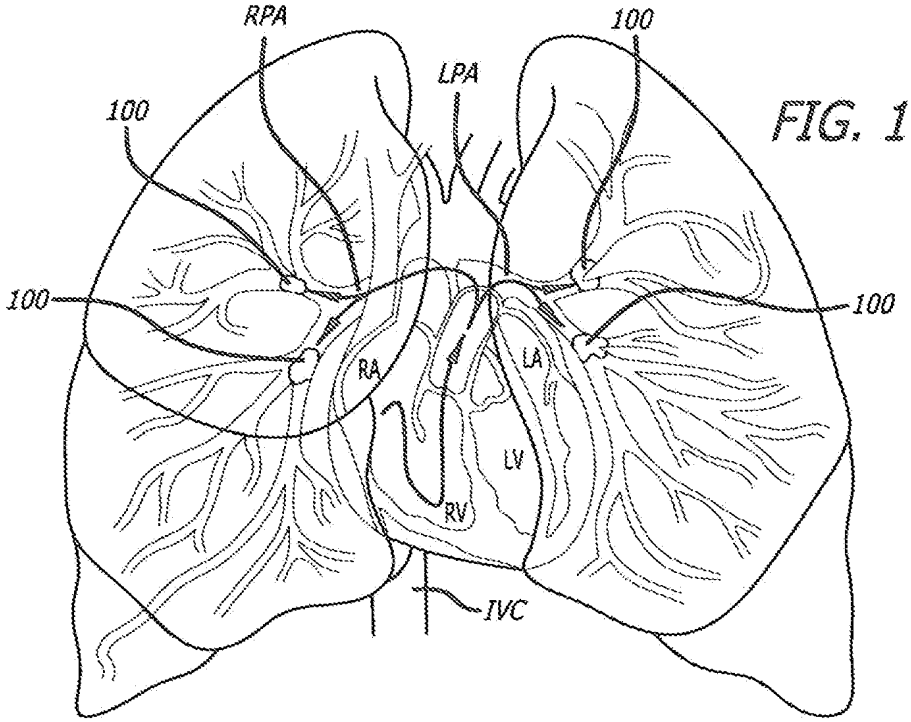


FIG. 1B

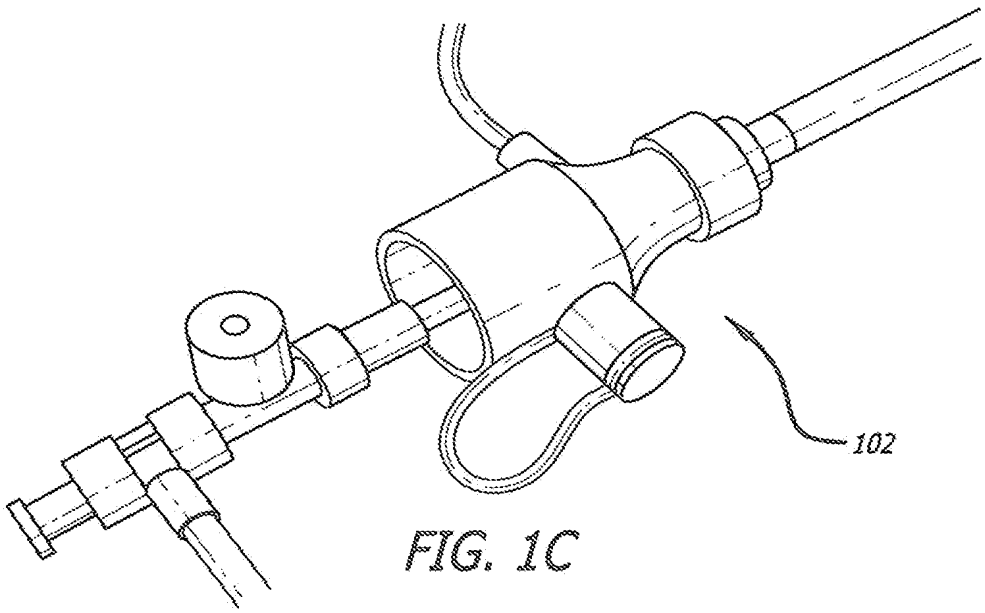


FIG. 1C

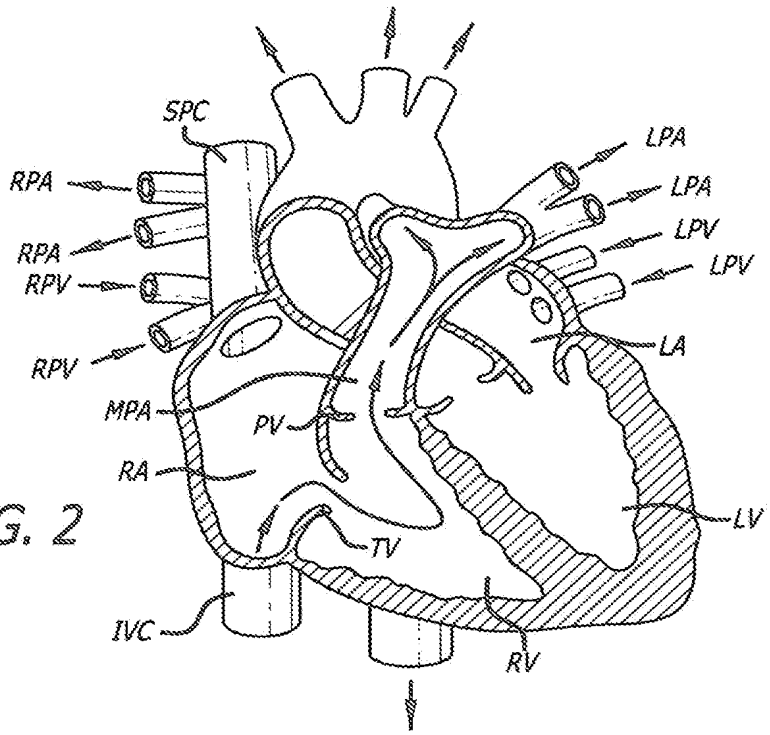

SPC
RPA
RPA
RPV
RPV
MPA
RA
IVC
PV
TV
RV
LV
LA
LPV
LPV
LPA
LPA

FIG. 2

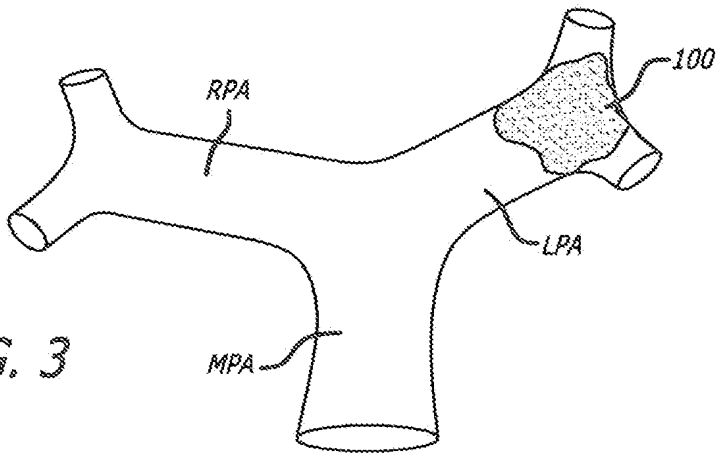

100
RPA
LPA
MPA

FIG. 3

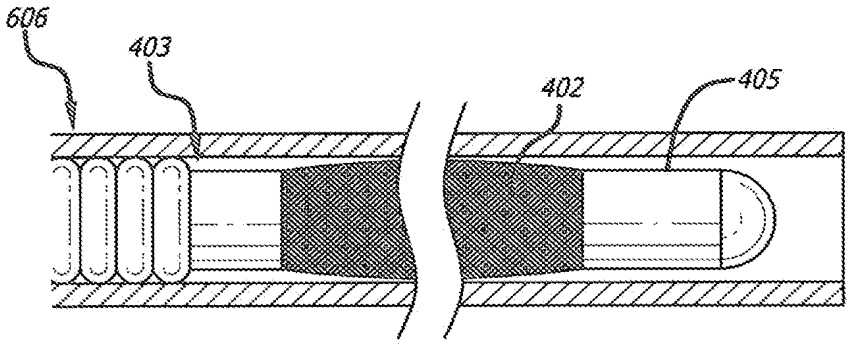


FIG. 4

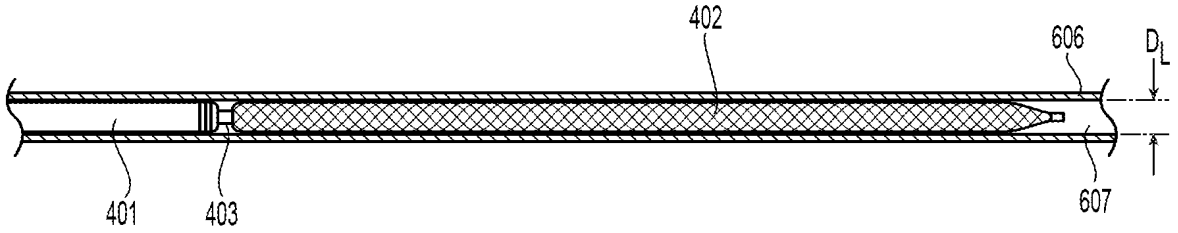

402
606
D_L
401
403
607

Fig. 5A

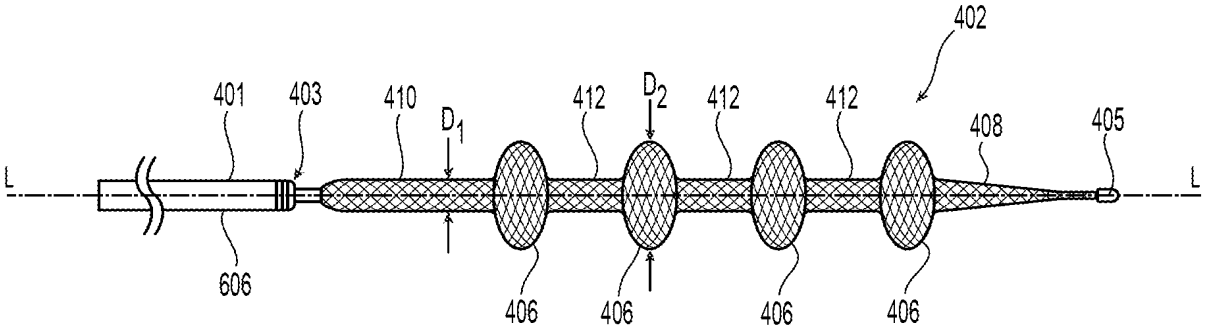

402
401
403
410
D_1
412
D_2
412
412
408
405
L
L
606
406
406
406
406

Fig. 5B

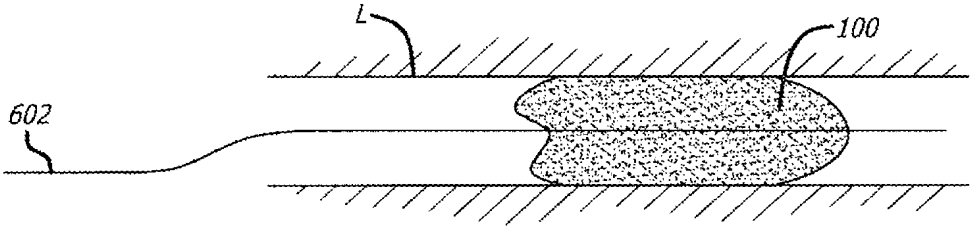


FIG. 6A

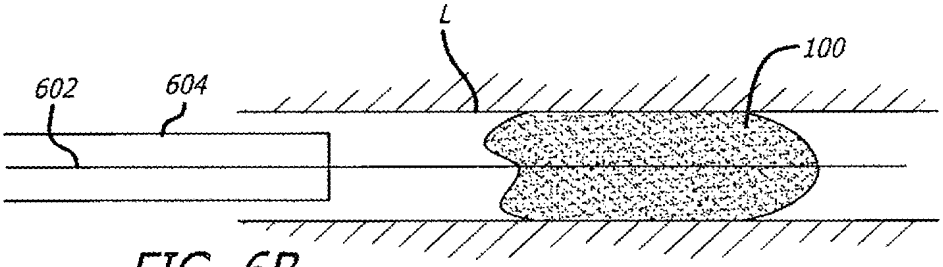


FIG. 6B

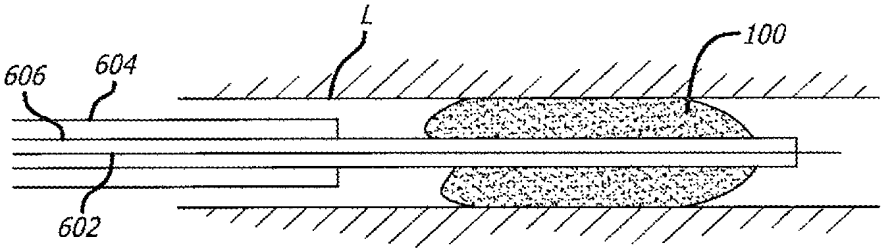


FIG. 6C

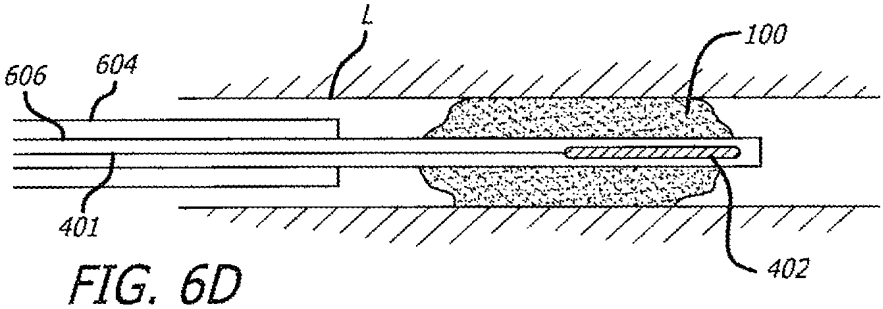


FIG. 6D

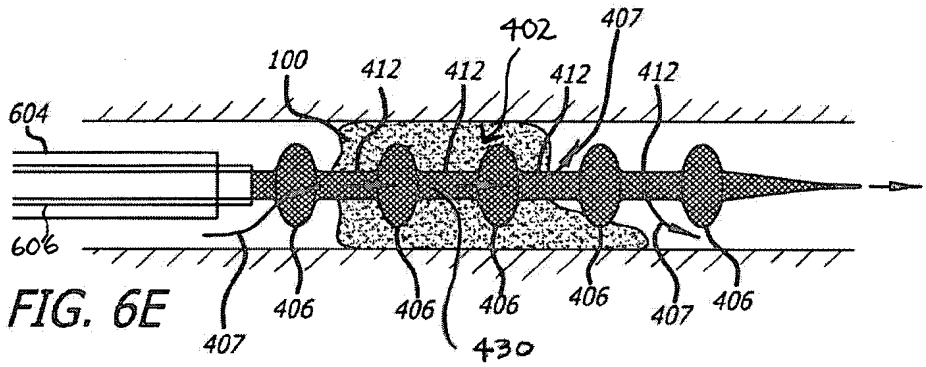


FIG. 6E

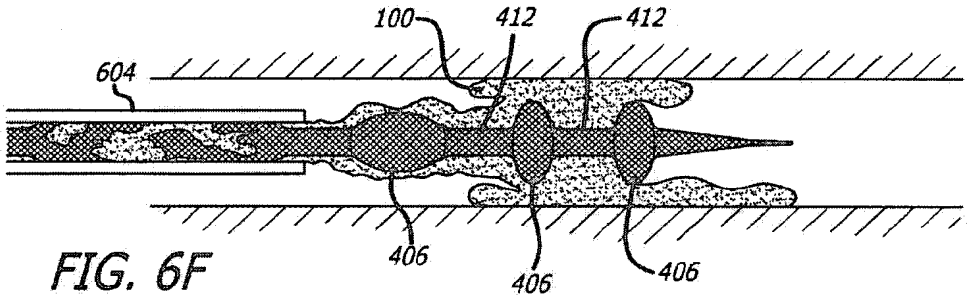


FIG. 6F

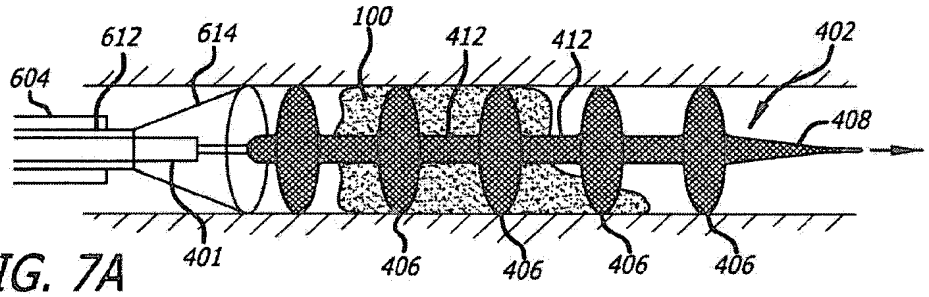


FIG. 7A

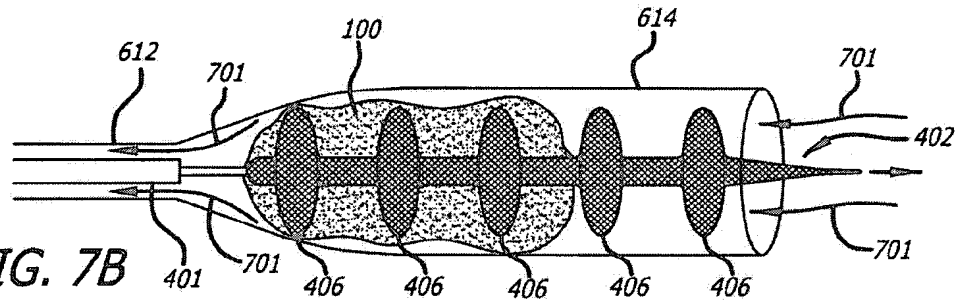


FIG. 7B

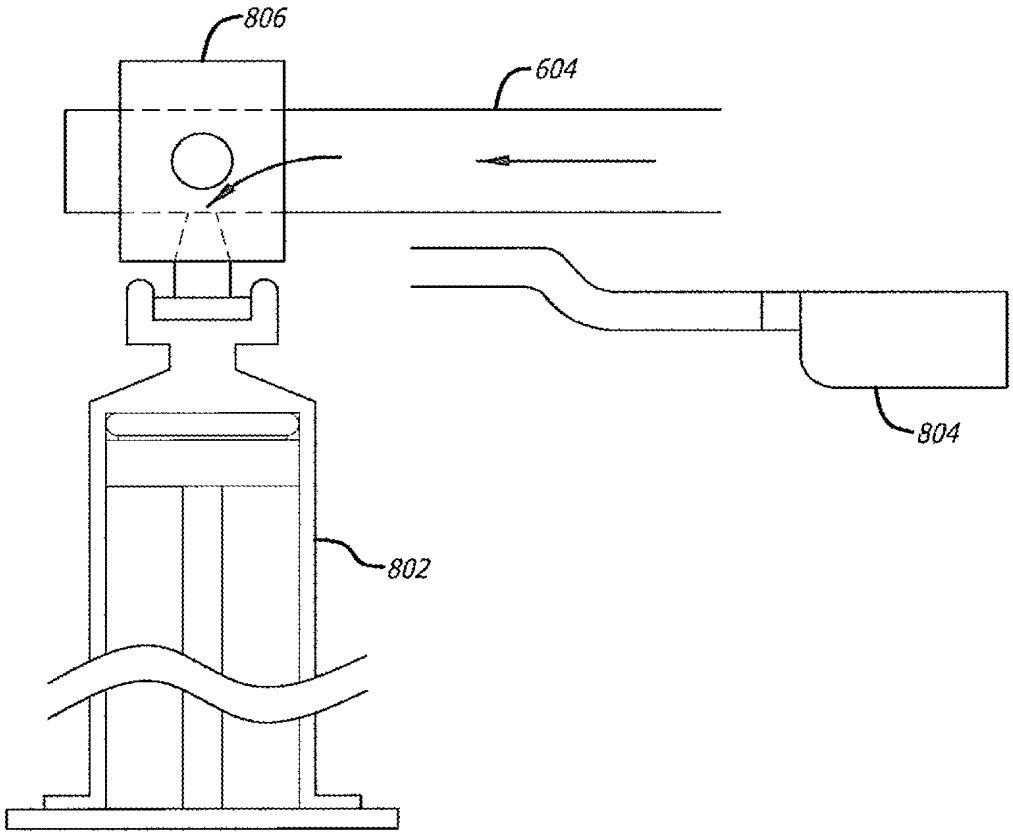


FIG. 8

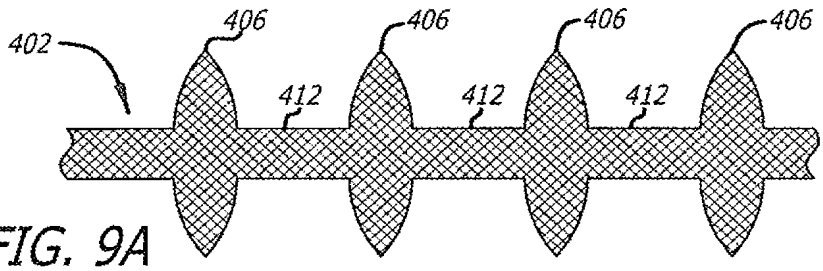


FIG. 9A

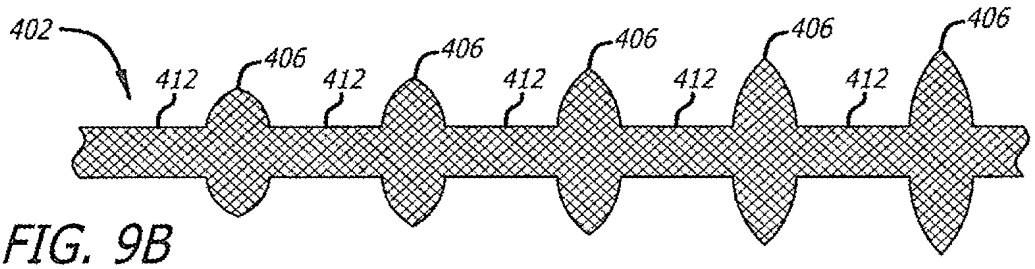


FIG. 9B

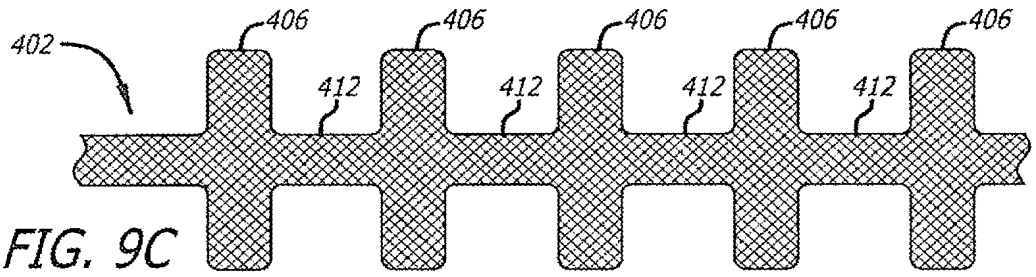


FIG. 9C

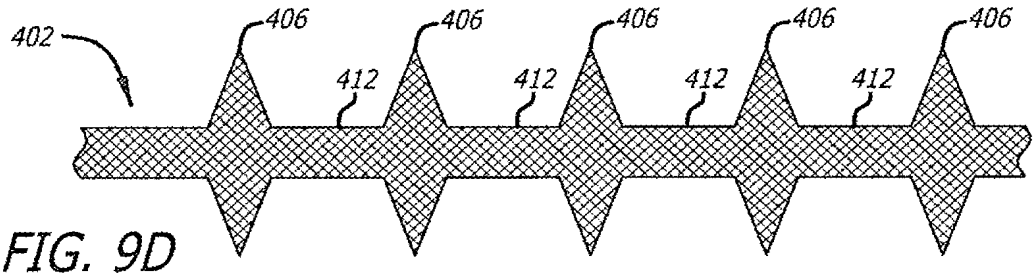


FIG. 9D

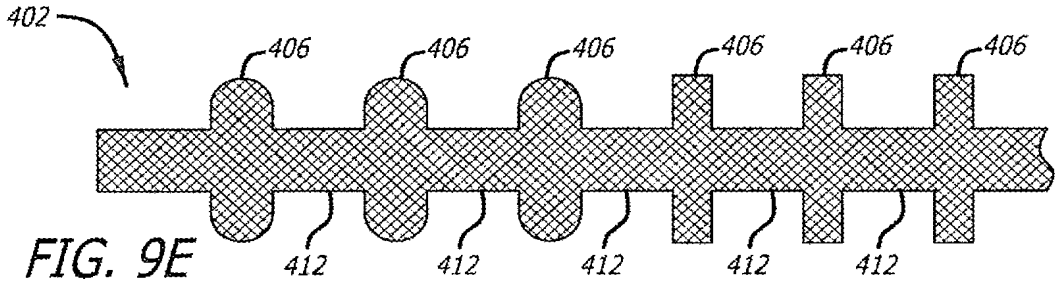


FIG. 9E

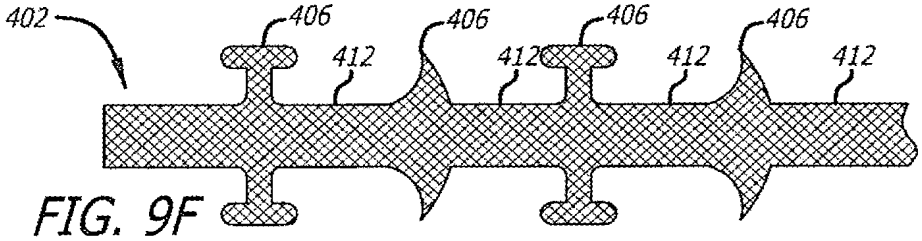


FIG. 9F

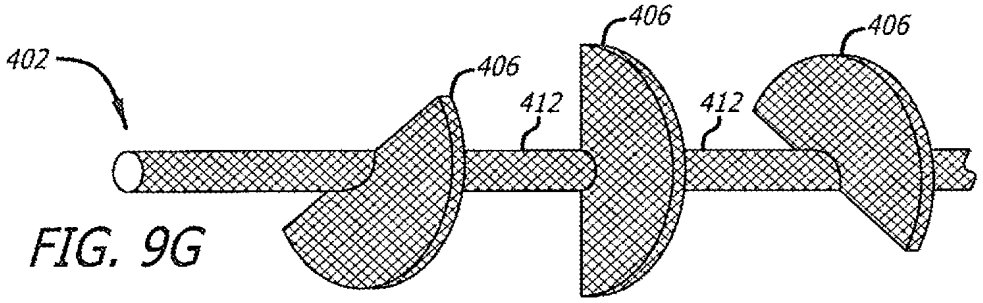


FIG. 9G

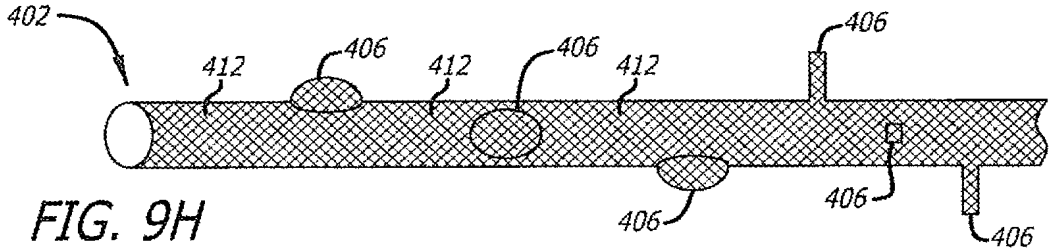


FIG. 9H

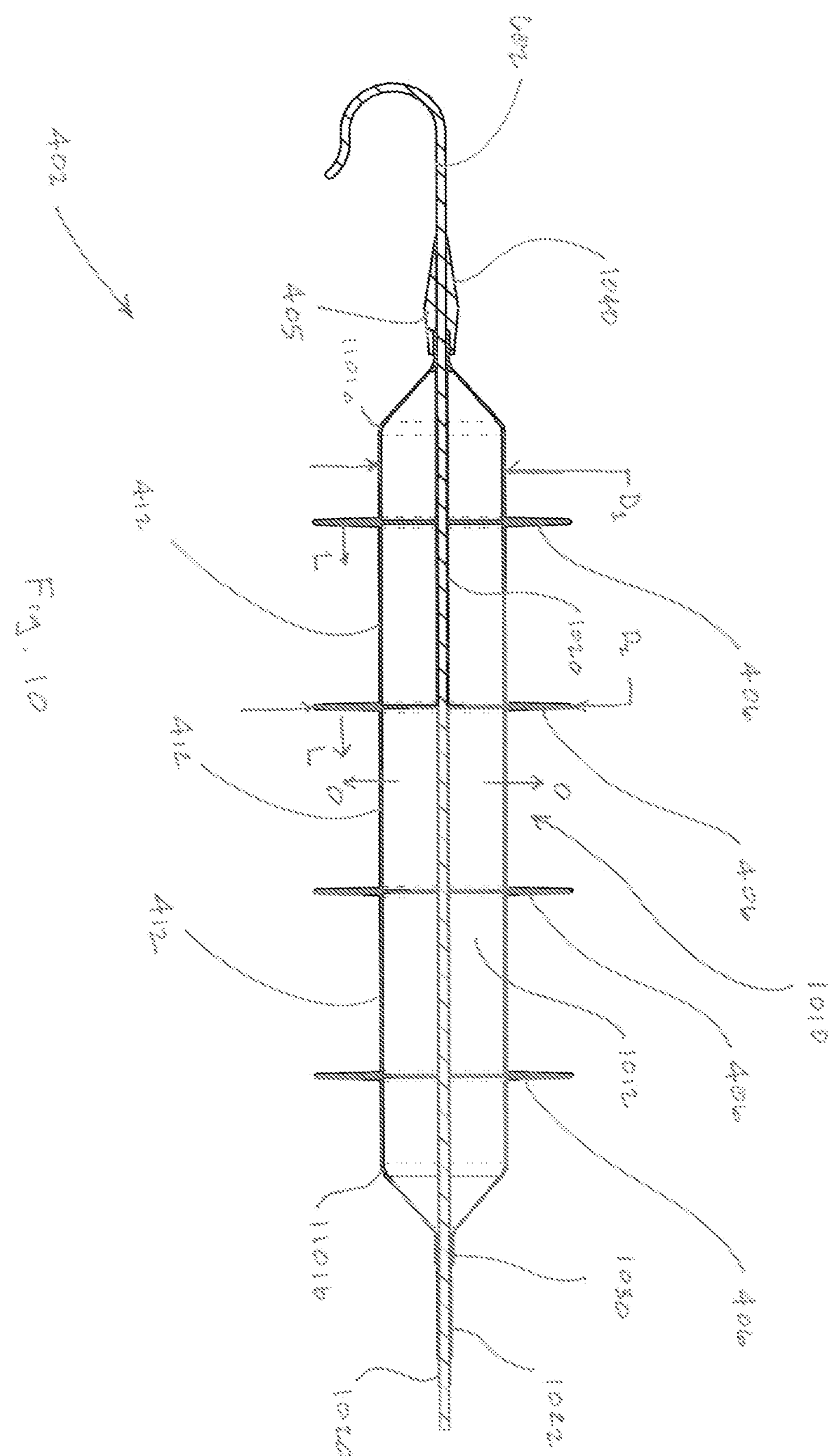

402
405
1040
1101a
1101b
412
412
412
406
406
406
406
1010
1012
1020
1030
1022
1026
D1
D2
L
L
O
O

Fig. 10

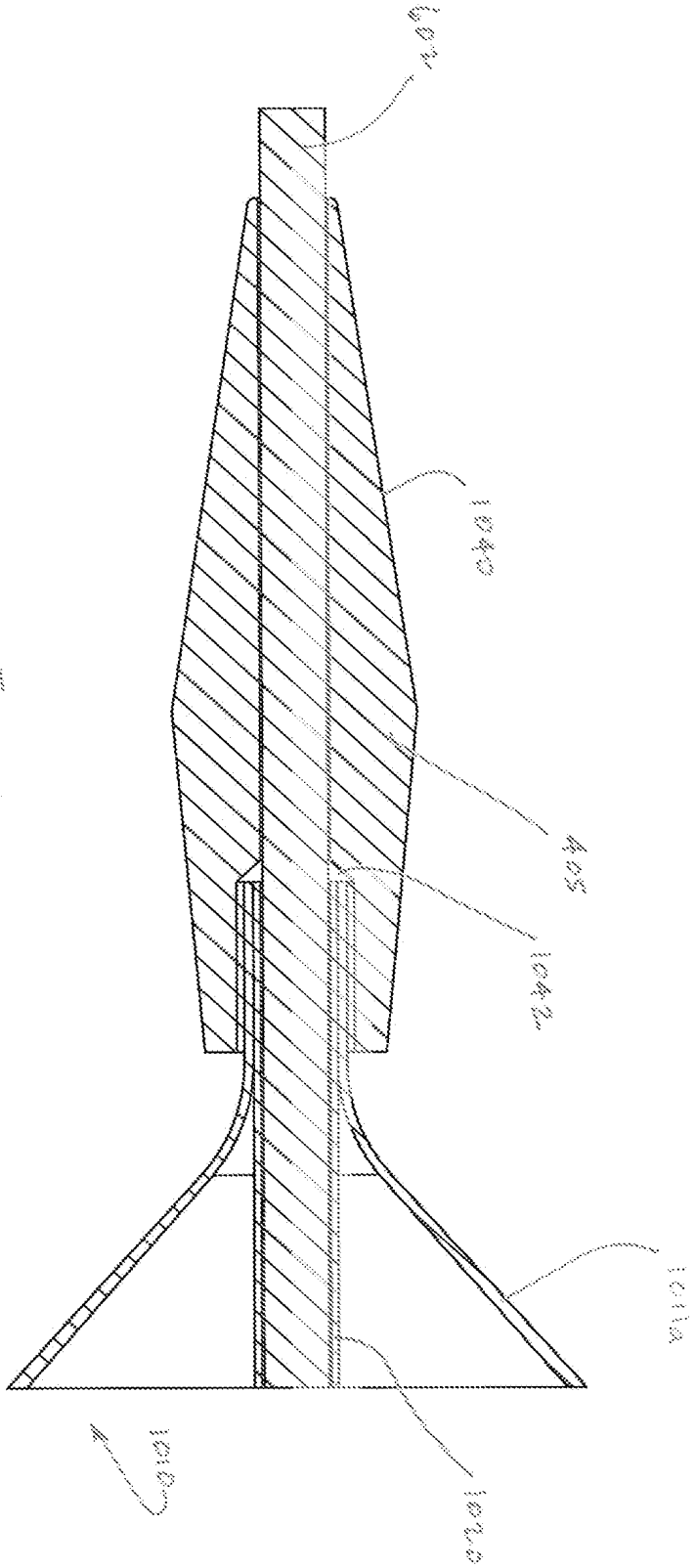


Fig. 11

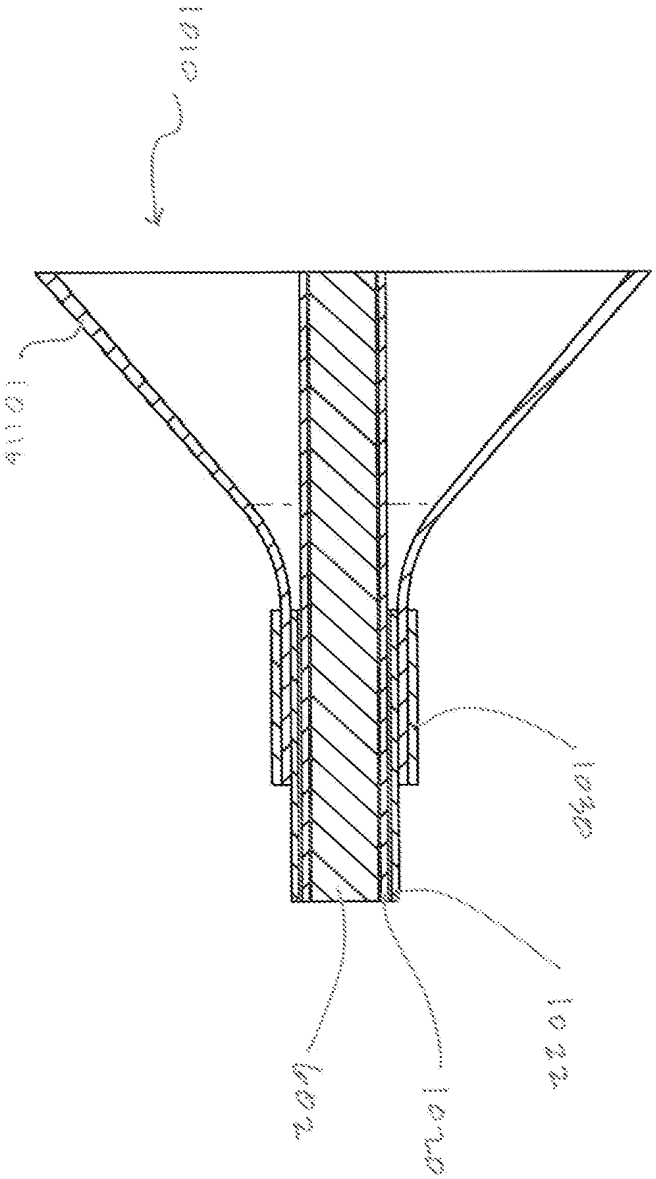


FIG. 12

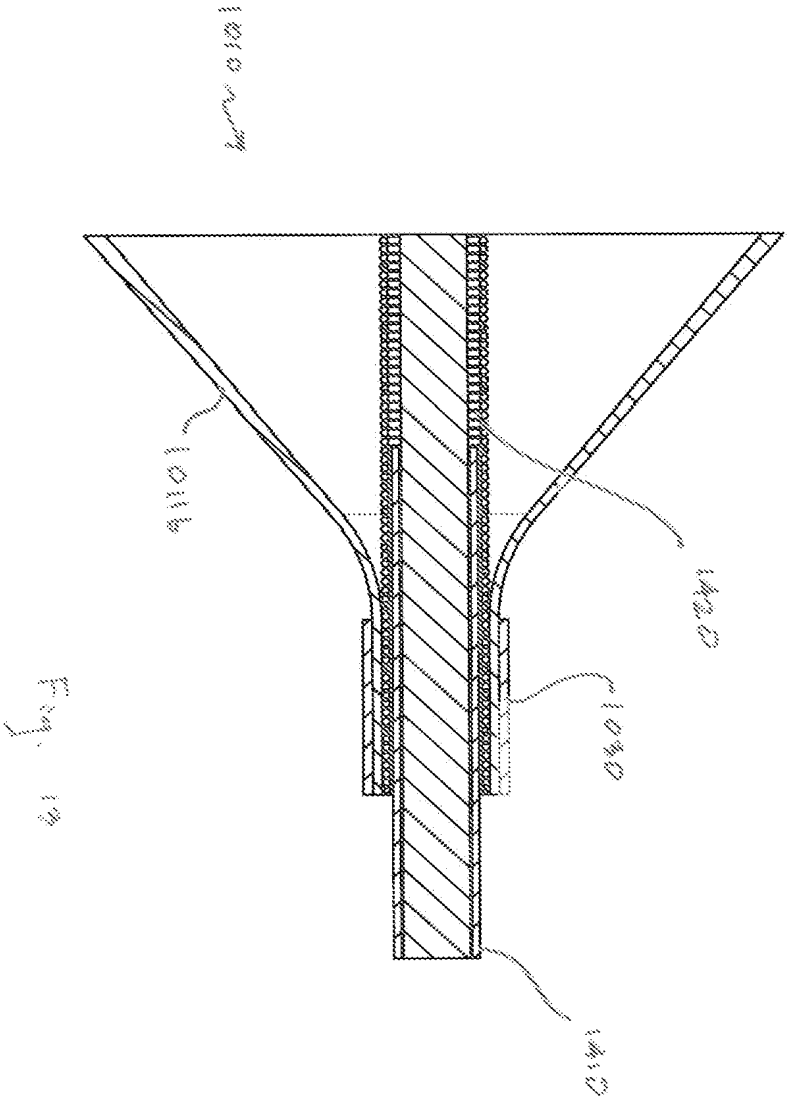


Fig. 1A

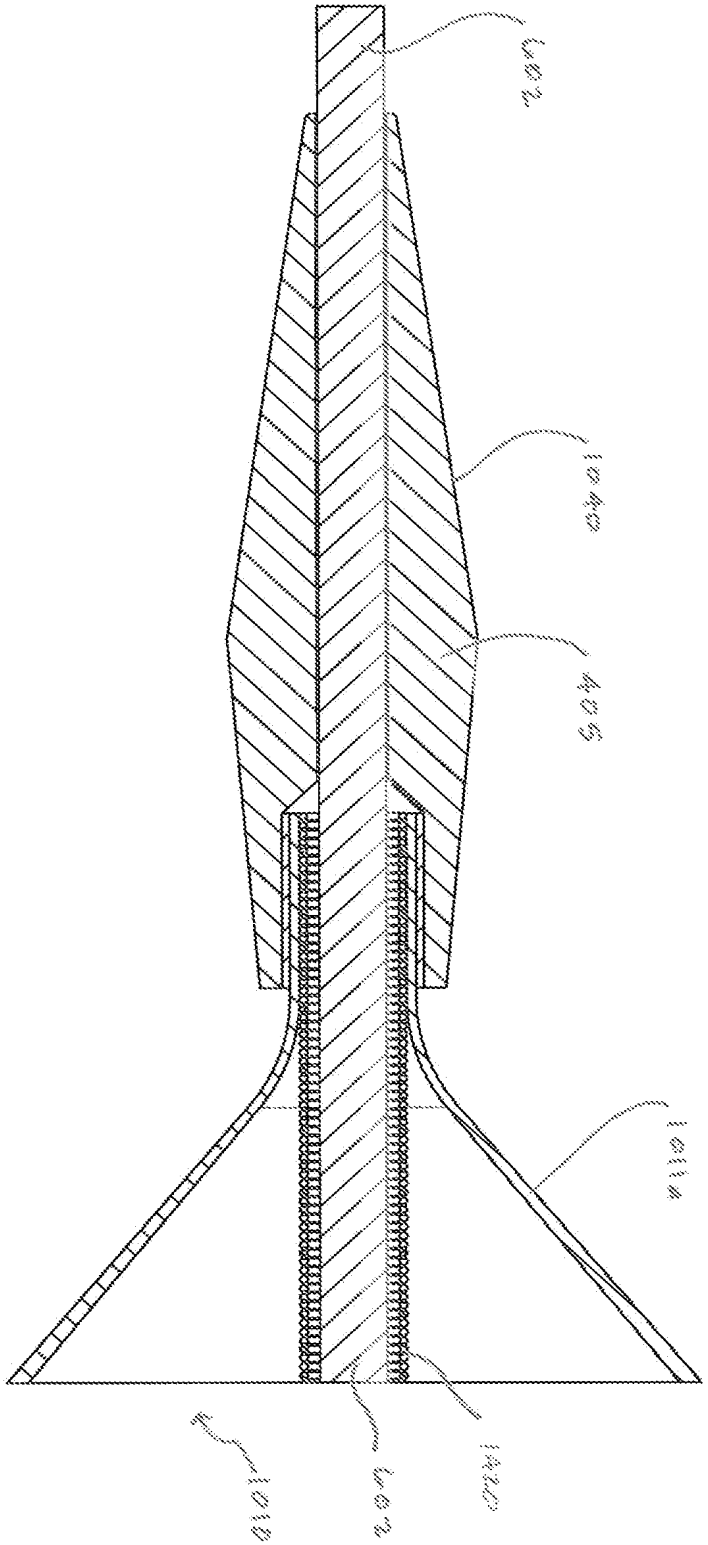


Fig. 14

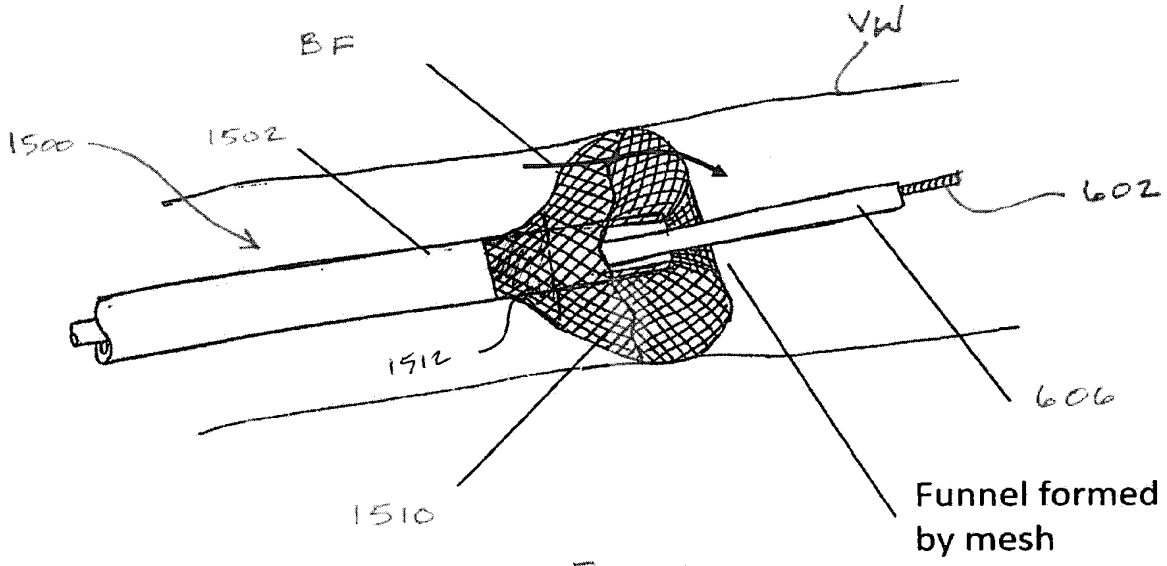


Fig. 15

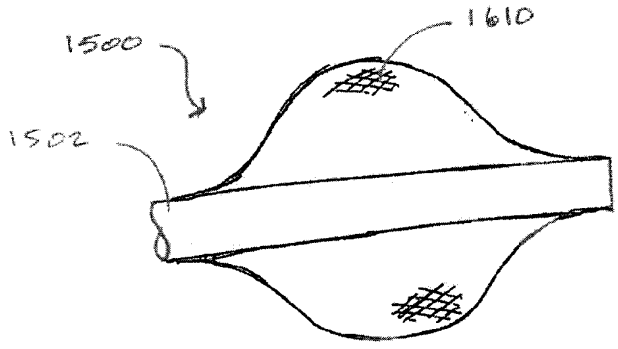


Fig. 16

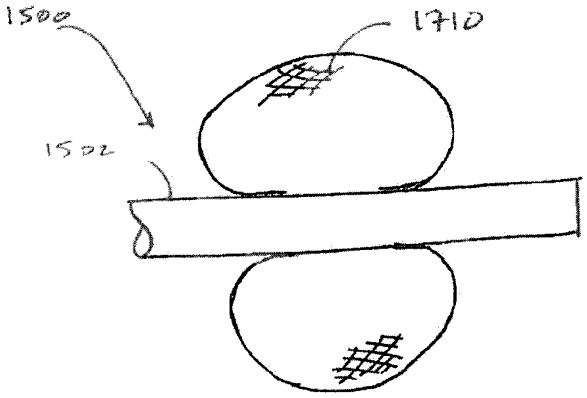


Fig. 17

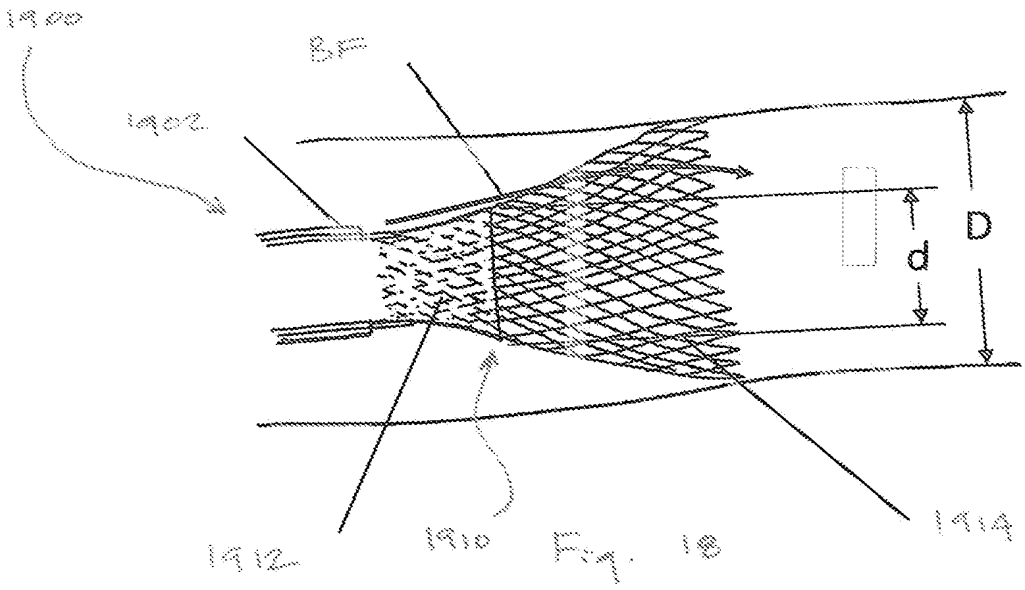


Fig. 18

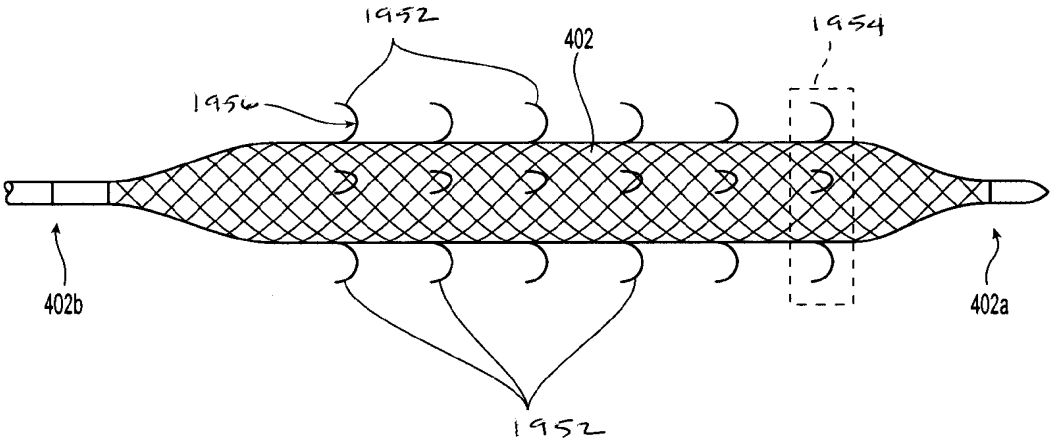


Fig. 19

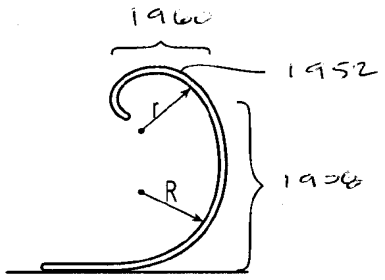


Fig. 20

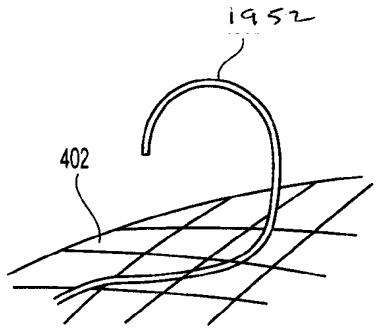


Fig. 21

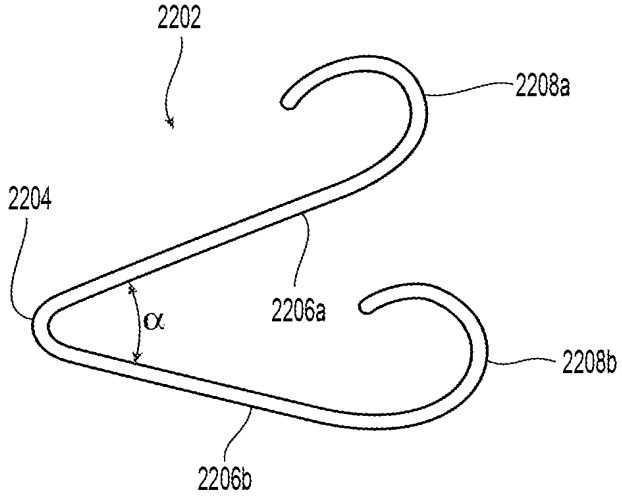


Fig. 22

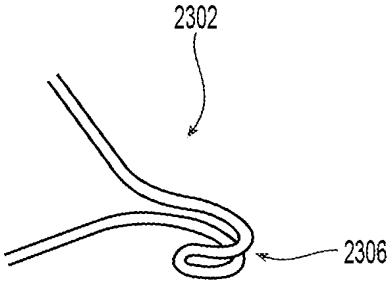


Fig. 23

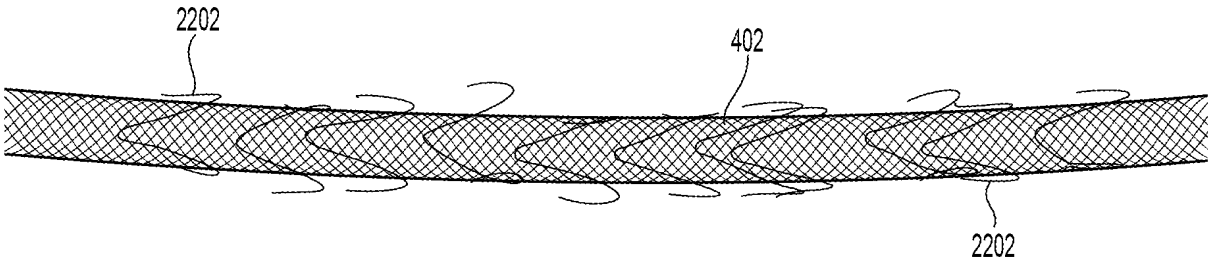


Fig. 24

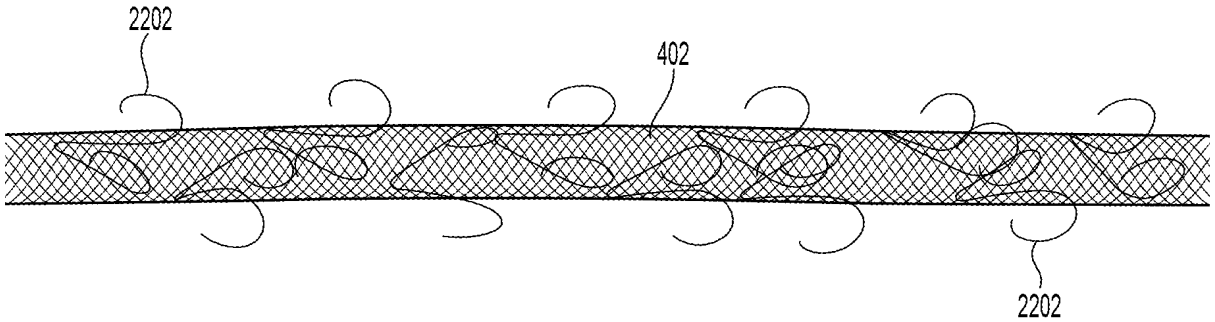


Fig. 25

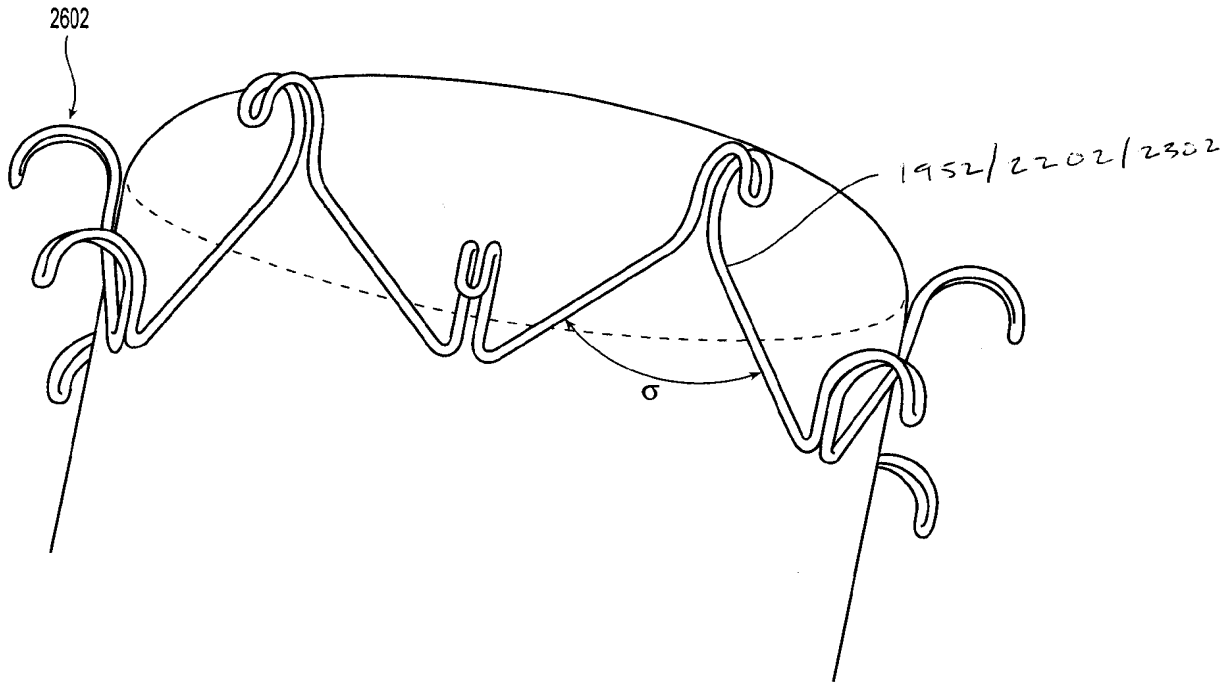


Fig. 26

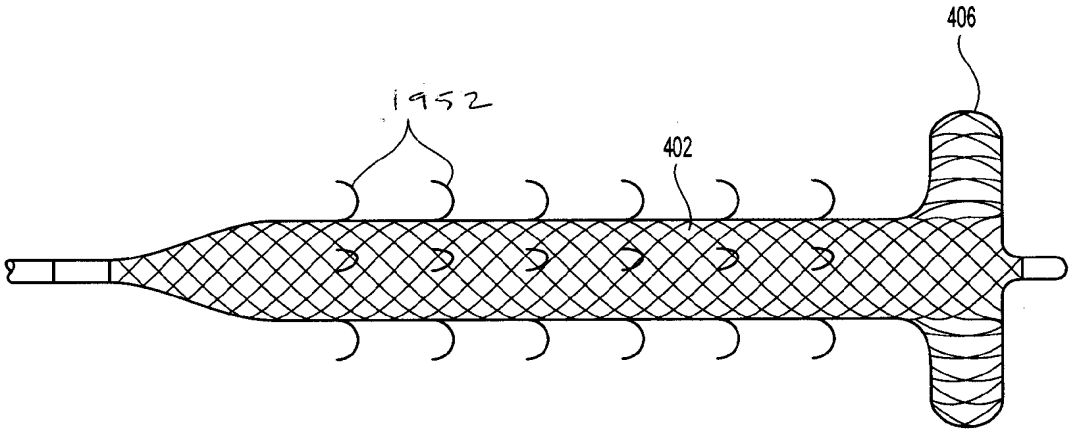


Fig. 27

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/071101

A. CLASSIFICATION OF SUBJECT MATTER

A61M 25/01(2006.01)i, A61M 25/08(2006.01)i, A61M 25/09(2006.01)i

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 25/01; A61M 29/00; A61M 25/08; A61M 25/09

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: embolism, pulmonary, expand, stent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011-0213403 A1 (ABOYTES, M.) 1 September 2011 See abstract; figs. 4A, 4B, and 7; paragraphs [0084]-[0089] and [0099]-[0101]; claims 1, 7, and 11.	1-3,6,15-18
Y		32
Y	US 6645222 B1 (PARODI, J. C. et al.) 11 November 2003 See abstract; fig. 6A; claim 1.	32
A	US 2008-0167678 A1 (MORSI, H.) 10 July 2008 See abstract; fig. 3; claims 1 and 2.	1-3,6,15-18,32
A	US 6254571 B1 (HART, C. C.) 3 July 2001 See abstract; figs. 1A and 1B; claims 1 and 2.	1-3,6,15-18,32
A	US 2006-0282111 A1 (MORSI, H.) 14 December 2006 See abstract; fig. 3; claim 1.	1-3,6,15-18,32

☐ 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 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
28 March 2014 (28.03.2014)	**31 March 2014 (31.03.2014)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
CHOI, Sung Hee
Telephone No. +82-42-481-8740

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/071101

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.: 33-40
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 33-40 pertain to methods for treatment of the human body by surgery and thus relate to a subject-matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

2. ☒ Claims Nos.: 5, 12-14, 27, 28
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:
Claims 5, 12-14, 27 and 28 are unclear, since they either directly or indirectly refer to one of claims which are not drafted in accordance with PCT Rule 6.4(a) (PCT Article 6).

3. ☒ Claims Nos.: 4, 7-11, 19-26, 29-31
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:

1. ☐ As all required addtional 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 any 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.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US2013/071101

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011-0213403 A1	01/09/2011	None	
US 6645222 B1	11/11/2003	EP 1061846 A2	27/12/2000
		EP 1061846 B1	03/03/2010
		EP 1210142 A2	05/06/2002
		EP 1210142 B1	19/01/2011
		EP 1416993 A2	12/05/2004
		EP 1427460 A2	16/06/2004
		EP 1427460 B1	31/08/2011
		EP 1545685 A1	29/06/2005
		EP 1545685 B1	17/11/2010
		EP 2236170 A2	06/10/2010
		EP 2236170 A3	29/06/2011
		EP 2236170 B1	27/03/2013
		EP 2311519 A1	20/04/2011
		EP 2335770 A1	22/06/2011
		US 2001-0044598 A1	22/11/2001
		US 2002-0022859 A1	21/02/2002
		US 2002-0087119 A1	04/07/2002
		US 2002-0107479 A1	08/08/2002
		US 2002-0151922 A1	17/10/2002
		US 2002-0173815 A1	21/11/2002
		US 2003-0023204 A1	30/01/2003
		US 2005-0131453 A1	16/06/2005
		US 2005-0228432 A1	13/10/2005
		US 2006-0041228 A1	23/02/2006
		US 2010-0204724 A1	12/08/2010
		US 2011-0160762 A1	30/06/2011
		US 6206868 B1	27/03/2001
		US 6413235 B1	02/07/2002
		US 6423032 B2	23/07/2002
		US 6540712 B1	01/04/2003
		US 6582396 B1	24/06/2003
		US 6632236 B2	14/10/2003
		US 6682505 B2	27/01/2004
		US 6905490 B2	14/06/2005
		US 6908474 B2	21/06/2005
		US 6936060 B2	30/08/2005
		US 6960222 B2	01/11/2005
		US 7927347 B2	19/04/2011
		WO 2004-002564 A1	08/01/2004
US 2008-0167678 A1	10/07/2008	US 7914549 B2	29/03/2011
		WO 2008-086180 A1	17/07/2008
US 6254571 B1	03/07/2001	WO 97-38631 A1	23/10/1997
US 2006-0282111 A1	14/12/2006	WO 2006-135823 A2	21/12/2006
		WO 2006-135823 A3	27/12/2007

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 July 2009 (02.07.2009)

PCT

(10) International Publication Number
WO 2009/082513 A1

(51) International Patent Classification:
A61M 37/00 (2006.01)

(21) International Application Number:
PCT/US2008/072352

(22) International Filing Date: 6 August 2008 (06.08.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/015,301 20 December 2007 (20.12.2007) US

(71) Applicant *(for all designated States except US)*: **VORTEX MEDICAL** [US/US]; 50 Loring Drive, Norwell, MA 02061 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **AKLOG, Lishan** [US/US]; 6216 East Shea Blvd., Scottsdale, AZ 85254 (US). **GLENNON, Michael** [US/US]; 50 Loring Drive, Norwell, MA 02061 (US).

(74) Agent: **PHAM, Chinh, H.**; Greenberg Trauig, LLP, One International Place, Boston, MA 02110 (US).

(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, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(54) Title: SYSTEMS AND METHODS FOR REMOVING UNDESIRABLE MATERIAL WITHIN A CIRCULATORY SYSTEM

(57) Abstract: A system for removing undesirable material from vessels and from chambers within the heart is provided. The system includes a suction cannula for removing the undesirable material from a site of interest within a patient. A filter device may be provided for capturing the undesirable material and removing it from the fluid flow. The system also includes pump for generating the necessary suction force through the suction cannula to dislodge the undesirable material from the site of interest and for generating a sufficient driving force to direct the fluid flow downstream within the system. The system further includes a reinfusion cannula for introducing fluid removed from the site of interest back into a patient. A method for removing undesirable material from vessels and from heart chambers is also provided.

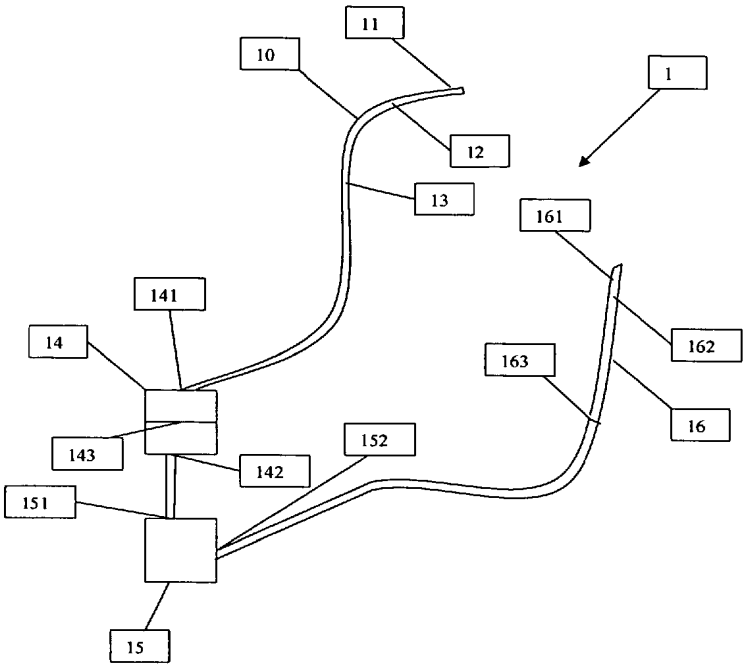


Fig. 1

WO 2009/082513 A1

SYSTEMS AND METHODS FOR REMOVING UNDESIRABLE MATERIAL WITHIN A CIRCULATORY SYSTEM

TECHNICAL FIELD

[0001] The present invention relates to systems and methods for removing undesirable materials from a site of interest within the circulatory system. More particularly, the present invention relates to systems and methods for removing substantially *en bloc* clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels, while reinfusing fluid removed from the site of interest back into the patient to minimize fluid loss.

BACKGROUND ART

[0002] Many of the most common and deadly diseases afflicting mankind result from or in the presence of undesirable material, most notably blood clots, in the blood vessels and heart chambers. Examples of such diseases include myocardial infarction, stroke, pulmonary embolism, deep venous thrombosis, atrial fibrillation, infective endocarditis, etc. The treatment of some of these conditions, which involve smaller blood vessels, such as myocardial infarction and stroke, has been dramatically improved in recent years by targeted mechanical efforts to remove blood clots from the circulatory system. Other deadly conditions, which involve medium to large blood vessels or heart chambers, such as pulmonary embolism (1/2 million deaths per year) or deep venous thrombosis (2-3 million cases per year) have not benefited significantly from such an approach. Present treatment for such conditions with drugs or other interventions is not sufficiently effective. As a result, additional measures are needed to help save lives of patients suffering from these conditions.

[0003] The circulatory system can be disrupted by the presence of undesirable material, most commonly blood clots, but also tumor, infective vegetations, and foreign bodies, etc. Blood clots can arise spontaneously within the blood vessel or heart chamber (thrombosis) or be carried through the circulation from a remote site and lodge in a blood vessel (thromboemboli).

[0004] In the systemic circulation, this undesirable material can cause harm by obstructing a systemic artery or vein. Obstructing a systemic artery interferes with the

delivery of oxygen-rich blood to organs and tissues (arterial ischemia) and can ultimately lead to tissue death or infarction. Obstructing a systemic vein interferes with the drainage of oxygen-poor blood and fluid from organs and tissues (venous congestion) resulting in swelling (edema) and can occasionally lead to tissue infarction.

[0005] Many of the most common and deadly human diseases are caused by systemic arterial obstruction. The most common form of heart disease, such as myocardial infarction, results from thrombosis of a coronary artery following disruption of a cholesterol plaque. The most common causes of stroke include obstruction of a cerebral artery either from local thrombosis or thromboemboli, typically from the heart. Obstruction of the arteries to abdominal organs by thrombosis or thromboemboli can result in catastrophic organ injury, most commonly infarction of the small and large intestine. Obstruction of the arteries to the extremities by thrombosis or thromboemboli can result in gangrene.

[0006] In the systemic venous circulation, undesirable material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (long-haul air travel, immobility) and clotting (cancer, recent surgery, especially orthopedic surgery). DVT causes harm by (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain and infection and (2) serving as a reservoir for blood clot to travel to other parts of the body including the heart, lungs (pulmonary embolism) and across a opening between the chambers of the heart (patent foramen ovale) to the brain (stroke), abdominal organs or extremities.

[0007] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries, a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs and therefore the entire body, resulting in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting low blood oxygen and build up of blood carbon dioxide. If the obstruction is further downstream, it can

cut off the blood flow to a smaller portion of the lung, resulting in death of lung tissue or pulmonary infarction.

[0008] The presence of the undesirable material within the heart chambers can cause harm by obstructing flow or by serving as a reservoir for emboli to other organs in the body. The most common site for obstruction within the heart is in the heart valves. Infective vegetations, a condition known as endocarditis, can cause partial obstruction to flow across a valve before destroying the valve. Patients with prosthetic valves, especially mechanical valves, are particularly prone to valve thrombosis and obstruction. The heart chambers are the most common source of emboli (cardioemboli) to the systemic circulation, including stroke. Emboli tend to arise from areas that are prone to stagnation of blood flow under pathologic conditions. The left atrial appendage in patients with atrial fibrillation is prone to thrombosis, as well as the left ventricular apex in patients with acute myocardial infarction or dilated cardiomyopathy. Infected vegetations or thrombi on the heart valves are also common sources of emboli. Undesirable material such as blood clots and infected vegetations can reside in the chambers of the right heart (atrium and ventricle), often associated with prosthetic material such as pacemaker leads or long-term indwelling catheters.

[0009] The most effective treatment for conditions resulting from the presence of blood clots or other undesirable materials within the circulation is, of course, to stabilize or eliminate the material before it has embolized. Alternatively, if obstruction to flow has already occurred but before the obstruction has caused permanent harm (infarction, shock, death), the material can be eliminated by utilizing biologic or mechanical means.

[00010] Biologic treatments involve the delivery of agents to the material, which either dissolve the material or, at a minimum, stabilize it until the body can eliminate it. In the case of infective vegetations, antimicrobial agents can, over time, decrease the chances of embolization. In the case of blood clots, the agents include 1) anticoagulant agents (heparin, warfarin, etc.) which prevent propagation of blood clots; and 2) more potent thrombolytic agents (streptokinase, urokinase, tPA, etc,) which actively dissolve clots. The agents are usually delivered systemically, i.e., into a peripheral or central vein and allowed to circulate throughout the body.

Thrombolytic agents can also be delivered through a catheter directly to the blood clot which can increase its effectiveness by increasing local concentrations but this does not completely eliminate the absorption into systemic circulation throughout the body.

[00011] Thrombolytic agents have been shown to increase survival in patients with hemodynamically significant pulmonary embolism as documented by echocardiographic evidence of right ventricular strain. The use of thrombolytic agents is the standard of care in this subgroup of patients with a high 20-25% early mortality. They are commonly used in to dissolve clots in other blood vessels including arteries to heart, abdominal organs and extremities.

[00012] There are two primary disadvantages to thrombolytic agents. First, every cell in the body is exposed to the agent which can lead to serious and often life threatening bleeding complications in remote areas such as the brain and stomach. The risk of major bleeding complications can be as high as 25% and the risk of often fatal bleeding into the brain can go up to 3%. Second, blood clots undergo a process called organization where the soft gel-like red/purple clot is transformed into a firmer, whitish clot by the cross-linking of proteins such as fibrin. Organized clots are much less amenable to treatment with thrombolytic agents. Thromboemboli, such as pulmonary emboli, can contain a significant amount of organized clot since the thrombus frequently developed at its original site (e.g., the deep veins of the legs) over a long period of time prior to embolizing to the remote site (e.g., the lungs).

[00013] Mechanical treatments involve the direct manipulation of the material to eliminate the obstruction. This can involve aspiration, maceration, and compression against the vessel wall, or other types of manipulation. The distinct advantage of mechanical treatment is that it directly attacks the offending material and eliminates the vascular obstruction independent of the specific content of the offending material. Mechanical treatments, if feasible, can usually prove to be superior to biologic treatments for vascular obstruction. Procedural success rates tend to be higher. The best example of this advantage is in the treatment of acute myocardial infarction. Although thrombolytic therapy has had a major impact on the management of patient with myocardial infarction, this option is now relegated to a distant second choice. The clear standard of care today for an acute myocardial infarction is an emergency percutaneous coronary intervention during which the coronary artery obstruction is

relieved by aspiration, maceration or balloon compression of the offending thrombus. This mechanical approach has been shown to decrease the amount of damaged heart tissue and improve survival relative to the thrombolytic biological approach.

[00014] Mechanical treatment, however, has played a limited role in the removal of blood clots found in larger blood vessels such as pulmonary arteries and heart chambers. Surgical pulmonary embolectomy involves opening the pulmonary artery and removing the offending clot under direct vision. This operation has been performed for nearly 100 years, but did not become practical until the introduction of the heart lung machine. Even then, it was generally relegated to a salvage procedure in moribund patients in whom all other options had been exhausted because of the inherent danger in the surgery and the recovery period. While surgical pulmonary embolectomy is very effective in completely evacuating pulmonary emboli whether soft-fresh and firm-organized clot, it is an invasive procedure.

[00015] Recent data has shown that the early outcomes with surgical pulmonary embolectomy are excellent, at least as good as thrombolytic treatment, as long as the procedure is performed in a timely fashion before the patient becomes very ill or suffers a cardiac arrest. The long term outcomes of patients surviving surgical pulmonary embolectomy have always been very good. Although these data have generated a renewed interest in performing surgical pulmonary embolectomy, its use remains limited because of the invasiveness of the procedure. Although minimally invasive approaches have been described, the standard procedure requires a 20-25cm incision through the sternal bone and placing the patient on cardiopulmonary bypass (the heart-lung machine).

[00016] Catheter-based removal of blood clots from larger blood vessels (e.g., pulmonary arteries) and heart chambers has had limited success, at least compared to smaller blood vessels (e.g., coronary arteries). Catheter pulmonary embolectomy, where the pulmonary emboli are removed percutaneously using one of several techniques, has been around for nearly 30 years but few patients currently receive these therapies. These techniques can be subdivided into three categories. With fragmentation thrombectomy, the clot is broken into smaller pieces, most of which migrate further downstream, decreasing the central obstruction but resulting in a "no-reflow" phenomenon. It is sometimes used in combination with thrombolytics which

preclude their use as an alternative to thrombolytics. With the rheolytic thrombectomy, high velocity saline jets create a Venturi effect and draw the fragments of the clot into the catheter. Finally the aspiration techniques draw the clot into a catheter via suction. With a Greenfield embolectomy, the catheter with the attached clot is repeatedly drawn out of the vein. All of these techniques rely on catheters which are small compared to the size of the clots and blood vessels. Their limited success is likely related to their inability to achieve a complete en-bloc removal of the material without fragmentation.

[00017] The experience with catheter-based treatment of deep venous thrombus has also had limited success. The operator must use relatively small catheters to remove or break up large amounts of well embedded clot. This procedure is therefore time-consuming, inefficient and ultimately not very effective in removal of the whole clot.

[00018] It is clear that all of the therapeutic options available to patients with clot or other undesirable material in medium or large blood vessels, such as those with pulmonary embolism, have serious limitations. Anticoagulation only limits propagation of clot, it does not remove it. Thrombolytic therapy is not targeted, carries a real risk of major bleeding, and is not very effective in firm/organized clots. Catheter embolectomy uses technology developed for small blood vessels, does not scale well to material residing in medium and large vessels or heart chambers, and thus is not very effective. Surgical embolectomy is highly effective but highly invasive. There is a real need for a direct mechanical treatment that is as effective as surgical embolectomy but can be performed using endovascular techniques.

[00019] Current efforts to apply existing catheter embolectomy technologies to medium to large blood vessels and heart chambers encounter at least two obstacles: fragmentation and excessive blood loss. Techniques which depend on fragmentation of the material tend to be inefficient and ineffective in medium to large blood vessels and heart chambers because the flow of blood will carry a significant portion of the fragmented material away before it can be captured in the catheter. On the other hand, techniques which depend on aspiration of undesirable material will result in excessive blood loss as the size of the catheter increases.

[00020] A need therefore exists for a system and method to endovascularly remove undesirable material residing in medium to large blood vessels and heart chambers with minimal fragmentation and without excessive blood loss.

SUMMARY OF THE INVENTION

[00021] The present invention relates generally to systems and methods for removing undesirable material residing in vessels, such as blood vessels, or within chambers of the heart. More specifically, the subject invention relates to systems and methods for using a cannula to remove substantially *en bloc*, from a site of obstruction or interest, an undesirable material, such as blood clots, embolisms and thromboembolisms, without significant fragmentation and without excessive fluid loss. In addition, the systems and methods of the present invention may simultaneously reinfuse aspirated (i.e., removed) and filtered fluid, such as blood, back into the patient on a substantially continuous basis to minimize any occurrences of fluid loss and/or shock. The subject invention may be particularly useful, but may not be limited to, the removal of blood clots, tumors, infective vegetations and foreign bodies from medium to large blood vessels and heart chambers.

[00022] In one embodiment, a system for removing an undesirable material from within a vessel is provided. The system includes a first cannula having a distal end and an opposing proximal end. The distal end of the first cannula, in an embodiment, may include or may be deployable to a diameter relatively larger than that of the proximal end. The first cannula may be designed for maneuvering within the vessel to a site of interest, such that an undesirable material can be captured substantially *en bloc* through the distal end and removed along the first cannula away from the site. The system may also include a pump, in fluid communication with the proximal end of the first cannula, so as to provide a sufficient suction force for removing the undesirable material from the site of interest. The system may further include a second cannula in fluid communication with the pump, so that fluid removed from the site of interest by the first cannula can be directed along the second cannula and reinfused through a distal end of the second cannula. In one embodiment, the distal end of the second cannula may be situated in spaced relation to the distal end of the first cannula. The system may also be provided with a filter device positioned in fluid

communication with the first cannula. The filter device, in an embodiment, may act to entrap or capture the undesirable material and remove it from the fluid flow. The system may further be provided with a reservoir in fluid communication with the filter device. The reservoir may act to transiently collect fluid being directed from the filter device and to provide a source of fluid for reinfusion by the second cannula. A second filter may also be included in fluid communication between the pump and the second cannula, so as to remove, prior to reinfusion, any debris that may have escaped from the filter device from the fluid flow.

[00023] In another embodiment, there is provided a method for removing an undesirable material from within a vessel. The method includes initially maneuvering a first cannula having a distal end and an opposing proximal end to a site of interest within the vessel, such that the distal end of the first cannula is positioned adjacent the undesirable material. Next, a second cannula, in fluid communication with the first cannula, may be positioned such that its distal end can be situated in spaced relation to the distal end of the first cannula. Thereafter, a suction force may be provided through the distal end of the first cannula to the site of interest, so as to remove, through the distal end of the first cannula, the undesirable material substantially *en bloc* from the site of interest. Subsequently, any fluid removed along with the undesirable material may be reinfused, through the distal end of the second cannula, to a location in spaced relation from the distal end of the first cannula. The suction and reinfusion of blood can occur, in an embodiment, continuously for a desired duration to minimize fluid loss in the patient. Alternatively, the step of suctioning an undesirable material can occur at an intermittent pulse for a desired duration following reinfusion of the removed fluid.

[00024] In a further embodiment, an apparatus for removing an undesirable material from within a vessel is provided. The apparatus includes an elongated tube having a distal end through which an undesirable material can be captured, a pathway extending along the tube to provide a passage for transporting the undesirable material from the distal end, and a proximal end in opposing relations to the distal end through which the undesirable material can exit. The apparatus also includes a funnel situated at the distal end of the tube, and designed for deployment between an flared open position and a collapsed closed position, so as to better engage and capture the

undesirable material. The apparatus further includes a mechanism positioned about a distal portion of the tube, which mechanism, upon actuation, can deploy the funnel between the closed position and the open position. In one embodiment, the funnel includes a plurality of strips, with each strip being pivotally coupled at one end to the distal end of the tube. The funnel may also include a substantially impermeable membrane extending across a space between adjacent strips, such that the membrane, in connection with the strips define the shape of the funnel. The mechanism, in an embodiment, includes a balloon positioned circumferentially about the tube at a location proximal to the funnel, and an attachment mechanism provided with one end attached to the funnel and an opposite end attached to the balloon. By design, upon expansion of the balloon, the attachment mechanism can pull on the funnel to deploy it into a flared open position. The apparatus may also include a jacket positioned circumferentially about the distal end of the tube, and extending from the funnel to the balloon to protect the vessel from potential irritation that may be caused by the balloon and the strips defining the funnel. As the jacket may be attached to the funnel and the balloon, in one embodiment, the jacket may act as the mechanism for deploying the funnel into a flared open position upon expansion of the balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

[00025] These and other features and advantages of the present invention will become more apparent from the following detailed descriptions taken in conjunction with the accompanying drawings wherein like reference characters denote corresponding parts throughout the several views.

[00026] Fig. 1 illustrates system for removing an undesirable material from within a vessel in accordance with one embodiment of the present invention.

[00027] Figs. 2A-H illustrate a distal end of a suction cannula in operation in connection with the system shown in Fig. 1.

[00028] Figs. 3A-B illustrate an alternate distal end of a suction cannula used in connection with the system shown in Fig. 1.

[00029] Figs. 4A-E illustrate a variety of cannulas for use in connection with the system shown in Fig. 1.

[00030] Fig. 5 illustrates a port through which another device may be introduced within a suction cannula used in connection with the system shown in Fig. 1.

[00031] Fig. 6 illustrates a system for removing an undesirable material from within a vessel in accordance with another embodiment of the present invention.

[00032] Fig. 7 illustrates a system of the present invention being deployed within a patient for removing an undesirable material from a site of interest.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[00033] As noted above, existing catheter techniques may not be effective in removing undesirable material, such as clots, from medium and large size blood vessels or from heart chambers, because these catheters tend to be small relative to the material to be removed. As a result, the material often needs to be fragmented in order to fit within the catheter. However, with fragmentation, the chances of the fragments being carried away in the bloodstream increases, resulting in downstream obstruction. If the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.

[00034] The present invention overcomes the deficiencies of existing devices and techniques and can act to remove substantially *en bloc* (i.e., wholly or entirely) undesirable material, such as thrombi and emboli, from the vasculature, including medium to large size blood vessels, and from heart chambers. Vessels from which the undesirable material may be removed, in accordance with an embodiment of the present invention, include, for example, those within the pulmonary circulation (e.g., pulmonary arteries), systemic venous circulation (e.g., vena cavae, pelvic veins, leg veins, neck and arm veins) or arterial circulation (e.g., aorta or its large and medium branches). The heart chambers may be, for example, in the left heart (e.g., the left ventricular apex and left atrial appendage), right heart (e.g., right atrium and right ventricle), or on its valves. The present invention can also act to remove tumors, infective vegetations and other foreign.

[00035] Although reference is made to medium and large vessels, it should be appreciated that the systems and methods, hereinafter disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired.

[00036] Referring now to Fig. 1, there is illustrated a system 1 for removing an undesirable material, substantially *en bloc*, from an obstruction site or site of interest within the vasculature, and for reinfusion of fluid removed (i.e., suctioned or aspirated) from the site of interest back into a patient, in order to minimize fluid loss within the patient. System 1, in an embodiment, may be provided with a first or suction cannula 10 for capturing and removing *en bloc* the undesirable material from the site of interest, such as that within a blood vessel or a heart chamber. Cannula 10, in an embodiment, may be an elongated tube and may include a distal end 11 through which the undesirable material can be captured and removed. Cannula 10 may also include a lumen or pathway 12 extending along a body portion of cannula 10. Pathway 12, in one embodiment, provides a passage along which the captured material and aspirated circulatory fluid, such as blood, that may be captured therewith may be transported and directed away from the site of interest. Cannula 10 may further include a proximal end 13 in opposing relations to the distal end 11, and through which the captured material may exit from the cannula 10.

[00037] Since cannula 10 may be designed for introduction into the vasculature, for instance, through a peripheral blood vessel, and may need to subsequently be maneuvered therealong to the site of interest, cannula 10, in an embodiment, may be made from a pliable material. In addition, as cannula 10 may be used to introduce a suction force to the site of interest for capturing the undesirable material, cannula 10 may be made from a sufficiently stiff material or may be reinforced with a sufficiently stiff material, so as not to collapse under a suction force. In one embodiment, cannula 10 may be constructed from a biocompatible material, such as polyvinyl chloride, polyethylene, polypropylene, polyurethane, Pebax®, silicone, or a combination thereof.

[00038] In certain instances, it may be desirable to maneuver cannula 10 to the site of interest using image guidance, for example, using fluoroscopy or echocardiography. In order to permit cannula 10 to be visualized, cannula 10, in an embodiment, may also include a radioopaque material or any material capable of being visualized.

[00039] To better engage and capture the undesirable material substantially *en bloc* and without significant fragmentation, the distal end 11 of cannula 10 may be designed to have a diameter that can be relatively larger than that of the proximal end

13. In one embodiment, as illustrated in Figs. 2A-D, distal end 11 of cannula 10 may be in the shape of a funnel 20, and may be provided with a diameter, for example, approximately at least three times that of pathway 12. Of course, depending on the surgical procedure being implemented, the ratio between the diameter of funnel 20 and pathway 12 can be varied, if so desired. Funnel 20, with its design, may be placed directly at a site of interest 23 to engage undesirable material 24 (Fig. 2C), or spatially away from the site of interest 23 to capture the undesirable material 24 (Fig. 2D). In a situation where the distal end 11 may be situated spatially away from the site of interest, by providing distal end 11 with funnel 20, a vortex effect may be generated during suctioning to better direct the undesirable material into the funnel 20. It is believed that fluid flowing into funnel 20 can often exhibit a laminar flow circumferentially along the interior surface of the funnel 20 to generate a vortex flow into the distal end 11 of suction cannula 10. Thus, in the presence of a vortex flow, such a flow can act to direct the undesirable material toward the distal end 11 to allow the material to subsequently be pulled into the distal end by suctioning.

[00040] To provide a funnel shaped distal end, cannula 10 may include, in an embodiment, a sheath 21 circumferentially situated about distal end 11 of cannula 10. Sheath 21, as illustrated, may be designed to slide toward as well as away from the distal end 11 of cannula 10. In that way, when the distal end 11 is positioned at the site of interest 23, and sheath 21 is retracted (i.e., slid away from the distal end 11), funnel 20 may be exposed and expanded into the desired shape in order to engage undesirable material 24. To collapse funnel 20, sheath 21 may be advanced toward the distal end 11 and over the funnel 20. Thereafter, cannula 10 may be maneuvered from the site of interest 23.

[00041] In order to enhance capture and removal of the undesirable material 24, looking now at Figs. 2E-G, cannula 10 may be designed to allow introduction of a catheter 25 with balloon 26 to the site of interest. In an example where the undesirable material 24 may be entrapped within funnel 20, catheter 25 with balloon 26 may be directed along the lumen or pathway 12 of cannula 10 and into funnel 20. Once catheter 25 has been advanced past the undesirable material 24 within funnel 20, balloon 26 may be inflated to a size sufficient to pull on the undesirable material entrapped within funnel 20. As balloon 26 is pulled down the funnel 20 towards

pathway 12, balloon 26 can dislodge the entrapped material and can eventually partially or substantially occlude a pathway 12, distal to the undesirable material 24, which in essence occludes the fluid communication between cannula 10 and the vessel. The suction force within pathway 12, as a result, can be enhanced to better remove the undesirable material. Similarly, as shown in Fig. 2H, in a situation where undesirable material 24 may be firmly lodged in the vessel at the site of interest 23 and the suction applied by cannula 10, spatially situated away from the site of interest 23, may insufficient to dislodge the undesirable material 24, catheter 25 and balloon 26 may be advanced past the distal end of cannula 10 and past the undesirable material 24 at the site of interest 23. Once past the undesirable material 24 the balloon 26 may be inflated and as balloon is withdrawn back towards the distal end 11 of cannula 10, it can dislodge the undesirable material and allow the suction to draw it into the distal end of cannula 10. Of course, this approach can also be applied when cannula 10 is situated directly at the site of interest 23 and the suction force may be insufficient to dislodge the undesirable material 24.

[00042] In another embodiment, looking now at Figs. 3A-B, funnel 20 located at distal end 11 of cannula 10 may be created by providing a plurality of independent strips 31, each coupled at one end to distal end 11 of cannula 10. In the embodiment shown in Fig. 3A, three strips 31 are illustrated. However, it should be appreciated that two or more strips 31 may be used, if so desired. Strips 31, in an embodiment, may be designed to pivot between a closed position, where strips 31 may be substantially adjacent one another, and an open position, where strips may be flared into a funnel 20, shown in Fig. 3A. To deploy strips 31, and thus funnel 20, between an open and closed position, cannula 10 may include a balloon 33 positioned circumferentially about cannula 10 and proximal to strips 31. In addition, an attachment mechanism, such as a string 34 or any similar mechanisms (e.g., rod, chain etc.), may be provided for each of the strips 31, with one end attached to one strip 31 and an opposite end attached to balloon 33. In this way, when balloon 33 is inflated and expands radially, balloon 33 may pull on each attachment mechanism 34, so as to deploy strips 31 into a flared open position. Balloon 33, in one embodiment, may be inflated through opening 37 through the use of any fluid, including water, air, or radioopaque contrast material. It should be noted that securing of the attachment mechanism to the strips

31 and balloon 33 can be accomplished using any methods or mechanisms known in the art. For instance, adhesives, knots, or soldering etc. may be used. Moreover, to the extent desired, strips 33 and balloon 31 may be designed to expand to a diameter larger than that of the vessel within which cannula 10 is being deployed. In that way, cannula 10 may be securely positioned at the site of interest for removal of the undesirable material substantially *en bloc*.

[00043] To better capture the undesirable material and direct it into the cannula 10, a membrane 35 may be placed across a space between adjacent strips 31 when the strips 31 are in the open position. In one embodiment, a continuous membrane 35 may be used to circumferentially stretch across each of the space between adjacent strips 31. Membrane 35 may also act to enhance suction at the site of interest, as it can cover up any open space between the strips 31. To that end, membrane 35, in an embodiment, may be made from a non-permeable material. It should be appreciated that membrane 35 and strips 31, as illustrated, together define funnel 20 at distal end 11 of cannula 10.

[00044] Furthermore, to protect the vessel from irritation or damage that may be caused by the presence of balloon 33 and/or strips 31, jacket 36, as shown in Fig. 3B, may be provided circumferentially about the distal 11 of cannula 10. In an embodiment, jacket 36 may extend substantially from a tip of each strip 31 to balloon 33. Jacket 36, however, can be affixed anywhere along each strip 31, if necessary. Since jacket 36 attaches at one end to strips 31 and at an opposite end to balloon 33, jacket 36, in an embodiment, may be used instead of attachment mechanism 34 to deploy strips 31 into an open position when balloon 33 is expanded. Of course, jacket 36 may also be used in conjunction with attachment mechanism 34 to deploy strips 31 into an open position. Furthermore, in one embodiment, jacket 36 may be lengthened, so that the end connected to strips 31 may instead be pulled over strips 31, into funnel 20, and attached substantially to a base of each strips 31 (i.e., base of funnel 20). With such a design, membrane 35 may not be necessary, as jacket 36 may serve the purpose of membrane 35 to cover the space between each of strips 31. In such an embodiment, at least that portion of jacket 36 extending over strips 31 and into the base funnel 20 can be impermeable.

[00045] In certain instances, balloon 33 may act to enhance the suction force being applied at the site of interest when removing the undesirable material. For instance, when cannula 10 is deployed downstream of the undesirable material, rather than substantially adjacent to the undesirable material, within a vessel having a venous circulation (i.e., flow toward the heart), balloon 33, when expanded radially, can substantially occlude the vessel, such that collateral fluid flow within the vessel can be minimized, thereby increasing the suction force that can be applied to the undesirable material. Additionally, the occlusion of such a vessel by balloon 33 can better direct the material being removed into the funnel 20 and prevent the material from being carried by the flow of blood past the funnel.

[00046] Alternatively, when cannula 10 is deployed upstream of the undesirable material within a vessel having an arterial circulation (i.e., flow away from the heart), rather than substantially adjacent to the undesirable material, balloon 33, when expanded radially, can substantially occlude the vessel, such that pressure being exerted on the downstream material by the fluid flow can be lessened. By lessening the pressure on the material to be removed, the suction force being applied at the site of interest can act to remove the material more easily.

[00047] As suction cannula 10 may be made from a pliable material, in order to efficiently direct it along a vessel to the site of interest, cannula 10 may be reinforced with wire or other material to optimize maneuverability within the vessel without kinking. Referring now to Fig. 4A, suction cannula 10 may, in addition to pathway 12, be provided with one or more additional pathway or lumen 41. In this multi-lumen design, pathway 12 may act, as noted above, to provide a passage along which the captured material may be transported and directed away from the site of interest. Lumen 41, on the other hand, can provide a passage along which a fluid can be directed to inflate balloon 33 through opening 37 (Figs. 3A-B). In certain embodiments, lumen 41 may also be used to accommodate other devices, such as other catheters or surgical instruments, for use in connection with a variety of purposes. For example, a device may be inserted and advanced along lumen 41 through the distal end 11 of suction cannula 10 to dislodge the undesirable material. An angiography catheter can be inserted and advanced along lumen 41 through the distal end 11 of suction cannula 10 to perform an angiogram to confirm the location

of the undesirable material or confirm that it has been successfully removed. A balloon embolectomy catheter can be inserted along lumen 41 toward the distal end 11 of suction cannula 10 to remove any material which may have clogged the cannula or past the any undesirable material firmly lodged in the vessel to draw it into the cannula. Although illustrated with such a multi-lumen design, any other multi-lumen design may be possible.

[00048] To introduce other devices, such as catheter 25 with balloon 26, into lumen 41 or pathway 12, cannula 10 may be provided with a port 51, as shown in Fig. 5, located at the proximal end 13 of cannula 10. It should be appreciated that in the embodiment where cannula 10 has only pathway 12 (i.e., single lumen cannula), port 51 may similarly be provided at the proximal end 13 of cannula 10 to allow the introduction of other devices into pathway 12.

[00049] Cannula 10 of the present invention may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size blood vessel. The size of cannula 10 may also be determined by the size of the undesirable material to be removed, so long as the undesirable material can be removed substantially *en bloc* without significant fragmentation. In one embodiment, suction cannula 10 may be designed to remove at least 10 cm^3 of undesirable material substantially *en bloc*. Of course, cannula 10 can be scaled and adapted for use within smaller vessels in the body and for removing a relatively smaller volume or amount undesirable material, if so desired.

[00050] Looking again at Fig. 1, system 1 can also include filter device 14 in fluid communication with the proximal end 13 of cannula 10. Filter device 14, in one embodiment, may include an inlet 141 through which fluid removed from the site of interest along with the captured undesirable material can be directed from cannula 10. Filter device 14 may also include an outlet 142 through which filtered fluid from within device 14 may be directed downstream of system 1. To prevent the undesirable material captured from the site of interest from moving downstream of system 1, filter device 14 may further include a permeable sheet 143 positioned within the fluid flow between the inlet 141 and the outlet 142.

[00051] Permeable sheet 143, in an embodiment, may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough,

while preventing any undesirable material captured from the site of interest from moving downstream of system 1. Examples of permeable sheet 143 includes coarse netting, fine netting, a screen, a porous filter, a combination thereof, or any other suitable filter material capable of permitting fluid to flow through while impeding movement of the captured undesirable material. It should be noted that, rather than just one, a plurality of permeable sheets 143 may be used. Alternatively, one permeable sheet 143 may be folded to provide multiple surfaces, similar to an accordion, for use in connection with filter device 14. By using a plurality of permeable sheets 143 or by folding sheet 143, the number of filtration surfaces through which the fluid must flow increases to enhance filtration and further minimize any occurrence of any undesirable material from moving downstream of system 1.

[00052] Although a permeable sheet 143 is described, it should be appreciated that filter device 14 may be of provided with any design capable of entrapping the undesirable material, while allowing fluid to move therethrough. To that end, filter device 14 may include a mechanical trap to remove the undesirable material from the fluid flow. Such a mechanical trap may be any trap known in the art and may be used with or without permeable sheet 143.

[00053] Still looking at Fig. 1, system 1 may also be provided with a pump 15 designed to generate negative pressure, so as to create a necessary suction force through cannula 10 to pull any undesirable material from the site of interest. In one embodiment, pump 15 may include an intake port 151 in fluid communication with outlet 142 of filter device 14. Intake port 151, as illustrated, may be designed to receive filtered fluid from filter device 14. Pump 15 may also be designed to generate the positive pressure, so as to create a necessary driving force to direct fluid through exit port 152 and downstream of system 1 for reinfusion of fluid removed from the site of interest back into the body. In an embodiment, the suction force and the drive force may be generated by pump 15 simultaneously and may take place continuously or intermittently for a set duration. Pump 15, as it should be appreciated, may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood. Examples of such a pump includes a kinetic pump, such as a centrifugal pump, and an active displacement pump, such as a rollerhead pump.

[00054] In an alternate embodiment, an independent vacuum device (not shown), may be provided for generating the necessary suction force at the site of interest, while a pump 15 may act to generate the necessary driving force for reinfusion purposes. In such an embodiment, pump 15 may be in fluid communication with the filter device 14, while the vacuum device may be in fluid communication with suction cannula 10 upstream to the filter device 14. The independent pump 15 and vacuum device may operate intermittently for a set duration, and if desired, either the vacuum device or pump 15 may operate continuously, while the other operates intermittently.

[00055] Downstream of pump 15, system 1 may further include a second or reinfusion cannula 16 in fluid communication with the exit port 152 of pump 15. Reinfusion cannula 16, in an embodiment, may be designed to permit filtered fluid, directed from filter device 14 by way of pump 15, to be reinfused back into a patient at a desired site. To that end, reinfusion cannula 16 may be designed for placement within the same or different vessel within which suction cannula 10 may be located.

[00056] Reinfusion cannula 16, in one embodiment, may be an elongated tube and includes a distal end 161 through which cleansed or filtered fluid can be reinfused back into the body. In an embodiment, distal end 161 of reinfusion cannula 16 may be designed so that it can be situated in spaced relation to the distal end 11 of the suction cannula 10 when system 1 is in operation. Reinfusion cannula 16 may also include a lumen or pathway 162 extending along its body portion to provide a passage along which the filtered fluid, such as blood, may be transported to a reinfusion site. Reinfusion cannula 16 may further include a proximal end 163 in opposing relations to the distal end 161, and through which the filtered fluid from pump 15 may enter into the cannula 16.

[00057] Furthermore, similar to suction cannula 10, since reinfusion cannula 16 may be designed for introduction into the vasculature, and may need to be maneuvered therealong, reinfusion cannula 16, in one embodiment, may be made from a pliable material. In one embodiment, reinfusion cannula 16 may be constructed from a biocompatible material, such as polyvinyl chloride, polyethylene, polypropylene, polyurethane, Pebax®, silicone, or a combination thereof. In certain instances, it may be desirable to maneuver reinfusion cannula 16 to the reinfusion site using image guidance, for example, using fluoroscopy or echocardiography. To permit reinfusion

cannula 16 to be visualized, reinfusion cannula 16, in an embodiment, may also be made to include a radioopaque material.

[00058] Since reinfusion cannula 16 may be made from a pliable material, in order to efficiently direct it along a vessel to the reinfusion site, reinfusion cannula 16 may be reinforced to optimize maneuverability within the vessel without kinking. Moreover as shown in Fig. 4B, reinfusion cannula 16 may be provided with one or more additional lumens. With a multi-lumen design, lumen 162, as noted above, may act to provide a passage along which the filtered fluid may be transported and directed to the reinfusion site. Lumen 42, on the other hand, can provide a passage through which a guide wire can be inserted to assist in the guiding the reinfusion cannula 16 to the reinfusion site, or through which other instruments and devices may be inserted for various surgical procedures. With such a multi-lumen design, reinfusion cannula 16 can serve as an introducer sheath by providing lumen 42 through which these instruments can pass, while filtered blood can be reinfused through lumen 162. Although illustrated with such a multi-lumen design, any other multi-lumen design may be possible.

[00059] Although illustrated as a separate component from suction cannula 10, in certain embodiments, the reinfusion cannula 16 may be designed to be substantially integral with suction cannula 10. In one embodiment, as illustrated in Fig. 4C, reinfusion cannula 16 may be incorporated as part of a double or multi- lumen introducer sheath 43 for insertion into the same vessel within which the suction cannula 10 may be situated. In particular, suction cannula 10 may be inserted and maneuvered through one lumen 44 of sheath 43, while reinfusion cannula 16 may be in fluid communication with lumen 45 of sheath 43. In such an embodiment, lumen 45 may include a distal end 451 in spaced relations to the distal end 11 of cannula 10, so that cleansed or filtered fluid may be introduced to the reinfusion site away from the site of interest where the distal end 11 of cannula 10 may be positioned.

[00060] Alternatively, as illustrated in Fig. 4D, reinfusion cannula 16 may be incorporated as part of a double or multi- lumen introducer sheath 43 where the reinfusion cannula 16 and the suction cannula 10 may be concentrically aligned along a shared axis A. In the embodiment shown in Fig. 4D, reinfusion cannula 16 may have a diameter that can be relatively larger than that of suction cannula 10. To that

end, reinfusion cannula 16 can accommodate suction cannula 10 within pathway 162 of the reinfusion cannula 16, and allow suction cannula 10 to extend from within pathway 162, such that the distal end 11 of suction cannula 10 may be positioned in spaced relations relative to the distal end 161 of reinfusion cannula 16. The spaced relations between distal end 161 and distal end 11 allows filtered fluid to be introduced to the reinfusion site away from the site of interest, where the removal of the undesirable material may be occurring.

[00061] In another embodiment, reinfusion cannula 16 and suction cannula 10 can be integrated into a single multi-lumen suction-reinfusion cannula 46, as shown in Fig. 4E. In the embodiment shown in Fig. 4E, multi-lumen cannula 46 may include a distal suction port 461 through which undesirable material from the site of interest can be removed, and a proximal reinfusion port 462 through which cleansed or filtered fluid may be reinfused back into the body. The spaced relations between the suction port 461 and reinfusion port 462 allows filtered fluid to be introduced to the reinfusion site away from the site of interest where the removal of the undesirable material may be occurring.

[00062] In an embodiment, the size of the reinfusion cannula, whether independent from the suction cannula, part of a multi-lumen introducer sheath, part of a multi-lumen combined suction-reinfusion cannula, or in concentric alignment with the suction cannula, may be designed so that it can handle a relatively rapid reinfusion of large volumes of fluid by pump 15.

[00063] With reference now to Fig. 6, system 1 may also include a reservoir 61. Reservoir 61, in one embodiment, may be situated in fluid communication between filter device 14 and pump 15, and may act to transiently collect fluid filtered from the site of interest, prior to the filtered fluid being directed into reinfusion cannula 16. By providing a place to transiently collect fluid, reservoir 61 can allow the rate of suctioning (i.e., draining, aspirating) to be separated from rate of reinfusing. Typically, the rate of reinfusion occurs at substantially the same rate of suctioning, as the volume of fluid suctioned from the site of interest gets immediately directed along the system 1 and introduced right back to the reinfusion site in a patient. However, the availability of a volume of transiently collected fluid in reservoir 61 now provides a source from which the amount or volume of fluid being reinfused back into the

patient can be adjusted, for example, to be less than that being suctioned from the site of interest, as well as the rate at which fluid can be reinfused back into the patient, for example, at a relatively slower rate in comparison to the rate of suctioning. Of course, if so desired or necessary, the reinfusion rate and volume can be adjusted to be higher, relative to the rate and volume of suction.

[00064] In accordance with one embodiment of the present invention, reservoir 61 may be a closed or an open container, and may be made from a biocompatible material. In an embodiment where reservoir 61 may be a closed container, system 1, likewise, will be a closed system. As a result, pump 15 may be used as both a suction source and a driving force to move fluid from the site of interest to the reinfusion site. In such an embodiment, pump 15 can generate a suction force independently of or alternately with a driving force to allow reservoir 61 collect filtered fluid from filter device 14. In one embodiment, pump 15 may be provided with a gauge in order to measure a rate of flow of the fluid being reinfused.

[00065] Alternatively, where reservoir 61 may be an open container, reservoir 61, in such an embodiment, may be designed to accommodate both a volume of fluid, typically at the bottom of reservoir 61, and a volume of air, typically at the top of reservoir 61, to provide an air-fluid interface within reservoir 61. As a result, using pump 15 in fluid communication with reservoir 61 may not provide the needed driving force and/or suction force to adequately remove the undesirable material and to subsequent reinfuse fluid back into a patient. To address this, system 1, in an embodiment, may include a separate and independent vacuum source, in fluid communication with the volume of air at the top of reservoir 61, for providing the necessary suction force from the top area of reservoir 61 where air exists, through filter device 14, through the distal end 11 of cannula 10, and to the site of interest. A port provided above the fluid level within reservoir 61 may be provided to allow the independent vacuum source to be in fluid communication with the volume of air within reservoir 61. Pump 15, on the other hand, may be in fluid communication with the volume of fluid within reservoir 61, and may act to generate the necessary driving force for reinfusion purposes.

[00066] It should be appreciated that although shown as separate components, to the extent desired, reservoir 61 and filter device 14 may be combined as a single unit.

[00067] Still referring to Fig. 6, system 1 may further include a second filter device 62 positioned in fluid communication between pump 15 and reinfusion cannula 16. Second filter device 62 may act to remove any debris or material (e.g., ranging from smaller than microscopic in size to relatively larger) that may have escaped and moved downstream from filter device 14, so that the fluid may be substantially cleansed prior to reinfusion. In an embodiment, second filter device 62 may include a porous membrane 63 whose pores may be measurably smaller than that in filter device 14, but still capable of allowing fluid to flow therethrough.

[00068] Since fluid such as blood needs to be filtered through system 1, it should be noted that system 1 and its components may be made from a biocompatible material to minimize any adverse reaction when fluid removed from the site of interest gets reinfused back into the body.

[00069] In operation, system 1 of the present invention may be introduced into the vasculature, preferably through a peripheral blood vessel, to remove undesirable material, such as a clot, emboli, or thrombi, substantially *en bloc* and without significant fragmentation, and subsequently reinfusing fluid removed from the site of interest back into a patient. In particular, system 1 and its components disclosed above can collectively form a substantially closed circuit through which fluid and an undesirable material from a site of interest can be removed by suction, cleared of the undesirable material, filtered to remove any additional debris, and actively introduced back into a patient at a reinfusion site.

[00070] With reference now to Fig. 7, there is shown one embodiment of the system of the present invention being utilized for removal of an undesirable material within a patient 700. System 70, as illustrated, includes a suction cannula 71, filter device 72, pump 73, second filter device 74 and reinfusion cannula 75. It should be appreciated that depending on the procedure and to the extent desired, system 70 may not need all of the components shown, or may need other components in addition to those shown.

[00071] In general the method of the present invention, in one embodiment, includes, initially accessing a first blood vessel 701 either by surgical dissection or percutaneously with, for instance, a needle and guide wire. The first blood vessel through which suction cannula 71 may be inserted into patient 700 can be, in an embodiment, any blood vessel that can be accessed percutaneously or by surgical

dissection such as femoral vein, femoral artery or jugular vein. Next, suction cannula 71 may be inserted into the first blood vessel 701 over the guide wire, and advanced toward a site of interest 702, for instance, in a second vessel or a heart chamber 703 where an undesirable material 706 may be residing. The second blood vessel or heart chamber, in an embodiment, can be the main pulmonary artery, branch pulmonary arteries, inferior vena cavae, superior vena cavae, deep veins of the pelvic, legs, arms or neck, aorta, or any other medium to large blood vessel for which the use of a cannula is suitable for removing undesirable material without causing undesirable damage to the blood vessel. In addition, the advancement of suction cannula 71 may be gauged or documented by fluoroscopic angiography, echocardiography or other suitable imaging modality.

[00072] In the case of pulmonary embolism, the suction cannula 71 may normally be introduced through the femoral, jugular or subclavian vein. Alternatively, the suction cannula 71 may be introduced, if desired, directly into the cardiac chambers using a minimally invasive surgical or endoscopic, thoracoscopic, or pericardioscopic approach.

[00073] Thereafter, a third blood vessel 704 may be accessed either by surgical dissection or percutaneously with, for example, a needle and guide wire. Subsequently, reinfusion cannula 75 may be inserted into the third blood vessel 703 using an open or over the guide wire technique. The third blood vessel through which the reinfusion cannula 75 may be inserted, in one embodiment, can be any large vein, such as the femoral vein or jugular vein. Reinfusion cannula 75 may then be advanced toward a reinfusion site, for example, within a fourth blood vessel 705. The fourth blood vessel, in one embodiment, can be the femoral vein, iliac vein, inferior vena cava, superior vena cava or right atrium.

[00074] Once reinfusion cannula 75 is in place and components of system 70 have connected, pump 73 may be activated, and suction cannula 71 may then be placed against and in substantial engagement with the undesirable material 706 at the site of interest 702 for removal by suctioning through the suction cannula 71. The undesirable material 706 and circulatory fluid removed from the site of interest 702 may thereafter be directed along suction cannula 71 into filter device 72 where the undesirable material 706 can be entrapped and removed from the fluid flow. The

resulting filtered fluid may next be directed downstream by way of pump 73 into the second filter device 74, where any debris or material (e.g., ranging from smaller than microscopic in size to relatively larger) that may have escaped and moved downstream from filter device 74 can be further captured and removed from the fluid flow prior to reinfusion. The resulting cleansed fluid may then be directed into the reinfusion cannula 75 and introduced back into the patient 700.

[00075] It should be appreciated that in certain instances, prior to connecting the suction cannula 71 and the reinfusion cannula 75, system 70 may need to be primed with fluid to minimize or eliminate any air and/or air bubbles from the system prior to the initiation of suction and reinfusion. To that end, the suction cannula 71 and reinfusion cannula 75 can be primed separately with fluid or by allowing blood to backfill the cannulae after insertion. The remaining components of the system 70 including all tubing, the filter device 72, the pump 73 and any other components of system 70 may also need to be primed with fluid prior to connecting them to the cannulae. In one embodiment, this can be achieved by temporarily connecting these components in fluid communication with other as a closed circuit and infusing fluid through a port, similar to port 51 in Fig. 5, while providing another port through which air can be displaced. Once these components have been fully primed with fluid, the circuit can be detached and connected to the primed suction cannula 71 and reinfusion cannula 75 in the appropriate configuration. Examples of a priming fluid include crystalloid, colloid, autologous or heterologous blood, among others.

[00076] During operation, pump 73, in one embodiment, may remain activated so that suction and continuous reinfusion of blood can occur continuously for a desired duration or until the removal of the undesirable material has been confirmed, for instance, by visualizing the captured undesirable material in the filter device 72. Alternatively pump 73 can be activated intermittently in short pulses, either automatically or manually by an operator (e.g., surgeon, nurse or any operating room attendant), for a desired duration or until the removal of the undesirable material has been confirmed by visualization of the material within filter device 72.

[00077] It should be appreciated that since suction cannula 71 may be deployed within any vessel within patient 700, depending on the procedure, in addition to being placed substantially directly against the undesirable material at the site of interest, suction

cannula 71 may be deployed at a location distant from the site of interest where direct engagement with the undesirable material may not be possible or desired.

[00078] In a situation where the suction cannula 71 is positioned within a vessel exhibiting a venous flow and at a distant location from the undesirable material, it may be desirable to place the distal end of suction cannula 71 downstream of the undesirable material, so that the fluid flow can push the undesirable material from the site of interest into suction cannula 71 during suction. To the extent there may be some difficulties with suctioning the undesirable material from its location, if necessary, a catheter may be deployed through suction cannula 71 and to the site of interest, where the undesirable material may be dislodged location for subsequent removal.

[00079] On the other hand, when suction cannula 71 is positioned within a vessel exhibiting arterial flow and at a distant location from the undesirable material, it may be necessary to place the distal end of suction cannula 71 upstream of the undesirable material for the purposes of removal, even though the undesirable material must move against the fluid flow in order to enter into the suction cannula 71. In such a situation, since the fluid flow in the vessel tends to exert a pressure against the undesirable material at the site of interest, and thus may make the undesirable material difficult to remove, suction cannula 71 may include a flow occlusion mechanism, similar to balloon 33 shown in Fig. 3. When expanded radially, the mechanism can substantially occlude the vessel, such that pressure being exerted on the downstream material by the fluid flow can be lessened. By lessening the pressure on the undesirable material to be removed, the suction force being applied at the site of interest can act to remove the material more easily. Again, if necessary, a catheter may be deployed through suction cannula 71 and to the site of interest, where the undesirable material may be dislodged or drawn back into the cannula to facilitate its removal.

[00080] The method of the present invention may also utilize a fluid reservoir, similar to reservoir 61 shown in Fig. 6, in connection with system 70. Such a reservoir may be placed in fluid communication between filter device 72 and pump 73. The reservoir, in an embodiment, may be an independent reservoir or may be integrated with filter device 72 as a single unit, similar to that shown in Fig. 7. By utilizing a

reservoir, a volume of transiently collected fluid may be used to independently control the rate or volume of suctioning (i.e., draining, aspirating) and/or the rate or volume of reinfusion.

[00081] In an embodiment where the reservoir may be an open container, it should be appreciated that system 70 may not be a substantially closed system. As a result, rather than utilizing a pump that can generate both a suction and a driving force for a closed system, an independent vacuum device 76 may be employed to generate the necessary suction force, from the top of the reservoir where a volume of air exists, for removal of the undesirable material, while independent pump 73 may be employed to generate the necessary driving force, from the bottom of the reservoir where a volume of aspirated fluid exists, for reinfusion.

[00082] The method of the present invention may also utilize a suction cannula 71 with a deployable funnel tip, similar to funnel 20 in Fig. 2 or in Fig. 3. In such an embodiment, the funnel may be deployed after suction cannula 71 has been positioned adjacent the site of interest. Thereafter, once the suction force has been activated, the funnel may be advanced to engage the undesirable material for removal. The funnel may remain deployed while the suction force is activated, and through multiple cycles, if necessary, until the undesirable material can be removed. Subsequently, the funnel may be retracted in order to reposition or remove suction cannula 71.

[00083] The method of the present invention may further utilize reinfusion cannula 75 that has been incorporated into an introducer sheath, such as sheath 43 as a multi-lumen cannula (Fig. 4C) or as one which concentrically aligns the suction cannula and reinfusion cannula (Fig. 4D). In this embodiment, the sheath/reinfusion cannula 75 may initially be inserted into a first blood vessel. Suction cannula 71 may then be inserted into the introducer lumen of the sheath/reinfusion cannula 75, and the assembly advanced together to a site of interest in a second blood vessel or heart chamber.

[00084] The method of the present invention may also further utilize a combined multi-lumen suction/reinfusion cannula, similar to cannula 46 shown in Fig. 4E. In such an embodiment, the combined suction/reinfusion cannula may initially be inserted into a first blood vessel to a location where its distal suction lumen can be placed adjacent the site of interest within a second blood vessel, while its proximal

located reinfusion lumen can be positioned at an appropriately spaced location from the suction lumen.

[00085] The method of the present invention may, in an embodiment, be employed to remove a plurality of undesirable materials, for instance, within the same vessel or its branches, from multiple vessels within the same vascular bed (e.g. left and right pulmonary arteries), from different vascular beds (e.g. pulmonary artery and iliofemoral veins), or a combination thereof. In such an embodiment, after the first undesirable material has been removed, the suction force may be deactivated. The next undesirable material to be removed may then be located, for example, using an appropriate imaging modality. Suction cannula 71 may thereafter be advanced to the location of this second undesirable material, and the suction force reactivated as above until this second undesirable material may be removed. The cycle may be repeated until each undesirable material at the various identified locations has been removed. Once all undesirable material has been removed, an appropriate procedure to prevent the development of or migration of new material, such as placement of an inferior vena cava filter, may be performed.

[00086] The method of the present invention may also be employed in combination with a balloon embolectomy catheter or other devices suitable for dislodging clots or other undesirable material from a cannula or a vessel. For example, should an undesirable material be lodged within suction cannula 71, a balloon catheter can be inserted through, for instance, a side port, similar to port 51 in Fig. 5, of suction cannula 71 and advanced past the lodged undesirable material. The balloon catheter may subsequently be inflated distal to the undesirable material. Once inflated, the suction force may be activated and the inflated catheter withdrawn along the suction cannula 71 to dislodge the undesirable material its location of obstruction. In a situation where the undesirable material may be adherent to a vessel wall, or for some other reason cannot be dislodged by simply applying suction to the site of interest, the balloon catheter can be inserted through the side port of suction cannula 71, advanced past a distal end of cannula 71, and past the adherent undesirable material. The balloon catheter may then be inflated distal to the undesirable material. Once inflated, the suction force may be activated and the inflated catheter withdrawn along the

suction cannula 71. As it is withdrawn, the balloon catheter can act to drag the undesirable material into suction cannula 71.

[00087] The method of the present invention may further be employed in combination with a distal protection device (not shown), such as a netting device, designed to be positioned downstream of the undesirable material, when removal may be performed within a vessel having arterial flow. In particular, with suction cannula 71 positioned upstream of the undesirable material, the netting device may be inserted through a side port in suction cannula 71, advanced past the undesirable material to a downstream location. The netting device may then be deployed to an open position approximating the diameter of the vessel. The deployed netting device may then act to entrap any material that may be dislodged from the site of interest and pushed downstream by the fluid flow. In the absence of the netting device, a dislodged material may be pushed downstream and may be lodged in a more life threatening location.

[00088] It is evident from the above description that the systems, including the various components, and methods of the present invention can act to remove clots and other types of undesirable material from the circulation, particularly from medium to larger vessels and heart chambers. Important to achieving this includes the ability of the operator to perform substantially *en bloc* removal of the undesirable material without significant fragmentation from the site of interest. Such a protocol may only be achieved previously with invasive, open surgery. In addition, by providing a system with components to permit aspirated fluid from the site of interest to be reinfused back to the patient, the system of the present invention allows a sufficiently and relatively large suction cannula to be employed for the removal of a relatively large undesirable material 15 in substantially one piece, without fragmentation. Furthermore, by providing a definitive mechanical treatment to the problem, the systems and methods of the present invention provide an attractive alternative to treatments, such as thrombolysis, which may not be an option or may be ineffective for many patients, and which may carry a significant risk of major complications. As such, the systems and methods of the *p*resent invention now provide a significant contribution to the field of cardiovascular medicine and surgery, particularly thromboembolic disease.

[00089] Although references have been made in connection with surgical protocols, it should be appreciated that the systems and methods of the present invention may be adapted for use in connection with non-surgical protocols, and in connection with any vessel capable of permitting fluid flow therethrough and capable of being obstructed. For instance, the system of the present invention may be adapted for use in connection with clearing obstructed oil pipelines, water pipes, and air ducts, among others.

[00090] While the present invention has been described with reference to certain embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt to a particular situation, indication, material and composition of matter, process step or steps, without departing from the spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims appended hereto.

What is claimed is:

1. A system for removing an undesirable material from within a vessel, the system comprising:

a first cannula having a distal end and an opposing proximal end, the first cannula designed for maneuvering within a vessel to a site of interest, such that the undesirable material can be captured substantially *en bloc* through the distal end and removed along the first cannula away from the site;

a pump, in fluid communication with the proximal end of the first cannula, to provide a sufficient suction force for removing the undesirable material from the site of interest; and

a second cannula in fluid communication with the pump and being designed to have its distal end situated in spaced relation to the distal end of the first cannula, such that fluid removed from the site of interest by the first cannula can be directed along the second cannula and reinfused through the distal end of the second cannula.

2. A system as set forth in claim 1, wherein the first cannula is designed to remove the undesirable material from one of a medium size blood vessel, a large size blood vessel, or a heart chamber.

3. A system as set forth in claim 1, wherein the first cannula is designed to remove the undesirable material without substantial fragmentation.

4. A system as set forth in claim 1, wherein the distal end of the first cannula includes a diameter that is relatively larger than that of the proximal end of the first cannula.

5. A system as set forth in claim 4, wherein the distal end of the first cannula can occlude fluid flow adjacent the site of interest in order to enhance the suction force applied to the undesirable material.

6. A system as set forth in claim 1, wherein the distal end of the first cannula is deployable to expand from a first diameter to a relatively larger second diameter.

7. A system as set forth in claim 6, wherein the distal end of the first cannula is funnel shape.

8. A system as set forth in claim 6, wherein the distal end of the first cannula includes a mechanism for substantially occluding fluid flow adjacent the site of interest, in order to enhance suction force being applied to the undesirable material.

9. A system as set forth in claim 1, wherein the first cannula is made from a radioopaque material to permit visualization of the cannula for image guidance purposes.

10. A system as set forth in claim 1, wherein the first cannula is made from a material sufficiently pliable to permit maneuvering of the cannula within the vessel.

11. A system as set forth in claim 1, wherein the first cannula is made from a material sufficiently strong, so as to not collapse under suction.

12. A system as set forth in claim 1, wherein the first cannula is reinforced with to prevent kinking.

13. A system as set forth in claim 1, wherein the first cannula is constructed of a material including one of polyvinyl chloride, polyethylene, polypropylene, polyurethane, Pebax®, silicone, or a combination thereof.

14. A system as set forth in claim 1, wherein the first cannula includes a side port to permit introduction of other instruments or devices into the first cannula.

15. A system as set forth in claim 1, wherein the first cannula includes multiple lumens.

16. A system as set forth in claim 1, wherein the pump can simultaneously generate a negative pressure to create a suction force necessary to pull the undesirable material into the first cannula and a positive pressure to create a driving force necessary to reinfuse fluid through the second cannula.

17. A system as set forth in claim 1, wherein the pump can intermittently generate one of a negative pressure to create a suction force necessary to pull the undesirable material into the first cannula and a positive pressure to create a driving force necessary to reinfuse fluid through the second cannula.

18. A system as set forth in claim 1, wherein the second cannula is made from a material sufficiently pliable to permit maneuvering of the cannula within a vessel.

19. A system as set forth in claim 1, wherein the second cannula includes a side port to permit introduction of other instruments or devices into the second cannula.

20. A system as set forth in claim 1, wherein the second cannula includes multiple lumens.

21. A system as set forth in claim 1, wherein the second cannula and the first cannula are integral in an assembly and include respective distal ends that are in spaced relation relative to one another.

22. A system as set forth in claim 1, wherein the second cannula is integrated as part of an introducer sheath through which the first cannula can be advanced such that the respective distal ends of the second cannula and the first cannula are in spaced relation relative to one another.

23. A system as set forth in claim 1, further including a filter device in fluid communication with the first cannula for entrapping the undesirable material as it exits from the first cannula and removing it from the fluid flow.

24. A system as set forth in claim 23, wherein the filter device includes a permeable sheet capable of permitting fluid directed from the first cannula to flow therethrough, while impeding the undesirable material from flowing downstream within the system.

25. A system as set forth in claim 1, further including a reservoir in fluid communication with the filter device for collecting fluid being directed from the filter device and providing a source of fluid for reinfusion by the second cannula.

26. A system as set forth in claim 1, further including a reservoir and a filter device as an integral unit.

27. A system as set forth in claim 1, further including a second filter positioned in fluid communication between the pump and the second cannula for removing undesirable debris from the fluid flow prior to reinfusion by the second cannula.

28. A system as set forth in claim 1, wherein the undesirable material captured from the site of interest includes one of a clot, a thrombus, an embolus, a tumor, an infective vegetation, and a foreign body.

29. A system as set forth in claim 1, wherein the fluid removed from the site of interest includes blood.

30. A method for removing an undesirable material from within a vessel, the method comprising:

maneuvering a first cannula having a distal end and an opposing proximal end to a site of interest within a vessel in a patient, such that the distal end of the first cannula is positioned adjacent the undesirable material;

positioning a second cannula, in fluid communication with the first cannula, such that its distal end is situated in spaced relation to the distal end of the first cannula;

providing a suction force, through the distal end of the first cannula, to the site of interest, so as to remove the undesirable material *en bloc* from the site of interest through the distal end of the first cannula; and

reinfusing, through the distal end of the second cannula, any fluid removed along with the undesirable material to a location in spaced relation from the distal end of the first cannula.

31. A method as set forth in claim 30, wherein, in the step of maneuvering, the vessel includes one of a medium size blood vessel, a large size blood vessel, or a heart chamber.

32. A method as set forth in claim 30, wherein, in the step of maneuvering, the distal end of the first cannula includes a diameter that is relatively larger than that of the proximal end of the first cannula.

33. A method as set forth in claim 30, wherein the step of maneuvering includes substantially occluding fluid flow within the vessel adjacent the distal end of the first cannula, so as to enhance the suction force applied to the undesirable material.

34. A method as set forth in claim 33, wherein the step of occluding occurs within a vessel exhibiting venous circulation.

35. A method as set forth in claim 33, wherein the step of occluding occurs within a vessel exhibiting arterial circulation.

36. A method as set forth in claim 30, wherein the step of maneuvering includes expanding, at the site of interest, the distal end of the first cannula from a first diameter to a relatively larger second diameter.

37. A method as set forth in claim 30, wherein the step of positioning includes one of placing the distal end of the second cannula within the same vessel as that of the distal end of the first cannula, placing the distal end of the second cannula within a different vessel as that of the distal end of the first cannula, or placing the distal end of the second cannula in spaced relation to the distal end of the first cannula.

38. A method as set forth in claim 30, wherein the step of providing includes generating the suction force and a driving force for reinfusion from one source.

39. A method as set forth in claim 30, wherein the step of providing includes generating the suction force and a driving force for reinfusion from different sources.

40. A method as set forth in claim 30, wherein the step of providing includes removing the undesirable material without substantial fragmentation.

41. A method as set forth in claim 30, wherein the step of providing includes removing at least 10 cm^3 of the undesirable material without substantial fragmentation.

42. A method as set forth in claim 30, wherein the step of providing includes entrapping, downstream of the proximal end of the first cannula and towards a source for the suction force, the undesirable material so as to remove it from the fluid flow.

43. A method as set forth in claim 42, wherein in the step of entrapping includes permitting fluid flow to continue into the second cannula, while impeding movement of the undesirable material toward the second cannula.

44. A method as set forth in claim 42, further including capturing undesirable debris downstream of the entrapped undesirable material but before to the second cannula, so as to remove the debris from the fluid flow prior to reinfusing.

45. A method as set forth in claim 30, wherein the step of reinfusing includes collecting fluid directed from the proximal end of the first cannula and using the collected fluid as a source of fluid for reinfusion.

46. A method as set forth in claim 30, wherein prior to providing a suction force, the method includes priming the circuit with fluid to minimize presence unwanted air being introduced into the patient.

47. A method as set forth in claim 30, wherein the undesirable material being removed from the site of interest includes one of a clot, a thrombus, an embolus, a tumor, an infective vegetation, and a foreign body.

48. A method as set forth in claim 30, wherein, in the step of reinfusing, the fluid removed from the site of interest includes blood.

49. A method as set forth in claim 30, wherein the step of reinfusing includes introducing a sufficient amount of fluid back into the patient, so as to minimize fluid loss in the patient.

50. A method for removing an undesirable material from within a vessel, the method comprising:

identifying in a patient a site of interest within a vessel having an undesirable material to be removed therefrom;

maneuvering to the site of interest a pathway along which the undesirable material can be directed away from the site of interest;

applying a suction force through the pathway to the site of interest, such that a fluid flow is created into the pathway and that the undesirable material is pulled into the pathway and away from the site of interest;

entrapping the undesirable material after it has exited the pathway, so as to remove the material from the fluid flow; and

introducing the fluid flow back into the patient at a location in spaced relation to the site of interest, so as to minimize fluid loss in the patient.

51. An apparatus for removing an undesirable material from within a vessel, the apparatus comprising:

an elongated tube having a distal end through which an undesirable material can be captured, a pathway extending along the tube to provide a passage for transporting the undesirable material from the distal end, and a proximal end in opposing relations to the distal end through which the undesirable material can exit;

a funnel situated at the distal end of the tube, and designed for deployment between a collapsed closed position and an flared open position, so as to better engage and capture the undesirable material; and

a mechanism positioned about a distal portion of the tube, the mechanism, upon actuation, can deploy the funnel between the closed position and the open position.

52. An apparatus as set forth in claim 51, wherein the tube is made from a material sufficiently pliable to permit maneuvering of the cannula within the vessel.

53. An apparatus as set forth in claim 51, wherein the tube is made from a material sufficiently strong, so as to not collapse under suction.

54. An apparatus as set forth in claim 1, wherein the tube includes a side port to permit introduction of other instruments or devices into the first cannula.

55. An apparatus as set forth in claim 51, wherein the tube includes multiple lumens.

56. An apparatus as set forth in claim 51, wherein the funnel includes a plurality of strips, each pivotally coupled at one end to the distal end of the tube.

57. An apparatus as set forth in claim 56, wherein the funnel includes a substantially impermeable membrane extending across a space between adjacent strips.

58. An apparatus as set forth in claim 51, wherein the mechanism comprises:

a balloon positioned circumferentially about the tube at a location proximal to the funnel; and

an attachment mechanism attached at one end to the funnel and at an opposite end to the balloon, so that upon expansion of the balloon, the mechanism can pull on the funnel to deploy it into a flared open position.

59. An apparatus as set forth in claim 58, wherein the balloon is designed to also occlude the vessel within which the apparatus is situated upon expansion of the balloon.

60. An apparatus as set forth in claim 58, wherein the attachment mechanism includes one of a string, a rod, a chain, or other similar mechanisms.

61. An apparatus as set forth in claim 58, further including a jacket provided circumferentially about the distal end of the tube, and extending from the funnel to the balloon.

62. An apparatus as set forth in claim 61, wherein the jacket acts as the mechanism for deploying the funnel into a flared open position upon expansion of the balloon.

63. An apparatus as set forth in claim 61, wherein the jacket extends into the funnel and is attached to a base of the funnel, so as to act as a membrane defining the funnel.

64. An apparatus as set forth in claim 51, wherein the mechanism includes a sheath designed to slide toward and away from the distal end of the tube.

65. An apparatus as set forth in claim 64, wherein the sheath, when actuated to slide away from the distal end tube, exposes the funnel to permit the funnel to be deployed into the flared open position.

66. An apparatus as set forth in claim 64, wherein the sheath, when actuated to slide toward the distal end of the tube, covers up the funnel to permit the funnel to be deployed into a collapsed closed position.

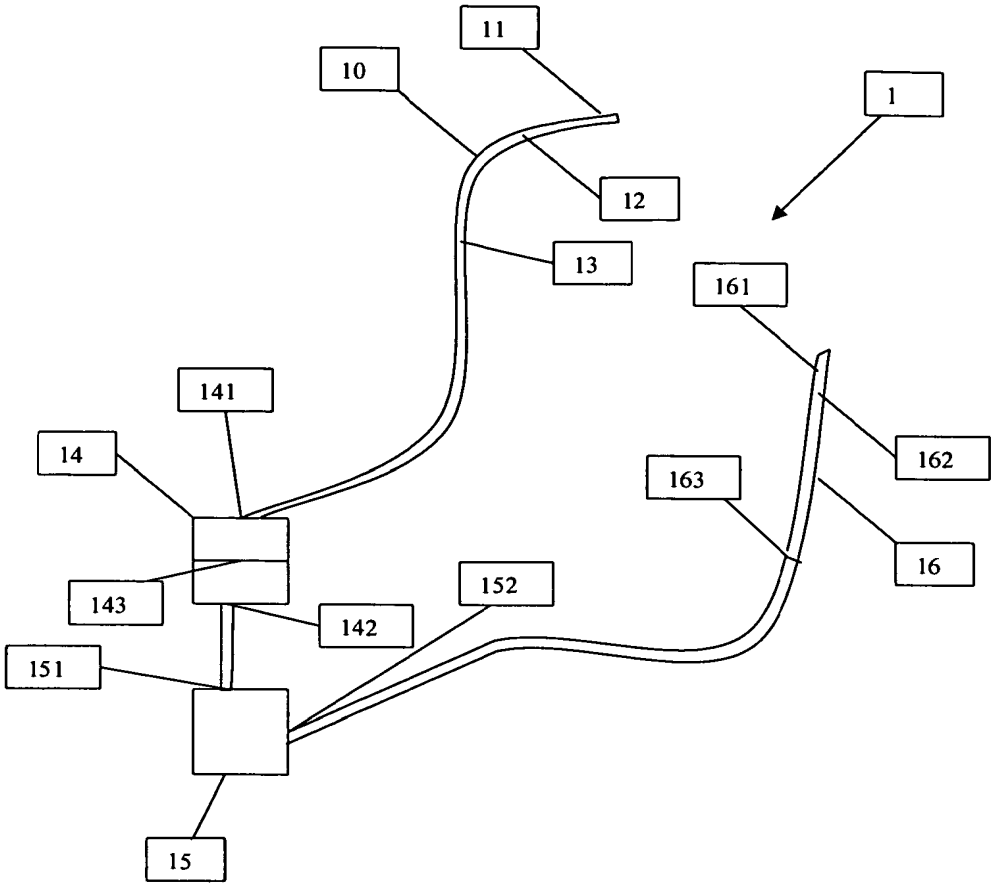


Fig. 1

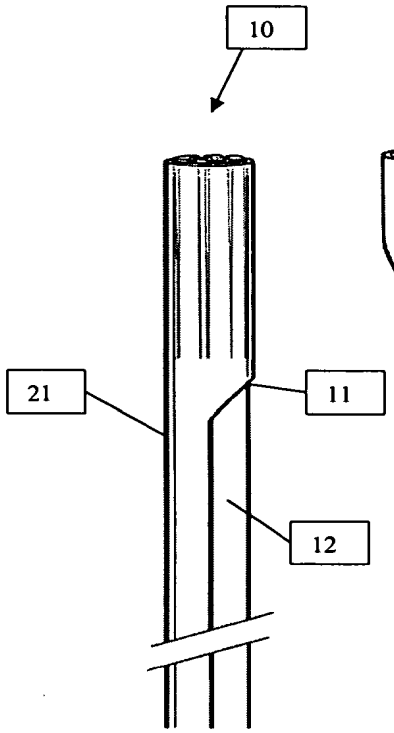


Fig. 2A

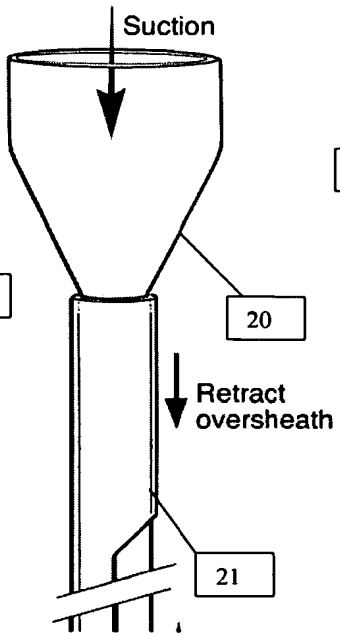


Fig. 2B

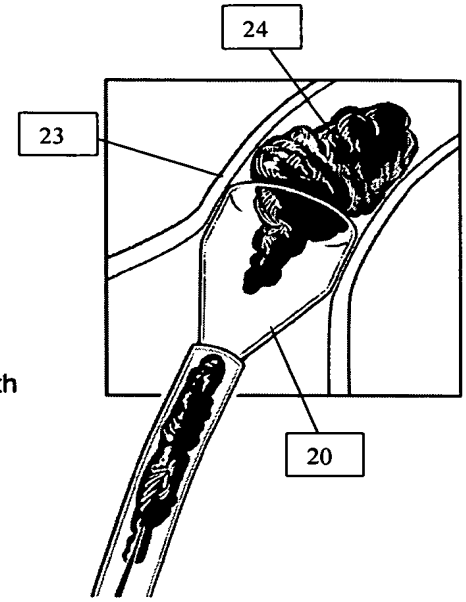


Fig. 2C

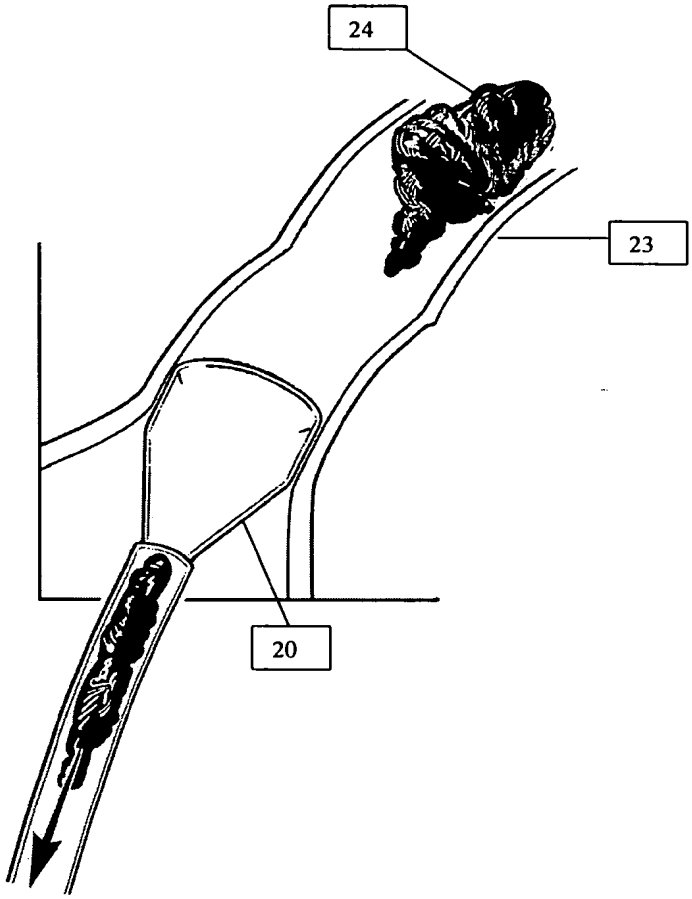


Fig. 2D

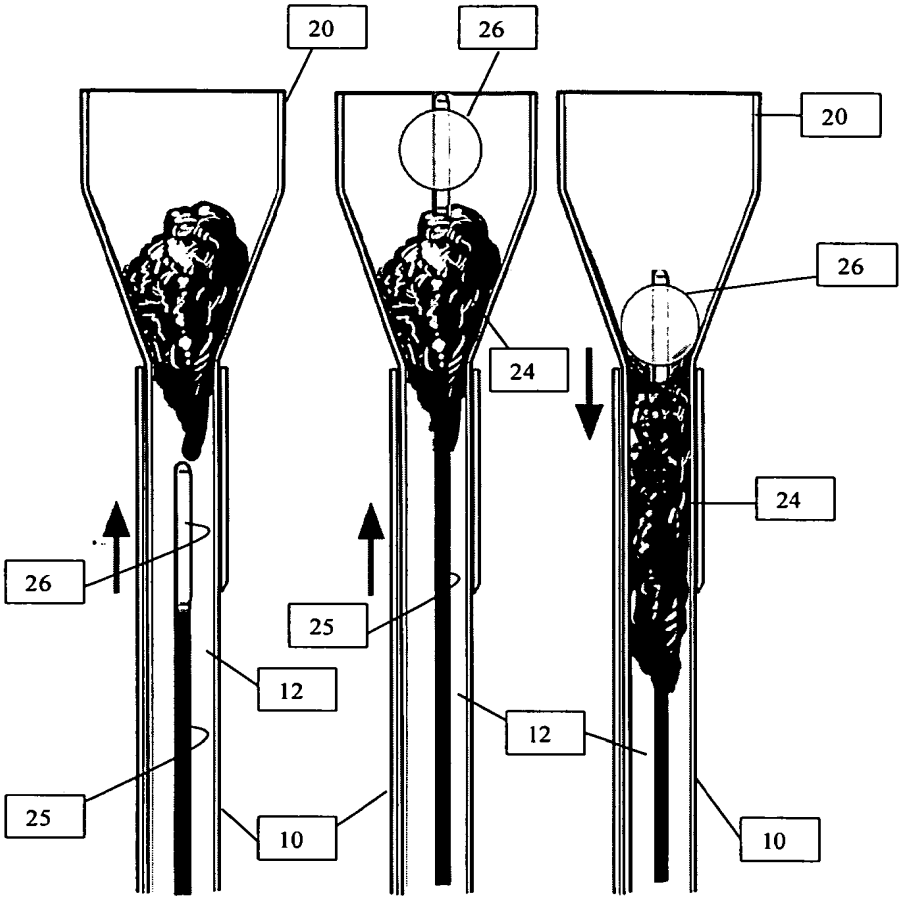


Fig. 2E Fig. 2F Fig. 2G

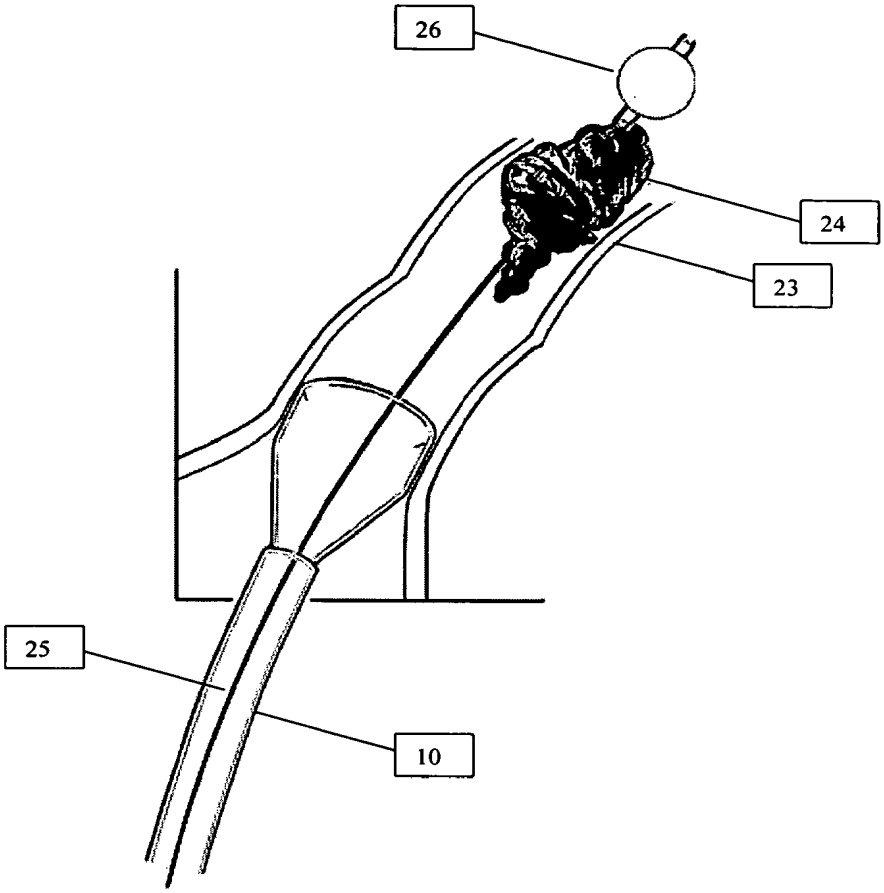


Fig. 2H

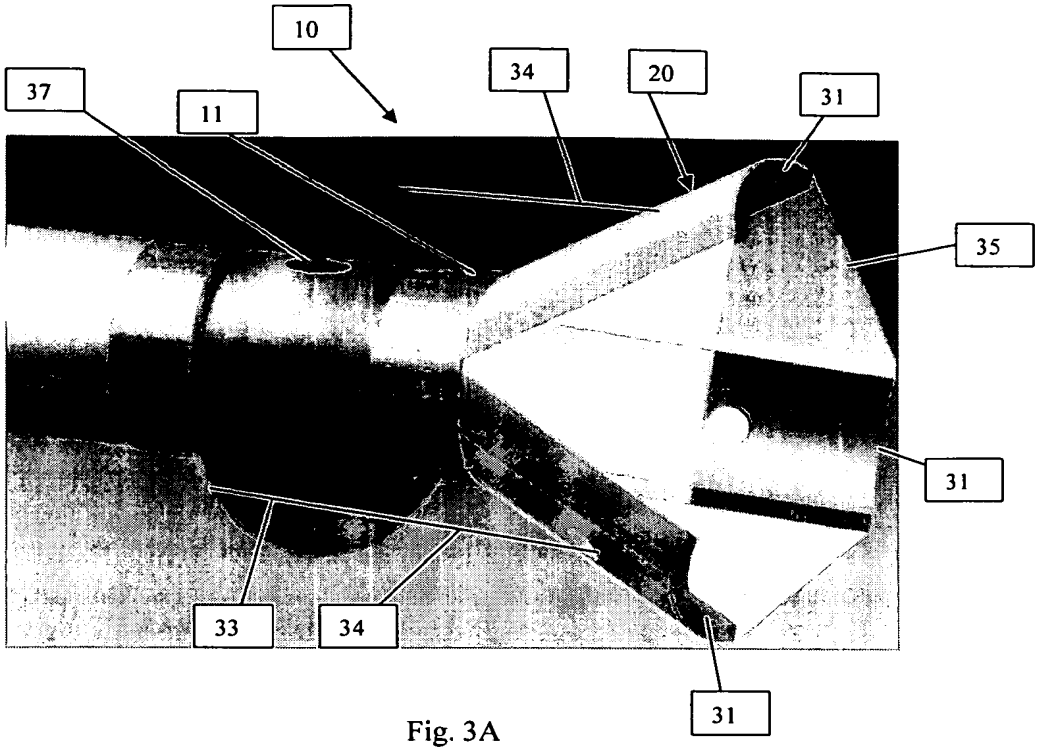


Fig. 3A

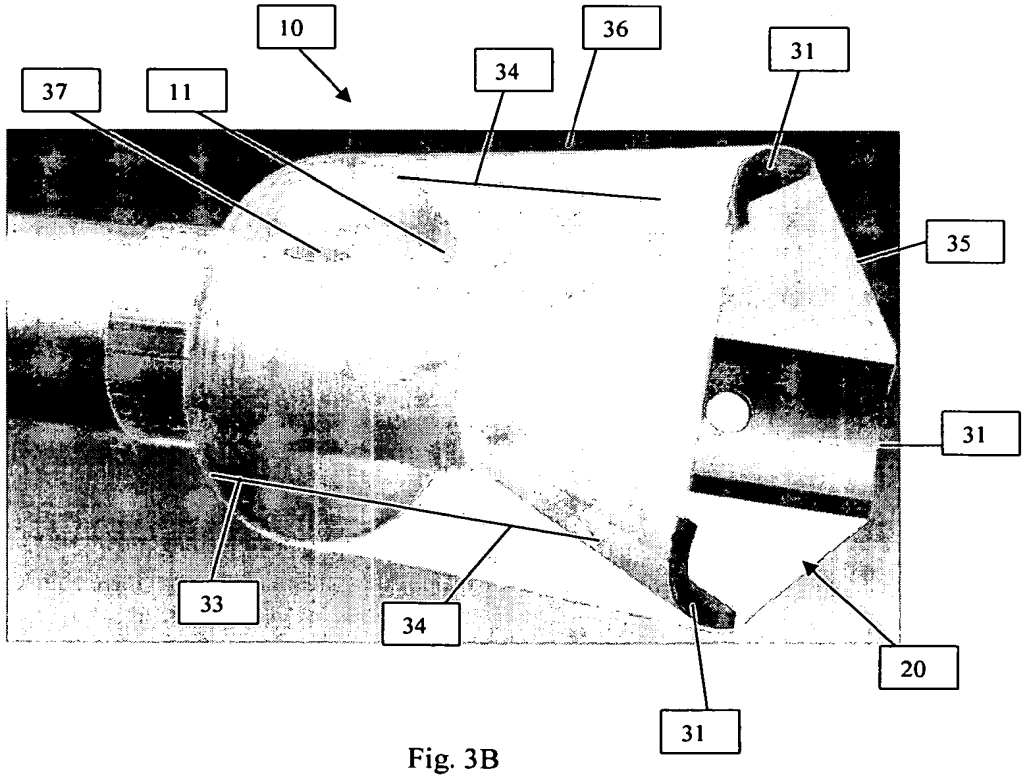


Fig. 3B

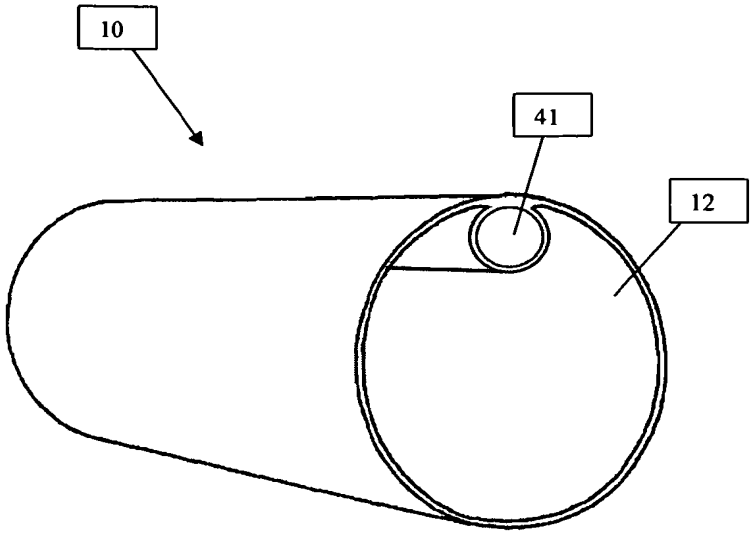


Fig. 4A

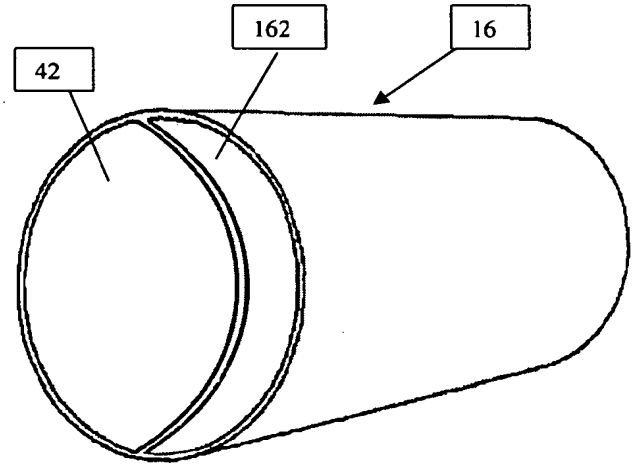


Fig. 4B

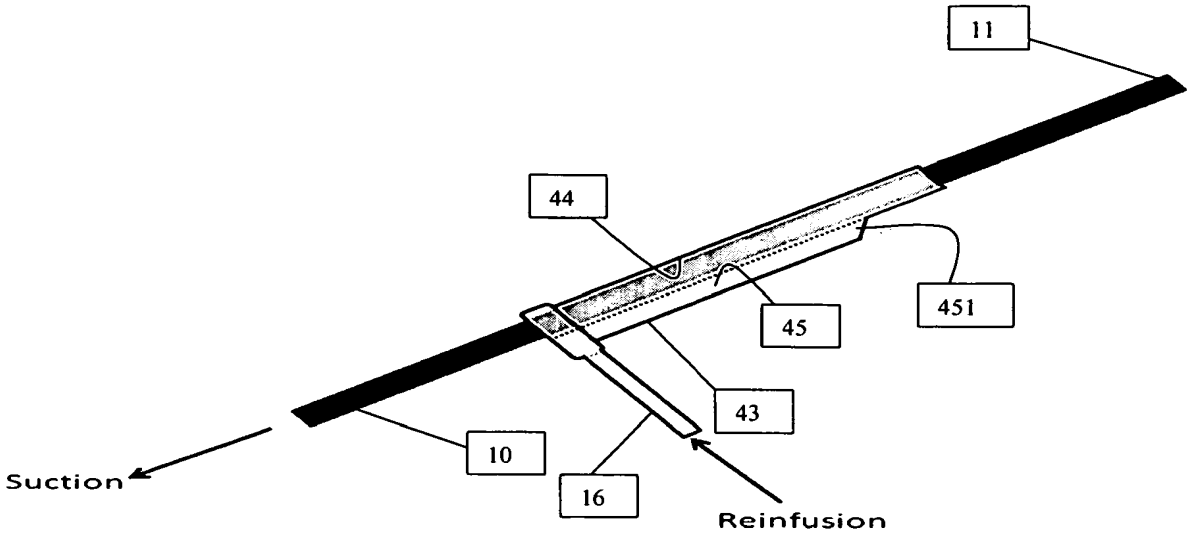

11
44
45
451
43
10
16
Suction
Reinfusion

Fig. 4C

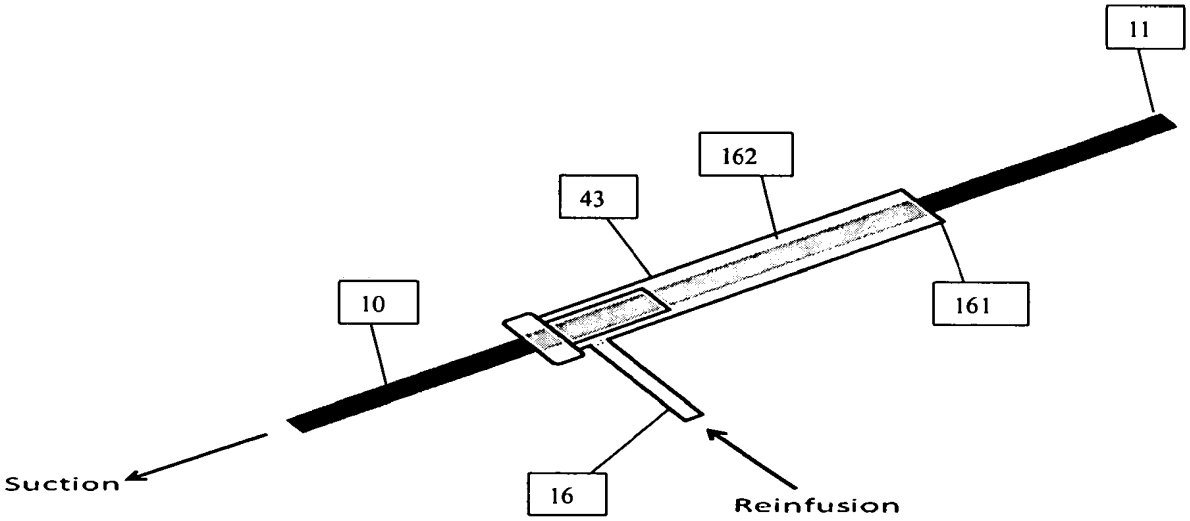

11
162
43
10
161
16
Suction
Reinfusion

Fig. 4D

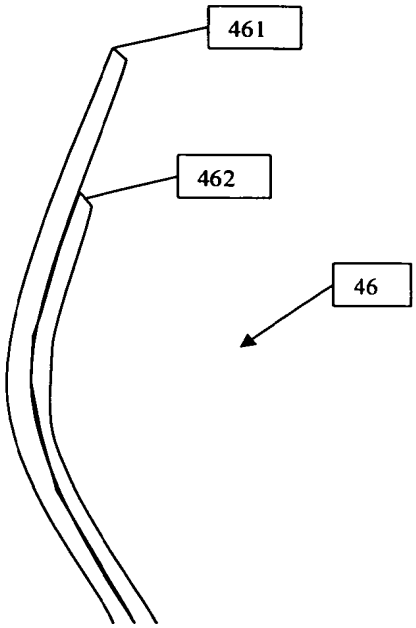


Fig. 4E

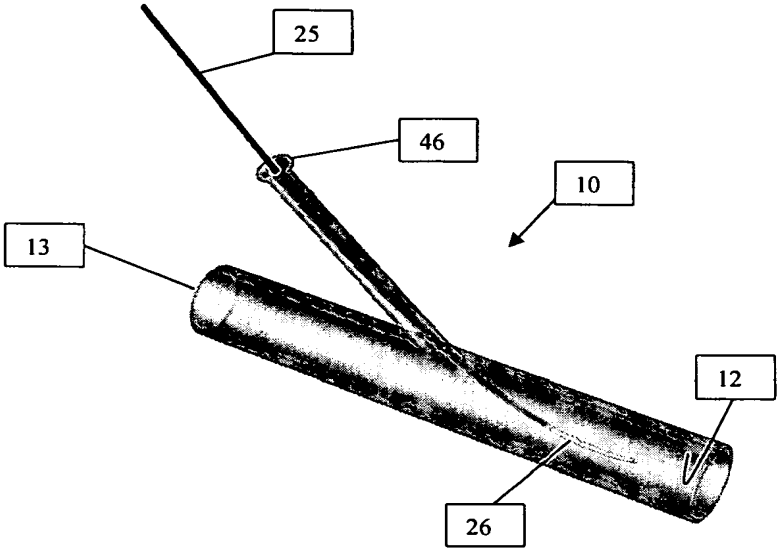


Fig. 5

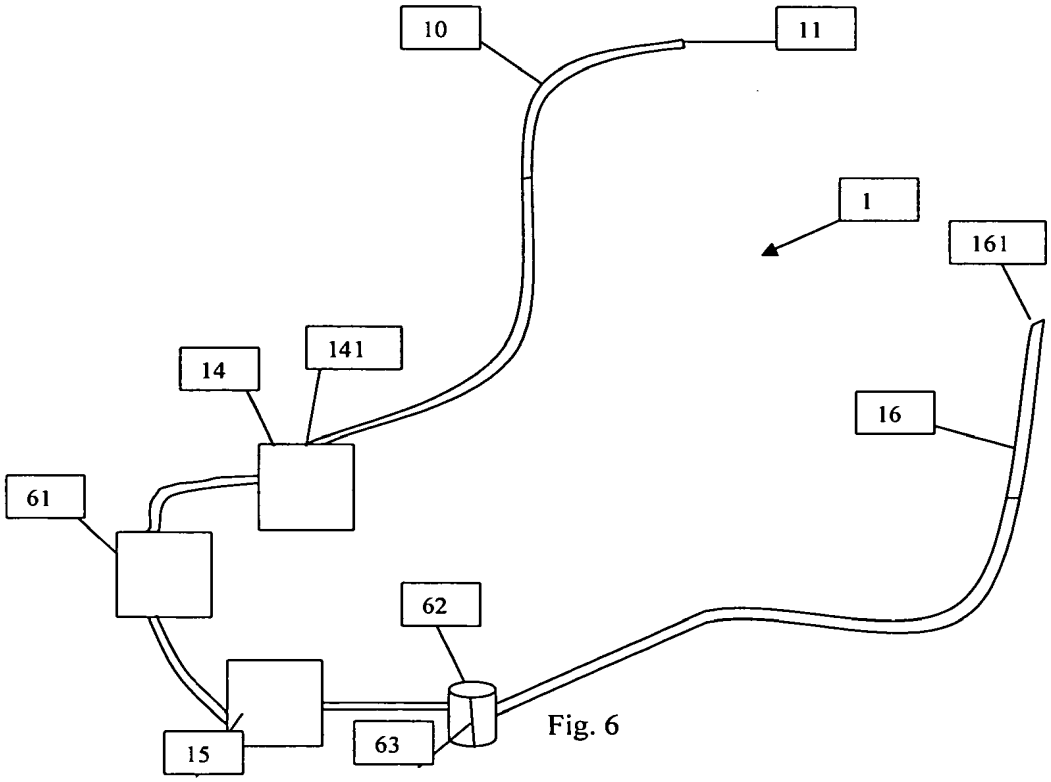


Fig. 6

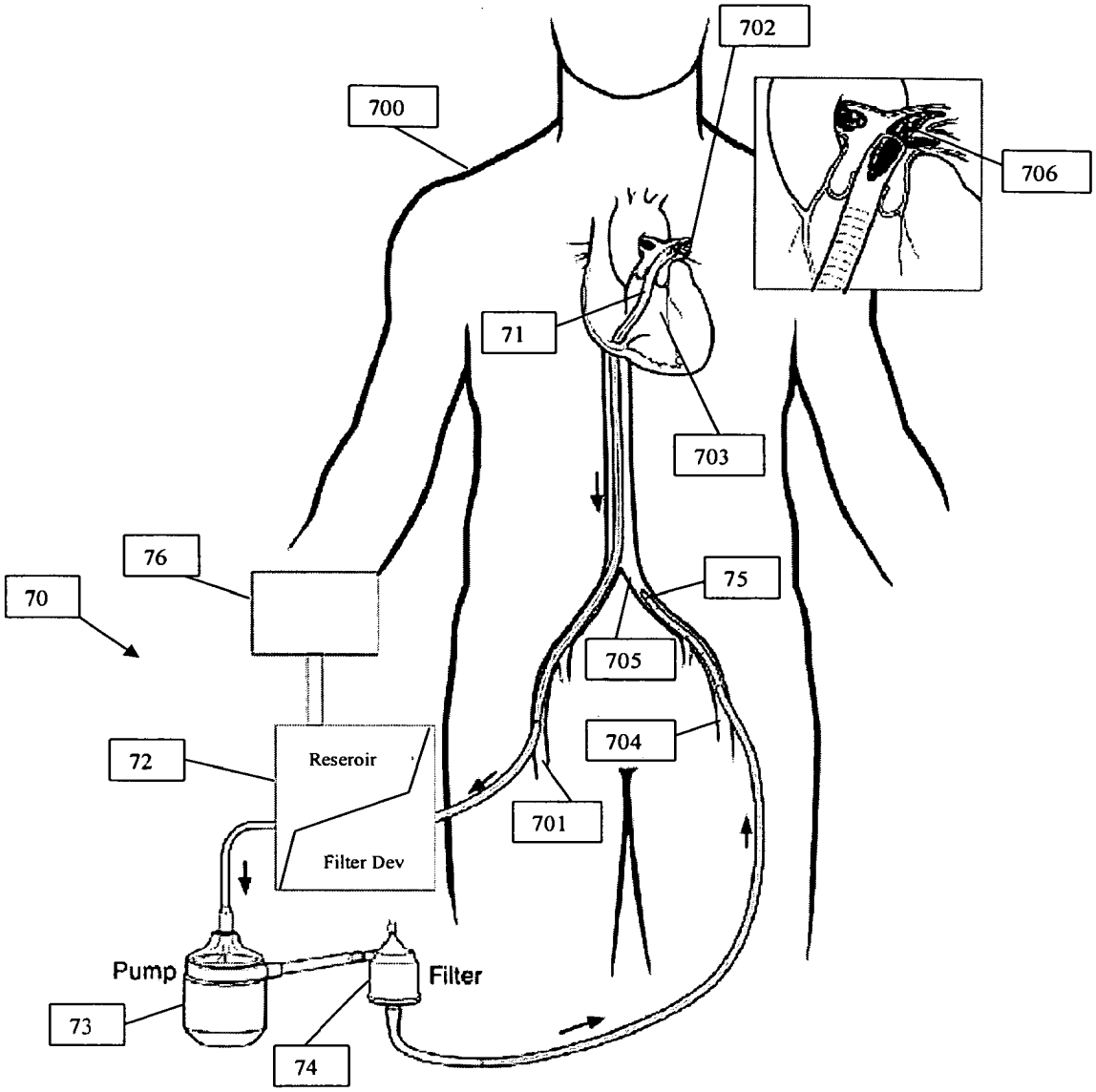

702
700
706
71
703
76
70
75
705
72
Reseroir
704
701
Filter Dev
Pump
Filter
73
74

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/72352

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 37/00 (2008.04)
USPC - 604/5.01
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)
USPC: 604/5.01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 604/5.01, 5.04, 6.09, 6.11, 6.16

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB,USPT,USOC,EPAB,JPAB), Freepatentsonline, Google Scholar
Search Terms: clot removal, suction, reinfusion, filter, balloon, occlude, reservoir, pump, vein, artery, heart, vacuum

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,719,717 B1 (Johnson et al.) 13 April 2004 (13.04.2004), entire document especially FIG. 2F, col. 1, line 51-54, 57 and 65-67; col. 2, line 6-7,19-34, 36-38, 43-45 and 48-54; col. 3, line 23-39, 42-45, 48-56, 61-64 and 66-67; col. 4, line 8-10 and 57-59; col. 5, line 10-18, 30-36, 48-52, 56-58 and 63-67; col. 6, line 2-5, 18-20 and 59-67 and col. 7, line 1-3	1-4, 6-7, 10-11, 14-21, 23-26, 28-32, 36-45, 47-55 and 64-66 --- 5, 8-9, 12-13, 22, 27, 33-35, 46 and 56-63
Y	US 5,188,618 A (Thomas) 23 February 1993 (23.02.1993), especially col. 3, line 22-25	5, 8 and 33-35
Y	US 5,158,533 A (Strauss et al.) 27 October 1992 (27.10.1992), especially col. 3, line 24-26, col. 4, line 23-25 and col. 8, line 53-66	12 and 46
Y	US 2001/0049486 A1 (Evans et al.) 06 December 2001 (06.12.2001), especially para [0012], [0031] and [0035]	22, 27 and 37
Y	US 2002/0165574 A1 (Reesemann et al.) 07 November 2002 (07.11.2007), especially para [0106], [0114], [0133], [0152] and [0156]	9, 13, 56-57
Y	US 2003/0093112 A1 (Addis) 15 May 2003 (15.05.2003), especially Fig. 4, para [0012], [0028] and [0029]	58-63
Y	US 6,905490 B2 (Parodi) 14 June 2005 (14.06.2005), especially Fig. 3C and col. 7, line 30-42	62-63

☐ Further documents are listed in the continuation of Box C. ☐

* 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 October 2008 (20.10.2008)	04 NOV 2008
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)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 February 2022 (10.02.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/032173 A1

(51) International Patent Classification:
A61M 5/32 (2006.01) *A61M 5/315* (2006.01)

(21) International Application Number:
PCT/US2021/045072

(22) International Filing Date:
06 August 2021 (06.08.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/061,902 06 August 2020 (06.08.2020) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventors; and
(71) Applicants: **RUGGLES, Kendall Anne** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US). **MERRITT, Benjamin Edward** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US). **STRAUSS, Brian Michael** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventors: **THRESS, John Coleman**; 9 Parker, Suite #100, Irvine, California 92618 (US). **HUNTER, Evan Stuart**; 9 Parker, Suite #100, Irvine, California 92618 (US). **ZIKRY, Christopher Andrew**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(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, IT, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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,

(54) **Title:** AUTOMATICALLY-LOCKING VACUUM SYRINGES, AND ASSOCIATED SYSTEMS AND METHODS

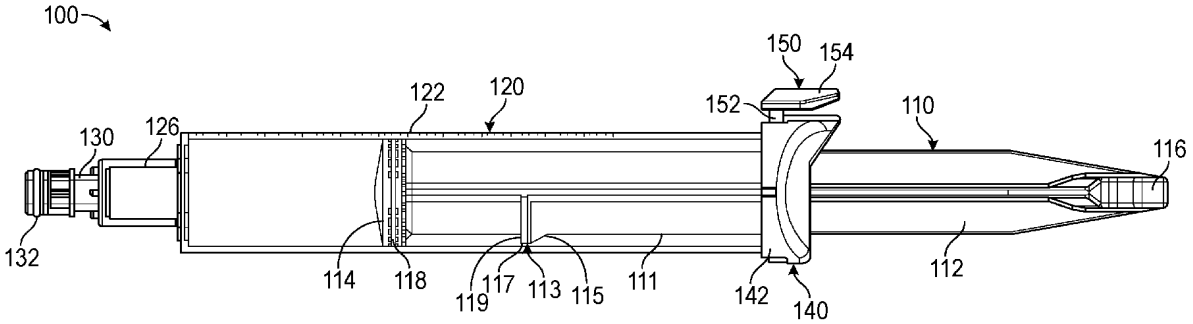


FIG. 1B

(57) **Abstract:** Automatically-locking syringes are disclosed herein. A syringe in accordance with embodiments of the present technology can include (i) a barrel, (ii) a plunger slidably positioned within the barrel, and (iii) a lock plate coupled to the barrel. The plunger also extends through an opening in the lock plate, and a biasing member is configured to bias the lock plate to a locking position. When the plunger is moved from a depressed position to a withdrawn position, the lock feature engages the lock plate to drive the lock plate away from the locking position to thereby permit the lock feature to pass through the opening in the lock plate. After the lock feature passes through the opening, the biasing member drives the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

[Continued on next page]

WO 2022/032173 A1

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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))*

AUTOMATICALLY-LOCKING VACUUM SYRINGES, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/061,902, filed August 6, 2020, and titled "AUTOMATICALLY-LOCKING VACUUM SYRINGES, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology relates generally to systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to automatically-locking syringes for generating and releasing stored vacuum pressure to aspirate clot material from a blood vessel.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long distance air travel, immobility) and clotting (e.g., cancer, recent surgery such as orthopedic surgery,). DVT can obstruct drainage of venous blood from the legs leading to swelling, ulcers, pain and infection. DVT can also create a reservoir in which blood clots can collect and then travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body. This can result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. Embolectomies, for example, are a surgical technique involving incising a blood vessel and placing a balloon-tipped device (such as the Fogarty catheter) at the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to withdraw the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and restenosis regularly occurs after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhaging, and in many patients the thrombolytic agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack the ability to be appropriately fixed against the vessel. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through

tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all the clot material.

[0010] Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0012] Figures 1A and 1B are an exploded isometric view and a side view, respectively, of a vacuum-pressure locking syringe in accordance with embodiments of the present technology.

[0013] Figures 2A and 2B are isometric views of the syringe of Figures 1A and 1B in a depressed position and a withdrawn position, respectively, in accordance with embodiments of the present technology.

[0014] Figure 3A is a side view, and Figures 3B and 3C are enlarged side views, of the syringe illustrating the steps of locking a plunger of the syringe to a lock member of the syringe in accordance with embodiments of the present technology.

[0015] Figure 4 is an enlarged isometric view of a portion of the syringe in accordance with additional embodiments of the present technology.

[0016] Figures 5A and 5B are an isometric view and a side view, respectively, of a syringe in a withdrawn position in accordance with additional embodiments of the present technology.

[0017] Figure 5C is an isometric of the syringe of Figures 5A and 5B in a depressed position in accordance with embodiments of the present technology.

[0018] Figure 6A is a side view of a vacuum-pressure locking syringe in accordance with additional embodiments of the present technology.

[0019] Figures 6B and 6C are enlarged side views of a locking mechanism of the syringe of Figure 6A in a first position and a second position, respectively, in accordance with embodiments of the present technology.

[0020] Figure 7 is a partially schematic side view of a clot treatment or clot removal system incorporating the syringe of Figures 1A–4, the syringe of Figures 5A–5C, and/or the syringe of Figures 6A–6C in accordance with embodiments of the present technology.

[0021] Figures 8A and 8B are enlarged, partially-schematic side views of a vacuum indicator of the clot removal system of Figure 7 in a vacuum-off position and a vacuum-on position, respectively, in accordance with embodiments of the present technology.

[0022] Figure 9 is a perspective view of a vacuum indicator in a vacuum-off position in accordance with additional embodiments of the present technology.

[0023] Figures 10A and 10B are perspective views of a vacuum indicator in a vacuum-off position and a vacuum-on position, respectively, in accordance with additional embodiments of the present technology.

[0024] Figure 11 is a side-view of the syringe of Figures 1A and 1B including a vacuum indicator in accordance with embodiments of the present technology.

[0025] Figures 12A and 12B are perspective views of a syringe including a vacuum indicator in accordance with additional embodiments of the present technology.

[0026] Figures 13A–13C are side views of a vacuum indicator in a vacuum-off position, a partial-vacuum position, and a full-vacuum position, respectively, in accordance with additional embodiments of the present technology.

[0027] Figures 14A and 14B are an isometric view and a top view of a syringe in accordance with additional embodiments of the present technology.

[0028] Figures 14C and 14D are enlarged side views of a vacuum indicator of the syringe of Figures 14A and 14B in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology.

[0029] Figures 14E and 14F are enlarged partially transparent side views of the vacuum indicator of Figures 14A–14D in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology.

[0030] Figure 14G is an enlarged side cross-sectional view of the vacuum indicator of Figures 14A–14F in the vacuum-off position in accordance with embodiments of the present technology.

[0031] Figures 15A and 15B are an isometric view and a side view of a syringe in accordance with additional embodiments of the present technology.

[0032] Figures 15C and 15D are enlarged side views of a vacuum indicator of the syringe of Figures 15A and 15B in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology.

[0033] Figures 15E and 15F are enlarged partially transparent side views of the vacuum indicator of Figures 15A–15D in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology.

[0034] Figure 15G is an enlarged side cross-sectional view of the vacuum indicator of Figures 15A–15F in the vacuum-off position in accordance with embodiments of the present technology.

[0035] Figure 16 is an enlarged side cross-sectional view of the vacuum indicator of Figures 15A–15G further including a biasing member in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0036] The present technology is generally directed to automatically-locking syringes, such as for use in clot removal systems for aspirating clot material from a blood vessel of a human patient. In some embodiments, an automatically-locking syringe can include (i) a barrel, (ii) a lock plate coupled to the barrel, and (iii) a plunger slidably positioned within the barrel and having a lock feature configured to engage the lock plate. The plunger also extends through an opening in the lock plate, and a biasing member is configured to bias the lock plate toward a locking position. When the plunger is moved through the barrel from a depressed position to a withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate away from the locking position to thereby permit the lock feature to pass through the opening in the lock plate. When the lock feature passes through the opening, the biasing member is configured to bias the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position. Accordingly, in one aspect of the present technology, the plunger is automatically locked in position via engagement of the lock plate with the lock feature when the plunger is withdrawn a selected distance.

[0037] In additional embodiments, an automatically-locking syringe can include (i) a barrel having a flange, (ii) a plunger slidably positioned within the barrel, and (iii) at least one lock

member coupled to the plunger. The lock member can include a body and a first arm hingedly coupled to the body. The first arm is configured to be biased at least partially outwardly away from a longitudinal axis of the plunger to a locking position. When the plunger is in a withdrawn position, the first arm can engage the flange of the barrel to inhibit movement of the plunger through the barrel from the withdrawn position to a depressed position. The syringe can further include an actuator that is movable between a first position and a second position. The actuator can include a second arm configured to engage the first arm in the second position to drive the first arm inwardly toward the longitudinal axis and away from the locking position. Accordingly, when the plunger is withdrawn, moving the actuator from the first position to the second position can drive the first arm radially inward away from the locking position to permit movement of the plunger through the barrel from the withdrawn position to the depressed position.

[0038] Specific details of several embodiments of the present technology are described herein with reference to Figures 1A–16. The present technology, however, may be practiced without some of these specific details. In some instances, well-known structures and techniques often associated with the disclosed syringes, clot removal systems, and the like have not been shown in detail so as not to obscure the present technology. The terminology used in the description presented below is intended to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain specific embodiments of the disclosure. Certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0039] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be arbitrarily enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles, and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles, and features without departing from the spirit or scope of the present technology.

[0040] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0041] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Vacuum-Pressure Locking Syringes

[0042] Figures 1A and 1B are an exploded isometric view and a side view, respectively, of a vacuum-pressure locking syringe ("syringe 100") in accordance with embodiments of the present technology. The syringe 100 is in a partially-withdrawn position in Figure 1B. Referring to Figures 1A and 1B together, the syringe 100 includes a plunger 110 slidably positioned within a barrel 120. The barrel 120 is shown as partially transparent in Figure 1B for clarity. The barrel 120 can include a barrel portion 122 (e.g., a cylindrical portion) extending between a flange 124 and a tip 126. In some embodiments, the barrel portion 122 can have a volume of about 60 cc or greater than 60 cc. The tip 126 is configured to be releasably or permanently coupled to an adaptor 130 (shown as partially transparent in Figures 1A and 1B). In some embodiments, the tip 126 can define a bore 128 having a size of about 26 French or greater. In the illustrated embodiment, the adaptor 130 is a Toomey-tip adaptor having a sealing member 132 (e.g., an O-ring) extending around an exterior surface thereof for sealingly engaging (e.g., connecting to) a Toomey fitting or Toomey adaptor. In other embodiments, the adaptor 130 can be omitted and the tip 126 of the barrel 120 can be directly coupled to another device or system (not shown), and/or the tip 126 can be another type of tip such as, for example, a Luer lock, Lock slip, and/or needle.

[0043] In the illustrated embodiment, the plunger 110 includes a shaft 112 extending between a flange 114 and a grip portion 116. The grip portion 116 is configured to be grasped by a user for withdrawing (e.g., retracting, pulling) and/or depressing (e.g., advancing, pushing) the plunger 110 through the barrel 120 during operation of the syringe 100. The plunger 110 can include a sealing member 118 positioned around the flange 114 and configured to sealingly engage an interior surface of the barrel portion 122 to define a sealed volume (e.g., of negative/vacuum

pressure) within the barrel 120. The various components of the syringe 100 can comprise metal, plastic, and/or other suitable materials.

[0044] As best seen in Figure 1B, the shaft 112 of the plunger 110 includes a lower edge or surface 111 and a lock feature 113 extending/protruding from the lower surface 111. In the illustrated embodiment, the lock feature 113 includes (i) a ramp portion 115, (ii) a plateau portion 117 extending from the ramp portion 115, and (iii) a stop surface 119 extending from the plateau portion 117. The ramp portion 115 can extend/slope at angle relative to the lower surface 111 in a direction (i) away from the lower surface 111 and (ii) toward the flange 114 of the plunger 110. The plateau portion 117 can extend away from the ramp portion 115 in a direction toward the flange 114 and generally parallel to the lower surface 111. The stop surface 119 can extend away from the plateau portion 117 in a direction generally perpendicular to the plateau portion 117 and the lower surface 111. In some embodiments, the lock feature 113 can be a tab, flat face, half disc, and/or other feature extending from the lower surface 111 of the shaft 112.

[0045] In the illustrated embodiment, the syringe 100 further includes a base 140 and a lock member 150 operably coupled to the base 140. In some embodiments, the base 140 can be coupled to the flange 124 of the barrel 120. Accordingly, the base 140 can couple the lock member 150 to the barrel 120. The base 140 can include a body 142 having an opening 143 extending therethrough and configured to slidably receive the shaft 112 of the plunger 110. The lock member 150 can include a lock plate 152 coupled to a button portion 154. The lock plate 152 can include an opening 153 (i) extending therethrough, (ii) defined by an edge portion 156, and (iii) configured to slidably receive the shaft 112 of the plunger 110. In some embodiments, the lock member 150 can be movably coupled to the base 140 via, for example, a biasing member (e.g., an arm 358 illustrated in Figures 3B and 3C, springs 460 illustrated in Figure 4, and/or another type of biasing member). As described in greater detail below with reference to Figures 3A–4, the lock plate 152 is configured to engage the lock feature 113 of the plunger 110 when the plunger 110 is withdrawn to a selected position to lock the plunger 110 in the selected position. The selected position can correspond to a pre-selected vacuum volume of the barrel 120. The button portion 154 is actuatable (e.g., depressible) by a user to release the lock plate 152 from the lock feature 113 to release the plunger 110 to, for example, permit the plunger 110 to move through the barrel 120 to expel any contents (e.g., bodily fluids such as blood and clot material) collected in the barrel 120 from the tip 126.

[0046] Figures 2A and 2B are isometric views of the syringe 100 in a depressed position (e.g., a first position, an emptied positioned, zero-vacuum position) and a withdrawn position (e.g., a second position, a vacuum-storage position, a vacuum-generation position, full-vacuum position), respectively, in accordance with embodiments of the present technology. The barrel 120 is shown as partially transparent in Figures 2A and 2B for clarity. Referring to Figures 2A and 2B together, in general, a user can move the syringe 100 from the depressed position to the withdrawn position by pulling the grip portion 116 of the plunger 110 in the direction of arrow A (Figure 2A) relative to the barrel 120 to withdraw the plunger 110 through the barrel 120, the base 140, and the lock member 150. In some embodiments, withdrawing the plunger 110 can charge a vacuum (e.g., generate negative pressure) within the barrel 120. Moreover, the lock plate 152 of the lock member 150 can engage the lock feature 113 (obscured in Figure 2B) of the plunger 110 when the plunger 110 is withdrawn past the lock plate 152 to automatically lock the plunger 110 in the withdrawn position. To move the syringe 100 from the withdrawn position to the depressed position, the user can (i) actuate the button portion 154 of the lock member 150 (e.g., depress the button portion 154 in the direction of arrow B in Figure 2B) to disengage the lock plate 152 from the lock feature 113 to unlock the plunger 110 from the lock member 150 and then (ii) push the plunger 110 in the direction of arrow C (Figure 2B) relative to the barrel 120.

[0047] Figure 3A is a side view, and Figures 3B and 3C are enlarged side views, of the syringe 100 illustrating the process of locking the plunger 110 to the lock member 150 in accordance with embodiments of the present technology. The syringe 100 is in a partially-withdrawn position in Figures 3A and 3B. More specifically, Figures 3A and 3B illustrate the syringe 100 as the lock feature 113 passes through the opening 153 (Figure 1A) in the lock member 150 during withdrawal of the plunger 110 from the depressed position to the withdrawn position. Figure 3C illustrates the syringe 100 after the lock feature 113 has been withdrawn through the opening 153 past the lock plate 152. The barrel 120 is shown as partially transparent in Figures 3A–3C, and the base 140 is shown as partially transparent in Figures 3B and 3C for clarity.

[0048] Referring to first to Figures 3B and 3C together, the lock member 150 further includes an arm 358 (e.g., a biasing member) operably coupling the lock member 150 to the base 140. In the illustrated embodiment, for example, the arm 358 projects away from (e.g., perpendicular) to the lock plate 152 and presses against (e.g., engages, attaches to) the base 140. The arm 358 can be a spring arm, living hinge, lever arm, or other member that is (i) hingedly/movably coupled to the lock member 150 and (ii) configured to bias the lock plate 152

upward to a locking position (e.g., a first position) as shown in Figures 3C and 1B (e.g., in an upward direction indicated by arrow D in Figure 3C). As the lock feature 113 is withdrawn past the lock plate 152, the lock feature 113 can engage the lock plate 152 and drive the lock plate 152 against the biasing force of the arm 358 away from the locking position (e.g., toward a second position) as shown in Figure 3B (e.g., in a downward direction indicated by arrow E in Figure 3B).

[0049] More specifically, referring to Figures 3A and 3B together, as the plunger 110 is withdrawn toward the lock member 150 in the direction of the arrow A, the ramp portion 115 of the lock feature 113 first engages the edge portion 156 (Figure 1A) of the lock plate 152 at a first side 357a of the lock plate 152 opposite a second side 357b. As the plunger is withdrawn farther, the angled ramp portion 115 drives the lock plate 152 (and the button portion 154) downward in the direction of the arrow E against the biasing force of the arm 358 (e.g., away from the locking position) until the lock plate 152 reaches the plateau portion 117 of the lock feature 113. That is, the ramp portion 115 of the lock feature 113 translates the longitudinal force of the plunger 110 into radial movement of the lock plate 152. Continued withdrawal of the plunger 110 slides the lock plate 152 over/against the plateau portion 117 until the lock feature 113 reaches the stop surface 119. Referring to Figure 3C, when the lock plate 152 passes the end of the plateau portion 117, the arm 358 can drive the lock plate 152 upward in the direction of arrow D to the locking position. The plunger 110 is then inhibited from moving/advancing past the lock plate 152 toward the depressed position (e.g., in the direction of the arrow C shown in Figure 2B). Specifically, the second side 357b of the lock plate 152 can engage/contact the stop surface 119 of the lock feature 113 to inhibit advancement of the plunger 110. In other embodiments, the lock feature 113 and/or the lock plate 152 can have different configurations/arrangements that facilitate locking of the plunger 110 in the withdrawn position. For example, in some embodiments the plateau portion 117 of the lock feature 113 can be omitted.

[0050] To unlock the plunger 110 from the lock member 150, the user can actuate the button portion 154 of the lock member 150 by, for example, pressing the button portion 154 downward in the direction of arrow E. The movement of the button portion 154 drives the lock plate 152 downward relative to the lock feature 113 until the edge portion 156 (Figure 1A) of the lock plate 152 fully passes the stop surface 119 of lock feature 113, thereby permitting movement of the lock feature 113 through the opening 153 (Figure 1A) of the lock plate 152. The user can then advance the plunger 110 through the barrel 120 to expel any contents collected in the barrel 120.

[0051] Accordingly, in one aspect of the present technology, the plunger 110 is automatically locked in position—via the lock plate 152 and lock feature 113—when the plunger 110 is withdrawn a selected distance. In contrast, many conventional locking syringes require the user to rotate the plunger relative to the barrel to facilitate locking of the plunger. Such rotation can be difficult when the syringe has a large volume—for example, 60 cc or greater—and thus requires a relatively significant retraction force to withdraw the plunger. Therefore, the syringe 100 of the present technology has improved usability compared to conventional locking syringes, especially during procedures that require multiple withdrawals of the plunger 110 over the course of the procedure. In some embodiments, the lock member 150 and the lock feature 113 can be configured (e.g., shaped, positioned) such that the syringe 100 automatically locks at a selected position corresponding to a selected volume of the barrel 120. In some embodiments, the selected volume can be about 60 cc or greater.

[0052] In another aspect of the present technology, the syringe 100 is lockable at only a single position. This can be particularly useful where the syringe 100 is used in procedures in which a single operational volume is preselected/desired, such as during a clot removal procedure that includes aspirating clot material from a vessel, as described in greater detail below with reference to Figure 6.

[0053] Figure 4 is an enlarged isometric view of a portion of the syringe 100 in accordance with additional embodiments of the present technology. The barrel 120 is shown as partially transparent in Figure 4 for clarity. In the illustrated embodiment, the lock plate 152 of the lock member 150 is operably coupled to the base 140 via a pair of springs 460 (only one of the springs 460 is visible in Figure 4). The springs 460 are configured to bias the lock plate 152 to the first position shown in Figures 4 and 1B, and can replace or supplement the arm 358 described in detail above with reference to Figures 3A–3C. More particularly, each of the springs 460 can be a compression spring operably coupled between a first spring mount 462 of the lock plate 152 and a second spring mount 464 of the body 142 of the base 140. In a similar manner as described in detail above with reference to Figures 3A–3C, (i) the lock feature 113 can engage the lock plate 152 and drive the lock plate 152 against the biasing force of the springs 460 during withdrawal of the plunger 110, and (ii) the springs 460 can drive the lock plate 152 upward after the lock feature 113 passes through the lock plate 152 to automatically lock the plunger 110 in the withdrawn position.

[0054] Figures 5A–5C are an isometric view, a side view, and another isometric view, respectively, of a syringe 500 in accordance with additional embodiments of the present technology. The syringe 500 is in a withdrawn/retracted position in Figures 5A and 5B, and in a depressed/advanced position in Figure 5C. Referring to Figures 5A–5C together, the syringe 500 can include several features generally similar or identical to the syringe 100 described in detail above with reference to Figures 1A–4. In the illustrated embodiment, for example, the syringe 500 includes a plunger 510 configured to be slidably positioned within a barrel 520. The barrel 520 is shown as partially transparent in Figures 5A–5C for clarity. The barrel 520 can include a barrel portion 522 extending between a flange 524 and a tip 526. In some embodiments, the tip 526 is configured to be releasably or permanently coupled to an adaptor 530 (e.g., a Toomey tip adaptor; shown as partially transparent in Figures 5A–5C). The plunger 510 can include a shaft 512 extending between a flange 514 and a grip portion 516. The plunger 510 can include a sealing member 518 positioned around the flange 514 and configured to sealingly engage an interior surface of the barrel portion 522 to define a sealed volume (e.g., of negative/vacuum pressure) within the barrel 520.

[0055] In the illustrated embodiment, the syringe 500 further includes a pair of lock members 570 (identified individually as a first lock member 570a and a second lock member 570b) operably coupled to an actuator 580. In some embodiments, the shaft 512 of the plunger 510 includes a spline 511 (e.g., a wall portion), and the lock members 570 can be positioned on opposite sides of the spline 511. The lock members 570 can each include a body 572 and an arm 574 hingedly/movably attached to the body 572. The arms 574 can be spring arms, living hinges, lever arms, or other members configured to be biased outwardly away from a longitudinal axis L (Figure 5A) of the syringe 500. The bodies 572 can each include a first end portion 573 and a second end portion 575 opposite the first end portion 573, and can each include/define an elongate opening 576 extending between the first and second end portions 573, 575. The lock members 570 can be formed of plastic, metal, and/or other suitable materials and can be single integral parts (e.g., injected molded parts) or can be formed of discrete parts coupled together.

[0056] In the illustrated embodiment, the actuator 580 includes a push portion 582 and a pair of elongate arms 584 (identified individually as a first arm 584a and a second arm 584b) extending away from the push portion 582. In some embodiments, the push portion 582 is slidably coupled to the spline 511 of the shaft 512 and configured to slide at least partially between (i) a first position in which the push portion 582 abuts and/or is adjacent to the grip portion 516 of the

plunger 510 and (ii) a second position in which the push portion 582 abuts and/or is adjacent to the second end portions 575 of the arms 574. The plunger 580 is shown in the second position in Figures 5A–5C. The first arm 584a can extend at least partially through the opening 576 in the first body 570a, and the second arm 584b can extend at least partially through the opening 576 in the second body 570b. In some embodiments, the arms 584 are slidably positioned within the openings 576 such that movement of the push portion 582 between the first and second positions advances/retracts the arms 584 through the openings 576. In some embodiments, in the first position, the arms 584 of the actuator 580 do not extend over the arms 574 of the lock members 570. In the second position, the arms 584 of the actuator 580 can extend over/around all or a portion of the arms 574 of the lock members 570 to move (e.g., pinch) the arms 574 inwardly toward the longitudinal axis L—counter to the biasing force of the arms 574 (e.g., in the direction of arrows F in Figure 5B). The actuator 580 can be formed of plastic, metal, and/or other suitable materials and can be a single integral part or can be formed of discrete parts coupled together.

[0057] In the withdrawn position shown in Figures 5A and 5B, the arms 574 of the lock members 570 are biased outwardly such that end portions of the arms 574 engage the flange 524 of the barrel 520. Accordingly, the arms 574 inhibit/lock the plunger 110 from advancing farther into the barrel 520 toward the depressed position. To unlock the plunger 510, a user can push the push portion 582 of the actuator to move the push portion 582 at least partially from the first position to the second position (e.g., toward the barrel 520 and the lock members 570). The movement of the push portion 582 drives the arms 584 through the openings 576 in the bodies 572 and over/around the arms 574 of the lock members 570 to move the arms 574 inward toward the longitudinal axis L and out of engagement with the flange 524. The user can then advance the plunger 510 toward the depressed position (Figure 5C) to expel any contents collected in the barrel 520.

[0058] To subsequently withdraw the plunger 510 from the depressed position to the retracted position, the user can first move the actuator 580 to the first position to free the arms 574 of the lock members 570 from the arms 584 of the actuator 580. Accordingly, the arms 574 of the lock members 570 can return to their outwardly-biased position and, in some embodiments, can contact an inner surface of the barrel portion 522. Then, as the plunger 510 is withdrawn through the barrel 520, the arms 574 of the of lock members 570 can spring (i) outward as they are withdrawn from the barrel 520 (e.g., after they past the flange 524) and (ii) into engagement with the flange 524. Accordingly, in one aspect of the present technology, the plunger 510 is

automatically locked in position—via the arms 574 of the lock members 570—when the plunger 510 is withdrawn a selected distance.

[0059] In some embodiments, the lock members 570 can be configured (e.g., shaped, positioned) such that the syringe 500 automatically locks at a selected position corresponding to a selected volume of the barrel 520. In some embodiments, the selected volume can be about 60 cc or greater. In some embodiments, the syringe 500 can include only one of the lock members 570, or more than two of the lock members 570.

[0060] Figure 6A is a side view of a vacuum-pressure locking syringe ("syringe 600") in accordance with additional embodiments of the present technology. The syringe 600 is in a depressed position in Figure 6A. The syringe 600 can include several features generally similar or identical to the syringe 100 described in detail above with reference to Figures 1A–3C. In the illustrated embodiment, for example, the syringe 600 includes a plunger 610 slidably positioned within a barrel 620. The barrel 620 is shown as partially transparent in Figure 6A for clarity. The syringe 600 further includes a base 640 and a lock member 650 operably coupled to the base 640. The lock member 650 includes a lock plate 652 coupled to a button portion 654. The plunger 610 includes a lower edge or surface 611 including a plurality of lock features 613 extending/protruding from the lower surface 611. Each of the lock features 613 can include (i) a ramp portion 615, (ii) a plateau portion 617 extending from the ramp portion 115, and (iii) a stop surface 619 extending from the plateau portion 617.

[0061] When the plunger 610 is withdrawn through the barrel 620, the lock features 613 are configured to engage the lock plate 652 to automatically lock the plunger 110 in a withdrawn position corresponding to the position of the lock feature 613. More specifically, a user can withdraw the plunger 610 to a desired location/volume and the lock feature 613 nearest the lock plate 652 can engage the lock plate 652 to automatically lock the plunger 610 in position. To move the syringe 600 from the withdrawn position to the depressed position, the user can (i) actuate the button portion 654 of the lock member 650 to disengage the lock plate 652 from the lock feature 613 to unlock the plunger 610 from the lock member 650 and then (ii) push the plunger 610 relative to the barrel 620. In one aspect of the present technology, the syringe 600 includes multiple ones of the lock features 613 that permit the syringe 600 to be automatically locked at multiple different positions. In the illustrated embodiment, the plunger 610 includes 12 locking features while, in other embodiments, the syringe 600 can include any number of lock

features 613 to facilitate locking of the syringe 600 at any desired position/volume. Moreover, the location of the lock features 613 can be selected to provide refined volume and vacuum control.

[0062] In the illustrated embodiment, the syringe 600 further includes a locking mechanism 690 that is actuatable to enable/disable the auto-locking functionality of the syringe 600. More specifically, Figures 6B and 6C are enlarged side views of the locking mechanism 690 of the syringe 600 in a first position and a second position, respectively, in accordance with embodiments of the present technology. Referring to Figures 6B and 6C together, the locking mechanism 690 can include a pin 692 operably coupled to the base 650 via a biasing member 694. In the illustrated embodiment, the pin 692 includes a head portion 693 and an engagement portion 695. The biasing member 694 can be operably coupled between the head portion 693 and the base 640, and the engagement portion 695 can at least partially extend through a channel 696 in the base 640. The lock member 650 can include an opening 698 configured to receive the engagement portion 695 of the pin 692 in the first position shown in Figure 6B.

[0063] In the first position shown in Figure 6B, the biasing member 694 (e.g., a tension spring) biases the lock pin 692 toward the lock member 650 such that the engagement portion 695 is positioned in the opening 698. Referring to Figures 6A and 6B together, in the first position the lock member 650 is partially depressed such that the lock features 613 are free to slide past the lock plate 652 without engaging the lock plate 652. Accordingly, the plunger 610 can be withdrawn/depressed through the barrel 620 without the lock features 613 automatically locking the syringe 600—and thus the syringe 600 functions similar to a conventional syringe when the locking mechanism 690 is in the first position. To enable to the auto-locking functionality of the syringe 600, a user can pull the pin 692 (e.g., the head portion 693) away from the lock member 650 (e.g., against the biasing force of the biasing member 694) to withdraw the engagement portion 695 from the opening 698 and disengage the engagement portion 695 from the lock member 650. Accordingly, in the second position, the lock member 650 is operable to engage the lock features 613 to auto-lock the syringe 600 (e.g., the lock member 650 can be biased towards as described with reference to Figures 3A–4). In other embodiments, the pin 692 can be operably coupled to the lock member 650 and configured to engage the base 640. In some embodiments, the syringe 100 and/or the syringe 500 described in detail with reference to Figures 1A–5C can include an identical or similar locking mechanism for enabling/disabling the autolocking functionality.

II. Selected Embodiments of Clot Treatment Systems

[0064] Figure 7 is a partially schematic side view of a clot treatment or clot removal system comprising an aspiration assembly 700 ("assembly 700") incorporating the syringe 100, the syringe 500, and/or the syringe 600 in accordance with embodiments of the present technology. In the illustrated embodiment, the assembly 700 includes a catheter subsystem 710 fluidly coupled to a tubing subsystem 720. In general, the assembly 700 (i) can include features generally similar or identical to those of the aspiration assemblies described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

[0065] In the illustrated embodiment, the catheter subsystem 710 includes a catheter 702 (e.g., an aspiration catheter) comprising an elongated shaft defining a lumen 704 and having a distal portion 703 and a proximal portion 705. The catheter subsystem 710 further includes a valve 706 that can be integral with or coupled to the proximal portion 705 of the catheter 702. In some embodiments, the valve is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 706 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 706 to be delivered through the catheter 702 to a treatment site in a blood vessel. The valve 706 includes a branch or side port 708 configured to fluidly couple the lumen 704 of the catheter 702 to the tubing subsystem 720. In some embodiments, the valve 706 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

[0066] The tubing subsystem 720 fluidly couples the catheter subsystem 710 to the syringe 100, the syringe 500, and/or the syringe 600 (collectively the "syringe 100/500/600"). More specifically, the tubing subsystem 720 can include one or more tubing sections 724 (individually labeled as a first tubing section 724a and a second tubing section 724b), at least one fluid control device 726 (e.g., a valve), and at least one connector 728 (e.g., a Toomey tip connector) for fluidly coupling the tubing subsystem 720 to the syringe 100/500/600 and/or other suitable components. More specifically, in the illustrated embodiment the fluid control device 726 is a stopcock that is

fluidly coupled to (i) the side port 708 of the valve 706 via the first tubing section 724a and (ii) the connector 728 via the second tubing section 724b.

[0067] The fluid control device 726 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 704 of the catheter 702 to the syringe 100/500. In some embodiments, the connector 728 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 702 and the fluid control device 726 to/from the syringe 100/500/600.

[0068] With reference to Figures 1A–7 together, the syringe 100/500/600 is configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter subsystem 710. For example, during operation of the assembly 700, a user can first close the fluid control device 726 before (i) withdrawing the plunger 110 of the syringe 100 until the plunger 110 automatically locks to build up vacuum pressure within the barrel 120 of the syringe 100, (ii) withdrawing the plunger 510 of the syringe 500 until the plunger 510 automatically locks to build up vacuum pressure within the barrel 520 of the syringe 500, and/or (iii) withdrawing the plunger 610 of the syringe 600 until the plunger 610 automatically locks at a location corresponding to one of the lock features 613. In this manner, a vacuum is charged within the syringe 100/500/600 (e.g., a negative pressure is maintained) before the syringe 100/500/600 is fluidly connected to the catheter subsystem 710. To aspirate the lumen 704 of the catheter 702, the user can open the fluid control device 726 to fluidly connect the syringe 100/500/600 to the catheter subsystem 710 and thereby apply or release the vacuum stored in the syringe 100/500/600 to the lumen 704 of the catheter 702.

[0069] Opening of the fluid control device 726 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing subsystem 720 and the catheter 702, thereby generating a suction pulse throughout the catheter 702. In particular, the suction is applied at the distal portion 703 of the catheter 702. In one aspect of the present technology, pre-charging or storing the vacuum in the syringe 100/500/600 before applying the vacuum to the lumen 704 of the catheter 702 is expected to generate greater suction forces and corresponding fluid flow velocities at and/or near the distal portion 703 of the catheter 702 compared to simply activating the syringe 100/500/600 while it is fluidly connected to the catheter 702. When the distal portion 703 is intravascularly positioned near clot material within a patient (e.g., a human patient), the suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove clot material from within a blood vessel of the patient.

III. Selected Embodiments of Vacuum Indicators

[0070] Referring to Figure 7, in some embodiments the assembly 700 can include a vacuum indicator 730 (shown schematically) operably coupled to the tubing subsystem 720. As described in greater detail below with reference to Figures 8A and 8B, the vacuum indicator 730 can provide an indication, such as a visual indication, of whether the assembly 700 is under vacuum pressure. In the illustrated embodiment, the vacuum indicator 730 is operably coupled to the tubing subsystem 720 between the fluid control device 726 and the valve 706 (e.g., to the first tubing section 724a, between separate portions of the first tubing section 724a). In other embodiments, the vacuum indicator 730 can be operably coupled to the tubing subsystem 720 between the fluid control device 726 and the connector 728 (e.g., to the second tubing section 724b, between separate portions of the second tubing section 724b).

[0071] Figures 8A and 8B are enlarged, partially-schematic side views of the vacuum indicator 730 in a vacuum-off position and a vacuum-on position, respectively, in accordance with embodiments of the present technology. Referring to Figures 8A and 8B together, the vacuum indicator 730 includes a body 832 and a flexible member 834 operably coupled to the body 832. The flexible member 834 is shown as partially transparent in Figures 8A and 8B for clarity. In some embodiments, the body 832 is an integral or one-piece member of plastic, metal, or another suitably rigid material. The body 832 can include a first connector portion 836a (e.g., a first barb), a second connector portion 836b (e.g., a second barb), and a central portion 838 extending between the first and second connector portions 836a, b. The body 832 can further define a lumen 837 extending therethrough between the first and second connector portions 836a, b. The first connector portion 836a can be coupled to a first tube 825a and the second connector portion 836b can be coupled to a second tube 825b. In some embodiments, the first and second tubes 825a, b can together form the first tubing section 724a (Figure 7) such that the vacuum indicator 730 is fluidly coupled between the fluid control device 726 and the valve 706.

[0072] In the illustrated embodiment, the central portion 838 of the body 832 includes/defines (i) a recess 840 extending circumferentially thereabout (ii) and an opening 842 positioned in the recess 840 and extending through the central portion 838 to the lumen 837. In some embodiments, the recess 840 can have a different shape and/or can extend only partially around the central portion 838, and/or the body 832 can include more than one of the openings 842 positioned in the recess 840. The flexible member 834 can be a thin compliant tube that is positioned over the recess 840 and the opening 842. In some embodiments, opposing end portions

of the flexible member 834 are secured to the body 832 via a first attachment member 844a and a second attachment member 844b. The first and second attachment members 844a, b can comprise adhesives, welds, fasteners, collars, or other components that mechanically secure the flexible member 834 over the recess 840 such that the flexible member 834 forms a seal over the recess 840. In some embodiments, the flexible member 834 can have a thickness of between about 0.005 inch to about 0.100 inch.

[0073] With additional reference to Figure 7, when the assembly 700 is not under vacuum, the flexible member 834 is positioned over the recess 840 in a relaxed state such that the flexible member 834 has a generally cylindrical shape as shown in Figure 8A. When a vacuum is generated in the assembly 700, the vacuum is applied to the flexible member 834 via the opening 842 and pulls/sucks the flexible member 834 into the recess 840 as shown in Figure 8B. The deformation of the flexible member 834 provides a visual indication to a user of the assembly 700 that the assembly 700 is under vacuum. When the vacuum is released, the flexible member 834 returns/rebounds to the vacuum-off position shown in Figure 8A to provide a visual indication that the assembly 700 is not under vacuum.

[0074] In some embodiments, the thickness of the flexible member 834, the size of the opening 842, and/or the number of openings 842 can be selected such that the flexible member 834 deforms to the vacuum-on position (Figure 8B) and returns to the vacuum-off position (Figure 8A) at a selected level of vacuum. For example, making the flexible member 834 thinner will cause it to indent under less vacuum while making the flexible member 834 thicker will require more vacuum to indent. Likewise, a thinner flexible member 834 will be less likely to rebound to the vacuum-off position (Figure 8A) and therefore require more pressure (e.g., positive pressure) to rebound, while a thicker flexible member 834 will rebound with little to no pressure.

[0075] In some embodiments, the vacuum indicator 730 can include a housing 846 (shown schematically) at least partially surrounding the flexible member 834. The housing 846 can be formed of a rigid material (e.g., plastic, metal) and can be coupled to the body 832. In some embodiments, the housing 846 is configured to inhibit or even prevent excessive deformation of the flexible member 834 when the assembly 700 is under positive pressure. For example, when positive pressure is applied to the assembly 700, the flexible member 834 can flex outwardly away from the body 832 and contact the housing 846. The housing 846 can therefore inhibit the flexible member 834 from flexing further outwardly, which could damage or rupture the flexible member 834.

[0076] In some aspects of the present technology, the vacuum indicator 730 can aid the user during a clot removal procedure on a patient using the assembly 700. Sometimes, for example, after applying the vacuum stored in the syringe 100/500/600 to the lumen 704 of the catheter 702, clot material can at least partially clog the distal portion 703 of the catheter 702—causing the assembly 700 to cavitate. In such instances, it is often desirable to remove the assembly 700 from the patient to thereby remove the clot material clogging and/or attached to the distal portion 703 of the catheter 702. However, user error and/or leakage of the assembly 700 (e.g., out of the valve 706) can dissipate the vacuum in the assembly 700, thereby releasing and/or decreasing the force holding the clot material to the catheter 702. The vacuum indicator 730 can provide a fast and easy visual indication to the user of whether the assembly 700 is maintaining vacuum. Thus, based on the position of the vacuum indicator 730, the user can determine how to proceed with the procedure—for example, whether to continue withdrawing the assembly 700 from the patient.

[0077] In some aspects of the present technology, the vacuum indicator 730 is a passive device that adds no or very little volume to the flow path of the assembly 700. Adding volume to the flow path of the assembly 700 can reduce the amount of aspirational force that can be generated at the distal portion 703 of the catheter 702. Accordingly, the vacuum indicator 730 can provide an indication of vacuum (e.g., on or off) without negatively affecting the clot removal capabilities of the assembly 700. In contrast, for example, a vacuum gauge coupled along the flow path of the assembly 702 would increase the volume thereof and reduce the aspirational force of the assembly 700. Moreover, the recess 840 can have a relatively small volume such that the vacuum indicator 730 is not prone to clogging during use of the assembly 700 (e.g., clogging with blood clots during a thrombectomy procedure using the assembly 700). In contrast, a vacuum gauge or similar mechanism would be more prone to clogging, possibly rendering them non-functional.

[0078] Figure 9 is a perspective view of a vacuum indicator 930 in a vacuum-off position in accordance with additional embodiments of the present technology. The vacuum indicator 930 can include some features, functions, and/or advantages that are generally similar or identical to the vacuum indicator 730 described in detail above with reference to Figures 8A and 8B. For example, in the illustrated embodiment the vacuum indicator 930 includes a body 932 and a flexible member 934 operably coupled to the body 932. The flexible member 934 is shown as partially transparent in Figure 9 for clarity. The body 932 can include a first connector portion 936a (e.g., a first barb), a second connector portion 936b (e.g., a second barb), and a central portion 938 extending between the first and second connector portions 936a, b. The body 932 can further

define a lumen 937 extending therethrough between the first and second connector portions 936a, b. The first and second connector portions 936a, b can be coupled to, for example, various tubes of the first tubing section 724a and/or the second tubing section 724b (Figure 7).

[0079] In the illustrated embodiment, the central portion 938 of the body 932 includes/defines a plurality of longitudinal openings 950 extending through the central portion 938 to the lumen 937. In some embodiments, the openings 950 can be equally spaced about the body 932. In other embodiments, the central portion 938 can include more or fewer of the openings 950 and/or the openings 950 can be positioned differently about the central portion 938. The flexible member 934 can be a thin compliant tube that is sealingly secured to the body 932 over the openings 950 via a first attachment member 944a and a second attachment member 944b.

[0080] With additional reference to Figure 7, when the assembly 700 is not under vacuum, the flexible member 934 is positioned over the openings 950 in a relaxed state such that the flexible member 934 has a generally cylindrical shape as shown in Figure 9. When a vacuum is generated in the assembly 700, the vacuum is applied to the flexible member 934 via the openings 950 and pulls the flexible member 934 at least partially into one or more of the openings 950. The deformation of the flexible member 934 provides a visual indication to a user of the assembly 700 that the assembly 700 is under vacuum. When the vacuum is released, the flexible member 934 can return to the position vacuum-off shown in Figure 9 to provide a visual indication that the assembly 700 is not under vacuum. In some embodiments, the vacuum indicator 930 can include a housing (not shown) at least partially surrounding the flexible member 934 and configured to inhibit or even prevent excessive deformation of the flexible member 934 when the assembly 700 is under positive pressure.

[0081] Figures 10A and 10B are perspective views of a vacuum indicator 1030 in a vacuum-off position and a vacuum-on position, respectively, in accordance with additional embodiments of the present technology. The vacuum indicator 1030 can include some features, functions, and/or advantages that are generally similar or identical to the vacuum indicator 730 and/or the vacuum indicator 930 described in detail above with reference to Figures 8A–9. For example, referring to Figures 10A and 10B together, the vacuum indicator 930 includes a flexible member 934 fluidly coupled to a tube 1025. In some embodiments, the tube 925 is a portion of the first tubing section 724a or the second tubing section 724b (Figure 7).

[0082] In the illustrated embodiment, however, the flexible member 1034 is directly attached to the tube 1025 over a hole or opening 1027 (obscured in Figure 10A and shown

schematically) in the tube 1025. In some embodiments, opposing end portions of the flexible member 1034 are secured to the tube 1029 via a first attachment member 1044a and a second attachment member 1044b. The first and second attachment members 1044a, b can be clamps, collars, or other mechanical components that mechanically secure the flexible member 1034 over the opening 1027 such that the flexible member 1034 forms a seal over the opening 1027. The first and second attachment members 1044a, b can be secured to the tube 1025 via compression, adhesives, fasteners, and/or other suitable means of connection. In some embodiments, the opening 1027 can have a diameter of about 0.100 inch to about 0.300 inch.

[0083] With additional reference to Figure 7, when the assembly 700 is not under vacuum, the flexible member 1034 is positioned over the opening 1027 in a relaxed state such that the flexible member 1034 has a generally cylindrical shape as shown in Figure 10A. When a vacuum is generated in the assembly 700, the vacuum is applied to the flexible member 1034 via the opening 1027 and pulls the flexible member 1034 into the opening 1027 as shown in Figure 10B. The deformation of the flexible member 1034 provides a visual indication to a user of the assembly 700 that the assembly is under vacuum. When the vacuum is released, the flexible member 1034 returns to the vacuum-off position shown in Figure 10A to provide a visual indication that the assembly 700 is not under vacuum.

[0084] In some embodiments, a syringe configured in accordance with the present technology can include a vacuum indicator integrated therewith. For example, Figure 11 is a side-view of the syringe 100 of Figures 1A and 1B including a vacuum indicator 1130 formed in the adaptor 130 in accordance with embodiments of the present technology. In the illustrated embodiment, the vacuum indicator 1130 includes a flexible member 1134 sealingly positioned over an opening 1152 in the adaptor 130. The flexible member 1134 can be formed from a compliant material, such as silicone, and can have a dome-like shape in a vacuum-off position shown in Figure 11. With additional reference to Figure 7, when the syringe 100 is coupled to the system 700 (e.g., to the connector 728) and the plunger 110 is drawn to pull a vacuum in the barrel 120, the vacuum is applied to the flexible member 1134 via the opening 1152 and pulls the flexible member 1134 into/toward the opening 1152. For example, the flexible member 1134 can invert when the assembly 700 is under vacuum. The inversion/deformation of the flexible member 1134 provides a visual indication to a user of the assembly 700 that the assembly 700 is under vacuum. When the vacuum is released, the flexible member 1134 can passively return to the vacuum-off

position shown in Figure 11 to provide a visual indication that the assembly 700 is not under vacuum.

[0085] Figures 12A and 12B are perspective views of a syringe 1200 including a vacuum indicator 1230 in accordance with additional embodiments of the present technology. The syringe 1200 is in a withdrawn position in Figure 12B. Referring to Figures 12A and 12B together, the syringe 1200 includes a plunger 1210 slidably positioned within a barrel 1220. The barrel 1220 is shown as partially transparent in Figure 1B for clarity. The plunger 1210 includes a flange 1214 configured to sealingly engage an inner surface of the barrel 1220 to define a sealed volume 1217 (Figure 12B: e.g., of negative/vacuum pressure) within the barrel 1220.

[0086] In the illustrated embodiment, the vacuum indicator 1230 includes a housing 1260 (shown as partially transparent in Figures 12A and 12B) coupled to the plunger 110 and defining a lumen 1262. The flange 1214 can include a through-hole 1264 fluidly coupling the lumen 1262 of the housing 1260 to the sealed volume 1217 within the barrel 1220. The vacuum indicator 1230 can further include an indication member 1266 slidably positioned within the lumen 1262. The indication member 1266 can be an elongate member and, in some embodiments, can have a color (e.g., a relatively bright color) that contrasts with a color of the housing 1260. In some embodiments, the indication member 1266 is configured to sealingly engage the housing 1260. For example, the housing 1260 can include one or more sealing members (e.g., O-rings; not shown) on an inner surface thereof and/or the indication member 1266 can include one or more sealing members (e.g. O-rings; not shown) on an outer surface thereof to provide a dynamic seal between the housing 1260 and the indication member 1266. In the illustrated embodiment, the indication member 1266 is operably coupled to the flange 1214 via a biasing member 1268 that extends through the lumen 1262. The biasing member 1268 (e.g., a compression spring) is configured to bias the indication member 1266 through the lumen 1262 in a direction away from the flange 1214 (e.g., as indicated by arrow F in Figure 12A).

[0087] With additional reference to Figure 7, when the syringe 1200 is coupled to the system 700 (e.g., to the connector 728) and the plunger 1210 is drawn to pull a vacuum in the sealed volume 1217 of the barrel 1220, the vacuum is applied to the indication member 1266 via the through-hole 1264 in the flange 1214 and the lumen 1262 of the housing 1260. The vacuum pulls the indication member 1266 through the lumen 1262 against the biasing force of the biasing member 1268 as indicated by arrow G in Figure 12B. The positioning of the indication member 1266 relative to the housing 1260 can provide a visual indication to a user of the assembly 700

that the assembly 700 is under vacuum. In some embodiments, for example, when the plunger 1210 is fully withdrawn, the indication member 1266 can be positioned entirely within the lumen 1262 and thus obscured by the housing 1260 as shown in Figure 12B. When the vacuum is released, the biasing member 1268 drives the indication member 1266 through the lumen 1262 in the direction of arrow F at least partially outside the housing 1260 (e.g., as shown in Figure 12A) to provide a visual indication that the assembly 700 is not under vacuum. In some aspects of the present technology, the position of the indication member 1266 relative to the housing 1260 can provide an indication of a varying level of vacuum in the assembly 700 (e.g., in contrast to a binary on/off indication).

[0088] In some embodiments, the plunger 1210 includes a grip portion 1216 configured to engage the indication member 1266, as shown in Figure 12A, to inhibit further movement of the indication member 1266 in the direction of arrow F when the assembly 700 is under positive pressure. In some embodiments, any of the vacuum-pressure locking syringes 100/500/600 described in detail above with reference to Figures 1A–6C can include the vacuum indicator 1230.

[0089] Figures 13A–13C are side views of a vacuum indication device or vacuum indicator 1330 in a vacuum-off position, a partial-vacuum position, and a full-vacuum position, respectively, in accordance with additional embodiments of the present technology. Referring to Figures 13A–13C together, the vacuum indicator 1330 includes a sealing indicator 1370 slidably positioned within a barrel 1320. The barrel 1320 includes a cap 1371 (e.g., a sealed cap), and a tip 1326 (e.g., a Luer connector) that can be directly coupled to another device or system, such as the fluid control device 726 (e.g., stopcock) of Figure 7, as shown in Figures 13B and 13C.

[0090] In some embodiments, the sealing indicator 1370 is configured to sealingly engage the barrel 1320 to define a first volume or chamber 1372 and a second volume or chamber 1374 within the barrel 1320. For example, the sealing indicator 1370 can include one or more sealing members (e.g. O-rings; not shown) on an outer surface thereof to provide a dynamic seal between the barrel 1320 and the sealing indicator 1370. In some embodiments, the one or more sealing members can engage the barrel 1320 with low friction to facilitate sliding movement of the sealing indicator 1370 within the barrel 1320. The first chamber 1372 can be a sealed volume with no outlet, while the second chamber 1374 can be open to the tip 1326.

[0091] With additional reference to Figure 7, when the assembly 700 is not under vacuum pressure, the sealing indicator 1370 can be positioned near an upper portion of the barrel 1320 proximate the cap 1371. When the syringe 100/500/600 is used to generate a vacuum in the

assembly 700, vacuum pressure is generated in the second chamber 1374. The vacuum pressure in the second chamber 1374 pulls the sealing indicator 1370 downward toward the tip 1326 of the barrel 1320 as shown in Figure 13B. As the sealing indicator 1370 moves downward away from the cap 1371, the volume of the first chamber 1372 increases, thereby generating vacuum pressure in the first chamber 1372. The vacuum pressure generated in the first chamber 1372 provides a resistive force that acts against the vacuum force in the second chamber 1374 to urge the sealing indicator 1370 upward toward the cap 1371. The vacuum force in second chamber 1374 must overcome the resistive vacuum force in first chamber 1372 to cause the sealing indicator 1370 to travel downward through the barrel 1320. In some embodiments, the vacuum indicator 1370 is configured (e.g., shaped, sized) such that the sealing indicator 1370 abuts the tip 1326 of the barrel 1320 in the full-vacuum position, as shown in Figure 13C, to indicate that a maxium vacuum level has been generated in the assembly 700. If vacuum force dissipates or is lost in the assembly 700, the resitive vacuum force in the first chamber 1372 can return the sealing indicator 1370 toward the vacuum-off position shown in Figure 13A.

[0092] In general, the opposing vacuum forces in the first and second volumes 1372, 1374, along with the friction forces between the barrel 1320 and the sealing indicator 1370, dictate the travel speed and location of the sealing indicator 1370 along the barrel 1320. In some aspects of the present technology, the vacuum indicator 1330 can provide a continuous resolution of the vacuum level at higher vacuum levels (e.g., greater than 25 inHg). That is, the position of the sealing indicator 1370 in the barrel 1320 can indicate a specific level of vacuum in the assembly 700.

[0093] Figures 14A and 14B are an isometric view and a top view of a syringe 1400 in accordance with additional embodiments of the present technology. The syringe 1400 is in a depressed/advanced position in Figures 14A and 14B. Referring to Figures 14A and 14B together, the syringe 1400 can include several features generally similar or identical to the syringe 100 described in detail above with reference to Figures 1A–4, and can be coupled to the assembly 700 of Figure 7 for use in a clot removal procedure. In the illustrated embodiment, for example, the syringe 1400 includes a plunger 1410 configured to be slidably positioned within a barrel 1420. The barrel 1420 is shown as partially transparent in Figures 14A and 14B for clarity. The barrel 1420 can include a barrel portion 1422 and a tip 1426. The plunger 1410 can include a shaft 1412 and a grip portion 1416. The syringe 1400 further includes a base 1440 and a lock member 1450 having a lock plate 1452 (obscured in Figure 14B and partially obscured in Figure 14A) and a

button portion 1454. The lock member 1450 is configured to automatically engage the base 1440 when the plunger 1410 is withdrawn to automatically lock the plunger 1410 in a withdrawn position, as described in detail above. The button portion 1454 can be actuatable (e.g., depressible) by a user to release the lock plate 1452 from the base 1440 to release the plunger 1410 to, for example, permit the plunger 1410 to move through the barrel 1420 to expel any contents (e.g., bodily fluids such as blood and clot material) collected in the barrel 1420 from the tip 1426. In the illustrated embodiment, however, the button portion 1454 extends generally parallel to the grip portion 1416 of the plunger 1410.

[0094] Moreover, in the illustrated embodiment the syringe 1400 further includes a vacuum indicator 1430 formed in and/or coupled to the tip 1426. Figures 14C and 14D are enlarged side views of the vacuum indicator 1430 in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology. Figures 14E and 14F are enlarged partially transparent side views of the vacuum indicator 1430 in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology. Figure 14G is an enlarged side cross-sectional view of the vacuum indicator in the vacuum-off position in accordance with embodiments of the present technology. Referring to Figures 14E–14G together, the vacuum indicator 1430 can include a flexible member 1434 (e.g., a diaphragm, a rolling diaphragm) sealingly positioned over an opening 1461 in the tip 1426. The flexible member 1434 can be formed from a compliant material, such as silicone.

[0095] Referring to Figures 14C–14G together, in the illustrated embodiment the vacuum indicator 1430 further includes (i) a non-transparent (e.g., opaque) bonnet or base 1435 positioned around and/or coupled to the flexible member 1434, (ii) a transparent tube 1437 coupled to and extending from the base 1435, and (iii) a non-transparent cap 1439 coupled to and positioned above the tube 1437. The base 1435, the tube 1437, and/or the cap 1439 can be integrally formed or can be separate components coupled together. The vacuum indicator 1430 can further include an indicator 1460 movably positioned within the tube 1437 and the cap 1439. The indicator 1460 can include a first indicator region 1462 and a second indicator region 1464 each having at last one different visual characteristic (e.g., color, pattern, size, thickness, shape) from one another. For example, in some embodiments the first indicator region 1462 can be a first color (e.g., red) while the second indicator region 1464 can be a different second color (e.g., green). In some embodiments, a first end portion of the indicator 1460 (e.g., a lower end of the first indicator region 1462) can be coupled to the flexible member 1434 and a second end portion of the indicator

1460 (e.g., an upper end of the second indicator region 1464) can be coupled to the cap 1439 via a biasing member 1466 (Figures 14F and 14G), such as a spring. As best seen in Figure 14G, in some embodiments the biasing member 1466 can extend at least partially through an internal channel 1469 of the indicator 1460.

[0096] When the tip 1426 of the syringe 1400 is not under vacuum, the vacuum indicator 1430 is in the vacuum-off position in which the biasing member 1466 biases the indicator 1460 toward the cap 1439 such that the first indicator region 1462 is positioned adjacent the transparent tube 1437—and thus visible to the user—as shown in Figures 14C and 14E. At the same time, the second indicator region 1464 is obscured by the non-transparent cap 1439 in the vacuum-off position. When the tip 1426 of the syringe 1400 is under vacuum, the vacuum indicator 1430 is in the vacuum-on position in which the vacuum pulls the flexible member 1434 into/toward the opening 1461, thereby pulling the indicator 1460 toward the opening 1461 against the biasing force of the biasing member 1466 such that the second indicator region 1464 is positioned adjacent the transparent tube 1437—and thus visible to the user—as shown in Figures 14D and 14F. At the same time, the first indicator region 1462 is obscured by the non-transparent base 1435 in the vacuum-on position. In this manner, the first and second indicator regions 1462, 1464 are configured to provide a visual indication to the user of whether the syringe 1400 (and the coupled assembly 700 of Figure 7) is under vacuum or not.

[0097] Figures 15A and 15B are an isometric view and a side view of a syringe 1500 in accordance with additional embodiments of the present technology. The syringe 1500 is in a depressed/advanced position in Figures 15A and 15B. Referring to Figures 15A and 15B together, in some embodiments the syringe 1500 can be generally identical to the syringe 1400 described in detail above with reference to Figures 14A and 14B (e.g., including the plunger 1410, the barrel 1420, the 1426, the base 1440, and the lock member 1450). In the illustrated embodiment however, the syringe 1500 includes a different vacuum indicator 1530 formed in and/or coupled to the tip 1426.

[0098] Figures 15C and 15D are enlarged side views of the vacuum indicator 1530 in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology. Figures 15E and 15F are enlarged partially transparent side views of the vacuum indicator 1530 in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology. Figure 15G is an enlarged side cross-sectional view of the vacuum indicator in the vacuum-off position in accordance with embodiments of the present

technology. The vacuum indicator 1530 can include several features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the vacuum indicator 1430 described in detail above with reference to Figures 14C–14G, and can operate in a generally similar or identical manner to the vacuum indicator 1430.

[0099] For example, referring to Figures 15E–15G together, the vacuum indicator 1530 can include a flexible member 1534 (e.g., a diaphragm, a rolling diaphragm) sealingly positioned over the opening 1461 in the tip 1426. The flexible member 1534 can be biased to a first (e.g., preconvoluted) position in the vacuum-off position and can be pulled downward toward the opening 1461 to a second position in the vacuum-on position. Referring to Figures 15C–15G together, the vacuum indicator 1530 can further include (i) a non-transparent (e.g., opaque) base 1535 positioned around and/or coupled to the flexible member 1534, (ii) a transparent tube 1537 coupled to and extending from the base 1535, and (iii) a non-transparent cap 1539 coupled to and positioned above the tube 1537. The base 1535, the tube 1537, and/or the cap 1539 can be integrally formed or can be separate components coupled together. The vacuum indicator 1530 further includes an indicator 1560 positioned within the tube 1537 and the cap 1539. In the illustrated embodiment, the indicator 1560 includes a first indicator region or portion 1562 and a second indicator region or portion 1564 each having at last one different visual characteristic from one another. For example, in some embodiments the first indicator portion 1562 can be a first color (e.g., red) while the second indicator portion 1564 can be a different second color (e.g., green). In some embodiments, the second indicator portion 1564 is at least partially nested within the first indicator portion 1562 in the vacuum-off position (e.g., as best seen in Figure 15G). The first indicator portion 1562 (e.g., a lower end portion thereof) can be coupled to the flexible member 1534 while the second indicator portion 1564 (e.g., an upper end portion thereof) can be coupled to the cap 1539.

[0100] When the tip 1426 of the syringe 1500 is not under vacuum, the vacuum indicator 1530 is in the vacuum-off position in which the flexible member 1534 is in the first position and biases the first indicator portion 1562 upward toward the cap 1539 such that the second indicator portion 1564 is positioned adjacent the transparent tube 1537—and thus visible to the user—as shown in Figures 15C and 15E. At the same time, the first indicator portion 1562 at least partially surrounds the second indicator portion 1564 such that the second indicator portion 1564 is obscured and not visible to the user in the vacuum-off position. When the tip 1426 of the syringe 1500 is under vacuum, the vacuum indicator 1530 is in the vacuum-on position in which the

vacuum pulls the flexible member 1534 into/toward the opening 1461, thereby pulling the first indicator portion 1562 downward away from the cap 1539 and the second indicator portion 1564 such that the second indicator portion 1564 is visible through the transparent tube 1537, as shown in Figures 15D and 15F. At the same time, the first indicator portion 1562 is obscured by the non-transparent base 1535 in the vacuum-on position. In this manner, the first and second indicator portions 1562, 1564 are configured to provide a visual indication to the user of whether the syringe 1500 (and the coupled assembly 700 of Figure 7) is under vacuum or not.

[0101] In some embodiments, alternatively to or in addition to using the flexible member 1534 to bias the first indicator portion 1562 to the vacuum-off position, the vacuum indicator 1530 can include a biasing member configured to bias the first indicator portion 1562 to the vacuum-off position. Figure 16, for example, is an enlarged side cross-sectional view of the vacuum indicator 1530 further including a biasing member 1666, such as a spring, operably coupled between the cap 1539 and the first indicator portion 1562 in accordance with embodiments of the present technology. In the illustrated embodiment, the biasing member 1666 has an upper end portion 1667 coupled to the cap 1539 (e.g., a spring-mount thereof) and a lower end portion 1668 coupled to the first indicator portion 1562 (e.g., a spring mount thereof). In some embodiments the biasing member 1666 can extend at least partially through an internal channel 1669 of the second indicator portion 1564. When the tip 1426 of the syringe 1500 is not under vacuum, the biasing member 1666 can bias the first indicator portion 1562 toward the cap 1539 to the vacuum-off position. When the tip 1426 of the syringe 1500 is under vacuum, the flexible member 1534 can pull the first indicator portion 1562 toward the opening 1461 against the biasing force of the biasing member 1666 to the vacuum-on position.

IV. Further Examples

[0102] The following examples are illustrative of several embodiments of the present technology:

1. An automatically-locking syringe, comprising:

a barrel;

a plunger slidably positioned within the barrel, wherein the plunger is movable between a depressed position and a withdrawn position, and wherein the plunger includes a lock feature; and

a lock plate coupled to the barrel and having an opening extending therethrough, wherein the plunger is slidably positioned in the opening, wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position, and wherein—

when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and

after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

2. The syringe of example 1 wherein the lock feature includes a stop surface extending generally perpendicular to a longitudinal axis of the syringe, and wherein the lock plate is configured to engage the stop surface when (a) the lock plate is in the locking position and (b) the plunger is in the withdrawn position.

3. The syringe of example 1 or example 2, further comprising a button coupled to the lock plate, wherein the button is actuatable to move the lock plate away from the locking position to permit movement of the plunger from the withdrawn position to the depressed position.

4. The syringe of any one of examples 1–3 wherein the biasing member includes at least one of a spring and a living hinge.

5. The syringe of any one of examples 1–3 wherein the biasing member is an arm hingedly coupled to the locking plate.

6. The syringe of any one of examples 1–5 wherein the lock feature is one of a plurality of lock features positioned along a longitudinal axis of the plunger.

7. The syringe of example 6 wherein—

when the plunger is moved from the depressed position to the withdrawn position, individual ones of the lock features are configured to sequentially engage the lock

plate to drive the lock plate to the position away from the locking position to thereby permit the lock feature to pass through the opening, and

after the individual ones of the lock features sequentially pass through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

8. The syringe of example 6 or example 7, further comprising a locking mechanism configured to engage the lock plate to lock the lock plate in the position away from the locking position.

9. The syringe of any one of examples 1–8 wherein the barrel has a volume of about 60 cc or greater.

10. An automatically-locking syringe, comprising:

a barrel including a flange;

a plunger slidably positioned within the barrel, wherein the plunger is aligned along a longitudinal axis, and wherein the plunger is movable along the longitudinal axis between a depressed position and a withdrawn position;

a lock member coupled to the plunger, wherein the lock member includes a body and a first arm hingedly coupled to the body, and wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position; and

an actuator including a second arm, wherein the actuator is movable between a first position and a second position, and wherein the second arm is configured to engage the first arm in the second position to drive the first arm inwardly toward the longitudinal axis away from the locking position.

11. The syringe of example 10 wherein the first arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

12. The syringe of example 10 or example 11 wherein the lock member includes a third arm hingedly coupled to the body, wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position, wherein the actuator includes a fourth arm, and wherein the fourth arm is configured to engage the third arm in the second position to drive the third arm inwardly toward the longitudinal axis away from the locking position.

13. The syringe of example 12 wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis in a first direction, and wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis in a second direction opposite the first direction.

14. The syringe of example 12 or example 13 wherein the first arm and the third arm have an identical size and shape, and wherein the second arm and the fourth arm have an identical size and shape.

15. The syringe of any one of examples 12–14 wherein the third arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

16. A clot treatment system, comprising:

a catheter;

a pressure source configured to generate vacuum pressure; and

a tubing subsystem configured to fluidly connect the catheter to the pressure source, wherein the tubing subsystem includes a vacuum indicator configured to provide an indication that the catheter is under vacuum pressure.

17. The clot treatment system of example 16 wherein the tubing subsystem includes an aperture, wherein the vacuum indicator includes a flexible member positioned over the aperture, and wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure to provide the indication that the catheter is under vacuum pressure.

18. The clot treatment system of example 17 wherein the vacuum indicator includes a housing positioned around the flexible member and configured to inhibit excessive deformation of the flexible member when the catheter is under positive pressure.

19. The clot treatment device of any one of examples 16–18, wherein the pressure source is an automatically-locking syringe.

20. The clot treatment device of claim 16 wherein—

the tubing subsystem includes a valve, a first tubing section, a fluid control device, and a second tubing subsystem,

the valve fluidly connects the catheter to the first tubing section,

the first tubing section is fluidly connected between the valve and the fluid control device,

the second tubing system fluidly connects the fluid control device to the pressure source, and

the vacuum indicator is fluidly connected between the valve and the fluid control device.

21. A syringe, comprising:

a barrel having a tip, wherein the tip includes an opening;

a plunger movable through the barrel to generate vacuum pressure within the barrel; and

a vacuum indicator positioned over the opening in the tip, wherein the vacuum indicator includes a transparent tube and an indicator movably positioned within the tube, wherein the indicator includes a first region having a first visual characteristic and a second region having a second visual characteristic different than the first visual characteristic, and wherein—

when the barrel is not under vacuum pressure, the first region is configured to be positioned adjacent the tube; and

when the barrel is under vacuum pressure, the second region is configured to be positioned adjacent the tube.

22. The syringe of example 21 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the indicator is movably positioned within the cap and the tube, and wherein—

when the barrel is not under vacuum pressure, the second region is configured to be positioned adjacent the cap; and

when the barrel is under vacuum pressure, the first region is configured to be positioned adjacent the cap.

23. The syringe of example 22 wherein the vacuum indicator further includes a biasing member coupled between the indicator and the cap, wherein the biasing member is configured to bias the indicator to position the first region adjacent the tube when the barrel is not under vacuum pressure.

24. The syringe of any one of examples 21–23 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and coupled to the indicator.

25. The syringe of example 24 wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure.

26. The syringe of example 24 or example 25 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the first portion of the indicator is coupled to the flexible member, and wherein the second portion of the indicator is coupled to the cap.

27. The syringe of any one of examples 21–26 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and a biasing member, wherein the first portion of the indicator is coupled to the biasing member, and wherein the second portion of the indicator is coupled to the flexible member.

28. The syringe of any one of examples 21–27 wherein the first and second portions of the indicator are movable relative to one another, and wherein the second indicator is at least partially nested within the second indicator.

V. Conclusion

[0103] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0104] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0105] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An automatically-locking syringe, comprising:

a barrel;

a plunger slidably positioned within the barrel, wherein the plunger is movable between a depressed position and a withdrawn position, and wherein the plunger includes a lock feature; and

a lock plate coupled to the barrel and having an opening extending therethrough, wherein the plunger is slidably positioned in the opening, wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position, and wherein—

when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and

after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

2. The syringe of claim 1 wherein the lock feature includes a stop surface extending generally perpendicular to a longitudinal axis of the syringe, and wherein the lock plate is configured to engage the stop surface when (a) the lock plate is in the locking position and (b) the plunger is in the withdrawn position.

3. The syringe of claim 1, further comprising a button coupled to the lock plate, wherein the button is actuatable to move the lock plate away from the locking position to permit movement of the plunger from the withdrawn position to the depressed position.

4. The syringe of claim 1 wherein the biasing member includes at least one of a spring and a living hinge.

5. The syringe of claim 1 wherein the biasing member is an arm hingedly coupled to the locking plate.

6. The syringe of claim 1 wherein the lock feature is one of a plurality of lock features positioned along a longitudinal axis of the plunger.

7. The syringe of claim 6 wherein—

when the plunger is moved from the depressed position to the withdrawn position, individual ones of the lock features are configured to sequentially engage the lock plate to drive the lock plate to the position away from the locking position to thereby permit the lock feature to pass through the opening, and

after the individual ones of the lock features sequentially pass through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

8. The syringe of claim 6, further comprising a locking mechanism configured to engage the lock plate to lock the lock plate in the position away from the locking position.

9. The syringe of claim 1 wherein the barrel has a volume of about 60 cc or greater.

10. An automatically-locking syringe, comprising:

a barrel including a flange;

a plunger slidably positioned within the barrel, wherein the plunger is aligned along a longitudinal axis, and wherein the plunger is movable along the longitudinal axis between a depressed position and a withdrawn position;

a lock member coupled to the plunger, wherein the lock member includes a body and a first arm hingedly coupled to the body, and wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position; and

an actuator including a second arm, wherein the actuator is movable between a first position and a second position, and wherein the second arm is configured to engage

the first arm in the second position to drive the first arm inwardly toward the longitudinal axis away from the locking position.

11. The syringe of claim 10 wherein the first arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

12. The syringe of claim 10 wherein the lock member includes a third arm hingedly coupled to the body, wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position, wherein the actuator includes a fourth arm, and wherein the fourth arm is configured to engage the third arm in the second position to drive the third arm inwardly toward the longitudinal axis away from the locking position.

13. The syringe of claim 12 wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis in a first direction, and wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis in a second direction opposite the first direction.

14. The syringe of claim 12 wherein the first arm and the third arm have an identical size and shape, and wherein the second arm and the fourth arm have an identical size and shape.

15. The syringe of claim 12 wherein the third arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

16. A clot treatment system, comprising:

a catheter;

a pressure source configured to generate vacuum pressure; and

a tubing subsystem configured to fluidly connect the catheter to the pressure source, wherein the tubing subsystem includes a vacuum indicator configured to provide an indication that the catheter is under vacuum pressure.

17. The clot treatment system of claim 16 wherein the tubing subsystem includes an aperture, wherein the vacuum indicator includes a flexible member positioned over the aperture, and wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure to provide the indication that the catheter is under vacuum pressure.

18. The clot treatment system of claim 17 wherein the vacuum indicator includes a housing positioned around the flexible member and configured to inhibit excessive deformation of the flexible member when the catheter is under positive pressure.

19. The clot treatment device of claim 16, wherein the pressure source is an automatically-locking syringe.

20. The clot treatment device of claim 16 wherein—

the tubing subsystem includes a valve, a first tubing section, a fluid control device, and a second tubing subsystem,

the valve fluidly connects the catheter to the first tubing section,

the first tubing section is fluidly connected between the valve and the fluid control device,

the second tubing system fluidly connects the fluid control device to the pressure source, and

the vacuum indicator is fluidly connected between the valve and the fluid control device.

21. A syringe, comprising:

a barrel having a tip, wherein the tip includes an opening;

a plunger movable through the barrel to generate vacuum pressure within the barrel; and

a vacuum indicator positioned over the opening in the tip, wherein the vacuum indicator includes a transparent tube and an indicator movably positioned within the tube, wherein the indicator includes a first portion having a first visual characteristic and a second portion having a second visual characteristic different than the first visual characteristic, and wherein—

when the barrel is not under vacuum pressure, the first portion is configured to be positioned adjacent the tube; and

when the barrel is under vacuum pressure, the second portion is configured to be positioned adjacent the tube.

22. The syringe of claim 21 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the indicator is movably positioned within the cap and the tube, and wherein—

when the barrel is not under vacuum pressure, the second portion is configured to be positioned adjacent the cap; and

when the barrel is under vacuum pressure, the first portion is configured to be positioned adjacent the cap.

23. The syringe of claim 22 wherein the vacuum indicator further includes a biasing member coupled between the indicator and the cap, wherein the biasing member is configured to bias the indicator to position the first portion adjacent the tube when the barrel is not under vacuum pressure.

24. The syringe of claim 21 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and coupled to the indicator.

25. The syringe of claim 24 wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure.

26. The syringe of claim 24 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the first portion of the indicator is coupled to the flexible member, and wherein the second portion of the indicator is coupled to the cap.

27. The syringe of claim 21 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and a biasing member, wherein the first portion of the indicator is coupled to the biasing member, and wherein the second portion of the indicator is coupled to the flexible member.

28. The syringe of claim 21 wherein the first and second portions of the indicator are movable relative to one another, and wherein the second indicator is at least partially nested within the second indicator.

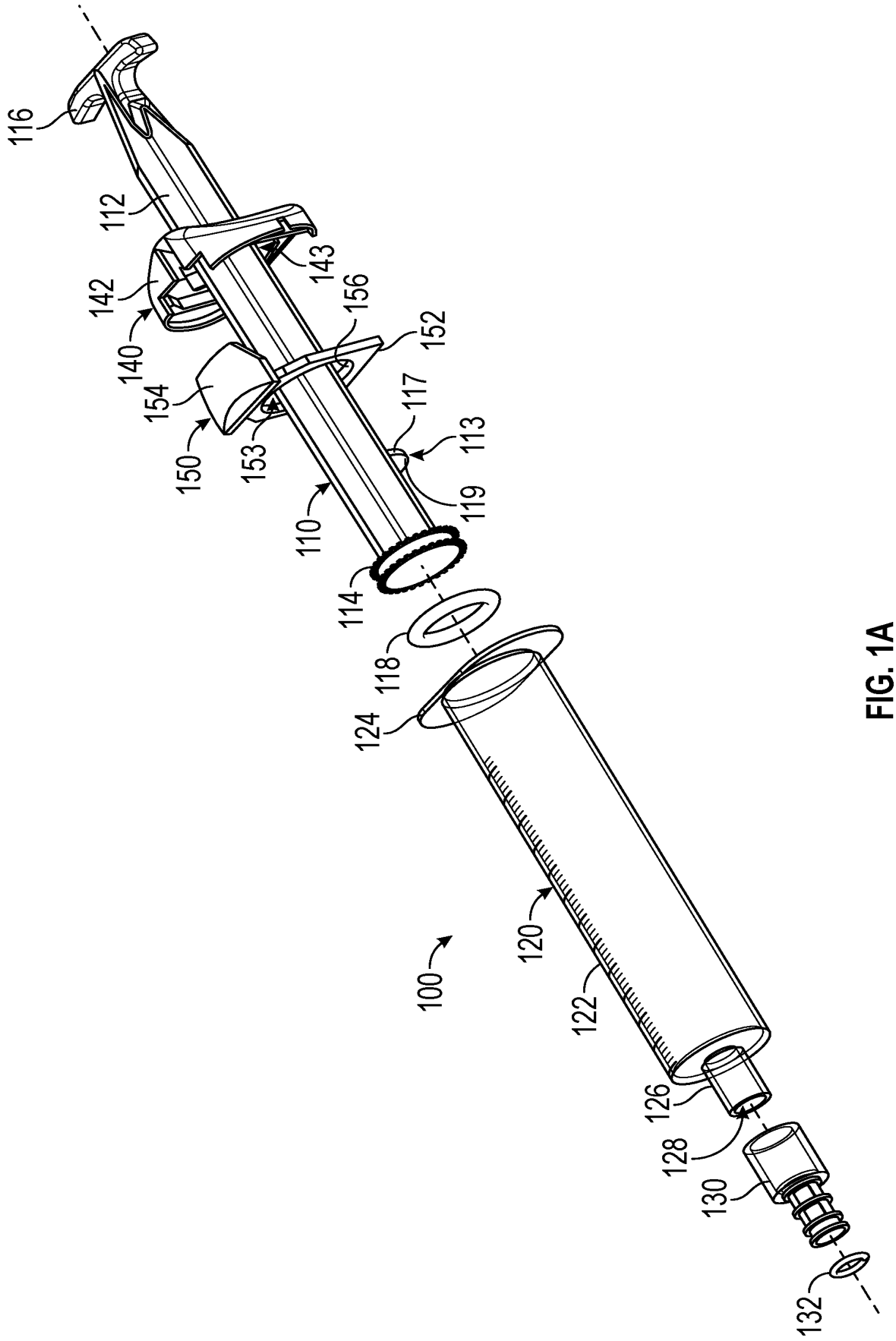

116
112
142
143
156
152
140
154
117
113
150
153
119
110
114
118
124
120
100
122
126
128
130
132

FIG. 1A

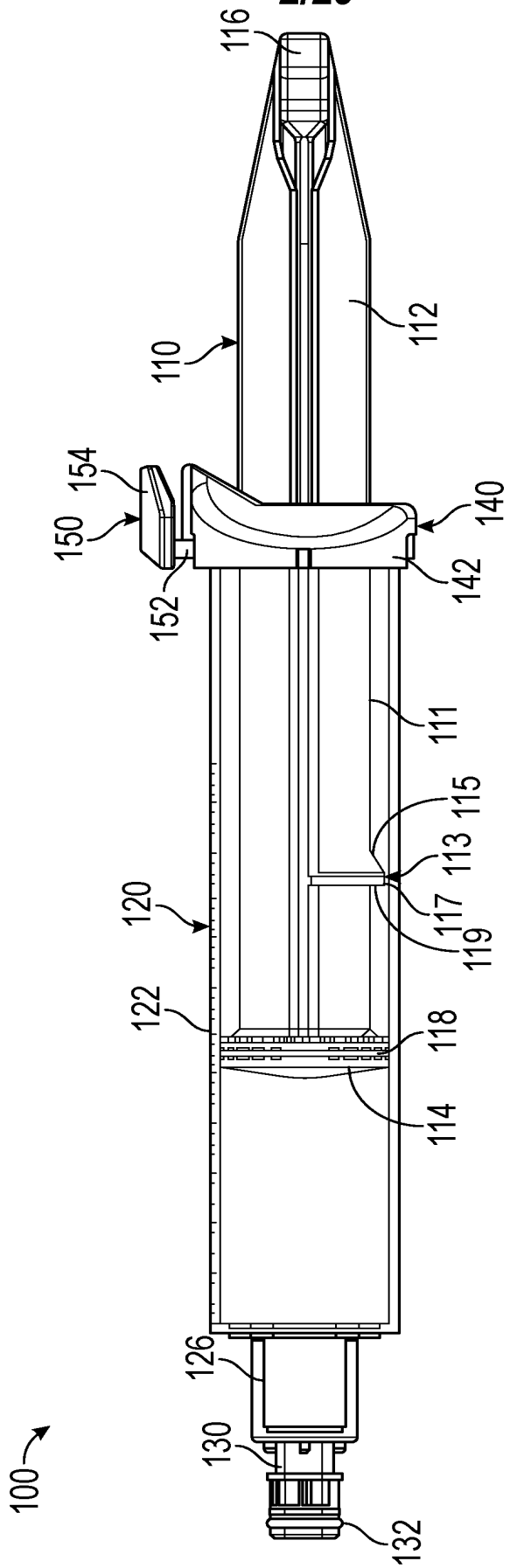

116
112
110
154
150
140
142
152
111
115
113
117
119
120
122
118
114
126
130
132
100

FIG. 1B

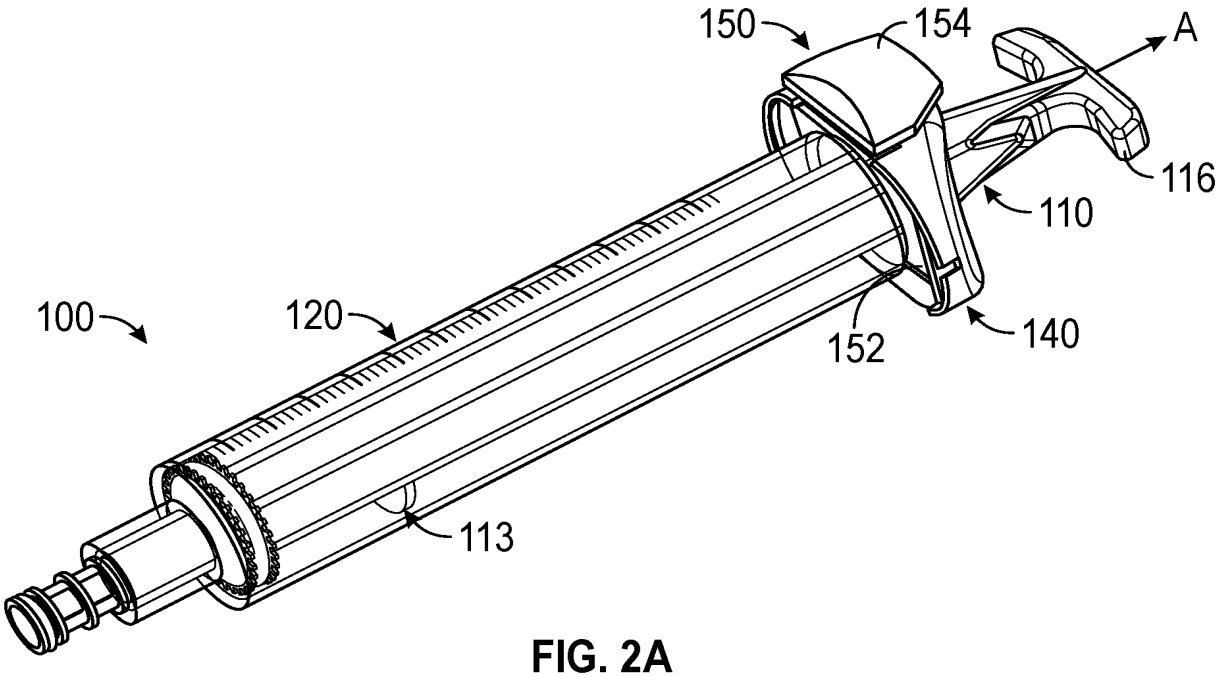

150
154
A
116
110
100
120
152
140
113

FIG. 2A

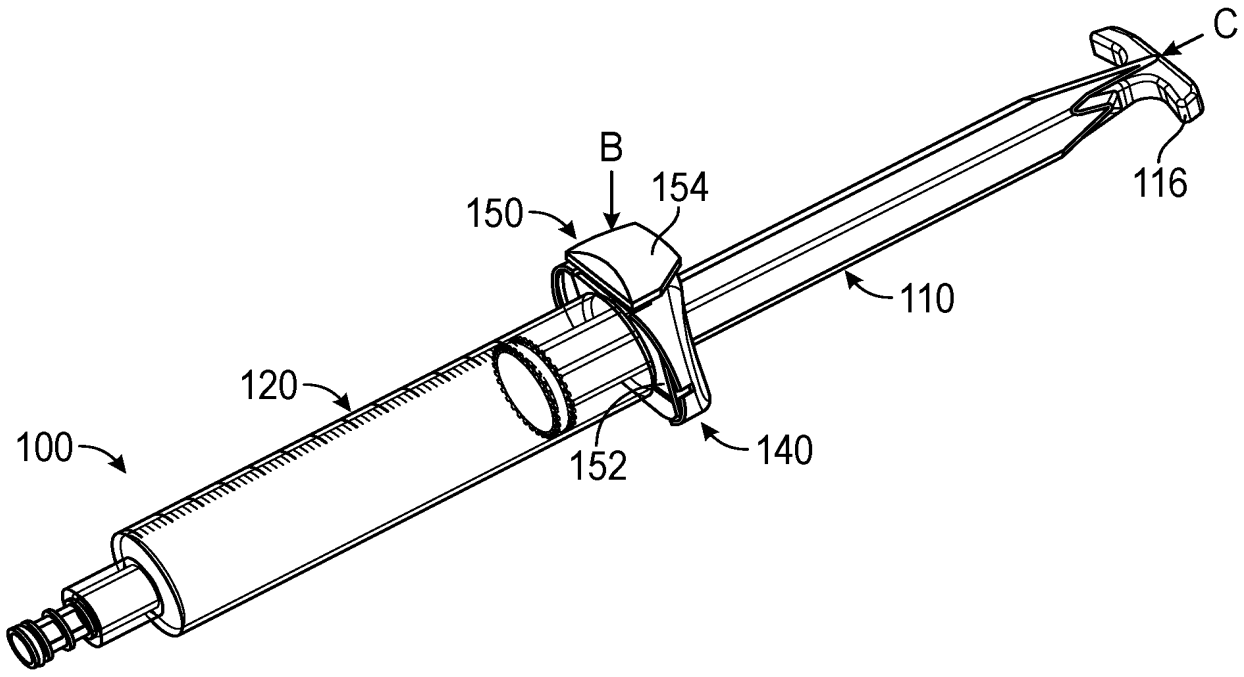

C
B
154
150
116
110
120
100
152
140

FIG. 2B

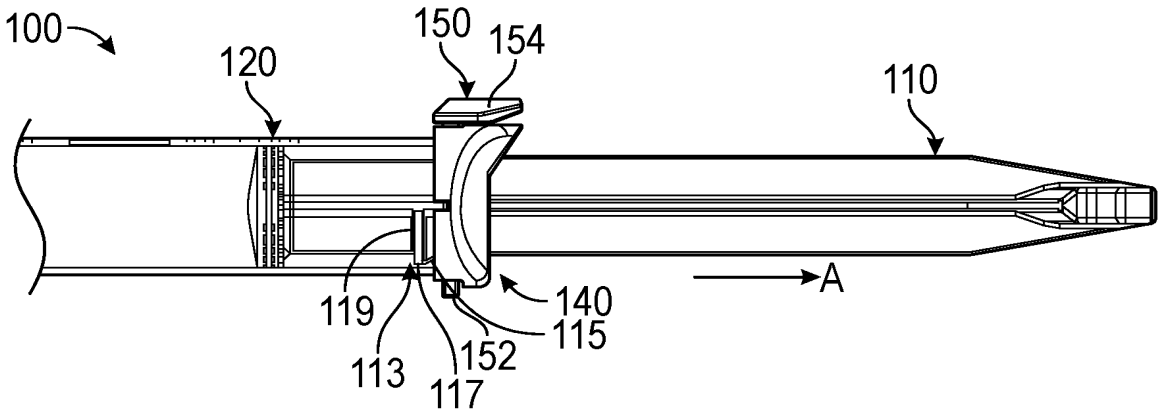

100
120
150
154
110
A
140
115
119
113
152
117

FIG. 3A

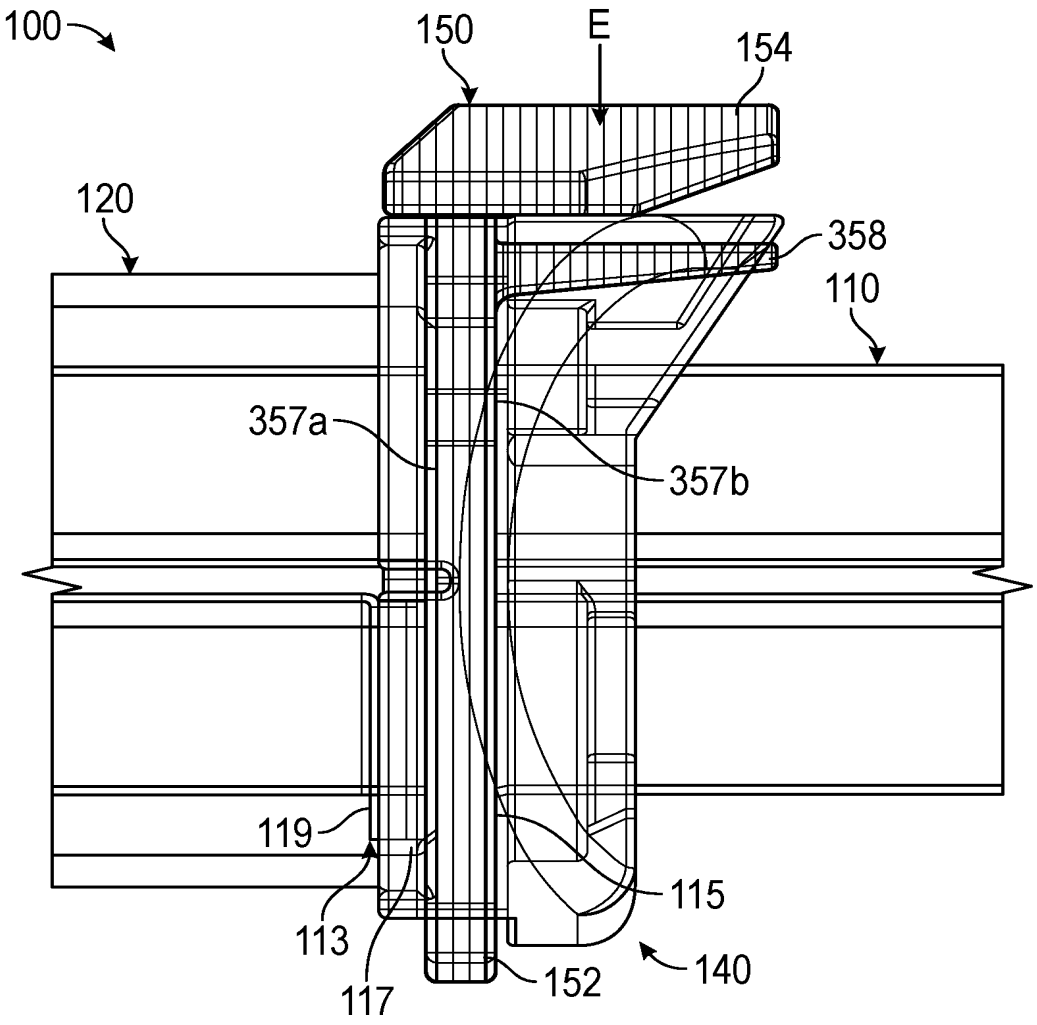

100
150
E
154
120
358
110
357a
357b
119
115
113
140
152
117

FIG. 3B

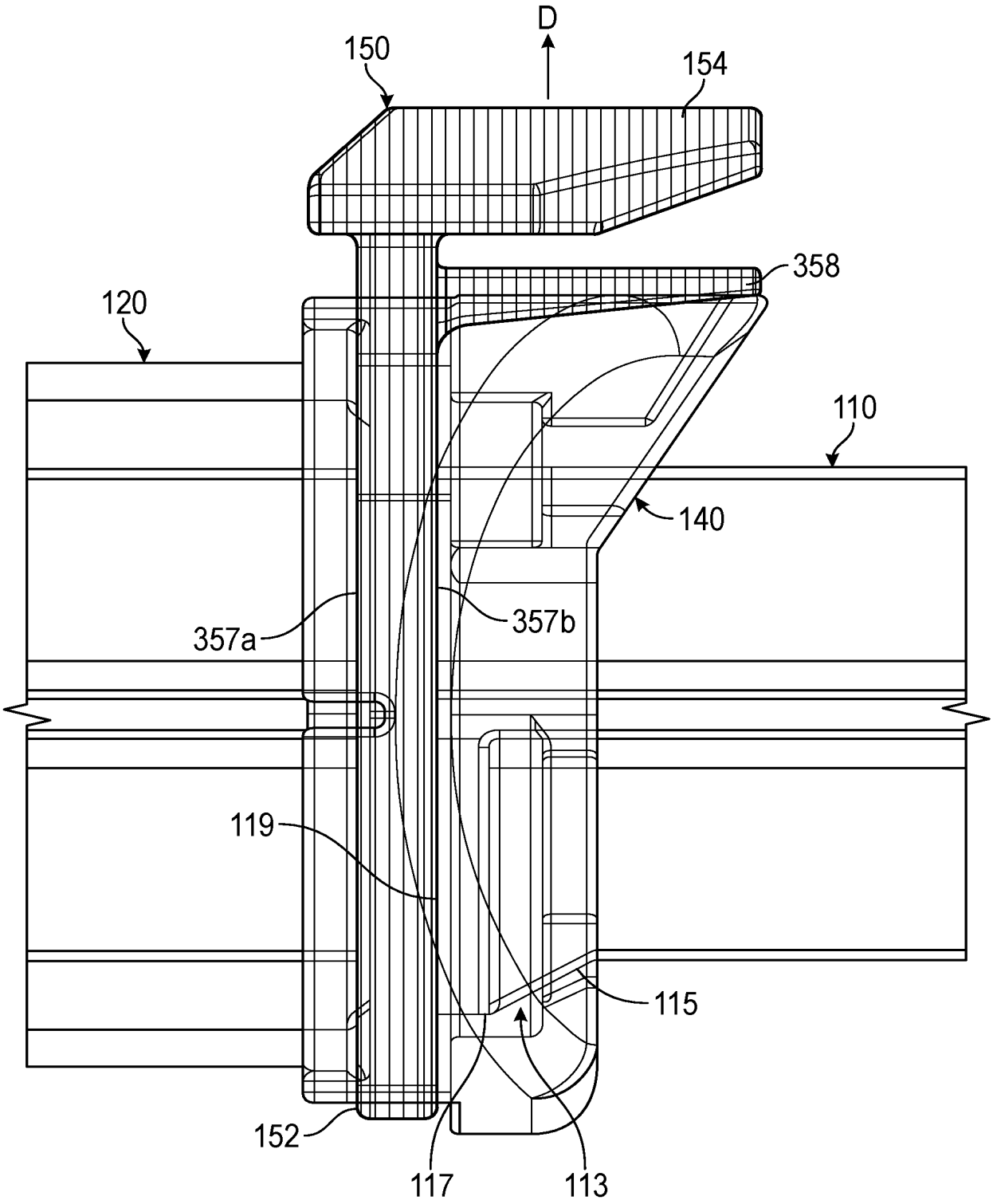


FIG. 3C

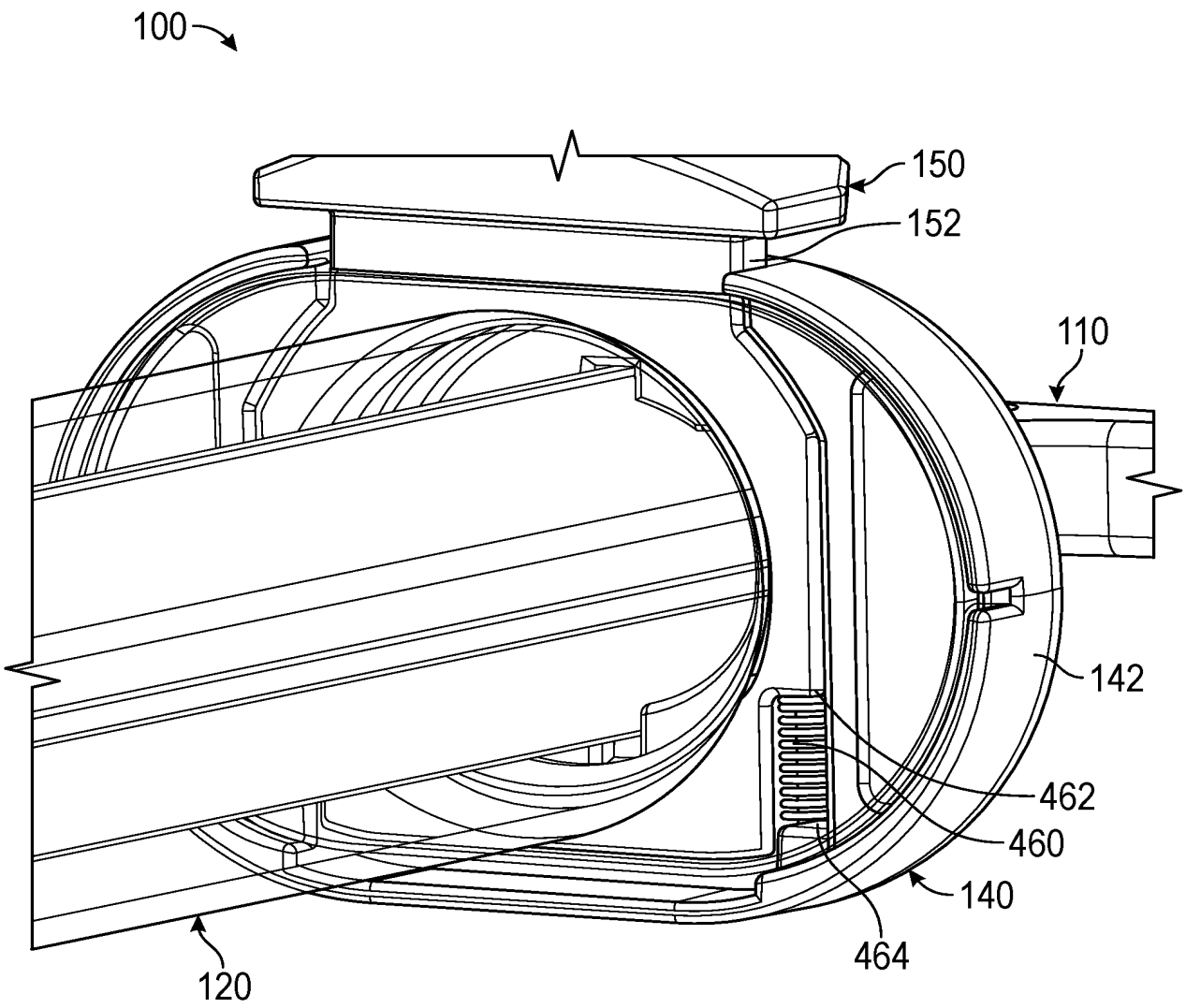


FIG. 4

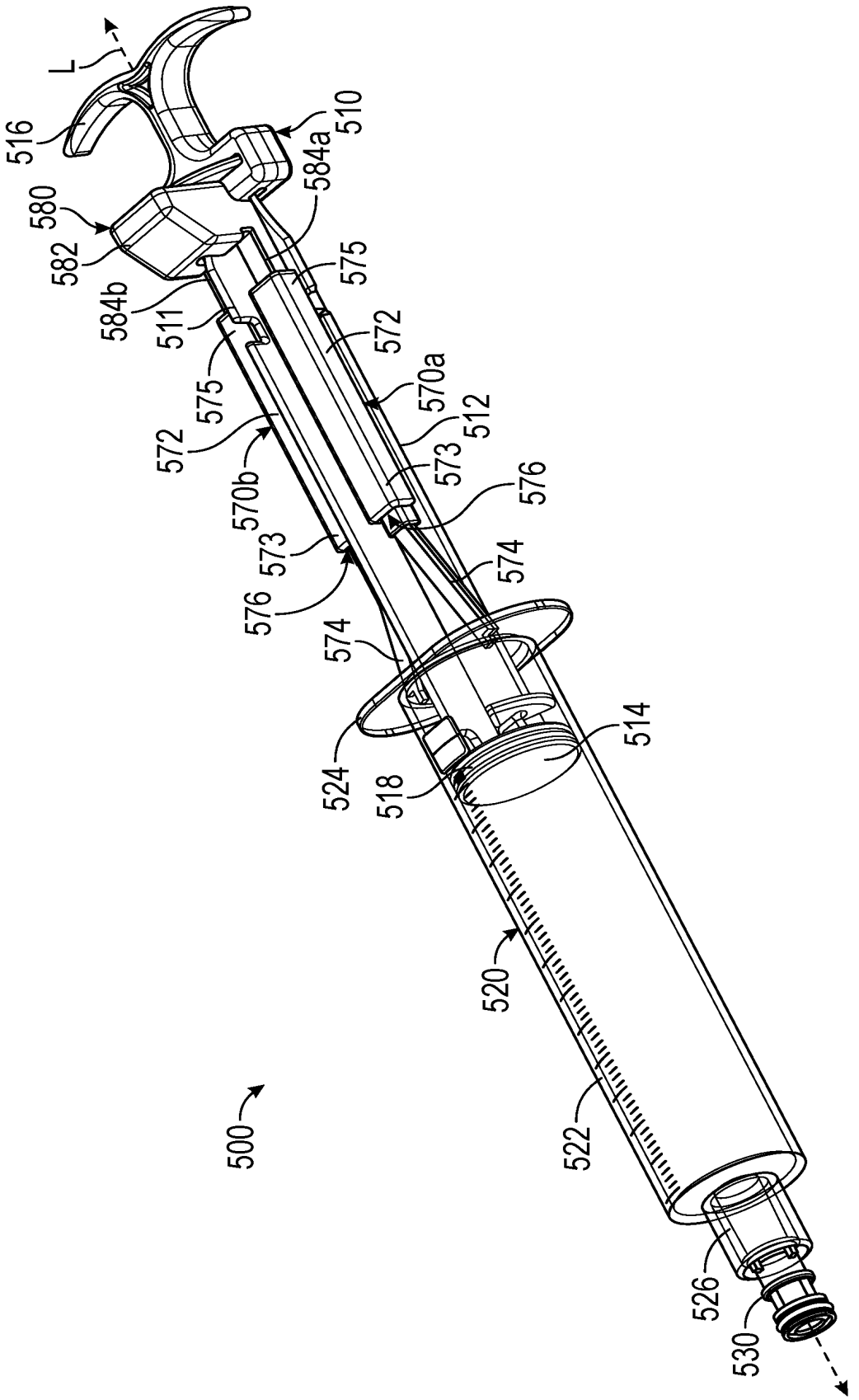

L
516
510
584a
580
582
575
584b
511
572
575
570a
572
512
570b
573
576
573
574
576
574
514
524
518
520
500
522
526
530

FIG. 5A

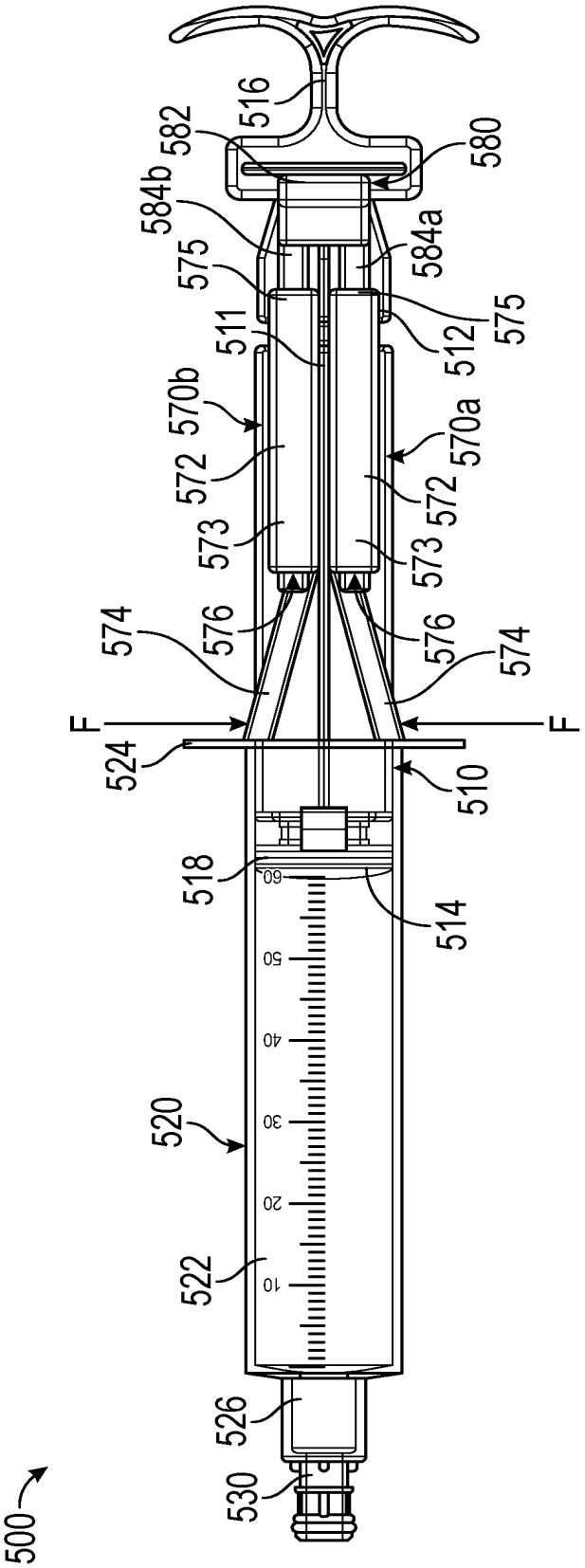

516
582
580
584b
584a
575
575
511
512
570b
570a
572
572
573
573
574
576
576
574
F
F
524
510
518
514
60
50
40
30
20
10
520
522
526
530
500

FIG. 5B

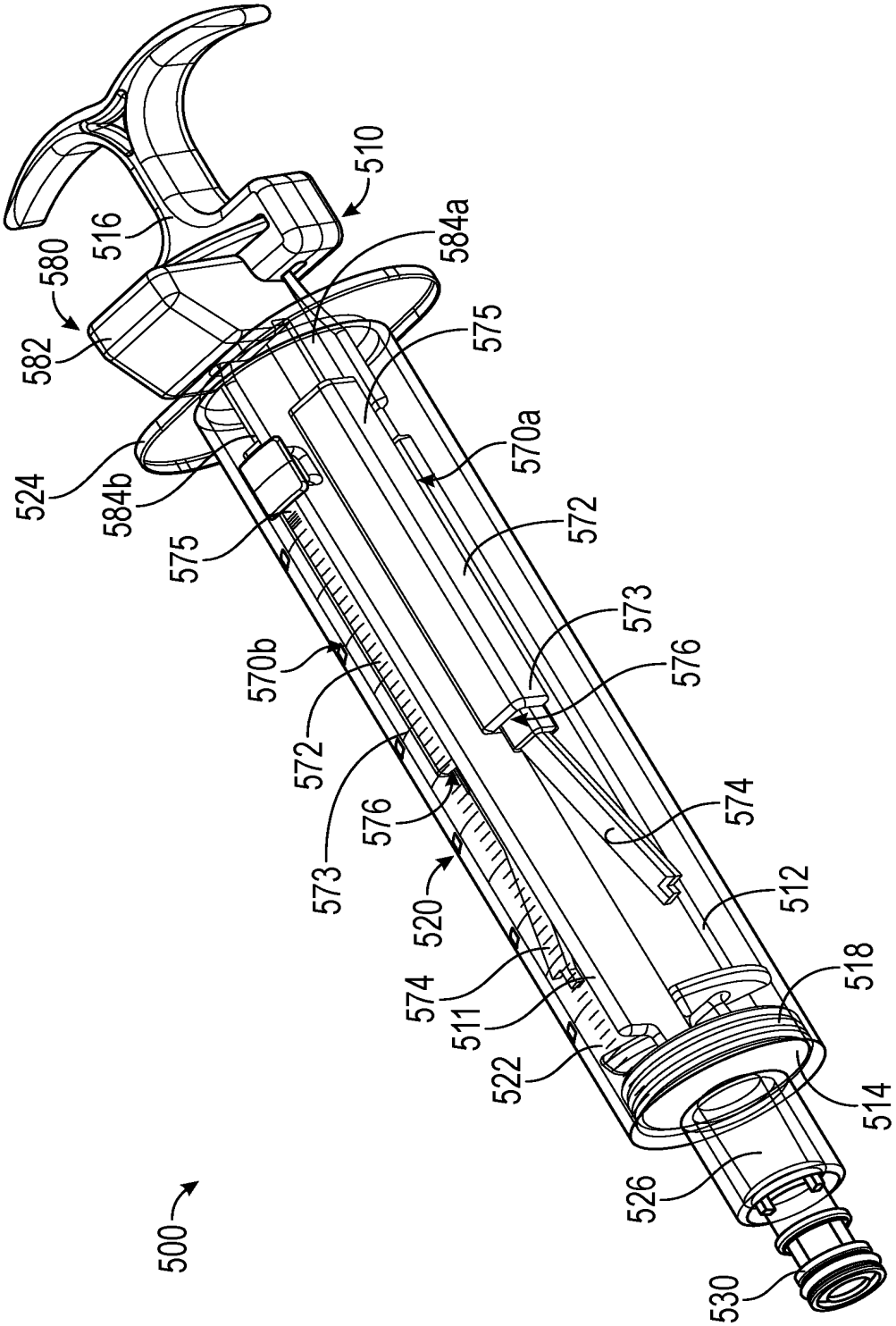

500
510
516
580
582
584a
575
570a
572
573
576
574
512
518
514
526
530
524
584b
575
570b
572
573
576
574
520
574
511
522

FIG. 5C

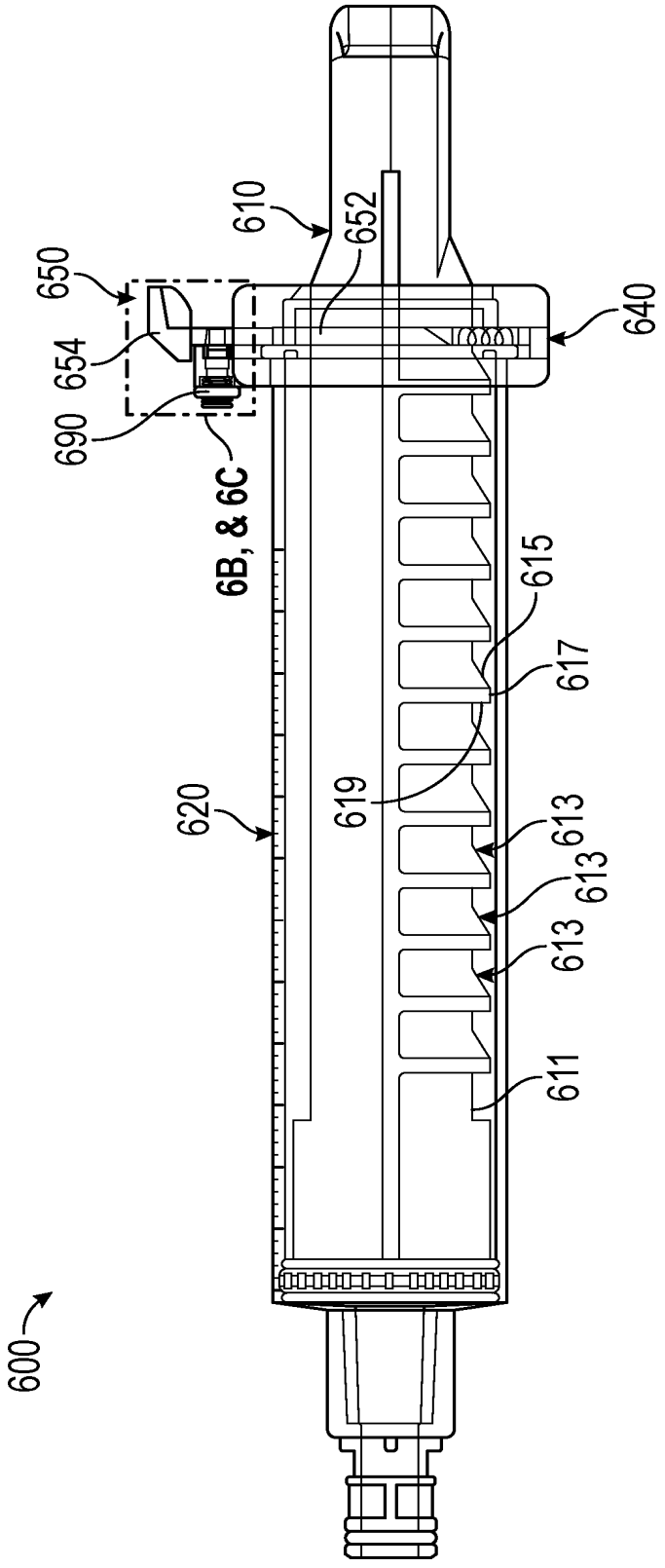


FIG. 6A

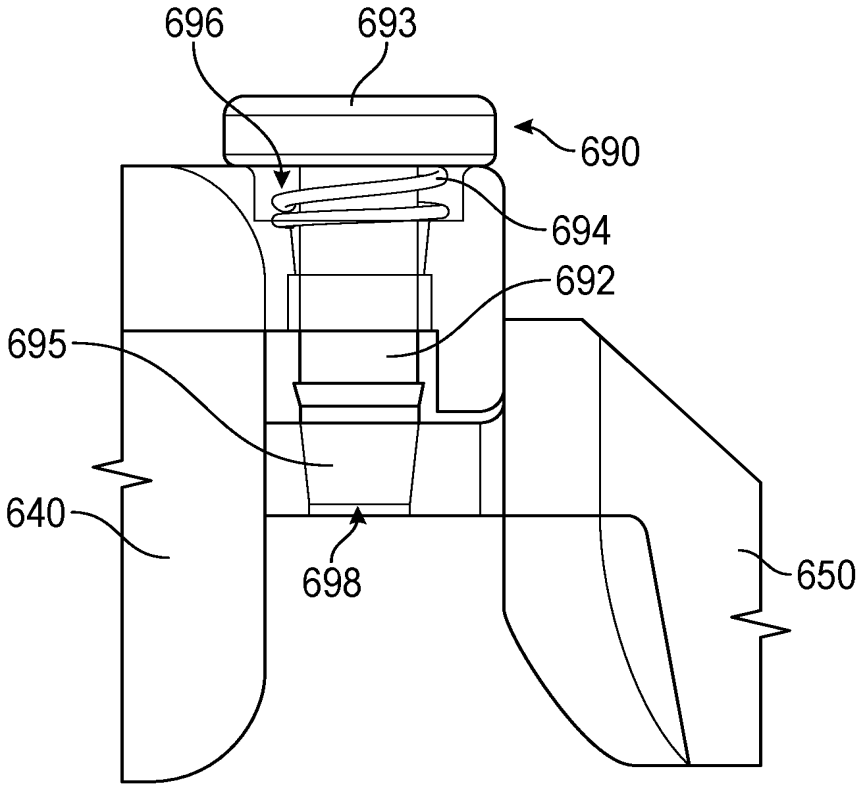

696
693
690
694
692
695
640
698
650

FIG. 6B

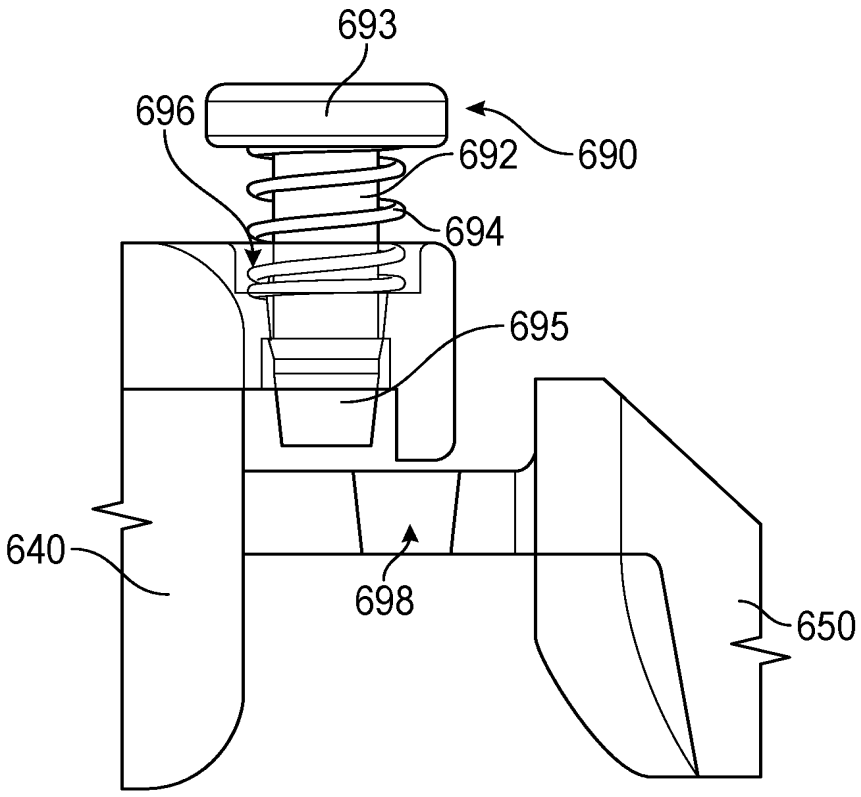

693
696
692
690
694
695
640
698
650

FIG. 6C

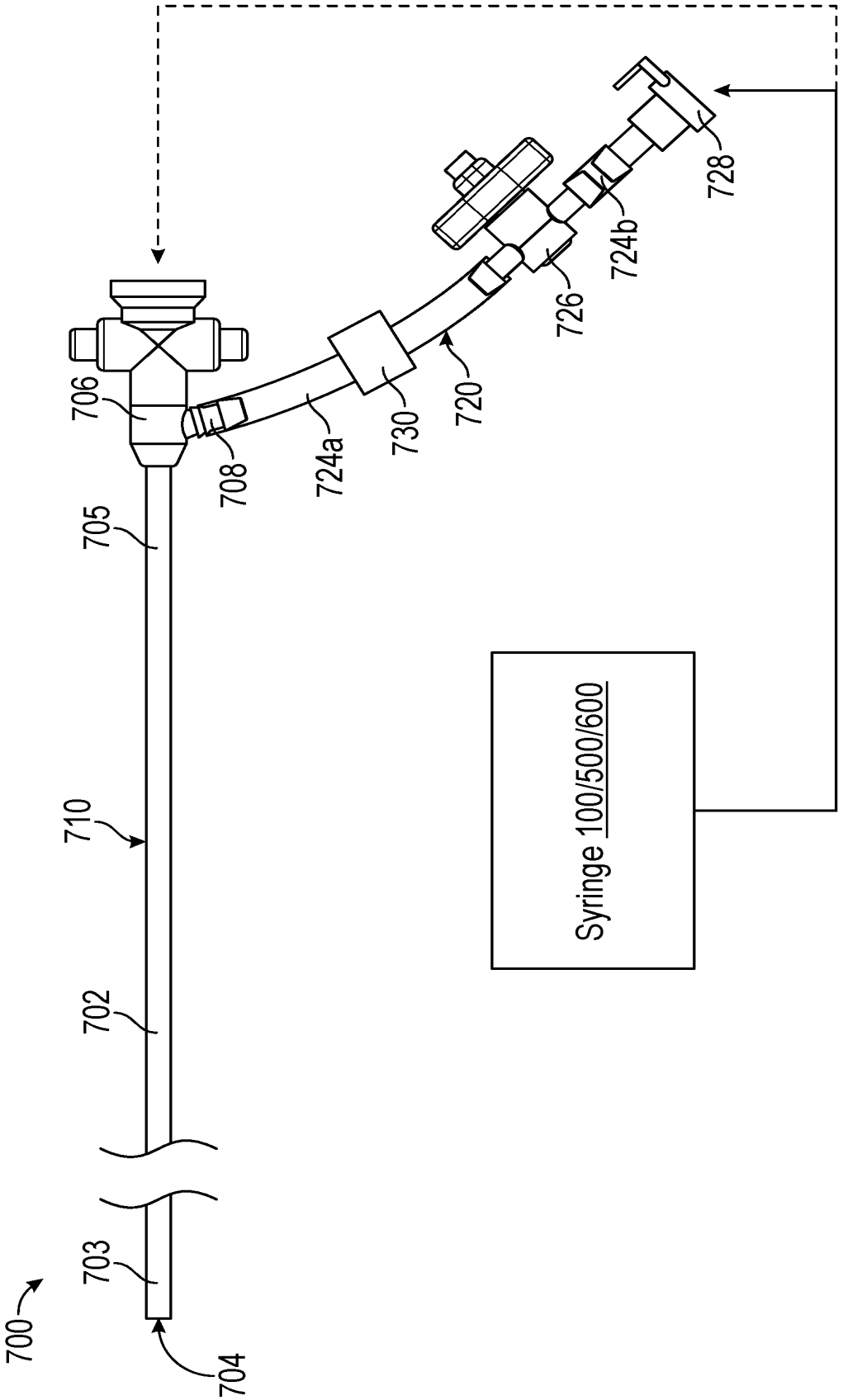

700
703
704
705
706
708
710
720
724a
724b
726
728
730
702
Syringe 100/500/600

FIG. 7

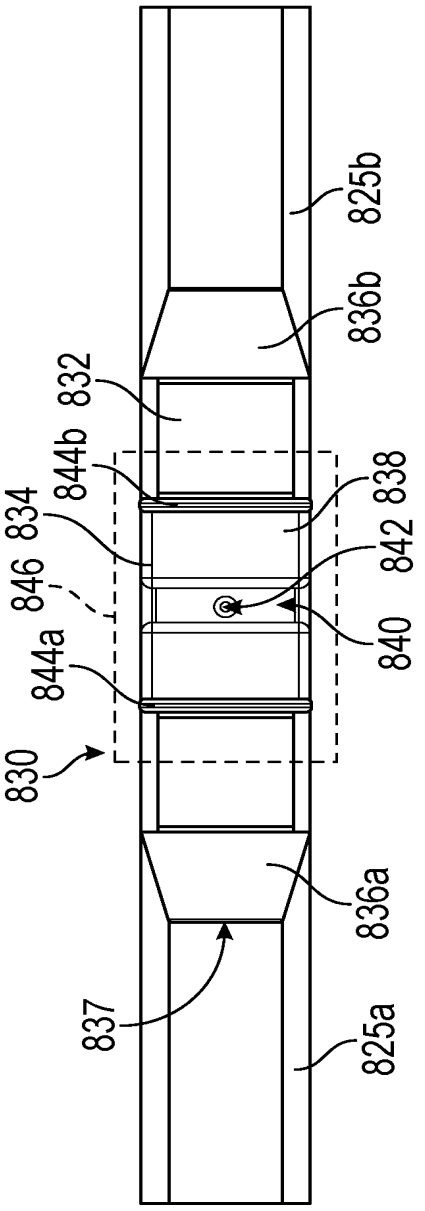

825b
836b
832
844b
838
834
842
846
840
844a
830
836a
837
825a

FIG. 8A

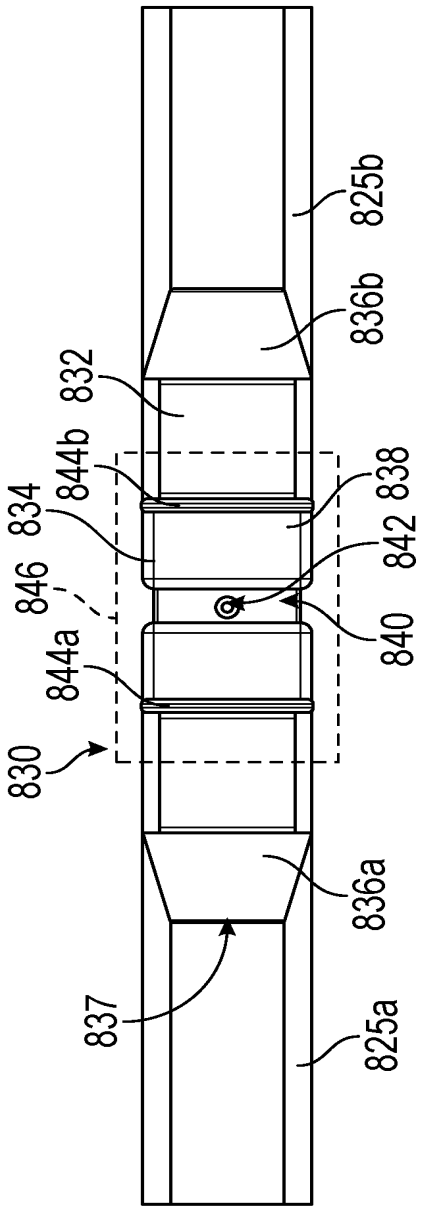

825b
836b
832
844b
838
834
842
846
840
844a
830
836a
837
825a

FIG. 8B

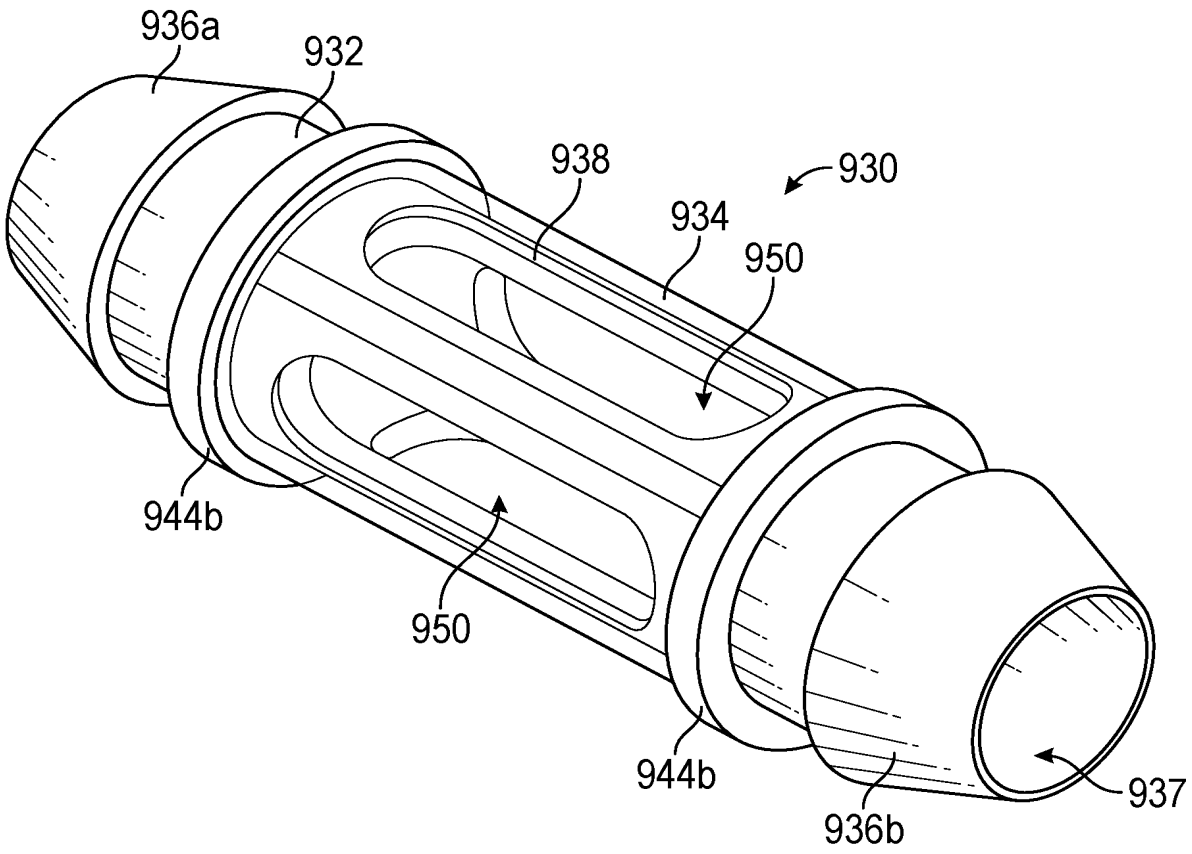


FIG. 9

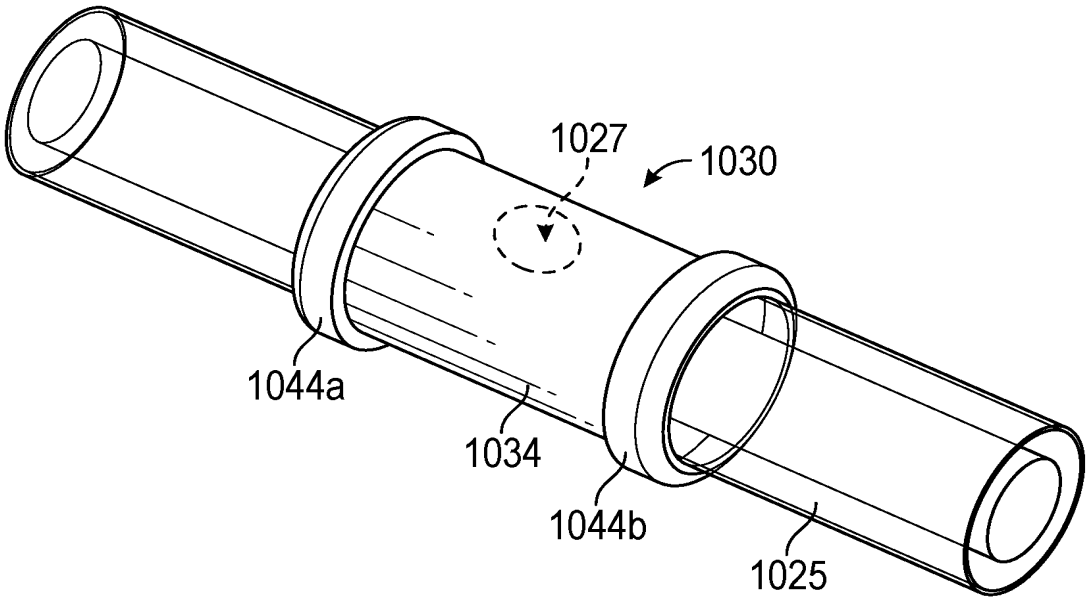


FIG. 10A

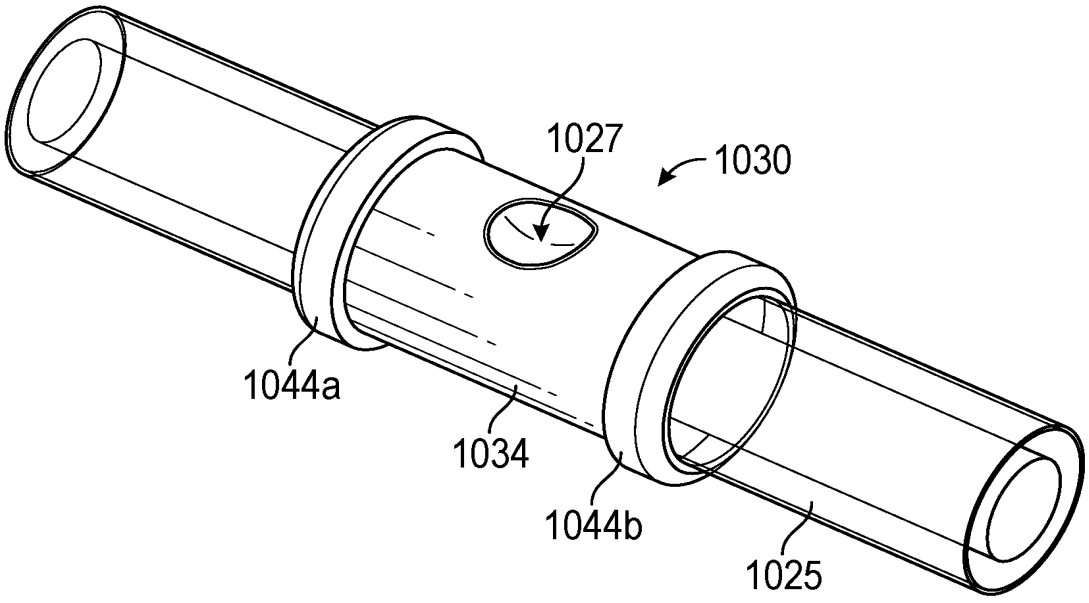


FIG. 10B

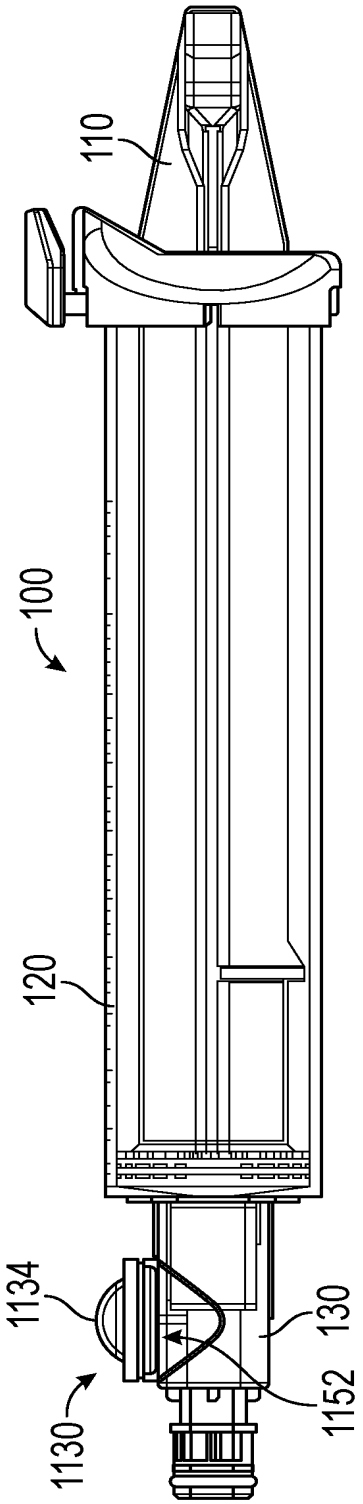


FIG. 11

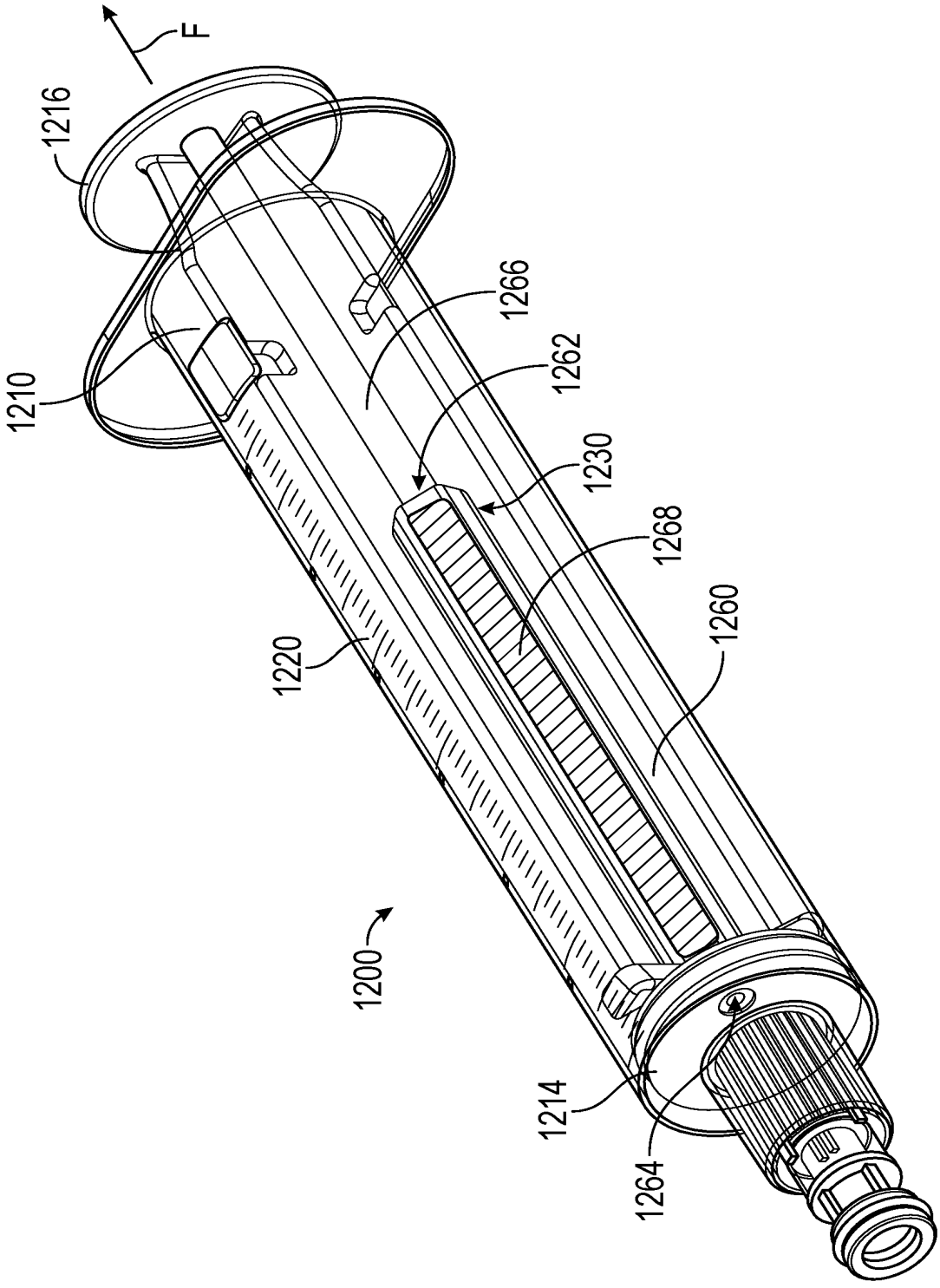


FIG. 12A

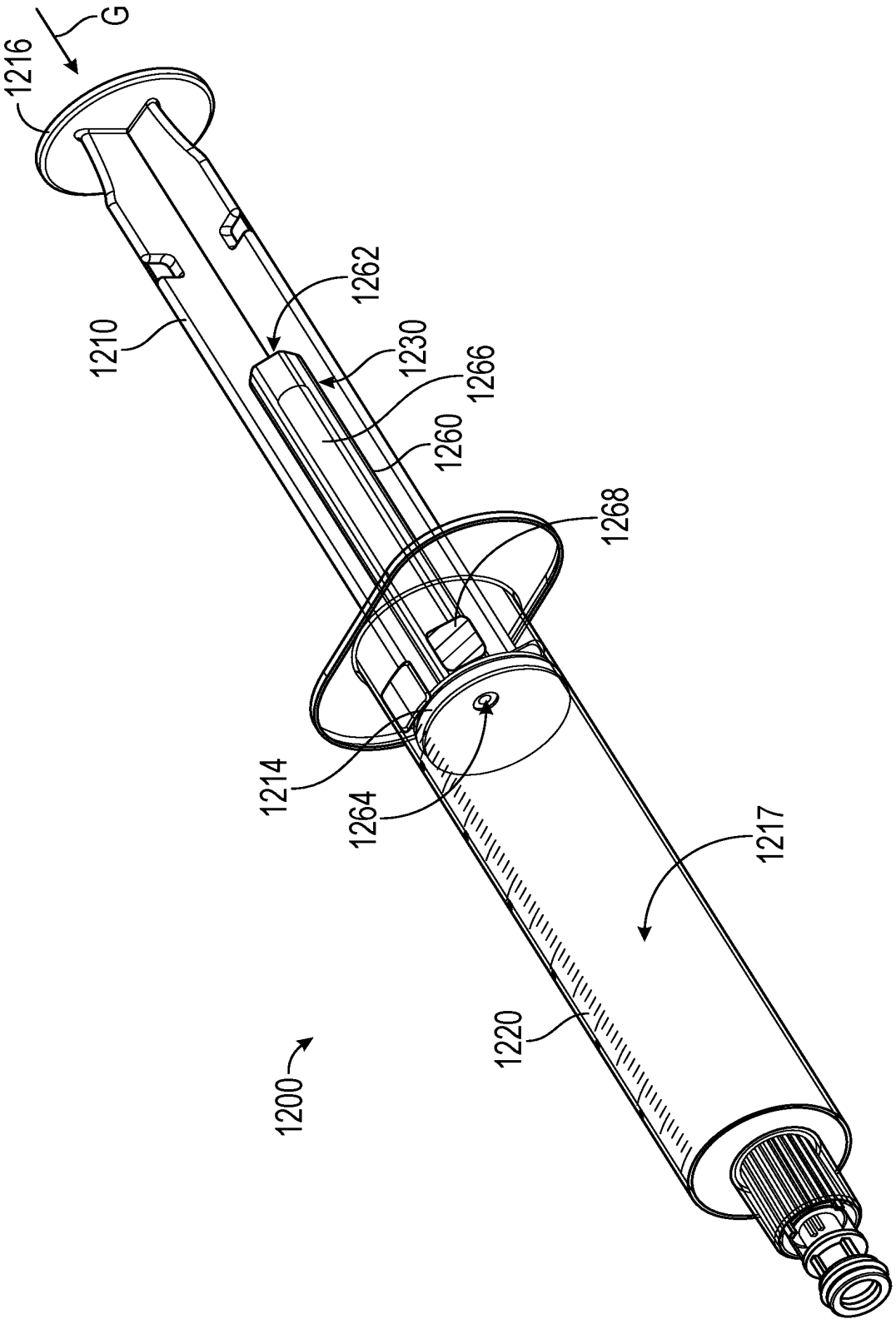


FIG. 12B

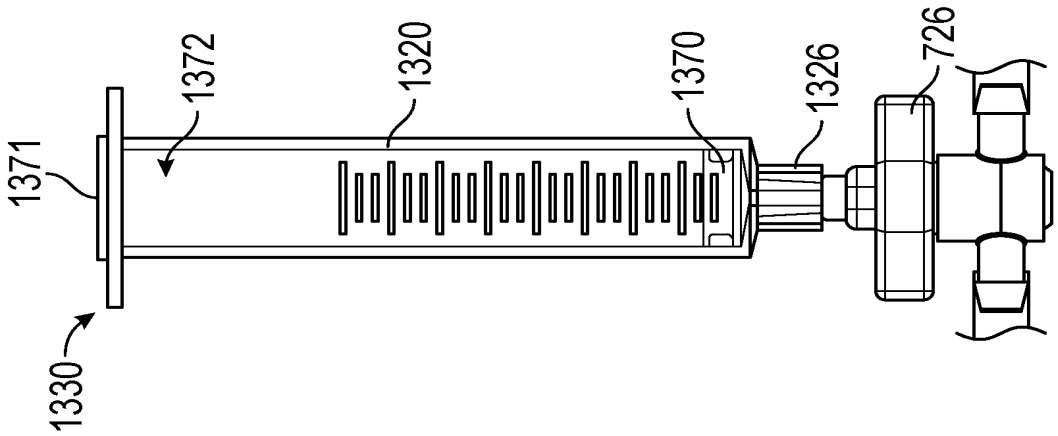


FIG. 13C

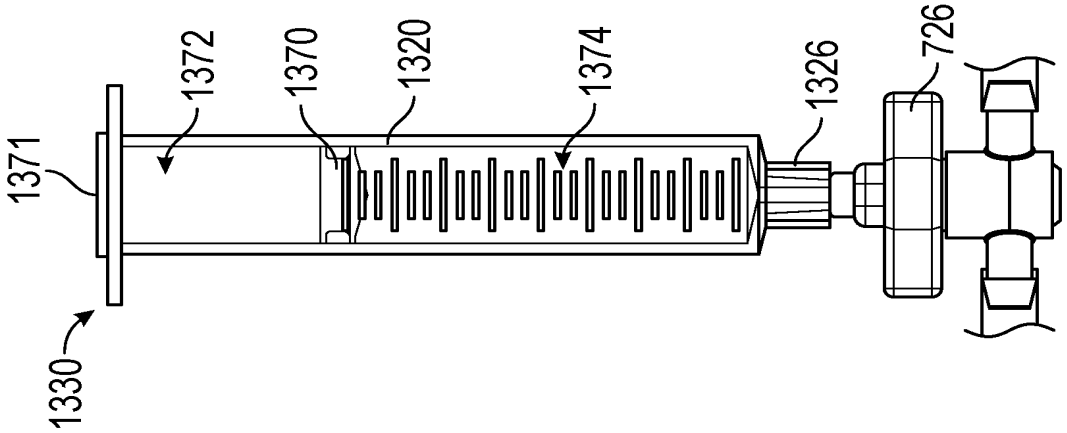


FIG. 13B

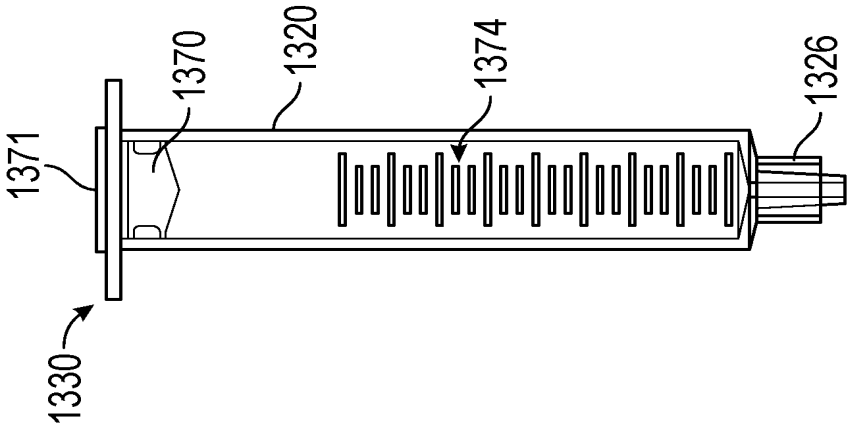


FIG. 13A

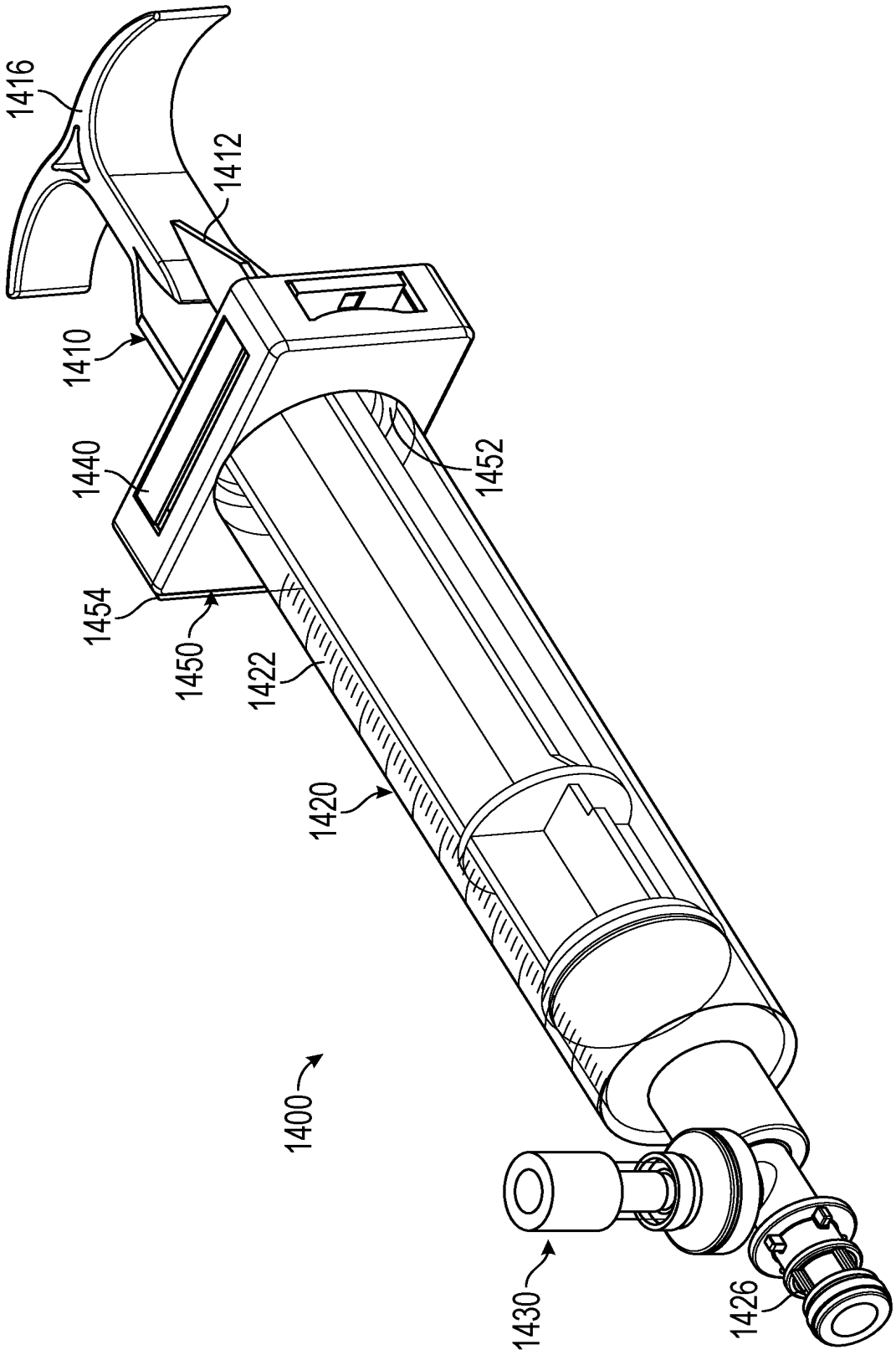


FIG. 14A

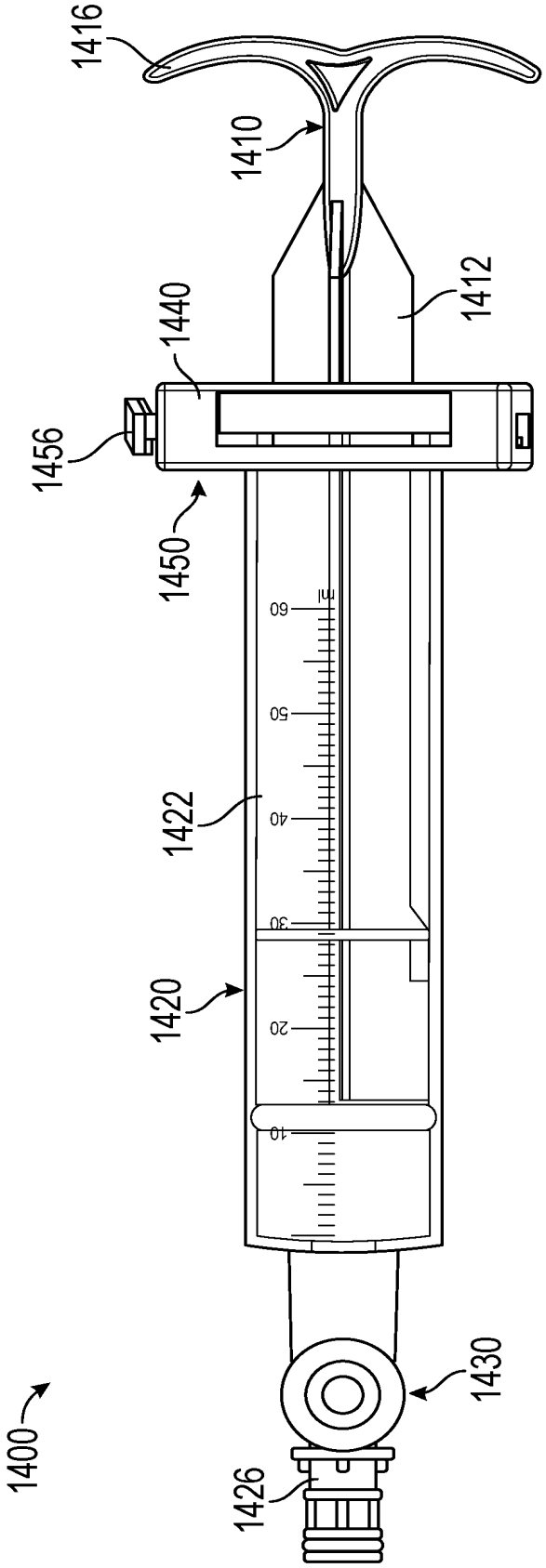

1416
1410
1412
1440
1456
1450
60
50
40
30
20
10
1422
1420
1430
1400
1426

FIG. 14B

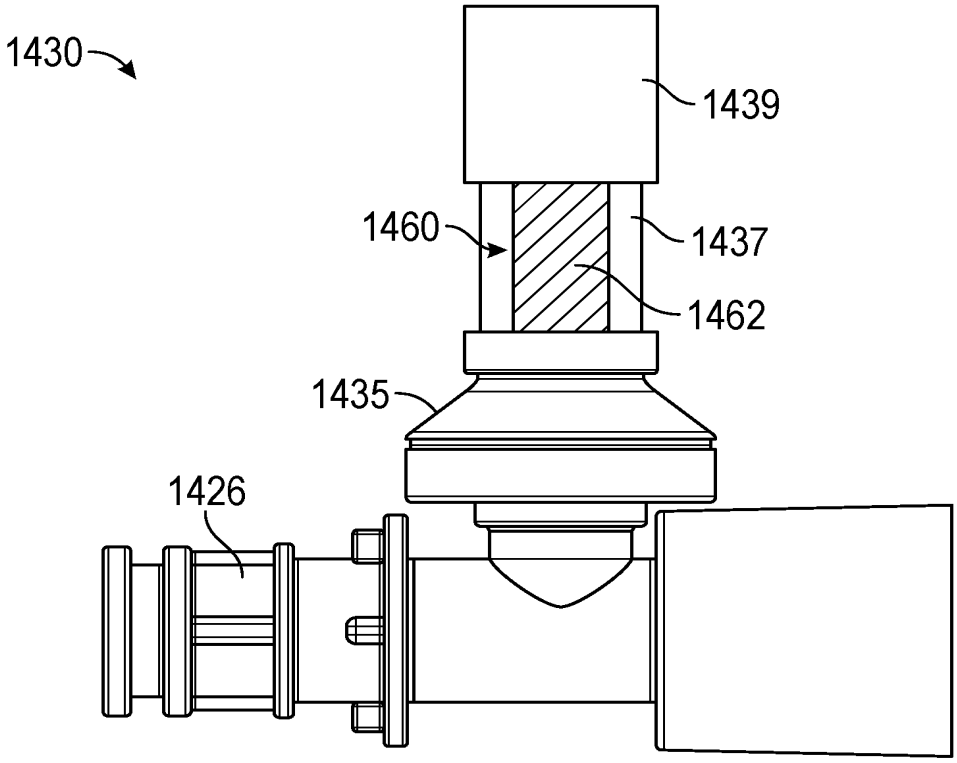


FIG. 14C

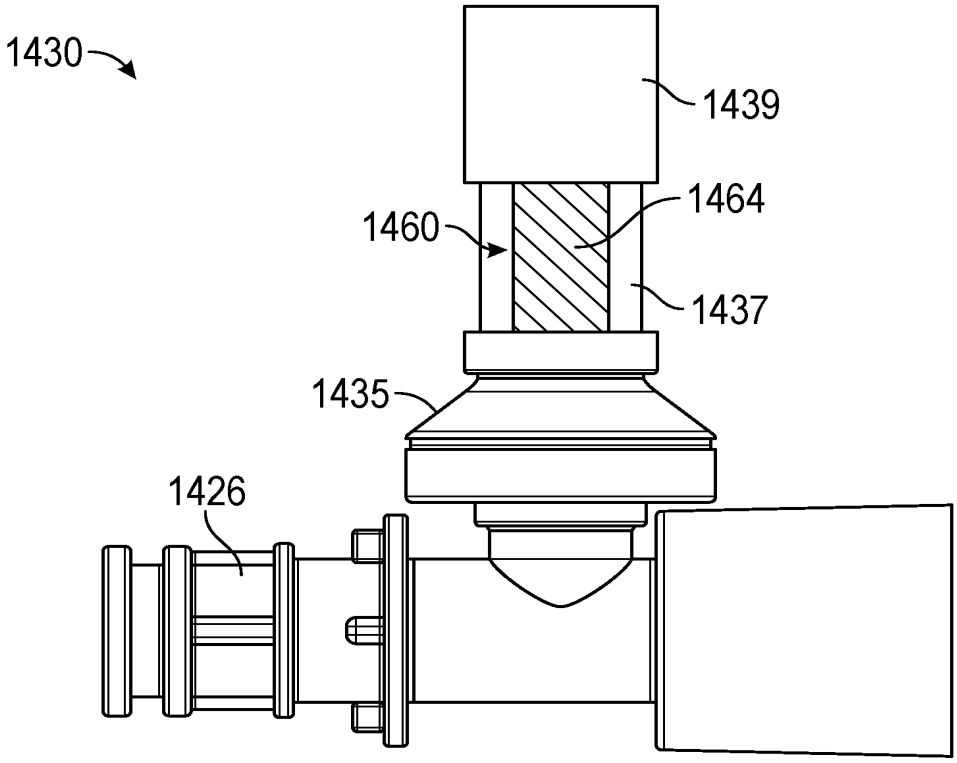


FIG. 14D

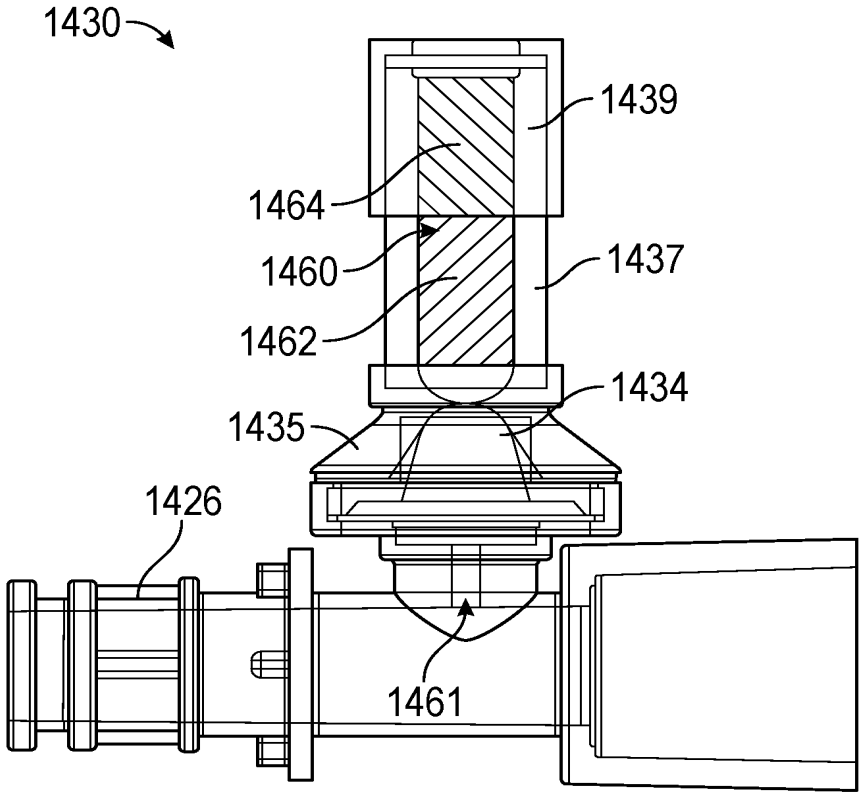


FIG. 14E

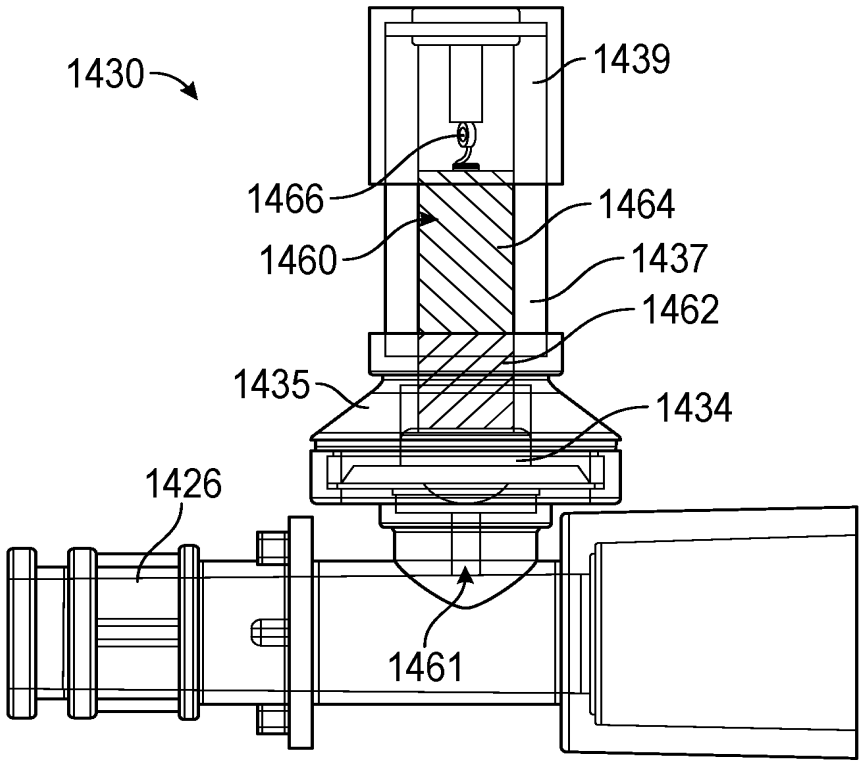


FIG. 14F

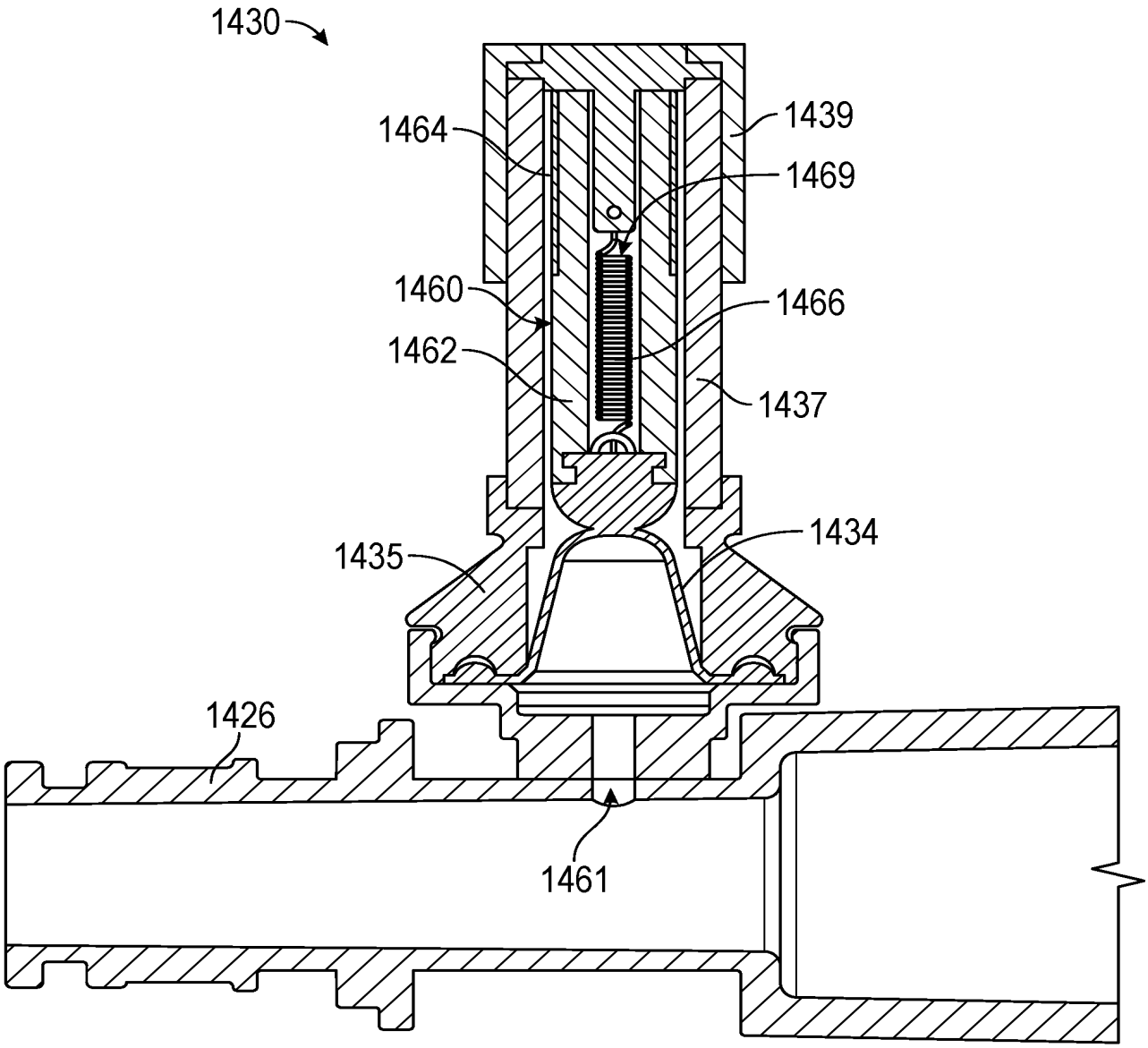


FIG.14G

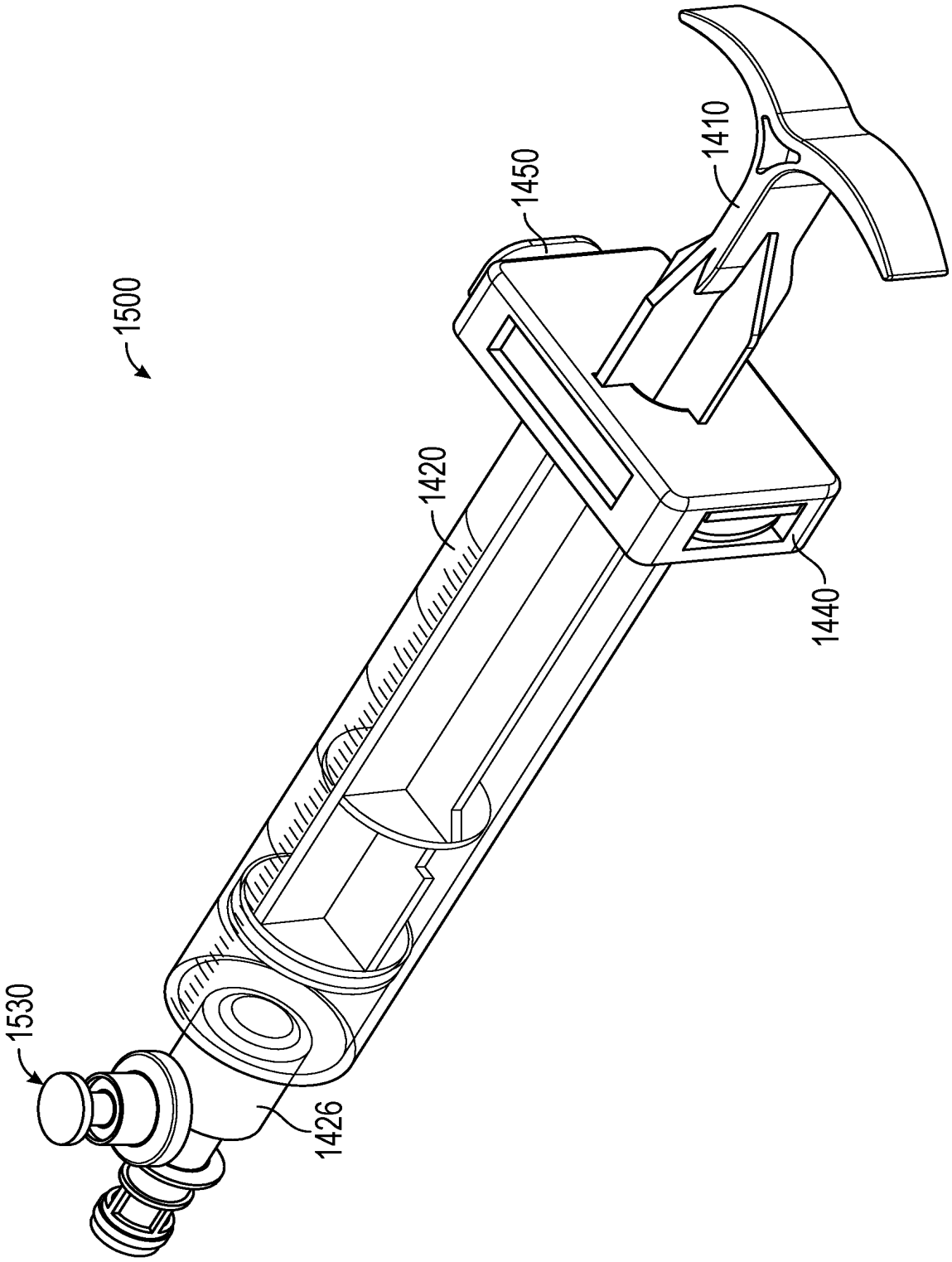


FIG. 15A

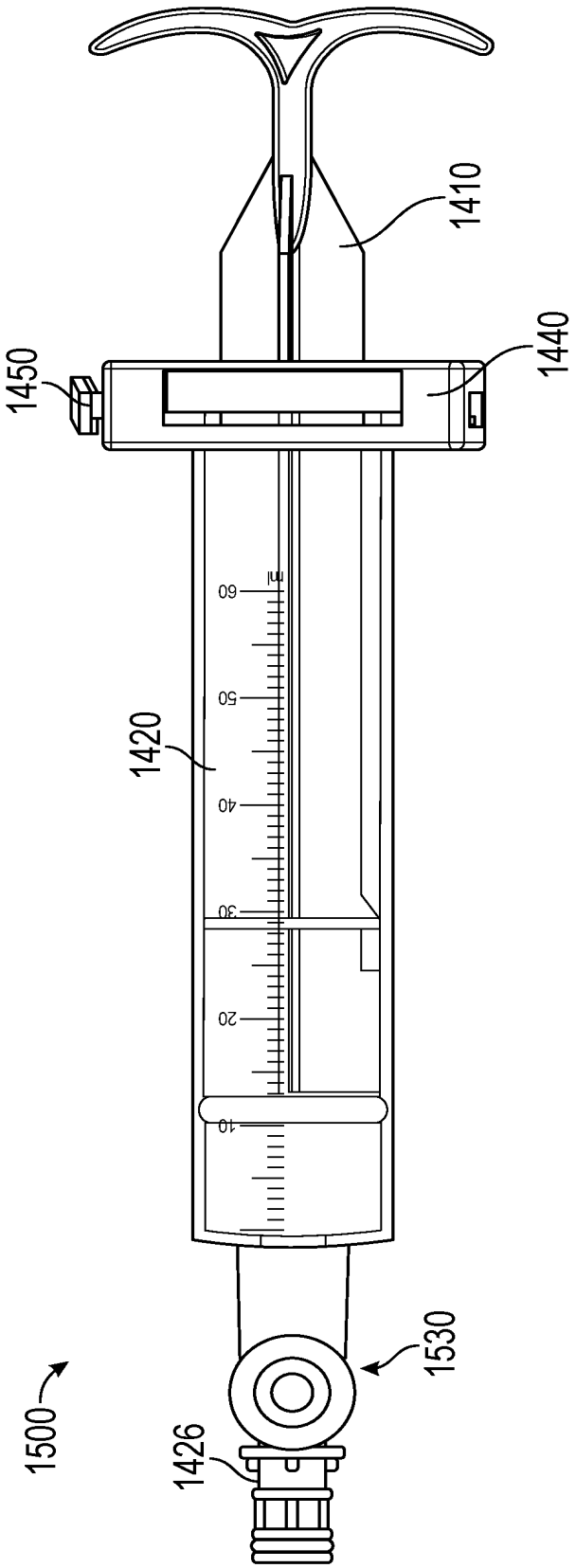


FIG. 15B

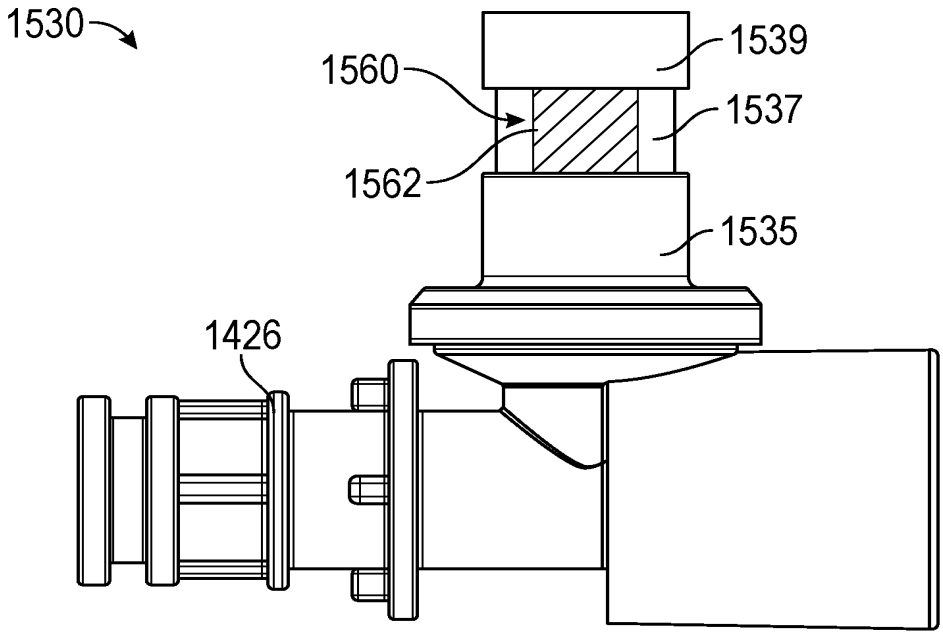


FIG. 15C

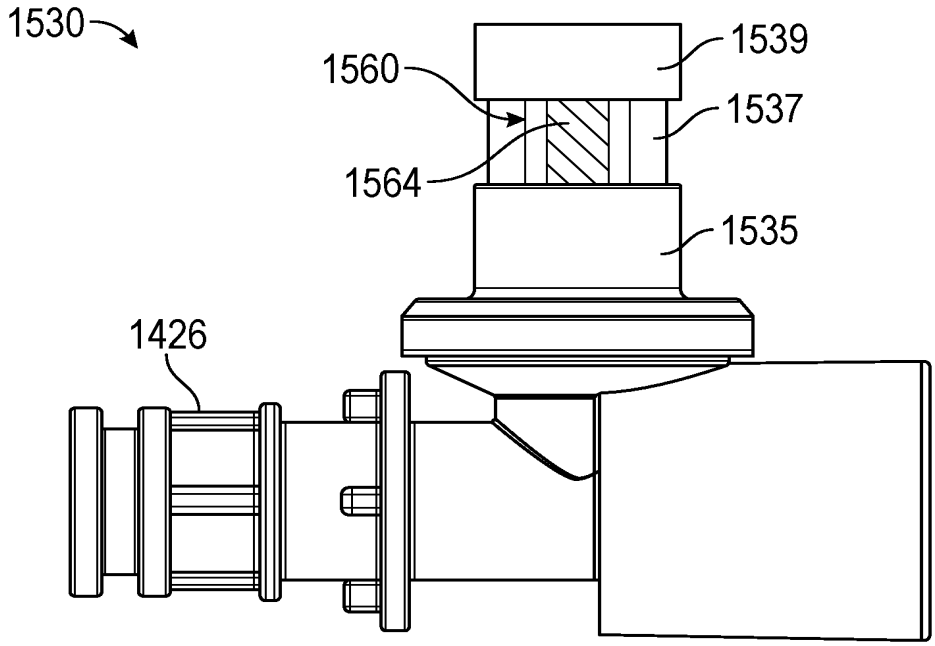


FIG. 15D

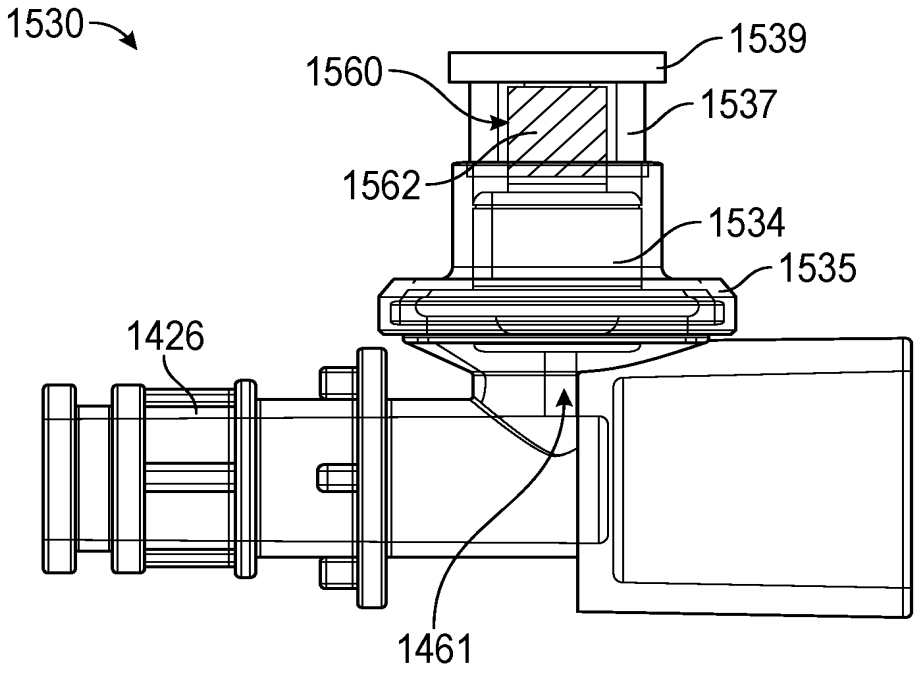


FIG. 15E

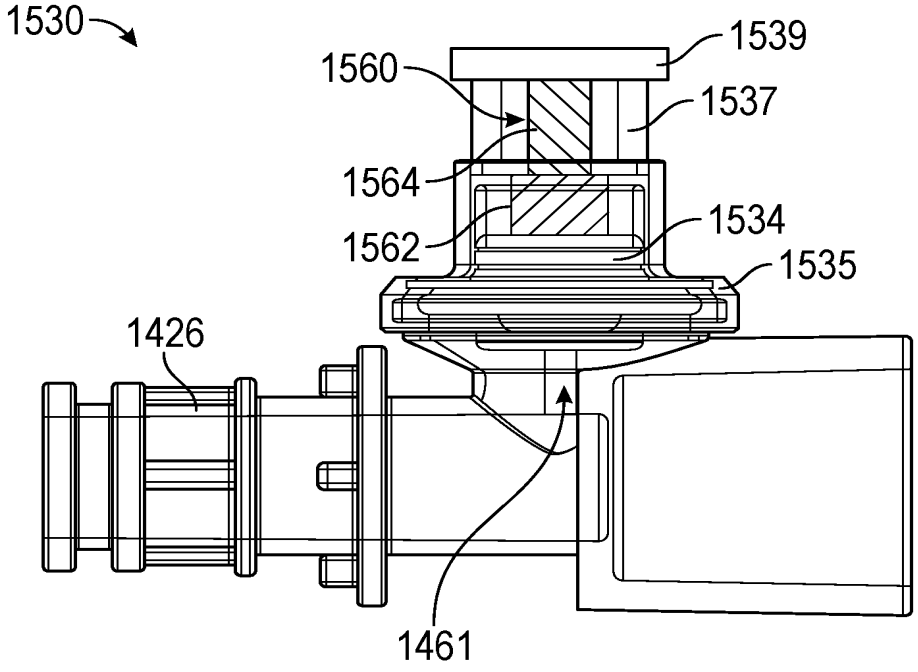


FIG. 15F

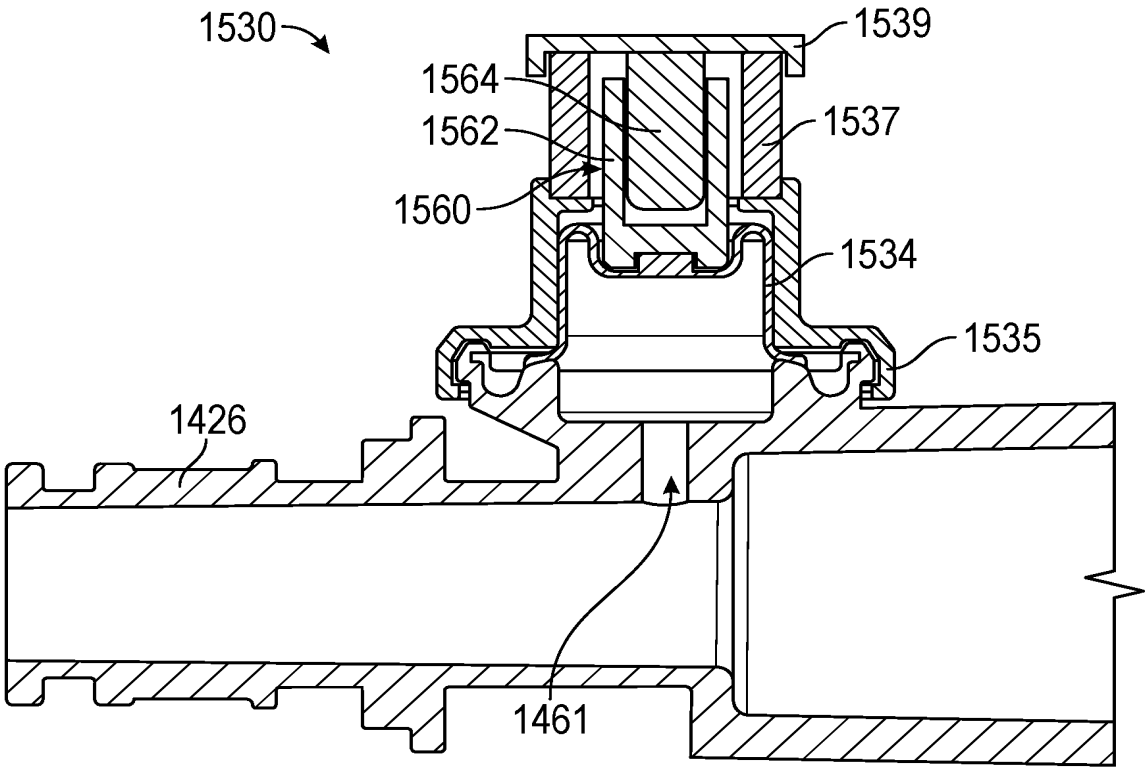


FIG. 15G

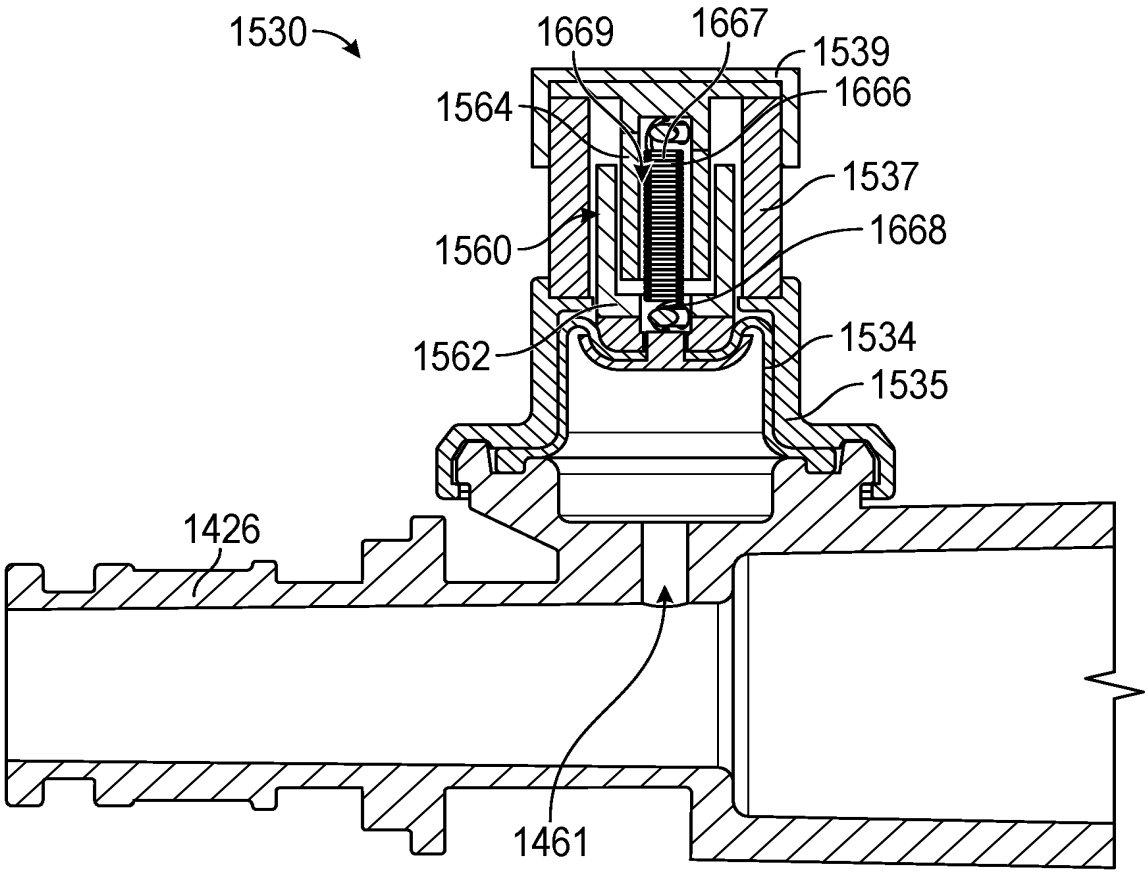


FIG.16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/45072

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 5/32; A61M 5/315 (2021.01)

CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315

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)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2013/0126559 A1 (COWAN et al.) 23 May 2013 (23.05.2013); entire document, especially para [0028], and Fig. 1-2.	1-10
A	US 2004/0122359 A1 (WENZ et al.) 24 June 2004 (24.06.2004); entire document, especially para [0063]-[0066], and Fig. 7.	1-15
A	WO 2011/073176 A1 (NOVARTIS AG) 23 June 2011 (23.06.2011); especially pg 6 ln 33 to pg 7 ln 2, and Fig. 1-3.	10-15
A, P	WO 2021/067134 A1 (BECTON, DICKINSON AND COMPANY) 8 April 2021 (08.04.2021); entire document.	1-15
A	US 2004/0267272 A1 (HENNIGES et al.) 30 December 2004 (30.12.2004); entire document.	1-15

☐ 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
"D" document cited by the applicant in the international application
"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 December 2021	JAN 20 2022
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. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/45072

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:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

-*- See Supplemental Box -*-

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.:
1-15

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)) (July 2019)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US 21/45072

-*- Box III.0 - Explanations where unity of invention is lacking

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 ln 66 to col 5 ln 20) having a barrel (50; Fig. 1-10; col 5 ln 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 ln 21-23).

Groups II-III share the common technical feature of a vacuum indicator.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 8 ln 36-50).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT SPECIFICATION (11) 1588072

1588072

(21) Application No. 3838/78 (22) Filed 31 Jan. 1978 (19)
(31) Convention Application No. 767696 (32) Filed 11 Feb. 1977 in
(33) United States of America (US)
(44) Complete Specification published 15 April 1981
(51) INT. CL.³ A61B 17/50
(52) Index at acceptance
A5R CX

(54) EXTRACTING DEVICE FOR REMOVING OBJECTS FROM HUMAN BODY PASSAGES

(71) I, WILLIAM HOWARD BEECHER, a citizen of the United States of America of 292 Boyd Avenue, Elmhurst, Illinois 60126, United States of America,

do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to an extracting device for removing kidney stones or other objects from the urinary tract or other passages of the human body, some of which, such as blood vessels, may be reached through incisions.

An object of the present invention is to provide a new and improved extracting device which can easily be inserted into the ureters or other narrow passages of the human body, and will be capable of removing kidney stones and other objects in a highly effective and efficient manner.

A further object is to provide such a new and improved extracting device which will be capable of removing kidney stones and other similar objects from narrow passages of the human body, without scratching or otherwise injuring the walls of the passages.

According to the present invention there is provided an extracting device comprising an outer flexible tube the distal end of which is insertable into a body passage, an inner flexible tube slideably received within the outer tube for free longitudinal sliding movement with the distal end of the inner tube normally projecting beyond the distal end of the outer tube, the inner and outer tubes having clearance space therebetween for carrying fluid under pressure, a thin, tubular, highly distendable and limp sleeve having its proximal end portion connected to the distal end of the outer tube, the sleeve having a distal end portion which is inverted and is connected to the distal end of the inner tube for insertion into the body passage, the sleeve being otherwise free to expand upon inflation, the tubular sleeve having first and second tubular surfaces on opposite sides of the sleeve,the first surface facing inwardly at the proximal end portion of the sleeve, the inverted distal end portion of the sleeve being turned inside out with the second surface facing inwardly, the sleeve being inflatable by fluid transmitted along said clearance space to dilate the body passage, the sleeve when inflated having an annular flaring portion bulging beyond the distal end of the inner tube and curved convexly in longitudinal section for sealing engagement with a foreign object in the body passage, the annular flaring curved portion being soft, pliable and capable of conforming to the shape of the foreign object to effect a seal therewith, the inner tube being operative to transmit suction for capturing and holding the foreign object in sealing engagement with the annular flaring portion of the sleeve, and means for retracting the inner tube relative to the outer tube while the suction pulls the foreign object within the confines of the sleeve and the sleeve is progressively turned inside out around the foreign object to envelop the foreign object for removal with the tubes.

The sleeve may be inflatable by compressed air or some other fluid transmitted along the clearance space between the outer and inner tubes. The inflation of the sleeve dilates the body passage, so as to loosen any kidney stone or the like which may be lodged in the passage. A pressure source and a control valve are preferably connected to the free end of the outer tube, for selectively supplying fluid pressure thereto so as to inflate the sleeve.

A vacuum source and a vacuum control valve are preferably connected to the free end of the inner tube, for selectively providing a vacuum or suction within the inner tube, to suck the kidney stone against the end of the inflated sleeve, so as to capture the kidney stone. The inner tube is then retracted relative to the outer tube, so that the kidney stone will be pulled into the confines of the sleeve. Simultaneously, the sleeve is preferably deflated so that the sleeve will enfold the kidney stone. The outer and inner tubes may then be withdrawn from the body passage, so as to remove the kidney stone or other object. The sleeve surrounds the kidney stone and

prevents it from scratching or otherwise injuring the inner walls of the body passage.

The flexible inner and outer tubes are preferably made of a resinous plastics material, such as polyethylene, for example. An X-ray contrast medium is preferably incorporated into or coated upon the material of the outer or inner tube, so that an X-ray fluoroscope may be used to assist in inserting the outer tube into the ureter or other body passage. Alternatively, the probe formed by the outer and inner tubes can be rendered visible on an X-ray fluoroscope by inserting a flexible metal wire within the inner tube. Alternatively, a fiber optic device can be used for observing and guiding the probe during insertion.

The inflatable sleeve is preferably made of a thin elastic latex rubber material or the like.

A manipulator is preferably connected to the free ends of the outer and inner tubes, so that the operator can easily advance and retract the inner tube, relative to the outer tube, with the thumb and fingers of one hand. The other hand may then be employed to operate the control valves which regulate the air pressure and the suction.

The inflatable sleeve preferably has first and second reduced end portions which are stretched around and secured to the outer and inner tubes. The second end portion is reentrant in that it extends into the sleeve, so that the inflated sleeve will project endwise beyond the end of the inner tube. In this way, the inflated sleeve will be capable of forming a seal with the kidney stone or other object to be removed.

One or more auxiliary tubes may be inserted through the inner tube to provide auxiliary communication with the body passage. The auxiliary tubes may be employed to supply various medications. The auxiliary tubes may also be employed to withdraw mucus or other fluids from the body passage. An auxiliary tube having a plurality of tube elements or bores may be employed if desired.

Alternately, one or more auxiliary tubes may be inserted into the body passage along with the outer tube.

While the extracting device is particularly well adapted for removing kidney stone from the urinary tract, the extracting device may also be employed for removing gallstones, by inserting the extracting device through a drainage tube which has been installed during gallbladder surgery. The extracting device may also be employed to remove foreign objects from the respiratory tract or the esophagus. In addition, the extracting device may be employed to remove blood clots, foreign materials or foreign bodies from blood vessels, by inserting the extracting device through an incision into the blood vessel.

The invention will now be described by way of example with reference to the accompanying drawings, in which:

Fig. 1 is an elevational view of an extracting device to be described as an illustrative embodiment of the present invention, the view being partly in longitudinal section.

Fig. 2 is a fragmentary longitudinal section of the extracting device, showing the inflatable sleeve in a changed position.

Fig. 3 is a fragmentary elevation of the manipulator for the extracting device, the view being taken generally as indicated by the line 3—3 in Fig. 1.

Fig. 4 is a fragmentary perspective view showing the inflatable sleeve on the insertable end of the extracting device.

Fig. 5 is a fragmentary perspective view, showing the manipulator for the extracting device.

Fig. 6(a) is a fragmentary enlarged longitudinal section of the extracting device, the view being partly diagrammatic.

Fig. 6(b) is a fragmentary section corresponding to a portion of Fig. 6(a) and showing a modified construction.

Fig. 6(c) is a fragmentary section corresponding to a portion of Fig. 6(a) and showing a modified construction with a sliding seal used with a snare, wire or one or more auxiliary tubes, to permit full use of the device with the snare, wire or one or more auxiliary tubes in place.

Figs. 7(a)—(g) are a series of fragmentary sections showing successive steps in a procedure whereby the extracting device may be used to capture and enfold a kidney stone or some other object in a human body passage.

Figs. 8(a)—(e) are a series of fragmentary sections showing successive steps in a procedure for advancing the insertable portion of the extracting device through a narrow body passage.

Fig. 9(a) is a fragmentary section showing the insertable portion of the extracting device, as employed in conjunction with an auxiliary tube adapted to be inserted into the body passage along with the extracting device.

Fig. 9(b) is a view similar to Fig. 9(a), but showing the extracting device in conjunction with two auxiliary tubes.

Fig. 9(c) is a view similar to Fig. 9(a), but showing the extracting device in conjunction with an auxiliary tube having three tube elements affording three individual passages.

Figs. 10(a)—(f) are a series of diagramatic sections showing several alternative constructions of the inflatable sleeve.

Figs. 11(a)—(f) are fragmentary longitudinal sections showing the insertable portion of the extracting device in conjunction with a snare to assist in capturing a kidney stone or other object, the views showing successive

steps of a procedure for capturing and enfolding the object.

Fig. 12 is an enlarged fragmentary section showing the insertable portion of the extracting device in conjunction with a stiffening wire or auxiliary tube, inserted through the inner tube of the extracting device.

Fig. 13 is a fragmentary enlarged longitudinal section showing the extracting device in conjunction with a plurality of auxiliary tubes, inserted through the inner tube of the extracting device.

Fig. 14(a) is a fragmentary enlarged section of the insertable portion of the extracting device in conjunction with an auxiliary tube having a plurality of tube elements to afford a plurality of individual passages, the tube being inserted through the inner tube of the extracting device.

Fig. 14(b) is a fragmentary cross section of the auxiliary tube shown in Fig. 14(a).

As just indicated, Figs. 1—6 illustrate an extracting device 20 comprising an outer flexible tube or sheath 22 capable of being inserted into a narrow passage of the human body, such as one of the ureters. The outer tube 22 is sufficiently long to be inserted through the urethra and the bladder into one of the ureters, and along such ureter as far as possible toward the corresponding kidney. The diameter of the outer tube 22 is such as to fit snugly but comfortably into one of the ureters. The inflatable sleeve 28 can be made in various sizes to accommodate various sized objects to be removed. The inner tube 24 and the outer tube 22 can be sized accordingly. The outer tube 22 may be made of a resinous plastics material, such as polyethylene, for example. The tube 22 is sufficiently flexible to conform to the shape of the body passage, while being sufficiently stiff to provide for insertion of the tube without causing it to collapse.

The outer tube 22 may be inserted into one of the ureters with the aid of an auxiliary device such as a cystoscope and an X-ray system having a fluoroscope. Thus, the insertable portion of the extracting device 20 should preferably incorporate a material which is sufficiently opaque to X-rays to be visible on the fluoroscope. For this purpose, an X-ray contrast medium may be incorporated into the plastics material of the outer tube 22 or may be coated thereon. Alternately, a flexible metal wire may be inserted within the extracting device 20, as will be discussed below in greater detail. The wire is visible on the X-ray fluoroscope and also may serve to stiffen the insertable portion of the extracting device 20, so that it will be easier to insert. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion.

As shown in Fig. 6, an inner flexible tube 24 is telescopically received within the outer tube 22, with an annular clearance space 26 therebetween for transmitting air or some other fluid under pressure. The inner tube 24 is freely slidable within the outer tube 22. As in the case of the outer tube 22, the inner tube 24 is preferably made of a resinous plastics material, such as polyethylene, for example. If desired, an X-ray contrast material may be incorporated into the material of the inner tube 24, or may be coated thereon so that the inner tube will be visible on an X-ray fluoroscope. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion. In addition to serving as a conduit for air or some other fluid, the inner tube may be inserted more easily into the body passage by the operator, without causing the outer tube 22 to collapse.

An inflatable sleeve or dilator 28 is connected between the insertable end of the outer tube 22 and the corresponding end of the inner tube 24. The sleeve 28 is thin, highly flexible and limp, and also is preferably elastic so as to be capable of stretching when inflated with compressed air or some other fluid. The sleeve 28 is preferably made of thin latex rubber or some other similar material. The thin rubber material may be similar to that employed for surgical rubber gloves and other thin rubber objects. A thin resinous plastics film material can also be used.

The thin flexible sleeve 28 has one end portion 28*a* which is stretched around and secured to the insertable end of the outer tube 22, as by means of a suitable cement or adhesive. The sleeve 28 has a second end portion 28*b* which is stretched around the insertable end of the inner tube 24 and is secured thereto, as by means of a suitable cement or adhesive. Any other suitable means, such as a tieing ring or collar, may be employed to secure the ends of the sleeve 28 to the ends of the tubes 22 and 24.

As shown in Figs. 6(a) and 10(a), the end portion 28*b* of the flexible sleeve 28 is reentrant, in that end portion 28*b* extends into the sleeve 28. With this construction, the sleeve 28 projects beyond the end of the inner tube 22, particularly when the sleeve 28 is inflated, as shown, for example, in Fig. 7(b).

As shown in Fig. 6(a), the extracting device 20 preferably includes a system or means 30 for supplying air or some other fluid under pressure to the clearance space 26 between the outer and inner tubes 22 and 24, so as to inflate the thin flexible sleeve 28. The system 30 also preferably includes means for producing suction or a vacuum in the inner tube 24 to assist in capturing the kidney stone or other object which is to be removed from the body passage.

As shown in Fig. 6, the free end of the outer tube 22 is provided with a connector or fitting 32 to which a flexible hose 32*a* or the

like may be connected, the hose being represented diagramatically by a solid line. Similarly, the inner tube 24 is provided with a connector or fitting 34 to which a hose 34*a* or the like may be connected. As shown, the hoses 32*a* and 34*a* extend radially or at right angles to the outer and inner tubes 22 and 24. The inner tube 24 extends through an annular seal 36 mounted in an opening 38 in the fitting 32, such opening being coaxial with the outer tube 22.

The illustrated system 30 of Fig. 6 for selectively producing air pressure incorporates an air compressor 40 which supplies compressed air to a pressure line 42 to which a pressure gauge 44 may be connected. A pressure regulator 46 and a combination flow control valve and meter 46*a* are preferably connected between the high pressure line 42 and a low pressure line 48 to which another pressure gauge 50 may be connected. A storage tank 52 may also be connected to the low pressure line 48, if desired.

In this embodiment, a filter 54 and a control valve 56 are connected between the low pressure line 48 and the hose or conduit 32*a* which is connected to the end fitting 32 on the outer tube 22. The illustrated control valve 56 is of a three-way type, adapted to connect the interior of the outer tube 22 to either the pressure line 48 or a vent line 58 leading to the atmosphere. In the position of the valve 56 shown in Fig. 6(a), the outer tube 22 is connected to the vent line 58 by an internal passage 60 within the valve 56. It will be apparent that the valve 56 may be shifted to a position in which the internal passage 60 establishes a connection between the pressure line 48 and the interior of the tube 22. The pressure regulator 46 and the flow control valve and meter 46*a* may be adjustable so that the air pressure in the low pressure line 48 may be varied, as desired.

In the system 30*a* of Fig. 6(a), a combined compressor and vacuum pump 40*a* supplies vacuum to an output vacuum line 62, to which a vacuum gauge 64 may be connected. It will be realized that the compressor and the vacuum pump may be provided as two separate units, if desired. In this embodiment, a vacuum regulator 66 and a combustion flow control valve and meter 66*a* are connected between the vacuum line 62 and a regulated vacuum line 68 to which another vacuum gauge 70 may be connected. A storage tank 72 may also be connected to the vacuum line 68 if desired.

A filter 74 and a vacuum control valve 76 are preferably connected between the regulated vacuum line 68 and the hose 34*a* which leads to the fitting 34 on the end of the inner tube 24. The control valve 76 may be of the three-way type and is shown in a position in which the interior of the inner tube 24 is connected to a vent line 78 by an internal passage 80 within the valve 76. It will be evident that the valve 76 can be shifted into a position in which the regulated vacuum line 68 is connected to the interior of the inner tube 24. The vacuum regulator 66 and flow control valve 66*a* may be adjustable so that the vacuum in the line 68 may be varied, as desired.

In the system 30*a* of Fig. 6(a), the combined compressor and vacuum pump 40*a* supplies pressure to an auxiliary pressure supply system 81, illustrated as comprising a compressor output pressure line 81*a* to which a control valve 81*b* may be connected. It will be realized that the compressor and the vacuum pump may be provided as two separate units if desired. The illustrated control valve 81*b* is of a three-way type, adapted to connect the compressor output pressure line 81*a* to either a high pressure input line 81*c* or a vent line 81*d*, leading to the atmosphere. In the position of the valve 81*b* shown in Fig. 6(a), the compressor output pressure line 81*a* is connected to the high pressure input line 81*c*. It will be apparent that the valve 81*b* may be shifted to a position in which the compressor output pressure line 81*a* is connected to the vent 81*d*. A gauge 81*e* may be connected to the high pressure input line 81*c*. A pressure regulator 81*f* and a combination flow control valve and meter 81*g* are preferably connected between the high pressure input line 81*c* and a low pressure line 81*h* to which another pressure gauge 81*i* may be connected. A storage tank 81*j* may also be connected to the low pressure line 81*h* if desired. In this embodiment, a filter 81*k* is connected between the low pressure line 81*h* and a hose or conduit 81*m* which is connected to the auxiliary tube or tubes 130 and 132, to be described in connection with Figs. 9(a)—(d) and Figs. 12 to 14.

Fig. 6(b) shows a modified construction of the fitting 34 having an axial opening 82 through which an auxiliary tube, a snare or a stiffening wire may be inserted into the inner tube 24. A plug 84 may be provided to close the opening 82 when not in use.

Fig. 6(c) shows another modified construction in which the plug 84 of Fig. 6(b) is replaced by a sliding seal or bushing 85 through which the auxiliary tube, snare or stiffening wire 130 may be inserted into the inner tube 24. The seal is inserted into the opening 82 in the fitting 32. The plug 84 may be used to close the opening 82 when the seal 85 is not in use.

As shown in Figs. 1 to 5, a manipulator 90 is preferably connected to the free ends of the outer and inner tubes 22 and 24, to make it easy to advance and retract the inner tube 24 relative to the outer tube 22. By using the manipulator 90, the operator can advance and retract the inner tube 24 with the thumb

and fingers of one hand, so that the other hand can be used to operate the pressure and vacuum control valves 56 and 76 of Fig. 6.

As illustrated in Figs. 1 to 5, the manipulator 90 comprises a first member 92 which is telescopically slidable within a second member 94. The members 92 and 94 are connected to the outer and inner tubes 22 and 24, respectively. More specifically, the fitting or connector 32 on the free end of the outer tube 22 is mounted in the member 92, while the end fitting or connector 34 on the free end of the inner tube 24 is mounted in the member 94.

Finger and thumb rings are preferably provided on the telescopically slidable members 92 and 94. As shown, a thumb ring 96 is connected to the member 92 by means of a plunger rod 98. A swivel joint 100 is provided between the thumb ring 96 and the plunger rod 98, so that the thumb ring can be turned to an angle which is comfortable and convenient. The illustrated thumb ring 96 is made from a strip of sheet metal and can be bent to adjust the size of the thumb ring, as desired by the operator.

As shown, the member 94 is fitted with a pair of finger rings 102 which are also bent from a strip of sheet metal, so that the size of the rings 102 can easily be adjusted to suit the needs of the operator. The finger rings 102 are swingably mounted on the body member 94. For this purpose, the finger rings 102 are provided with a mounting member 104 having a pair of arms 106 which are swingably connected to the body member 94 by diametrically opposite pivots 108.

In the illustrated manipulator 90, two stop nuts 110 are mounted on the plunger rod 98, which is threaded to receive the stop nuts. It will be seen that the stop nuts 110 may be adjusted to limit the extent to which the plunger rod 98 may be depressed through the mounting member 104, which is apertured to provide a passage for the rod 98. In effect, the stop nuts 110 thereby provide an adjustment of the extent to which the inner tube 24 may be retracted relative to the outer tube 22.

The operation of the extracting device 10 is illustrated in Figs. 7 and 8, which should be taken in conjunction with Figs. 1—6. The unit comprising the outer flexible tube 22, the inner flexible tube 24 and the inflatable sleeve 28 constitutes a probe 120 which can readily be inserted into the urinary tract of the human body for removing kidney stones. The diameter of the outer tube 22 is such as to fit snugly but easily into the urethra and either of the ureters. Specifically, the probe 120 is properly lubricated and is inserted through the urethra into the bladder, and then through the bladder into one of the ureters. An X-ray fluoroscope and a cystoscope may be employed advantageously to assist in inserting the probe 120 into either urethra. In order that the probe 120 may be clearly visible on the X-ray fluoroscope, the probe preferably incorporates an X-ray contrast material which is relatively opaque to X-rays. Such material may be incorporated into the plastics material of either the outer tube 22 or the inner tube 24, or both. Alternatively, the X-ray contrast material may comprise a thin coating of a metal, such as gold, silver or aluminium. Another alternative is to insert a thin flexible metal wire into the inner tube 24, while the probe 120 is being inserted. The wire has the additional advantage of stiffening the probe 120. After the probe has been inserted, the wire can be removed. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion.

Figs. 7(a)—(g) show steps 1—7 of a procedure for capturing and removing a kidney stone 122 or some other similar object, which may be lodged in one of the ureters. As shown in Fig. 7(a), the probe 120 is inserted until it is close to the kidney stone 122. The sleeve 28 is then inflated, as shown in Fig. 7(b), by supplying compressed air through the clearance space 26 between the tubes 22 and 24. The compressed air is supplied by operating the compressed air control valve 56 to the position in which it transmits compressed air from the pressure line 48 to the fitting 32 on the free end of the outer tube 22.

The inflation of the sleeve 28 dilates the ureter to some extent, so as to dislodge or loosen the kidney stone 122. Suction is then applied to the inner tube 24, so as to suck the kidney stone 122 toward the end of the inner tube 24 and into engagement with the projecting end of the inflated sleeve 28, as shown in Fig. 7(c). The end of the thin rubber sleeve 28 forms a seal with the kidney stone 122, so that it is securely held against the end of the probe by the suction.

The inner tube 24 is then gradually retracted, while the sleeve 28 is simultaneously and gradually deflated, as shown in Figs. 7(c)—(g), so that the kidney stone 122 is pulled within the confines of the sleeve 28. It will be seen that the deflated sleeve 28 enfolds the kidney stone 122, as shown to best advantage in Fig. 7(g), so that the sleeve 28 is interposed between the kidney stone 122 and the inner walls of the ureter.

The suction is applied to the inner tube 24 by operating the suction control valve 76 of Fig. 6, so that it establishes communication between the vacuum line 68 and the end fitting 34 on the inner tube 24. The suction is maintained while the probe 120 is withdrawn from the urinary tract. The kidney stone 122 remains a captive within the confines of the sleeve 28, so that the kidney stone is removed from the urinary tract. During the removal of the probe 120, the sleeve 28 prevents the

kidney stone 122 from scratching or otherwise injuring the inner walls of the urinary tract.

Fig. 8 illustrates a procedure for using the inflatable sleeve 28 to assist in the insertion of the probe 120 into a narrow passage such as a ureter. In Fig. 8(a), the probe 120 has been inserted as far as possible with the sleeve 28 deflated. The sleeve 28 is then inflated, as shown in Fig. 8(b), so as to dilate the passage. Next, the sleeve 28 is again deflated, as shown in Fig. 8(c), and the outer tube 22 is immediately advanced, as shown in Fig. 8(d), while some of the dilation persists. The advancing movement of the outer tube 22 causes the sleeve 28 to collapse.

The inner tube 24 is then advanced within the outer tube 22, as shown in Fig. 8(e), so that the sleeve 28 is no longer collapsed. It will be seen that Fig. 8(e) is the same as Fig. 8(a), except that the probe 120 has been advanced. If further advancing movement is needed, the successive steps of Figs. 8(a)—(e) are repeated. This may be done several times until the probe 120 has been fully inserted to the desired position in the ureter or other body passage.

In some cases, it may be desirable to insert an auxiliary tube 130, along with the probe 120, as shown in Fig. 9(a). The auxiliary tube 130 provides auxiliary communication with the ureter or other body passage and may be employed to convey various fluids to or from the body passage. For example, the auxiliary tube may be emplyed to carry air into the body passage, beyond the probe 120, so as to obviate or lessen the tendency of the suction, applied by the probe 120, to cause partial collapse of the walls of the body passage. When the auxiliary tube 130 is supplied with compressed air from the combination vacuum pump-compressor 40*a* of Fig.6(a), the throughput of the closed system will provide the same amount of compressed air (volume measured as free air at atmospheric pressure) as the amount of air evacuated by the vacuum side of the pump (volume measured as free air at atmospheric pressure). The auxiliary tube 130 may also be employed to introduce a lubricating fluid into the body passage. A fluid medication can also be introduced into the body passage through the auxiliary tube 130. It is also possible to use the auxiliary tube 130 to withdraw mucus or other body fluids from the body passage.

As shown in Fig. 9(b), two or more auxiliary tubes 130 may be inserted into the body passage along with the probe 120, two such auxiliary tubes being shown in this view.

Fig. 9(c) shows a modified auxiliary tube 132 having a plurality of tube elements forming a plurality of individual auxiliary passages. As shown to best advantage in the cross section of Fig. 9(d), the auxiliary tube 132 has three tube elements 132*a*, *b* and *c*, which may be employed for simultaneously handling different fluids.

The auxiliary tubes 130 and 132 are preferably made of a flexible resinous plastics material, such as polyethylene, for example. The triple tube 132 may be formed by extrusion of the plastics material.

Fig. 12 shows a modified arrangement in which the auxiliary tube 130 is inserted through the inner tube 24 of the probe 120. The auxiliary tube 130 may be inserted into the tube 24 through the sliding seal 85 of Fig. 6(c). As shown in Fig. 13, two or more of the auxiliary tubes 130 may be inserted through the inner tube 24, after being inserted into the tube through a suitable sliding seal.

Figs. 14(a) and (b) show that the triple auxiliary tube 132 may be inserted through the inner tube 24 after being inserted through a suitable sliding seal. In all cases, the auxiliary tubes 130 and 132 may be inserted along the inner tube 124 either before or after the probe 120 is inserted into the body passage. The auxiliary tubes 130 and 132 may be removed from the inner tube 24 without removing the probe 120 from the body passage. The plug 84 may then be inserted in the connector.

It may also be considered that Fig. 12 illustrated insertion of a flexible metal wire within the inner tube 24. The element 130 may be regarded as the wire. As previously indicated, the flexible wire may be employed to stiffen the tubes 22 and 24 of the probe 120, or to absorb X-rays so that the probe 120 will be clearly visible on an X-ray fluoroscope. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion.

Fig. 10 illustrates various alternative shapes for the inflatable sleeve 28. In Fig. 10(a), the sleeve 28 has a cylindrical sidewall 138 and radial endwalls 140 and 142. In Fig. 10(b) the sleeve has a tapered or frusto-conical sidewall 138(a).

In Figs. 10(c), (d) and (e), the cylindrical sidewall 138 is employed, but the endwall 142 is modified. Thus, the sleeve of Fig. 10(c) has a re-entrant, tapered, frusto-conical endwall 142(a) which may be advantageous in some instances to assist in the enfolding of the kidney stone by the sleeve. In Fig. 10(d), the sleeve has a stepped endwall 142(b). In Fig. 10(e), the sleeve has a re-entrant endwall 142(c) which is concavely curved. This construction may be advantageous in some cases for capturing and enfolding kidney stones.

In Fig. 10(f), the inflatable seal or sleeve 28 has one or more holes 143 which may be either molded in or pierced. Air or fluid from the inflator supply will pass through the holes 143 so as to obviate or lessen the tendency of the suction applied by the probe 120 to cause partial collapse of the walls of

the body passage. The various alternative shapes shown in Figs. 10(b), (c), (d) and (e) may also be provided with one or more holes 143.

Figs. 11(a)—(f) illustrate the successive steps of a procedure for using the probe 120 in conjunction with a snare 150 to assist in capturing and removing a foreign object, such as the illustrated kidney stone 122. The illustrated snare 150 comprises a capturing head or portion 154 and an operating portion or member 156, here shown as a flexible wire which is inserted through the inner tube 24, so as to be accessible to the operator at the free end of the probe 120. The wire 156 is freely slidable within the inner tube 24.

The capturing head 154 of the snare 150 may comprise a multitude of strands or filaments 158, made of a material such as tinsel, capable of entwining the kidney stone 122. The filaments 158 are in a form resembling a ball and are secured to the front end of the operating wire 156. The filaments 158 may be made of metal, a resinous plastics material, or any other suitable material.

In the procedure of Figs. 11(a)—(f), the probe 120 is inserted into the ureter, or some other body passage, until the capturing head 154 of the snare 150 is as close as possible to the kidney stone 122, as shown in Fig. 11(a). The sleeve 28 is then inflated, as shown in Fig. 11(b), by supplying air or some other fluid under pressure to the interior of the outer tube 22. The inflation of the sleeve 28 tends to dislodge or loosen the kidney stone 122 from the walls of the ureter.

As shown in Fig. 11(c), the snare 150 is then advanced by moving the operating wire 156 through the inner tube 24. As the capturing head 154 is advanced, the filaments 158 become entwined around the kidney stone 122, as will be evident from Fig. 11(c). As the snare 150 is advanced, suction is preferably applied to the interior of the inner tube, so that the suction assists in the capture of the kidney stone 122.

The snare 150 is then retracted by moving the operating wire 156 within the inner tube 24, so as to bring the capturing head 154 and the kidney stone 122 as close as possible to the end of the inner tube. Meanwhile, suction within the inner tube 22 is maintained. Then, the inner tube 22 is gradually retracted, as shown in Figs. 11(d)—(f), to draw the kidney stone 122 and the capturing head 154 of the snare 150 into the confines of the sleeve 28. Simultaneously, the sleeve 28 is gradually deflated, so that it will enfold the kidney stone 122 and the capturing head 154. The thin rubber sleeve 28 forms a seal with the kidney stone 122 and the capturing head 154, so that the suction effectively retains the kidney stone within the folds of the sleeve 28.

With the suction still maintained, the probe 120 may then be withdrawn from the body passage, to remove the kidney stone 122 or other object. The sleeve 28 is interposed between the kidney stone 122 and the walls of the body passage, so that neither the kidney stone nor the head 154 of the snare 150 will scratch or otherwise injure the walls of the body passage.

WHAT I CLAIM IS:—

1. An extracting device for insertion into a human body passage for removing foreign objects therefrom, said device comprising an outer flexible tube the distal end of which is insertable into a body passage, an inner flexible tube slideably received within the outer tube for free longitudinal sliding movement with the distal end of the inner tube normally projecting beyond the distal end of the outer tube, the inner and outer tubes having clearance space therebetween for carrying fluid under pressure, a thin, tubular, highly distendable and limp sleeve having its proximal end portion connected to the distal end of the outer tube, the sleeve having a distal end portion which is inverted and is connected to the distal end of the inner tube for insertion into the body passage, the sleeve being otherwise free to expand upon inflation, the tubular sleeve having first and second tubular surfaces on opposite sides of the sleeve, the first surface facing inwardly at the proximal end portion of the sleeve, the inverted distal end portion of the sleeve being turned inside out with the second surface facing inwardly, the sleeve being inflatable by fluid transmitted along said clearance space to dilate the body passage, the sleeve when inflated having an annular flaring portion bulging beyond the distal end of the inner tube and curved convexly in longitudinal section for sealing engagement with a foreign object in the body passage, the annular flaring curved portion being soft, pliable and capable of conforming to the shape of the foreign object to effect a seal therewith, the inner tube being operative to transmit suction for capturing and holding the foreign object in sealing engagement with the annular flaring portion of the sleeve, and means for retracting the inner tube relative to the outer tube while the suction pulls the foreign object within the confines of the sleeve and the sleeve is progressively turned inside out around the foreign object to envelop the foreign object for removal with the tubes.

2. A device according to Claim 1, in which the inner and outer tubes are made of a resinous plastics material.

3. A device according to Claim 1, in which the sleeve is made of rubber.

4. A device according to Claim 1, including manipulating means connected to the proximal ends of the tubes for advancing and retracting the inner tube relative to the outer

tube.

5. A device according to Claim 4, wherein said manipulating means includes first and second telescopically movable members connected to the respective inner and outer tubes, the first and second members having finger receiving rings for use in manually moving the members.

6. A device according to Claim 1, including first means for selectively supplying fluid under pressure to the proximal end of the clearance space to inflate the sleeve.

7. A device according to Claim 1 or 6, including second means for selectively supplying suction to the proximal end of the inner tube.

8. A device according to Claim 1, in which the proximal and distal end portions of the sleeve are of reduced diameters relative to the intermediate portion of the sleeve and are secured to the distal ends of the inner and outer tubes.

9. A device according to Claim 8, wherein the reduced distal end portion of the sleeve extends within the sleeve for receiving the distal end of the inner tube whereby the sleeve projects beyond the distal end of the inner tube.

10. A device according to Claim 1, including at least one auxiliary tube slideable within the inner tube to afford auxiliary communication with the body passage.

11. A device according to Claim 10, wherein the auxiliary tube includes a plurality of individual tube elements.

12. A device according to Claim 1, including at least one auxiliary tube extending along the outside of the outer tube and insertable in said body passage along with the outer and inner tubes to afford auxiliary communication with the body passage.

13. A device according to Claim 12, in which the auxiliary tube has a plurality of individual tube elements.

14. A device according to Claim 1, including a stiffening member slideably receivable in the inner tube for stiffening the inner and outer tubes to facilitate the insertion of the outer tube into the body passage.

15. A device according to Claim 1, including a snare having an operating member slideable within the inner tube, said snare being operative to assist in capturing a foreign object in the body passage.

16. A device according to Claim 1, including a snare having a thin flexible wire-like operating member slideably received in the inner tube, said snare having a capturing portion secured to the operating member and including a plurality of filaments disposed adjacent the sleeve to assist in capturing a foreign object.

17. An extracting device for insertion into a human body passage, substantially as hereinbefore described with reference to the accompanying drawings.

WITHERS & ROGERS,
Chartered Patent Agents,
4 Dyer's Buildings,
Holborn,
London, EC1N 2JT.
Agents for the Applicant.

Printed for Her Majesty's Stationery Office by Burgess & Son (Abingdon) Ltd.—1981. Published at The Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.

1588072 COMPLETE SPECIFICATION
6 SHEETS This drawing is a reproduction of the Original on a reduced scale
Sheet 1

FIG. 1

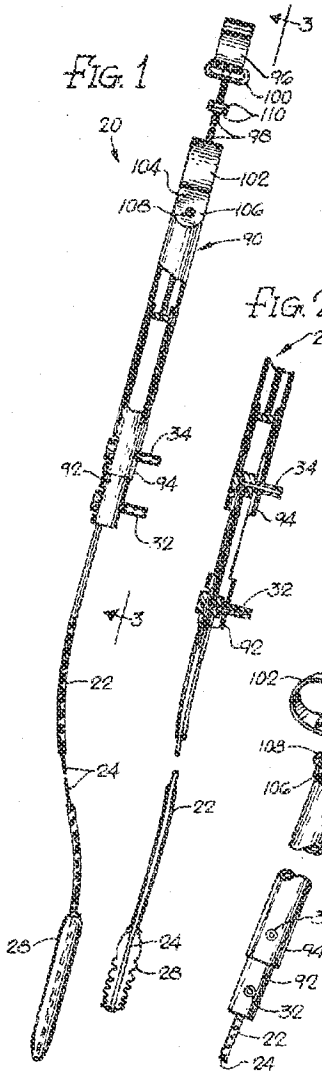


FIG. 2

FIG. 3

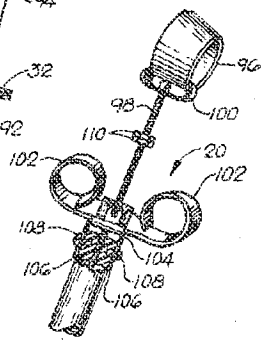


FIG. 5

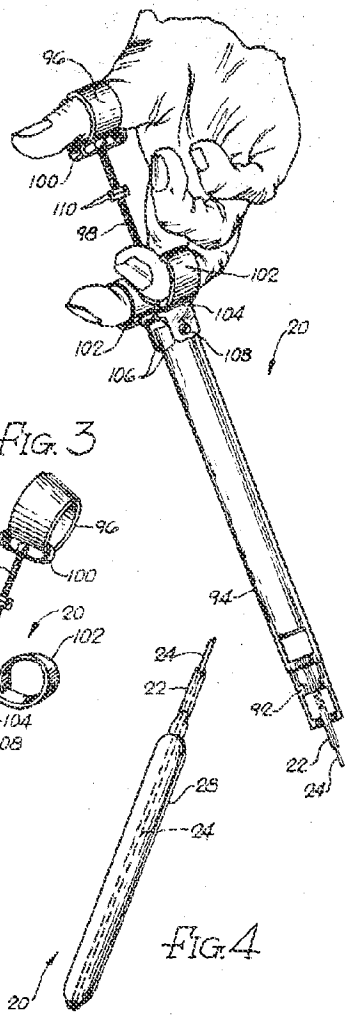
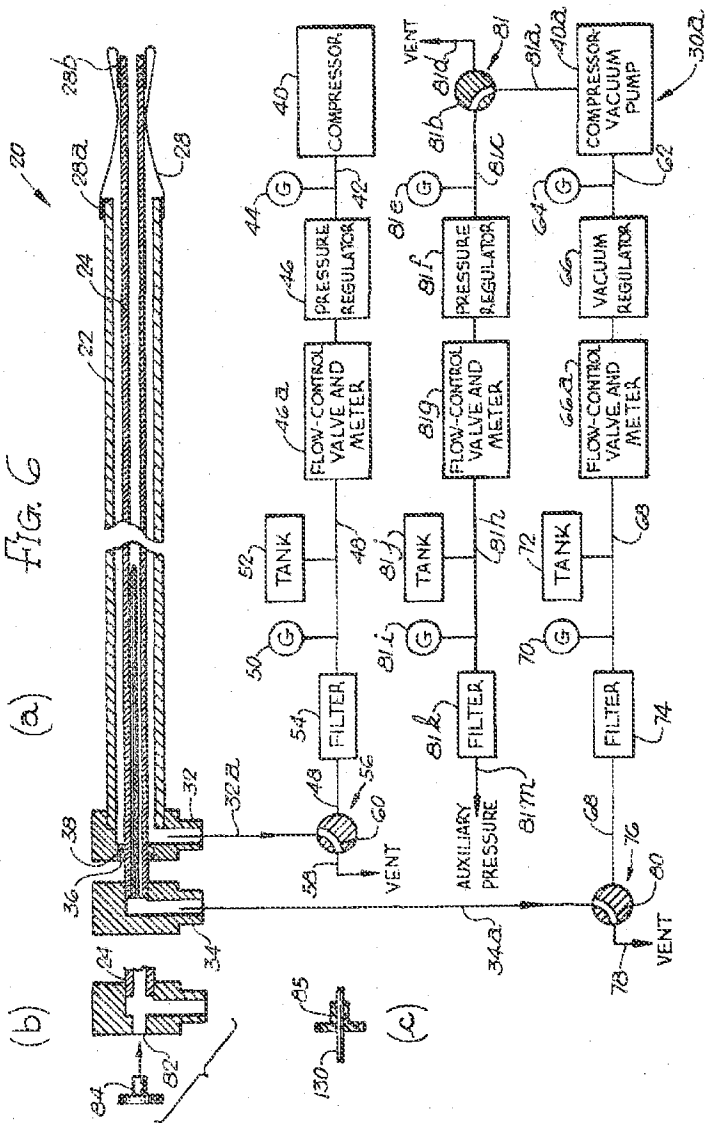


FIG. 4

1588072 COMPLETE SPECIFICATION
6 SHEETS This drawing is a reproduction of the Original on a reduced scale
Sheet 2

FIG. 6



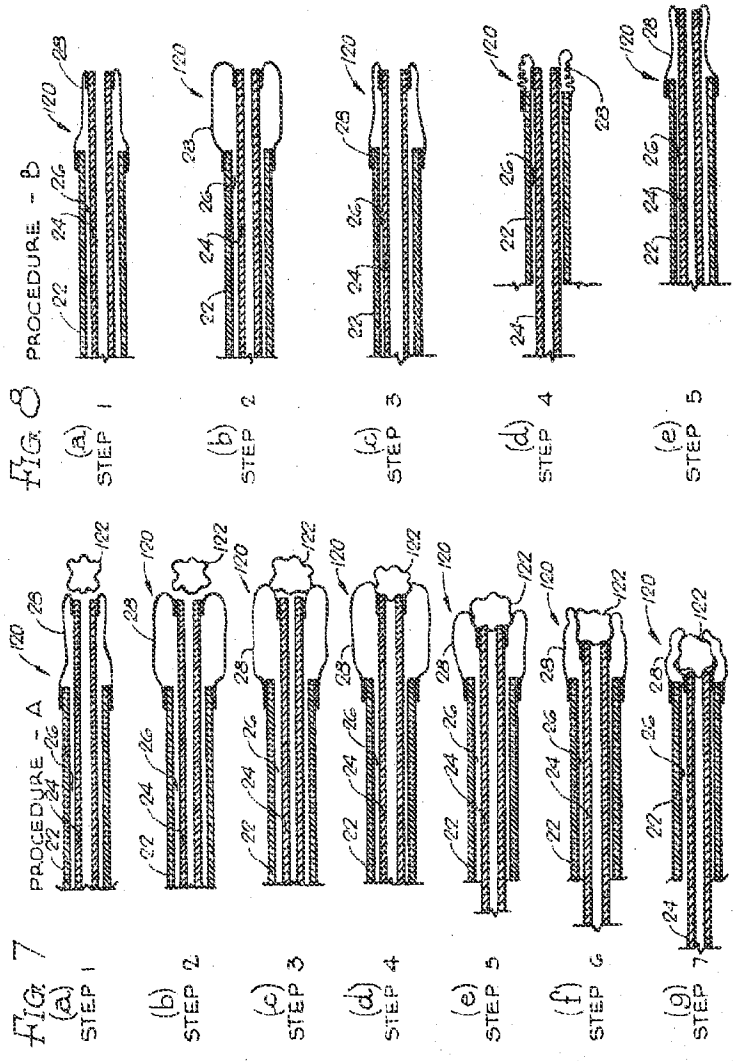


FIG. 7
PROCEDURE - A
(a) STEP 1
(b) STEP 2
(c) STEP 3
(d) STEP 4
(e) STEP 5
(f) STEP 6
(g) STEP 7
FIG. 8
PROCEDURE - B
(a) STEP 1
(b) STEP 2
(c) STEP 3
(d) STEP 4
(e) STEP 5

FIG. 9

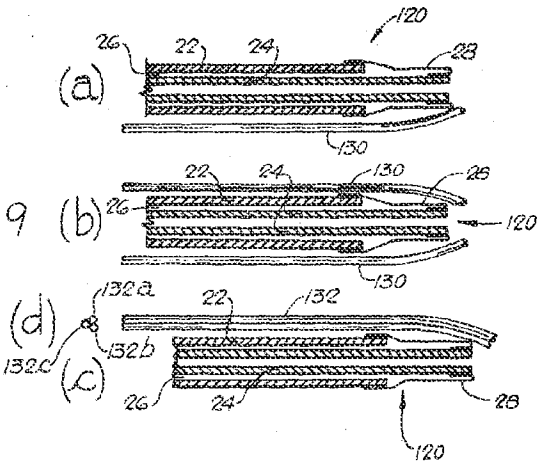

(a)
(b)
(d)
(c)
120
26
22
24
28
130
132a
132
132b
132c

FIG. 10

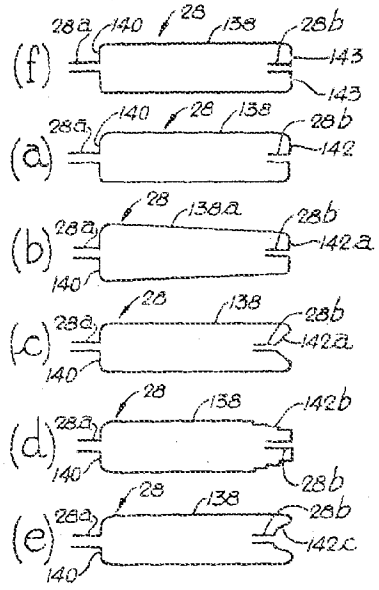

(f)
(a)
(b)
(c)
(d)
(e)
28a
140
28
138
28b
143
142
138a
142a
142b
142c

FIG. 11

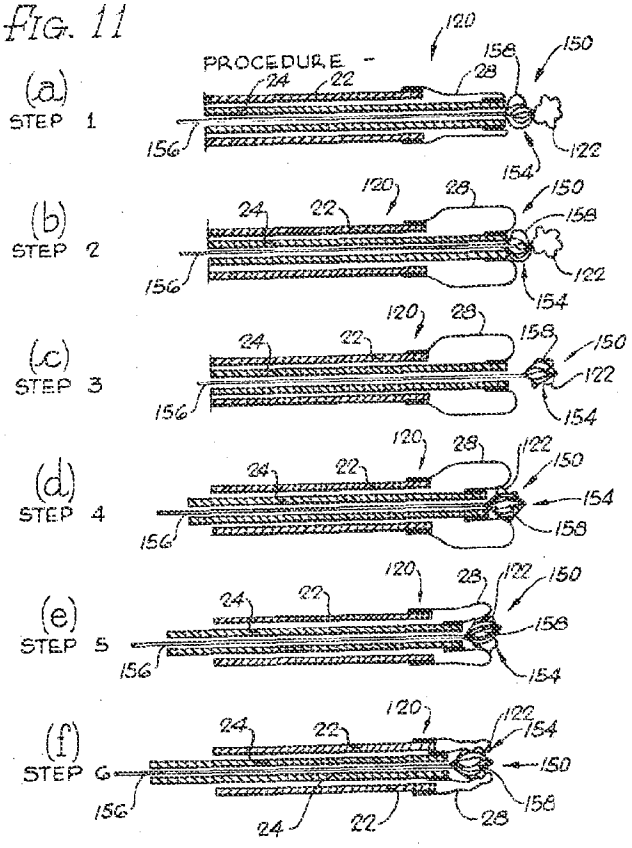

PROCEDURE
(a) STEP 1
(b) STEP 2
(c) STEP 3
(d) STEP 4
(e) STEP 5
(f) STEP 6
120
150
156
28
24
22
122
154
158

FIG. 12

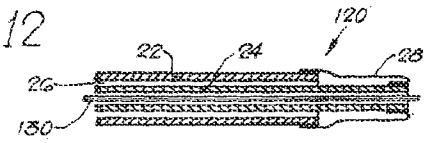


FIG. 13

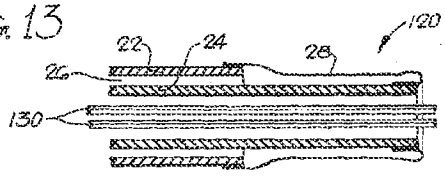
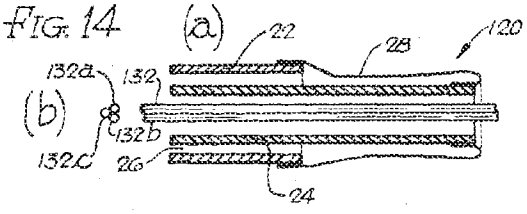


FIG. 14



Notice

DESCRIPTION JPH07323090A

[0001]

13 INDUSTRIAL APPLICABILITY The present invention relates to a medical tube suitably used for manufacturing a catheter such as a catheter for vasodilation and a catheter for endovascular treatment diagnosis.

[0002]

19 BACKGROUND ART The catheter has been an instrument used for draining and injecting body fluids and drugs from body cavities or tubular organs.

21 In recent years, catheters have become more sophisticated, and for example, angioplasty catheters used for percutaneous transluminal angioplasty (PTA) that dilates narrowed parts of blood vessels, urinary conduction and bladder temperature measurement. A urine-guided balloon catheter with a temperature sensor that can be performed at the same time, a thermodilution catheter that is placed inside the heart and used to measure heart rate output, and a drug used in intraarterial infusion therapy, etc., is injected into the target site for treatment. Catheter for drug injection treatment, catheter for angioplasty for injecting contrast agent for angioplasty, cyanoacrylate, ethylene-vinyl alcohol copolymer for aneurysms and arteriovenous malformations found in cerebral blood vessels, etc. Applications include liquid embolization substances such as dimethylsulfoxide solutions, granular embolization substances such as polyvinyl alcohol resin granules, and embolization catheters used for embolization in which an embolization member such as a coil is injected. Various applications other than the above have been attempted for these catheters.

[0003]

37 Until now, heart and brain surgery required large-scale surgery that required thoracotomy,

craniotomy, etc., and the key to success or failure of surgery was whether or not the postoperative recovery was good rather than the surgery itself. ..

40 The above-mentioned procedure using a catheter enables diagnosis and treatment with low physical aggression without incising the human body such as thoracotomy, laparotomy, and craniotomy. In addition, since it does not require major surgery, for example, the patient's intraoperative and postoperative pain is reduced, postoperative early recovery / early rehabilitation, less physical damage, less mental burden, and financial burden. It has advantages such as mitigation. In the future, diagnosis and treatment methods using catheters are expected to develop further.

[0004]

50 The medical tube, which is the main body of the high-performance catheter as described above, is required to have high flexibility and a wall thickness as thin as possible.

52 That is, it is desired that the outer diameter of the tube is as small as possible and the inner hole through which the fluid flows is made as large as possible in order to improve the insertability into the body. However, reducing the wall thickness conflicts with making it difficult to easily collapse. Generally, a tube with a thin wall is easy to break (poor kink resistance), easy to crush (weak to external pressure applied from the outside of the tube, that is, insufficient pressure resistance on the outside), and easy to burst (inside the tube). It is known that it is vulnerable to external pressure applied from, that is, its inner pressure resistance is insufficient).

[0005]

63 On the other hand, catheters used by inserting into body cavities or tubular organs are required to have operability so that they can be inserted quickly and reliably even when applied to a vasculature with a thin and complicated pattern. To.

66 In order to have high operability, it is necessary to satisfy the following points. The first is that the pushing force of the operator for inserting into the blood vessel can be reliably transmitted from the proximal end side to the distal end side of the catheter, that is, it has a so-called pushing property. The second is that the rotational force applied on the proximal end side of the catheter can be reliably transmitted to the distal end side, that is, it has so-called torque transmissibility. Third, it is possible to proceed smoothly in a curved blood vessel along a pre-inserted guide wire without damaging the inner wall of the blood vessel, so-called followability (hereinafter, "following to the guide wire" or simply "following"). "). Fourth, as mentioned above, the catheter tip reaches the target location, and even after the guide wire is pulled out, the catheter does not bend at the curved or bent part of the blood vessel, so-called kink resistance. To have.

[0006]

80 From such a demand, a medical tube using a reinforcing material has been proposed.

81 For example, Japanese Patent Application Laid-Open No. 58-38565 and Japanese Patent Application Laid-Open No. 60-126170 disclose a so-called "enhanced type" medical tube having a blade or a coil and a method for manufacturing the same. In these tubes, a reinforcing body is embedded in the resin in order to impart rigidity to the tubes. As a result, these tubes are very hard and have excellent pressure resistance, but thin-walled ones have the disadvantage of being easily broken. Examples of applications of reinforced tubes to catheters include US Pat. No. 4,516,972, International Application WO88 / 06465, Epoxy 3-54592, Epoxy 4-670, and Epoxy 4-44553. There are Japanese Patent Laid-Open No. 4-44554, Japanese Patent Application Laid-Open No. 2-191465, etc., but the main purpose is to give the catheter rigidity. Is manufactured by impregnating with a resin, and has the above-mentioned problems.

[0007]

95 For the purpose of improving the torque transmission, pushability and flexibility of the catheter, a catheter in which a flexible coating is placed on a vine winding spring body or a coil is available in US Pat. No. 4,351,341 and Special Table 3-50189. It is described in Japanese Patent Publication No. 4-792272, Japanese Patent Publication No. 2-172474, International Application No. WO 93/05842, etc., because these are merely a single coil coated with an outer sheath. In addition, although it has excellent kink resistance, it has the disadvantage that the wall surface must be thickened in order to have pressure resistance from the inside.

103 Further, in this tube, since the coil is exposed in the lumen of the catheter, the guide wire is easily caught by the coil. Further, in the catheter for embolization, there is a possibility that a granular embolic substance or an expansion member such as a coil may be caught in the gap of the coil and clogged due to the opening of the gap between the strands, especially when the tube is bent. It requires careful operation.

[0008]

111 Japanese Patent Publication No. 3-29669 has an example in which a torque cable composed of multi-layer coils wound in opposite directions is applied to a catheter, but this also does not have an inner sheath and has the above-mentioned problem. Have.

114 Japanese Patent Application Laid-Open No. 53-21910 and JP-A-5-15585 propose a spirally curved core material in which the inner and outer surfaces are covered with flexible inner and outer pipes by forming gaps. ing. These are structures that only cover the inside and outside of a single spiral tubular coil with a large gap, and although they are excellent in flexibility, they have insufficient inner and outer pressure resistance, torque transmission, and pushability, so they have a large diameter. Although it is sufficient as a guide tube and a flexible tube for a heart-lung machine, it has been virtually impossible to use it as a main body tube of a small-diameter catheter that is used by inserting it into the body cavity or the

central side of a tubular organ.

[0009]

126 INDUSTRIAL APPLICABILITY The present invention has been made in view of the above problems, and satisfies the properties required for a tube constituting a catheter applicable to various body cavities, that is, flexibility and flexibility. It is an object of the present invention to provide an unprecedented medical tube having excellent kink resistance, thin wall thickness, excellent torque transmission and pushability, and excellent inner and outer pressure resistance.

132 Another object of the present invention is to provide a medical tube through which a guide wire can be satisfactorily inserted without being caught on the inner surface of the catheter. Furthermore, it is an object of the present invention to obtain a medical tube particularly suitable for constructing a small-diameter catheter applied in a fine body cavity, such as a catheter for vasodilation and a catheter for cerebrovascular embolization.

[0010]

140 SOLUTION: Such an object is solved by the present invention of the following (1) to (13).

141 (1) A medical tube having a flexible tubular body having an open tip and a proximal end and a reinforcing body arranged inside the tubular body, the reinforcing body having at least a part thereof. , A coil layer composed of a first coil and a second coil provided substantially coaxially with the first coil and wound in the direction opposite to the first coil. Is arranged so that the width of the gap between the pitches of the first and second coils can be freely displaced over a predetermined length from the tip end to the base end, and the curvature of the tubular body is formed. A medical tube characterized by being configured to be flexibly curved without being restricted by the tubular body.

[0011]

152 (2) The medical tube according to (1) above, wherein the coil layer is substantially in close contact with the tubular body.

[0012]

157 (3) The medical tube according to (1) or (2) above, wherein the first and second coils are provided in close contact with each other.

[0013]

162 (4) The medical tube according to any one of (1) to (3) above, wherein the first and second coils are each wound in close contact winding.

[0014]

167 (5) The medical tube according to any one of (1) to (4) above, wherein the first and second coils are flat plate coils.

[0015]

172 (6) The coil layer further has one or more coils provided substantially coaxially with the first and second coils, and all the coils of the coil layer have a free width of the gap between pitches. The medical tube according to any one of (1) to (5), which is provided so as to be displaced to.

[0016]

179 (7) The medical tube according to (6), wherein all the coils in the coil layer are configured by winding adjacent coils in opposite directions.

[0017]

184 (8) A medical tube having a flexible inner layer, a reinforcing layer adhered to the outside of the inner layer, and a flexible outer layer adhered to the outside of the reinforcing layer, wherein the reinforcement is provided. The body, at least in part thereof, is provided substantially coaxially with the first coil and the first coil, wound in the direction opposite to the first coil, and substantially around the first coil. It is composed of a coil layer composed of a second coil that is not fixed, and the coil layer extends from the tip thereof toward the proximal end for a predetermined length, and is a gap between the pitches of the first and second coils. Almost all of the widths of the inner layer are arranged so as to be freely displaceable, and are configured to be flexibly curved with the curvature of the inner layer and the outer layer without being restricted by the inner layer and the outer layer. A medical tube featuring.

[0018]

198 (9) The above-mentioned (1) to (8), wherein the vicinity of the tip of the medical tube is made of a flexible material and has the most flexible tip portion on which the coil layer is not arranged. Medical tube.

[0019]

204 (10) A catheter for cerebrovascular embolization, comprising a tube body inserted into a body cavity, wherein the tube body is composed of the medical tube according to any one of

(1) to (9) above.

[0020]

210 (11) It has a tube body inserted into a body cavity, at least one lumen formed in the tube body, and an extension body provided at the tip of the tube body and having an internal space communicating with the lumen. A catheter for vasodilation, wherein the tube body is composed of the medical tube according to any one of (1) to (9).

[0021]

217 (12) An inner tube having a first lumen with an open tip, and an inner tube provided coaxially with the inner tube and having a tip at a position recessed by a predetermined length from the tip of the inner tube, and an outer surface of the inner tube. It has an outer tube forming a second lumen between them, a tip portion and a proximal end portion, the proximal end portion is attached to the outer tube, the distal end portion is attached to the inner tube, and the proximal end portion is attached. A contractionable or foldable extension that communicates with the second lumen in the vicinity, a first opening that communicates with the first lumen provided at the base end of the inner tube, and the outer tube. A balloon catheter having a second opening that communicates with the second lumen provided at the proximal end, wherein at least one of the inner tube and the outer tube is any of the above (1) to (9). A vasodilator catheter characterized by being composed of the medical tubing described in the above.

[0022]

232 (13) It is composed of the catheter for cerebrovascular embolization described in (10) above, a guide wire composed of a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material. Catheter device.

[0023]

239 (14) It is composed of the catheter for vasodilation according to the above (11) or (12), a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material. A catheter instrument consisting of a guide wire that can be inserted into a tube.

[0024]

246 In the medical tube of the present invention, at least a part of the reinforcing body is composed of the coil layer described above, and due to the configuration, at least the tip

portion is flexible, can be freely bent in all directions, and has kink resistance. ..

249 The coil body or the vine winding body having a spring property is rich in flexibility because the gap between the pitches can be freely widened and narrowed (freely displaceable).

251 It is preferable that the flexible tubular body or the flexible inner and outer layers are in close contact with the coil layer, but the coil layer may be adhered to the tubular body or the inner layer and the outer layer, or the gap may be formed. Embedding so as to be buried impairs the flexibility of the coil layer.

255 Therefore, it is preferable that the coil layer does not substantially adhere and is not embedded over a predetermined length from the tip end to the base end.

[0025]

260 The medical tube of the present invention has a structure in which the coil layer is arranged inside a flexible tubular body, that is, a structure in which the coil layer is arranged between the flexible inner layer and the outer layer, so that the wall of the tube is formed. It can be made thin and has high pressure resistance.

264 It is not possible to flow a liquid or the like only with a coil layer having a gap between winding pitches, but by providing a tubular body or an inner layer and an outer layer that cover the inside and outside of the coil layer, a fluid, a guide wire, or the above-mentioned embolic substance can be provided. Etc. to facilitate passage.

268 The pressure resistance of these tubular bodies or the inner and outer layers to the pressure applied from the opposite side to the coil is improved because they are supported from the back side by the coil.

271 This pressure resistance increases as the gap between pitches becomes smaller, that is, the coil winding becomes denser, and it does not depend on the wall thickness or material of the tubular body or the inner layer and the outer layer.

274 Therefore, even if the entire medical tube is thinned, the pressure resistance is not affected.

[0026]

278 Hereinafter, the configuration of the present invention will be described in detail with reference to the drawings.

280 1 is a plan view showing a configuration example of the medical tube of the present invention, FIG. 2 is a partially broken enlarged perspective view of the vicinity of the tip of the medical tube shown in FIG. 1, and FIG. 3 is a medical tube shown in FIG. A partially enlarged cross-sectional view showing the configuration of the tube, FIG. 4 is an enlarged cross-sectional view taken along the line I-I of FIG.

285 Hereinafter, the right side in FIGS. 1 to 3 is referred to as a "tip" and the left side is referred to as a "base end".

[0027]

290 The medical tube 1 shown in FIG. 1 is composed of a flexible tubular body 2.

291 The tubular body 2 is composed of a base portion 11 or a main body portion 11 and a tip portion 12 in order from the base end, and a lumen 14 is formed inside from the base end to the tip end.

294 In the illustrated example, the tip end side of the base portion 11 is formed with a tapered portion 13 whose inner diameter and outer diameter gradually decrease in a tapered shape from the base end side toward the tip end, whereby the tip end portion 12 is larger than the base portion 11. It has a small diameter.

298 In this way, by making the diameter of the medical tube 1 smaller at the tip portion 12 than at the base portion 11, the tip end side can be made relatively flexible and the base end side can be made relatively hard, and the pushability and the guide wire can be obtained. Followability can be improved.

302 Further, by making the inner diameter of the base portion 11 wider than that of the tip portion 12, the guide wire inserted in the tube 1 becomes easy to move smoothly, and the operability of the guide wire is improved.

305 In the present invention, the inner diameter and the outer diameter of the medical tube 1 are not limited to the above configurations, and may be substantially constant over the entire length of the tube 1, for example.

[0028]

311 As shown in FIG. 2, the tubular body 2 is composed of an inner layer 21 and an outer layer 22.

313 The inner layer 21 and the outer layer 22 are made of a thin-walled tube made of a flexible synthetic resin, are arranged substantially coaxially, extend from the base end to the tip end of the medical tube 1, and extend from the tip end and the base end. They are joined over a predetermined length by, for example, bonding or fusion.

317 Then, the space inside the inner layer 21 forms the lumen 14.

318 Further, the inner layer 21 and the outer layer 22 form the tapered portion 13 by gradually reducing the inner diameter and the outer diameter from the base end to the tip end in a predetermined length between the tip end and the base end. ..

321 Further, on the tip side of the tapered portion, the inner layer 21 and the outer layer 22 have substantially constant inner and outer diameters, respectively, and constitute the tip portion 12. Further, even on the proximal end side of this portion, the inner layer 21 and the outer layer 22 have substantially constant inner and outer diameters, respectively, and the tapered portion is also included to form the base portion 11.

[0029]

329 The constituent material of the tubular body 2, in other words, the constituent materials of the inner layer 21 and the outer layer 22 may be any material having a certain degree of flexibility, for example, polyethylene, polypropylene, polybutene, polymethylpentene,

polybutadiene, polyisoprene, and the like. Elastomers such as propylene-butene copolymers and ethylene-propylene copolymers, modified polyethylenes, modified polyolefins such as modified polypropylenes, fluororesins such as soft polyvinyl chloride and polytetrafluoroethylene, ethylene-vinyl acetate copolymers, polyesters. , Polyamite, polyacetal, polyurethane and other flexible resins, olefin-based elastomers, urethane-based elastomers, ester-based elastomers, polyvinyl chloride-based elastomers, polyamide-based elastomers, styrene-based elastomers and other elastomers, silicone rubber, Examples thereof include elastomers such as latex rubbers and natural rubbers, and blends of these materials.

341 Further, the resin and the elastomer are preferably thermoplastic, and if it is thermoplastic, the medical tube 1 can be easily manufactured.

[0030]

346 The inner layer 21 and the outer layer 22 do not necessarily have to be made of the same material, and further, an X-ray impermeable substance, a plasticizer, a pigment, or the like may be mixed with these materials.

349 In particular, as the constituent material of the inner layer 21, polyethylene, polypropylene, and fluororesin are particularly preferable from the viewpoints of ease of molding, ease of insertion into the coil layer 4, which will be described later, and chemical resistance.

[0031]

355 Further, since the outer layer 22 can easily coat the coil layer 4 described later, it is preferable to form the outer layer 22 with a solvent-swellable resin tube or a heat-shrinkable resin tube.

358 Examples of the solvent-swellable resin include the modified polyolefin, ethylene-vinyl acetate copolymer, polyamide elastomer, polyester elastomer, polyurethane and the like. In particular, from the viewpoint of adhesion and fusion with the inner layer 21, modified polyolefin is preferable, and among the modified polyolefin, modified polyethylene containing polyethylene as a main component is preferable. As the modified polyethylene, an adhesive resin made of ethylene and a copolymer made of, for example, acrylate, maleic anhydride, or the like as a raw material has a particularly preferable property. The tube made of this resin quickly swells with a solvent such as THF, the inner and outer diameters of the tube expands, and the outer layer 22 is surely restored to its original shape by removing the solvent by air drying or the like. If it is configured, it can be easily and surely coated and adhered to the coil layer 3 described later. Further, as the heat-shrinkable resin, a resin tube such as an electron beam-crosslinked polyolefin, crosslinked silicon, or a shape memory resin can be preferably used. Since these tubes can be contracted by heat, by forming the outer layer 22 with these tubes, the coil layer 3 described later can be easily inserted and adhered.

[0032]

375 As shown in FIGS. 2 to 4, a coil layer 3 having a role as a reinforcing body for reinforcing the strength of the medical tube 1 is arranged inside the tubular body 2, that is, between the inner layer 21 and the outer layer 22. Has been done.

378 In other words, the coil layer 3 which has a role as a reinforcing body for reinforcing the strength of the medical tube 1 is adhered to the outside of the inner layer 21, and the outer layer 22 is adhered to the outside of the coil layer 3. ing. The coil layer 3 shown in FIG. 2 is provided substantially coaxially with the first coil 31 wound on the outer peripheral surface of the inner layer 21 and the first coil 31, and is in close contact with the first coil 31. It is composed of a coil 31 of 1 and a second coil 32 that is wound in the opposite direction. The coil layer 3 has a long tube-like shape, and its outer peripheral surface and inner peripheral surface are arranged in the tube 1 in a state of being in contact with the tubular body 2, in other words, the inner layer 21 and the outer layer 22.

[0033]

390 A cutting-edge portion 16 in which the coil layer 3 is not arranged is formed near the tip of the tube 1.

392 The coil layer 3 extends in the proximal direction from a position slightly retracted from the tips of the tubular body 2, that is, the inner layer 21 and the outer layer 22, and the tip side of the coil layer 3 is the most composed of the inner layer 21 and the outer layer 22. It is a tip portion 16. Since the coil layer 3 is not arranged, the cutting edge portion 16 is more flexible than the portion on the proximal end side of the cutting edge portion 16. Therefore, when the tube 1 is inserted into a blood vessel, the irritation given to the blood vessel can be reduced. Further, since the coil layer 3 does not protrude from the tubular body 2, that is, the tips of the inner layer 21 and the outer layer 22, there is no possibility that the protruding portion will damage the body cavity or the tubular organ when inserted into the body cavity or the tubular organ. preferable. The length of the cutting edge portion 16, that is, the distance from the tip of the coil layer 3 to the tips of the tubular body 2 or the inner layer 21 and the outer layer 22 is preferably about 10 mm or less, more preferably 0.5 to 5 mm. Degree.

[0034]

408 The position of the coil layer 3 in the medical tube 1 is not particularly limited, but it is preferable that the coil layer 3 extends from the base end of the medical tube 1 to the vicinity of the tip end of the tube 1.

411 By arranging the coil layer 3 over the entire length of the tube 1 in this way, the torque and the pushing force applied to the base 11 can be satisfactorily transmitted to the vicinity of the tip of the tube 1 via the coil layer 3. In the illustrated example, in the vicinity of the base end of the tube 1, the coil layer 3 has a base end at a position slightly separated from the base ends of the tubular body 2, that is, the inner layer 21 and the outer layer 22, and the

medical tube 1 has a base end. The structure is such that the coil layer 3 is provided over almost the entire length.

[0035]

421 Then, in the medical tube 1, even if a pressure higher than that of the inner layer 21, that is, the lumen 14, is applied to the inner layer 21, the inner layer 21 is supported from the opposite side by the first coil 31, and is related to the thickness of the inner layer 21. However, it exhibits higher pressure resistance than the case of the inner layer 21 alone.

425 Further, even if a higher pressure is applied to the outer layer 22 than the outside of the outer layer 22, the outer layer 22 is supported from the opposite side by the second coil 32, and the outer layer 22 is supported from the opposite side regardless of the thickness of the outer layer 22 as compared with the case of the outer layer 22 alone. Demonstrates high pressure resistance. Therefore, the medical tube 1 has excellent pressure resistance inside and outside, and even if a pressure higher than the inside or the outside of the tube 1 is applied to the tube 1, the tube 1 is unlikely to be crushed or burst.

[0036]

435 In order to exert such an action satisfactorily, it is preferable that the coil layer 3 is in close contact with the tubular body 2 or the inner layer 21 and the outer layer 22.

437 In other words, the first coil 31 is preferably in close contact with the tubular body 2 or the inner layer 21, and the second coil 32 is preferably in close contact with the tubular body 2 or the outer layer 22. The first coil layer 31 and the second coil layer 32 may be in close contact with the inner layer 21 or the outer layer 22 over the entire length thereof, but at least a part thereof, for example, the tip portion 12 is predetermined. It may be in close contact over the length. Further, by bringing the first coil layer 31 and the second coil layer 32 into close contact with the inner layer 21 or the outer layer 22, the wall thickness of the medical tube 1 can be reduced, so that the diameter of the tube 1 can be reduced satisfactorily. be able to. Further, due to the close contact, the torque and the pushing force at the base 11 of the medical tube 1 can be reliably transmitted to the vicinity of the tip of the tube 1.

[0037]

451 In the illustrated example, the first coil 31 and the second coil 32 have an inner diameter and an outer diameter gradually decreasing from the proximal end to the distal end over a predetermined length between the tip and the proximal end, and the tapered portion. It constitutes 13.

455 Further, on the tip side of the tapered portion, the inner and outer diameters of the coils 31 and 32 are substantially constant, respectively, and constitute the tip portion 12. Further, even on the proximal end side of this portion, the inner diameter and the outer diameter of

the coils 31 and 32 are substantially constant, respectively, and the base portion 11 includes the tapered portion.

[0038]

463 As shown in FIG. 3, the first coil 31 is a medical tube in which a bundle 31A in which five flat wire wires 31a, 31b, 31c, 31d to 31e having a rectangular cross-sectional shape are bundled together. It is configured by winding right-handed toward the tip of 1.

466 Further, the second coil 32 is a bundle 32A in which five flat wire wires 32a, 32b, 32c, 32d to 32e having a rectangular cross-sectional shape as described above are bundled into a medical tube 1 The coil is wound in the direction opposite to that of the first coil 31, that is, left-handed, toward the tip of the coil.

[0039]

473 For these strands 31a to e and strands 32a to e, it is preferable that the width x of the gap between the strands in the bundles 31A and 32A described above is close to zero, respectively.

476 The closer the width x is to zero, the more the strands 31a to e or the strands 32a to e are in close contact with each other, which is advantageous for supporting the inner layer 21 and the outer layer 22. In other words, the larger the width x, the higher the possibility that the inner layer 21 and the outer layer 22 will fall into the gap between the strands 31a to e and the strands 32a to e, resulting in minute tearing.

[0040]

484 Further, in the first coil 31 and the second coil 32, the width of the gap between the pitches (in the illustrated example, the width of the gap between the pitches of the bundles 31A and 32A) y is the strands 31a to e and, respectively. It is preferably smaller than the width z of the strands 32a to e, more preferably about 30% or less of the width z, and more preferably closer to zero, that is, the coils 31 and 32 are tightly wound. ..

489 By doing so, it is possible to prevent the wires 31a to e of the coil 31 from jumping out of the gap of the coil 32, and it is possible to prevent the wires 32a to e of the coil 32 from falling into the gap of the coil 31. The thickness t of the first coil 31 and the second coil 32 is preferably about 0.005 to 0.1 mm, more preferably about 0.005 to 0.05 mm, respectively.

[0041]

496 The cross-sectional shapes of the first coil 31 and the second coil 32 are not limited to the rectangle shown in the figure, and may be, for example, a circle, an ellipse, a triangle, a square, a parallelogram, a polygon of a pentagon or more, and the like. May be good.

499 However, it is preferable that the coils 31 and 32 are flat plate coils in which the strands 31a

to 31a to 32a to e form a flat plate. By using a flat plate coil, the thickness of the coil layer 3 can be effectively reduced, and the coils 31 and 32 can be easily wound in close contact with each other. Further, it is preferable that the first coil 31 and the second coil 32 are in close contact with each other. By bringing the medical tube 1 into close contact, the wall thickness of the medical tube 1 can be reduced, so that the diameter of the tube can be reduced, and the torque and pushing force applied to the base 11 of the medical tube 1 are applied to the tube via the coils 31 and 32. It is possible to reliably convey to the vicinity of the tip of 1.

[0042]

510 Then, the coil layer 3 has a predetermined length from its tip toward the proximal end (in other words, in the distal end side portion of the coil layer 3) between the pitches of the first coil 31 and the second coil 32. Almost all of the width y of the gap is arranged so as to be freely displaceable, and is configured to be able to flexibly bend without being restricted by the tubular body 2 (inner layer 21 and outer layer 22).

515 As a result, the coil layer 3 can freely widen or narrow the width y of almost the entire gap between the pitches, and can be bent very flexibly without hindering the bending of the tubular body 2.

[0043]

521 Specifically, the first coil 31 is embedded so as to extend at least a predetermined length from its tip toward the proximal end, not to be fixed to the inner layer 21, and to fill almost all the gaps between the pitches. It has not been.

524 Almost all of the gaps between the pitches are voids because the material such as resin and the adhesive constituting the inner layer 21 do not substantially flow into the gaps. Similarly, the second coil 32 is also embedded so that it is not fixed to the outer layer 22 and fills almost all the gaps between the pitches, at least for a predetermined length from the tip end toward the base end. No material such as resin or an adhesive constituting the outer layer 22 has substantially flowed into almost all of the gaps between the pitches, resulting in voids. In the first and second coils 31 and 32 configured in this way, almost the entire width y of the gap between the pitches can be freely widened or narrowed due to the curvature of the inner layer 21 and the outer layer 22, which is extremely high. Can be flexibly curved.

[0044]

536 In the present invention, "the width of the gap between the pitches of the coil can be freely displaced" means that the width y of the gap between the pitches freely widens and narrows without substantially impairing the original flexibility of the coil. It is possible (displaceable).

[0045]

542 In the coil layer 3, it is preferable that the entire gap between pitches can be freely displaced in the tip side portion, but if the flexible curvature of this portion is not substantially hindered, the coil layer 3 may be part of the coil layer 3. For example, an adhesive, a resin material, or the like may flow into the gap to form a region that cannot be freely displaced.

546 Such a region has a length sufficiently shorter than the total length of the distal end side portion of the coil layer 3 (for example, 10% or less of the total length of the distal end side portion).

549 It should be noted that this region may be dispersedly provided at two or more locations on the tip end side portion of the coil layer 3, but it is preferably provided at one location, and in the case of two or more locations, the regions are as close as possible. Is preferable.

[0046]

555 Further, as shown in the figure, when the coil layer 3 is provided up to the vicinity of the base end of the tubular body 2, the adhesive is impregnated over a certain length on the base side of the coil layer 3 in order to improve the pushability of the catheter. , May be hard.

558 In this case, if the entire coil layer 3 is impregnated with the adhesive, the flexibility of the coil layer 3 is lost. Therefore, it is decided to impregnate only the base side of the medical tube 1, specifically, the medical tube 1. From the base end, it is preferable to impregnate the total length of the medical tube 1 over a length of about 5 to 50%, more preferably about 10 to 40%, still more preferably about 20 to 30%.

[0047]

566 The medical tube 1 configured in this way is highly flexible and has appropriate rigidity.

567 Further, a lubricant such as silicone oil may be applied between the coil layer 3 and the inner layer 21 and the outer layer 22 in order to improve the sliding of the coil layer 3. By doing so, the coil layer 3 can be bent more flexibly without being caught by the inner layer 21 and the outer layer 22.

[0048]

574 Examples of the constituent materials of the strands 31a to e and the strands 32a to e constituting the first coil 31 and the second coil 32 include metal materials such as stainless steel, tungsten, aluminum, Ni—Ti alloy, and brass. Highly rigid resins such as polytetrafluoroethylene (Teflon), polyvinyl chloride, polyamide, polyethylene terephthalate, polysulfone, polycarbonate, polyarylate, polyacetal, polyphenylene sulfide, polyetherketone, polyetheretherketone, polyimide, polyamideimide, etc. Materials, PAN-based, pitch-based, naphthalene-based, carbon fibers and carbon fibers such as their prepregs, ceramics, etc. can be used, but materials with high safety for medical use are preferable, and in particular, shaping and quenching is possible. Stainless steel such as SUS304 is preferable.

[0049]

586 From such a constituent material, the strands 31a to 32a to 32a to e are formed by appropriately selecting dimensions such as wall thickness and width, and these are wound at a predetermined pitch to form the coil shown in FIG. 2. Layer 3 is obtained.

589 In the production of the coil layer 3, for example, the strands 31a to e are spirally wound (in the illustrated example, in the right-handed direction toward the tip) along the rod-shaped core material, and then the strands 32a to e are wound. Is wound in the direction opposite to the strands 31a to e (in the illustrated example, in the left-handed direction toward the tip), and then the core material is removed.

[0050]

597 The dimensions of the medical tube 1 vary depending on the application, but the length is 200 to 2000 mm, preferably 1000 to 2000 mm, and the outer diameter is 0.35 to 4.3 mm, preferably 0.40 to 2.00 mm. The inner diameter is 0.25 to 4.00 mm, preferably 0.30 to 1.80 mm.

601 Further, the thickness (thickness) of the tube wall of the medical tube 1 is preferably thin, but when the wall thickness of the tube 1 is T and the inner diameter of the tube 1 is S, this wall thickness T is the inner diameter S. The value divided by (thickness inner diameter ratio) is preferably in the range of T / S = 0.05 to 0.50, and more preferably 0.07 to 0.326.

605 When this value is less than 0.05, the wall thickness T becomes too thin with respect to the inner diameter S, and the strength of the medical tube 1 is significantly reduced. On the other hand, if it exceeds 0.50, the wall thickness T and the outer diameter of the tube accompanying it increase too much, which is not preferable.

[0051]

612 In the illustrated example, the first coil 31 is right-handed and the second coil 32 is left-handed, each of which is configured as a set of five strands, but in the present invention, the coils 31 and 32 are right-handed. The order of left-handed winding and the number of strands to be bundled are free, and the above-mentioned width x and width y may differ depending on the part of the medical tube 1.

617 For example, by increasing the width x or the width y toward the tip, in other words, reducing the width x or the width y toward the base end, the closer the coils 31 and 32 are to the tip, the more flexible the bending becomes. Moreover, the closer it is to the base end, the more difficult it is to bend, and it is possible to obtain a medical tube having good flexibility near the tip end and excellent torque transmission and pushability. Further, the width z of the first coil 31 and the second coil 32 may be constant over the entire length of the medical tube 1 or may differ depending on the site. For example, by making the width z smaller toward the tip, in other words, increasing the width z toward the base end, the closer the coils 31 and 32 are to the tip, the easier it is to bend, and the closer it is to the base end, the more difficult it

is to bend. It is possible to obtain a medical tube having good flexibility near the tip and excellent torque transmission and pushing property.

[0052]

631 FIG. 5 is a partially broken enlarged perspective view showing the vicinity of the tip portion of another configuration example of the medical tube of the present invention.

633 The same configurations as those shown in FIGS. 1 to 4 are designated by the same reference numerals and the description thereof will be omitted.

[0053]

638 The medical tube 10 shown in FIG. 5 has almost the same configuration as the medical tube 1, but has a tip soft tip 15 made of a highly flexible material, and the tip 15 and the coil layer 3 are formed. It differs in that the tip 160 is configured from the portion near the tip of the unarranged tubular body 2 (inner layer 21 and outer layer 22).

642 The tip 15 is formed in a short tubular shape, and is bonded to the tubular body 2, in other words, the tips of the inner layer 21 and the outer layer 22 by adhesion or the like so that the lumen thereof communicates with the lumen 14. With this configuration, the cutting-edge portion 160 of the medical tube 10 has higher flexibility than the portion in which the coil layer 3 is arranged, so that a stimulus given to the blood vessel or the like when inserted into the blood vessel or the like is given. Can be reduced.

[0054]

651 As the constituent material of the advanced soft chip 15, it suffices to have flexibility, and for example, polyurethane, vinyl chloride-urethane copolymer, silicone RTV rubber and the like can be used.

654 The length of the chip 15 is 0.5 to 30 mm, preferably about 2 to 15 mm.

[0055]

658 Although the configuration example in which the coil layers form a two-layer structure has been described above, in the present invention, the coil layer may have a structure of three or more layers in which three or more coils are arranged substantially coaxially.

661 In this case, it is preferable that the adjacent coils are wound in opposite directions in each coil. Further, the coil layers in the present invention do not have to have the same number of layers over the entire length thereof. It may be provided in some places.

[0056]

667 Further, in the illustrated example, the coil layer 3 is arranged over almost the entire area of

the medical tube 1 and is formed so as to reinforce the medical tube 1 over almost the entire area. However, in the medical tube of the present invention, a part thereof. In the above, a reinforcing body other than the coil layer, for example, a tube or a tube body made of a member having high rigidity may be arranged, and such a body and the coil layer may be combined to form a reinforcing body.

673 However, by forming the reinforcing body only with the coil layer and forming the medical tube with a material having relatively high flexibility (flexibility) except for this coil layer, appropriate flexibility and rigidity (hardness) are obtained. With), good kink resistance, excellent torque transmission and push-in performance, and by using a guide wire, it can be inserted into the body cavity well following this guide wire, and it also has excellent pressure resistance. You can get a medical tube.

[0057]

682 Further, in the present invention, the coil layer is not limited to the one arranged over the entire length of the medical tube, for example, a configuration in which the coil layer 3 is not arranged in the middle of the medical tube 1 or the tip portion of the tube 1. The coil layer 3 may be arranged only on the twelve.

686 However, if the coil layer is arranged over almost the entire length of the medical tube, the torque and pushing force applied at the base 11 can be satisfactorily transmitted to the vicinity of the tip of the medical tube via the coil layer.

[0058]

692 Further, in the present invention, it is preferable that the outer surface of the tubular body 2 or the outer layer 22 is covered with a hydrophilic (or water-soluble) polymer substance (not shown).

695 As a result, when the outer surface of the tubular body 2 or the outer layer 22 comes into contact with blood, physiological saline, or the like, the coefficient of friction is reduced to impart lubricity, and the slidability of the medical tube 1 is further improved. As a result, pushability, followability, and kink resistance are further improved. Further, when the inner surface of the inner layer 21 is also lubricated with the hydrophilic polymer substance, silicone oil, oil or fat, etc., the guide wire inserted in the tube 1 becomes easy to move in the tube 1, and the guide wire can be operated. Sex improves.

[0059]

705 Examples of the hydrophilic polymer substance include the following natural or synthetic polymer substances or derivatives thereof.

707 <Natural polymer substance> 1) Starch-based examples: carboxymethyl starch, dialdehyde starch 2) Cellulose-based examples: CMC (carboxymethyl cellulose), MC (methyl cellulose), HEC (hydroxyethyl cellulose), HPC (hydroxypropyl cellulose) 3) Tannin, starch-based

examples: tannin, nignin Examples: alginic acid, gum arabic, guar gum, tragant gum, tamarint species 5) Protein examples: gelatin, casein, glue, collagen

[0060]

715 <Synthetic water-soluble polymer> Example: Polyvinyl alcohol 2) Polyethylene oxide-based Example: Polyethylene oxide, Polyethylene glycol 3) Acrylic acid-based Example: Polyacrylic acid sodium 4) Anhydrous maleic acid-based Example: Methyl vinyl ether Anhydrous maleic acid copolymer 5) phthalic acid-based example: polyhydroxyethyl phthalic acid ester 6) water-soluble polyester example: polydimethyllol propionic acid ester 7) ketone aldehyde resin example: methylisopropylketoneformaldehyde resin 8) acrylamide-based example: polyacrylamide, polydimethylacrylamide 9) Polyvinylpyrrolidone-based 10) Polyamine-based Example: Polyethyleneimine 11) Polyelectron Example: Polystyrenesulfonate Example: Water-soluble nylon, P (GMA-DMAA) block copolymer (poly (glycidyl methacrylate-dimethylacrylamide) block copolymer)

[0061]

728 Among these, in particular, a cellulose-based polymer substance (for example, hydroxypropyl cellulose), a polyethylene oxide-based polymer substance (polyethylene glycol), and a maleic anhydride-based polymer substance (for example, a methylvinyl ether anhydrous maleic acid copolymer). Such as maleic anhydride copolymers), acrylamide-based polymer substances (eg, polyacrylamide), water-soluble nylons (eg, AQ-nylon P-70 manufactured by Toray Co., Ltd.), polyglycidyl methacrylate-dimethylacrylamide copolymers. , It is preferable because a low friction coefficient can be stably obtained.

735 Among them, in particular, the polyglycidyl methacrylate-dimethylacrylamide copolymer, which is a block copolymer composed of a hydrophilic compound block and a hydrophobic compound block, is lubricated because the hydrophilic compound (polydimethylacrylamide) is a water-swellable compound. Since it has excellent properties and has a hydrophilic / hydrophobic microdomain structure, antithrombotic properties can also be expected.

[0062]

743 Further, the derivative of the polymer substance is not limited to a water-soluble substance, and as long as the water-soluble polymer substance has the basic composition, there is no particular limitation, and even an insolubilized polymer substance can be used as a molecular chain. It suffices as long as it has a degree of freedom and contains water.

747 For example, esterified products, salts, amidated products, anhydrides, halides, etherified products, hydrolysates, acetal products, formal products, and alkylols obtained by condensation, addition, substitution, oxidation, reduction reaction, etc. of the above polymer substances. Diazonium group, azide group, isocyanate group, acid chloride group, acid anhydride group, iminocarbonate ester group, amino group, carboxyl group, Cross-linked

products with substances having two or more epoxy groups, hydroxyl groups, aldehyde groups, reactive functional groups; copolymers with vinyl compounds, acrylic acids, methacrylic acid, diene compounds, maleic anhydride and the like can be mentioned.

[0063]

758 In order to fix the coating layer of such a hydrophilic polymer substance to the outer surface of the tubular body 2 or the outer layer 22, it is preferable to covalently bond with the reactive functional group present or introduced on the surface. ..

761 This makes it possible to obtain a long-lasting lubricious surface.

762 The reactive functional group existing or introduced in or on the surface of the tubular body 2 or the outer layer 22 may be any group as long as it reacts with the polymer substance and is bonded or crosslinked to fix it. , Azido group, isocyanate group, acid chloride group, acid anhydride group, iminocarbonate ester group, amino group, carboxyl group, epoxy group, hydroxyl group, aldehyde group and the like, and in particular, isocyanate group, amino group, epoxy group and aldehyde. Groups are suitable.

[0064]

771 The average molecular weight of the hydrophilic polymer substance is not particularly limited, but is preferably about 3 to 5 million.

773 As a result, a lubricating layer having high lubricity, an appropriate thickness, and an appropriate degree of swelling when water is contained can be obtained. The thickness of the lubricating layer made of such a hydrophilic polymer is not particularly limited, but is preferably about 0.1 to 100 μm, particularly preferably about 1 to 30 μm. The composition and coating method of the hydrophilic polymer substance are described in, for example, JP-A-53-106778, US Pat. No. 4,300,309, JP-A-60-259269, and Japanese Patent Application Laid-Open No. 1-33181. You can apply something like that.

[0065]

783 Further, in the present invention, it is preferable to apply a treatment for imparting higher biocompatibility to the outer surface of the tubular body 2 or the outer layer 22.

785 As biocompatibility, antithrombotic property is required, and various known methods can be mentioned for imparting antithrombotic property. However, it is preferable to fix heparin on the outer surface by coating with a heparin solution or heparin bonding. Further, if a thrombolytic agent is mixed with the constituent material of the tubular body 2 or the outer layer 22 and extruded to form a tube, the thrombolytic agent is gradually released when inserted into a blood vessel and used, which is preferable. ..

[0066]

794 FIG. 6 is a plan view showing a configuration example of the catheter for cerebrovascular embolization of the present invention.

796 Hereinafter, the catheter for cerebrovascular treatment of the present invention will be described with reference to the drawings. The same components as those of the configuration examples shown in FIGS. 1 to 4 are designated by the same reference numerals and the description thereof will be omitted. The cerebrovascular treatment catheter 4 of the present invention includes the medical tube 1 shown in FIGS. 1 to 4, the reinforcing tube 41 mounted around the outer periphery of the vicinity of the base end of the tube 1, the medical tube 1 and the reinforcing tube. It is composed of a hub 42 mounted near the base end of 41, a tip soft tip 43 joined to the tip of a medical tube 1, and a contrast marker 44.

[0067]

807 The reinforcing tube 41 is, for example, a heat-shrinkable tube 51 having a heat-shrinkable inner diameter slightly smaller than the outer diameter near the base end of the tube 1. It can be easily attached by fitting it in the vicinity of the base end of No. 1 and heating (for example, applying hot air) to shrink it.

811 Further, the hub 42 has a lumen communicating with the lumen 14 of the tube 1 and an opening communicating the lumen 14 with the outside, and has an injection port for a chemical solution, an embolic substance, etc. into the lumen 14 and a guide wire. It functions as an insertion port and also functions as a grip when operating the cerebrovascular treatment catheter 4.

[0068]

819 The tip soft chip 43 is made of a highly flexible material similar to the chip 15 described above.

821 The tip 43 is formed in the shape of a short cylinder, and is fixed and joined to the tip of the tube 1 by adhesion or the like so that the lumen thereof communicates with the lumen 14 of the tube 1. Further, the contrast marker 44 is configured by winding a platinum wire rod around the outer surface of the chip 53 in a coil shape. The marker 44 may be embedded in the tubular body 2, between the inner layer 21 and the outer layer 22, or in the tip soft tip 43. With such a structure, the tip 44 does not protrude to the outer surface of the catheter, so that a step is formed. Is not formed and irritation to blood vessels is reduced. The length of the chip 43 is about 0.5 to 30 mm, preferably about 2 to 15 mm.

[0069]

832 Since the cerebrovascular embolization catheter 4 is composed of the medical tube 1 as a tube body to be inserted into the cerebrovascular vessel, it is flexible and rich in kink resistance.

835 In addition, the pressure resistance on the inside and the pressure resistance on the outside

are also very excellent, it is hard to be crushed even if the wall thickness is thin, and it can be inserted well along the guide wire even in a blood vessel that branches and bends finely and complicatedly. It is difficult to rupture even if a high pressure is applied to the inside of the catheter 4 by pouring a large amount of a highly viscous contrast medium or embolic substance.

[0070]

844 The dimensions of the cerebral vascular embolization catheter 4 are about 1000 to 2000 mm in length, preferably about 1300 to 1700 mm, and the outer diameter is about 0.3 to 3 mm, preferably about 0.4 to 1.0 mm. The inner diameter is about 0.20 to 0.70 mm, preferably about 0.3 to 0.7 mm, and the wall thickness is about 0.04 to 0.15 mm, preferably about 0.06 to 0.1 mm.

[0071]

852 Further, in the cerebrovascular embolization catheter 4, the outer surface of the portion to be inserted into the blood vessel, that is, the outer surface of the tip soft tip 44 and the medical tube 1, is coated with a lubricating polymer substance and biocompatibility treatment is performed. Is preferable.

856 The coating of the lubricating polymer substance and the biocompatibility treatment can be performed in the same manner as described above.

858 The coating of the lubricating polymer substance and the biocompatibility treatment may be performed at the stage of manufacturing the medical tube 1 or after assembling the cerebrovascular embolization catheter 4.

[0072]

864 Further, in the cerebrovascular embolization catheter 4, in a part of the medical tube 1, an adhesive, a resin material or the like may be allowed to flow into the gap between the pitches of the coil layer 3 to regulate the displacement of the gap. ..

867 In particular, when the portion extending from the base end of the tube 1 to the predetermined length is made in this way, the hardness from the base end of the tube 1 to the predetermined length is increased, and the torque transmissibility and the pushing property of the catheter 4 can be further improved. In order to obtain the catheter 4 having such a configuration, for example, the gap may be impregnated with an adhesive or the like at the stage where the coil layer 3 is formed, or after the medical tube 1 is manufactured, the hub 42 is tubed. It is also possible to impregnate the base end of the tube 1 with an adhesive by utilizing the capillary phenomenon before attaching to 1.

[0073]

878 Next, the method and operation of the above-mentioned cerebrovascular embolization catheter 4 will be described.

880 First, a guiding catheter (not shown) having a lumen through which the catheter 4 can be inserted is inserted and indwelled from the femoral artery to the internal carotid artery, the external carotid artery, or the vertebral artery via the aorta. The inner surface of the guiding catheter has a hydrophilic coating. Next, a guide wire composed of a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material, or a metal elastic core material and the tip of the core material are provided. A catheter 4 in which a guide wire composed of a obtained X-ray contrast-enhanced coil and a fluorine-based coating material coated on the surface of the core material is inserted and set is placed along the lumen of the guiding catheter of the guiding catheter. It protrudes from the tip and is inserted to the target blood vessel together with the above guide wire. When the blood vessel branches on the way, the guide wire is preceded so that it can be selectively inserted into the target blood vessel, and then the catheter is pushed in. If it is difficult to insert along the guide wire, rotate the hand of the catheter and push it in while transmitting the rotation to the tip of the catheter to advance to the target blood vessel. The cerebral aneurysm existing in the target blood vessel is confirmed from the upstream side under fluoroscopy with a contrast medium of a catheter. When the target site is reached, the tip 11 of the catheter 4 is inserted into the cerebral aneurysm, the guide wire is removed, and then an embolic substance such as a liquid, granular, or microcoil is introduced. When the introduction is completed, the guiding catheter and the catheter 4 are removed from the body, hemostasis is performed, and the procedure is completed.

[0074]

904 Since the catheter 4 of the present invention is configured with the medical tube 1 of the present invention as a member, it is highly flexible and kink-resistant, and even a fine and complicated blood vessel of a cerebral aneurysm can be satisfactorily used. It can be inserted and has good followability to the guide wire, and even complicatedly curved and bent blood vessels can easily proceed along the guide wire without kinking.

909 In addition, it has excellent torque transmission and pushability, making it a catheter with good operability, and also has excellent pressure resistance on the inside and outside, so it is hard to collapse even without a guide wire in a fine and complicated blood vessel. There is little risk of bursting even if liquid or granular embolic material is poured.

[0075]

916 The catheter for cerebrovascular embolization of the present invention is not limited to the configuration shown in the figure. A cutting-edge portion that is more flexible than the portion in which the coil layer 3 that serves as a reinforcing body is arranged may be formed.

919 Even in such a configuration, since the cutting edge portion is composed of a flexible inner

layer 21 and an outer layer 22, it is very flexible, and therefore, when it is inserted into a body cavity such as a blood vessel, there is little irritation to the body cavity. It is also possible to prevent damage to the inner wall of the body cavity, and obtain a catheter that can be inserted quickly and with certain selectivity even in a body cavity having a fine and complicated pattern such as a cerebral blood vessel. Further, in this case, the contrast marker may be embedded and arranged between the inner layer 21 and the outer layer 22 at the most advanced portion.

[0076]

930 7 is a plan view showing a configuration example of the vasodilator catheter of the present invention, and FIG. 8 is a vertical cross-sectional view showing the tip of the vasodilator catheter shown in FIG. 7.

933 Hereinafter, the vasodilator catheter of the present invention will be described with reference to the drawings. The same components as those of the configuration examples shown in FIGS. 1 to 4 are designated by the same reference numerals and the description thereof will be omitted. The vasodilator catheter 5 shown in FIGS. 7 and 8 is provided at the tube body 50 inserted into the body cavity, at least one lumen 511 formed in the tube body 50, and the tip of the tube body 50. It has an expansion body 53 having an internal space communicating with the lumen 511, and the tube body 50 is composed of the medical tube 1 shown in FIGS. 1 to 4.

[0077]

944 Specifically, the catheter 5 is a so-called double lumen coaxial type guide wire movable (over the wire type) vasodilator catheter, and the tube body 50 is composed of an inner tube 51 and an outer tube 52. Has been done.

947 An inner pipe 51 having a first lumen 511 having an open tip and an inner pipe 51 provided coaxially with the inner pipe 51 and having a tip at a position retracted by a predetermined length from the tip of the inner pipe 51. It has an outer pipe 52 forming a second lumen 521, a tip portion 531 and a base end portion 532, the base end portion 532 is attached to the outer pipe 52, and the tip portion 531 is an inner pipe 51. A contractionable or foldable expansion body 53 that is attached to and communicates with the second lumen 521 near the proximal end portion 532, and a first that communicates with the first lumen 511 provided at the proximal end portion of the inner tube 51. Has an opening 581 and a second opening 591 communicating with a second lumen 521 provided at the base end of the outer tube 52. At least one of the inner tube 51 and the outer tube 52 is composed of the above-mentioned medical tube of the present invention.

[0078]

961 In the illustrated example, the inner tube 51 is configured using the medical tube 1 shown in

FIGS. 1 to 4, and as shown in FIG. 8, the flexible tubular body 2 and the tubular body 2 It has a coil layer 3 which has a role as a reinforcing body arranged inside.

964 The tubular body 2 is composed of a flexible inner layer 21 and a flexible outer layer 22, in other words, the inner tube 51 is adhered to the flexible inner layer 21 and the outer side of the inner layer 21. It has a structure having a coil layer 3 having a role as a reinforcing layer and a flexible outer layer 22 adhered to the outside of the coil layer 3. The coil layer 3 is composed of a first coil 31 and a second coil that is wound in the direction opposite to that of the first coil 31. The coil layer 3 is arranged so that the gap between the pitches of the first and second coils 31 and 32 can be freely displaced over a predetermined length from the tip end to the base end, and the tubular body 2 is curved. As a result, it can be flexibly curved without being restricted by the tubular body 2.

[0079]

976 The inner tube 51 has a first lumen 511 with an open tip.

977 The first lumen 511 is a lumen for inserting a guide wire, and communicates with a first opening 581 forming a guide wire port provided in the branch hub 57 described later. The inner pipe 51 has an outer diameter of 0.40 to 2.50 mm, preferably 0.55 to 2.40 mm, and an inner diameter of 0.25 to 2.35 mm, preferably 0.30 to 1.80 mm. ..

[0080]

984 The outer pipe 52 has an inner pipe 51 inserted therein and is provided coaxially with the inner pipe 51, and the tip thereof is provided at a position slightly retracted from the tip of the inner pipe 51.

987 A second lumen 521 is formed by the inner surface of the outer pipe 52 and the outer surface of the inner pipe 51. By forming in this way, the cross-sectional area of the second lumen 521 can be made large, and the lumen having a sufficient volume can be obtained. The second lumen 521 communicates with the extension 53 at its tip and at its proximal end, and the proximal end of the second lumen 521 is a fluid (eg, angiographic agent) for expanding the extension 53. Communicates with a second opening 591 of the branch hub 57 forming an injection port for injecting the fluid. The outer tube 52 has an outer diameter of 0.70 to 4.30 mm, preferably 0.75 to 4.00 mm, and an inner diameter of 0.70 to 3.80 mm, preferably 0.80 to 3.00 mm. ..

[0081]

999 The constituent material of the outer tube 52 may be any material having a certain degree of flexibility, for example, polyolefins such as polyethylene, polypropylene, polybutene, and ethylene-propylene copolymer, polyvinyl chloride, and ethylene-vinyl acetate copolymer weight. Thermoplastic resins such as coalesced, polyurethane and polyester, polyamide elastomers, polyester elastomers, silicone rubbers, polytetrafluoroethylene and the like can

be used, preferably the above-mentioned thermoplastic resins, and more preferably polyolefins.

[0082]

1009 The expansion body 53 is contractable, and in a non-expandable state, it can be folded around the outer periphery of the inner tube 51.

1011 The dilated body 53 is foldable and has a substantially cylindrical portion 533 having at least a substantially cylindrical shape and having substantially the same diameter so that the narrowed portion of the blood vessel can be easily dilated.

1014 The above-mentioned substantially cylindrical portion does not have to be a perfect cylinder, and may be a polygonal columnar portion. The base end portion 532 of the extended body 53 is liquid-tightly fixed to the tip end portion of the outer tube 52 by adhesion or heat fusion, and the tip end portion 531 is the tip end of the inner tube 51 as shown in FIG. It is directly adhered to the part in a liquid-tight manner. The extended body 53 forms an internal space 534 between the inner surface of the extended body 53 and the outer surface of the inner tube 51. The internal space 534 communicates with the second lumen 521 at the base end portion 532 on the entire circumference thereof. In this way, since the second lumen 521 having a relatively large volume is communicated with the base end of the expansion body 53, the expansion fluid can be injected from the second lumen 521 into the internal space 534 of the expansion body 53. It's easy. The constituent material of the extended body 53 is preferably one having a certain degree of flexibility, for example, polyolefins such as polyethylene, polypropylene and ethylene-propylene copolymer, polyvinyl chloride, ethylene-vinyl acetate copolymer, polyurethane and the like. Thermoplastic resin, polyamide elastomer, silicone rubber, latex rubber, polyethylene terephthalate, polyester, polyamide, polyphenylene sulfide and the like can be used. Preferred is polyphenylene sulfide.

[0083]

1034 Further, the extended body 53 has a tapered portion from the distal end side and the proximal end side of the substantially cylindrical portion 533 to the distal end portion 531 and the proximal end portion 532 fixed to the inner pipe 51 and the outer pipe 52. There is.

1038 As for the size of the extended body 53, the outer diameter of the substantially cylindrical portion 533 when expanded is 1.00 to 35.00 mm, preferably 1.50 to 30.00 mm, and the length is 10.00 to 80. It is 0.00 mm, preferably 15.00 to 75.00 mm, and the total length of the extension 53 is 15.00 to 120.00 mm, preferably 20.00 to 100.00 mm.

[0084]

1045 Further, a marker 54 made of an X-ray opaque material (for example, gold, platinum or an

alloy thereof) is provided on the outer surface of the inner tube 51 at a position between the tip end portion 531 and the base end portion 532. Has been done.

1048 This marker 54 makes it possible to easily confirm the position of the extended body 53 under fluoroscopy. As the form of the marker 54, it is preferable to crimp the ring formed of the above metal to the outer surface of the inner tube 51. This makes it possible to obtain a clear X-ray contrast image.

[0085]

1055 Further, a tip soft tip 55 is fixed and joined to the tip of the inner tube 52 as the most advanced portion of the inner tube 52.

1057 The tip soft tip 55 is formed in the shape of a short cylinder, and is fixed and joined to the tip of the inner tube 51 by adhesion or fusion so that its lumen communicates with the first lumen 511. By providing the tip 55, the possibility of damaging the blood vessel at the tip of the catheter 5 can be reduced. As the constituent material of the chip 55, it suffices to have flexibility, and for example, polyurethane, silicone RTV rubber, vinyl chloride-urethane copolymer, styrene-based elastomer and the like can be used. The length of the chip 55 is 0.5 to 5 mm, preferably about 0.5 to 3 mm.

[0086]

1067 Further, the catheter 5 shown in FIGS. 7 and 8 has a reinforcing tube 56 and a branch hub 57.

1069 In the illustrated example, the reinforcing tube 56 is attached around the outer periphery of the outer tube 52 near the base end. The reinforcing tube 56 is, for example, a tube 56 having heat shrinkage, formed so that the inner diameter after heat shrinkage is slightly smaller than the outer diameter near the base end of the outer pipe 52, and has heat shrinkage. Can be easily attached by fitting the outer tube 52 in the vicinity of the base end and heating (for example, applying hot air) to shrink the outer tube 52. The reinforcing tube is not limited to the above, and for example, the inner tube 51 may be provided with the same tube as the reinforcing tube 56.

[0087]

1080 The branch hub 57 has a first opening 581 that communicates with the first lumen 511 to form a guide wire port, and communicates with the inner tube hub 58 fixed to the inner tube 51 and the second lumen 521. It has a second opening 591 forming an injection port, and is composed of an outer pipe hub 59 fixed to the outer pipe 52.

1084 The inner tube hub 58 and the outer tube hub 59 are fixed to each other. As a constituent material of the branch hub 574, a thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate, and a methacrylate-butylene-styrene copolymer can be preferably used. Further, the branch hub 57 may not be provided, and a tube having a port member

forming an opening at the base end may be attached to each of the first lumen 511 and the second lumen 521 in a liquid-tight manner.

|0088|

1093 Next, the method and operation of the vasodilator catheter 5 will be described by taking as an example the case of treating a stenosis generated in a coronary artery blood vessel.

1095 First, before inserting the catheter 5 into the blood vessel, the air in the dilator 53 and the second lumen 521 is removed as much as possible and replaced with a liquid such as a contrast medium. At this time, the extended body 53 is kept in a contracted or folded state. Next, a sheath is placed in the patient's blood vessel by, for example, the Seldinger method, and then a guiding catheter is inserted into the blood vessel through the lumen of the sheath and placed at the entrance of the coronary artery. It is preferable that the inner surface of the guiding catheter has a hydrophilic coating. Next, a guide wire composed of a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material, or a metal elastic core material and the tip of the core material. A guide wire composed of the provided X-ray contrast-enhanced coil and the fluorine-based coating material coated on the surface of the core material is inserted into the first lumen 511, and the catheter 5 is inserted from the lumen of the guiding catheter. Insert into a blood vessel. Subsequently, the position of the marker 54 is visually recognized under fluoroscopy, and while confirming the positions of the catheter 5 and the tip of the guide wire, the guide wire is advanced to advance the catheter 5, and the catheter 5 is inserted to the stenosis and expanded. The body 53 is positioned within the stenosis.

|0089|

1115 After that, an injector with a pressure gauge is connected to the second opening 581 forming the injection port of the catheter 5, an angiographic agent is injected so as to be about several to ten and several atmospheres, and the dilator 63 is inflated. The lesion, the atheroma, is compressed and the stenosis is dilated.

1119 Then, the contrast medium is injected from the contrast medium injection port provided in the connector of the guiding catheter, and the peripheral blood flow is confirmed by X-ray imaging. When the blood flow is improved, the catheter 5 and the guide wire are removed, and then the guiding catheter is removed to complete the procedure.

|0090|

1126 Since the catheter 5 of the present invention is configured with the medical tube 1 of the present invention as a member, it is highly flexible and resistant to kink, and can be satisfactorily inserted into a relatively thin blood vessel such as a coronary artery. The followability to the guide wire is also good, and even a complicatedly curved or bent blood

vessel can easily proceed along the guide wire without kinking.

1131 In addition, it has excellent torque transmission and pushability, making it a catheter with good operability. Furthermore, it has excellent pressure resistance on the inside and outside, and even if an expansion fluid is poured into the internal space 534 of the expansion body 53 at high pressure. It is unlikely to collapse or burst. Further, even if a contrast medium is poured into the first lumen 511 during the operation, it is unlikely to be crushed or ruptured and can be safely handled.

[0091]

1140 In the illustrated example, the inner tube 51 is made of the medical tube 1, but the present invention is not limited to this, and the outer tube 52 may be made of the medical tube 1 or the inner tube. Both the 51 and the outer tube 52 may be composed of the medical tube 1.

1143 Further, the medical tube of the present invention constituting the inner tube 51 and the outer tube 52 is not limited to the illustrated medical tube 1, and is shown in FIG. 5, for example, in place of the medical tube 1 described above. A medical tube 10 may be used.

[0092]

1149 Further, in the illustrated example, a double lumen coaxial type guide wire movable (over-the-wire type) vasodilator catheter has been described, but the present invention is not limited to this, and the US patent 4,771,778 is not limited thereto. The so-called on-the-wire type vasodilator catheter in which the dilator is directly fixed to the guide wire described in the specification, etc., and the catheter described in the US patents 4,748,982, etc. are used for the blood vessel. It can also be applied to a so-called monorail type vasodilator catheter in which the guide wire can be replaced while it is inserted, and the medical tube of the present invention may be used for such a type of catheter tube.

[0093]

1160 The medical tube, the cerebral vascular treatment catheter, and the vasodilator catheter in the present invention have been described above, but the present invention is not limited to this, and for example, a vascular catheter such as a contrast catheter, a guiding catheter, and a drug injection are used. It may be applied to a catheter, a devascularization catheter for open heart surgery, an endoscopic catheter, a laparoscopic catheter, a thoracic laparoscopic catheter and the like.

[0094]

1169 Hereinafter, the present invention will be described in more detail based on specific examples.

1171 [Example 1] Using linear low-density polyethylene (manufactured by Mitsui Nisseki Polymer

Co., Ltd., trade name: Ultozex, grade 4570) as a raw material, an inner diameter of 0.47 mm and an outer diameter of 0.52 mm are obtained by ordinary extrusion molding. I got a tube.

1174 By pulling down the die from this tube, a molded body of the inner layer 21 was manufactured as a two-stage different diameter tube having an inner diameter of 0.41 mm and an outer diameter of 0.45 mm.

1177 The obtained inner layer 21 had a total length of 1700 mm, a small diameter tip portion of 800 mm, and a base length of 900 mm.

[0095]

1182 On the other hand, using a modified polyethylene resin (manufactured by Atchem, trade name Bondine, grade TX-8030) as a raw material, the take-up speed is changed in the middle of extrusion molding to manufacture a molded body of an outer layer 22 having a different diameter between the tip portion and the base portion. bottom.

1186 The total length of the outer layer 22 is 1700 mm, and the length of the tip portion having a small diameter is 750 mm. The length of the tapered portion was 50 mm, and the length of the base including the tapered portion was 950 mm. The inner diameter of the tip portion was 0.50 mm and the outer diameter was 0.56 mm, the tapered portion was smoothly changed, and the inner diameter of the base portion was 0.56 mm and the outer diameter was 0.63 mm.

[0096]

1195 Further, strands 31a to e made of stainless steel (SUS304), having a plate thickness t of 0.010 mm and a plate width z of 0.120 mm were prepared, and the strands 31a to e were combined into a bundle 31A. The first coil 31 was manufactured by winding the strands 31a to e right-handed on core materials having different diameters at the tip and the base in a state where the strands 31a to e were in close contact with each other without any gap.

1200 The gap y between the pitches of the coils 31 was 0.02 mm.

[0097]

1204 Subsequently, the strands 32a to e configured in the same manner as the strands 31a to e are prepared, the strands 32a to e are made into a bundle 32A as a set of five, and the strands 32a to e are brought into close contact with each other without a gap. In this state, the core material and the first coil 31 were overlapped and wound counterclockwise to produce a second coil 32.

1209 The gap y between the pitches of the coil 32 was set to 0.02 mm as in the coil 31.

[0098]

1213 Then, the core material was extracted to manufacture a coil layer 3 having a different

diameter between the tip portion and the base portion.

1215 The obtained coil layer 3 has an inner diameter of 0.47 mm, an outer diameter of 0.51 mm, a length of 730 mm, and a tapered portion having a length of 50 mm, and has a smooth diameter. It was changing. The inner diameter of the base was 0.53 mm, the outer diameter was 0.57 mm, and the length was 820 mm including the tapered portion.

[0099]

1222 The coil layer 32 was inserted into the outer layer 22 swollen in a THF solvent, the outer layer 22 was air-dried, and then the inner layer 21 was inserted into the coil layer 3.

1224 Then, these coil layers 3, the inner layer 21 and the outer layer 22 were heat-treated in an oven at 60 ° C. for 16 hours. By this heat treatment, the residual stress of the inner layer 21 was removed, the inner diameter and the outer diameter of the inner layer 21 were increased, and the inner layer 21 and the coil layer 3 were in close contact with each other. Further, both end portions of the inner layer 21 and the outer layer 22 were fused and fused at a position 1 mm ahead of the tip end and the base end of the coil layer 3 to obtain the medical tube 1 of the present invention shown in FIGS. 1 to 4. The obtained medical tube 1 has a total length of 1500 mm, an inner diameter of the tip portion 12 of 0.43 mm, an outer diameter of 0.57 mm, and a length of 730 mm, and the tapered portion 13 has a length of 50 mm and a smooth diameter. It had changed to. The inner diameter of the base 11 was 0.48 mm, the outer diameter was 0.64 mm, and the length was 770 mm.

[0100]

1238 [Comparative Example 1] High-density polyethylene (manufactured by Mitsubishi Yuka Co., Ltd., trade name Mitsubishi Polyeth-HD, grade EY40H) is molded by ordinary extrusion molding and has an inner diameter of 0.43 mm and an outer diameter of 0.57 mm. A tube of Comparative Example 1 having the same dimensions as the tip portion 12 of Example 1 was manufactured.

[0101]

1246 [Comparative Example 2] A reinforced tube having an inner diameter of 0.43 mm and an outer diameter of 0.57 mm reinforced with a metal braid and having the same dimensions as the tip portion 12 of the embodiment according to the method described in Japanese Patent Publication No. 4-670. Manufactured.

1250 Specifically, high-density polyethylene (manufactured by Mitsubishi Yuka Co., Ltd., trade name Mitsubishi Polyeth-HD, grade JY20) was coated on a copper wire having an outer diameter of 0.43 mm to a thickness of 15 μm using a cross molding machine. ..

1253 A 20 μm stainless steel (SUS304) blade wire is wound around a copper wire in a mesh pattern using a braider device (manufactured by Nagata Seiki Co., Ltd., model number STM-II), and then the same resin is melt-coated using a coating die. , The above blade wire was

buried. Then, the copper wire used for the core was stretched, stretched, and removed to prepare a tube of Comparative Example 3.

[0102]

1261 [Comparative Example 3] A tube of Comparative Example 2 composed of a coil layer 3 and an outer layer 22 was produced in the same manner as in Example 1 except that the inner layer 21 of Example 1 was not provided.

1264 Experiments 1 to 4 shown below were carried out for Examples 1 and Comparative Examples 1 to 3 to compare the mechanical strengths.

[0103]

1269 [Experiment 1] The flexural modulus and bending stress of the tips 12 of Example 1 and the tubes of Comparative Examples 1 to 3 were measured by a three-point bending test.

1271 The flexural modulus was used as a comparison of tube hardness, and the bending stress was used as a comparison of tube flexibility. The three-point bending test was performed by cutting the tip portion 21 of Example 1 and the tubes of Comparative Examples 1 and 2 to 20 mm each, using the jig 20 shown in FIG. 9, and referring to the bending test of JIS K7203. .. The test was carried out using an AUTOGRAPH AGS-100A manufactured by Shimadzu Corporation at a test speed of 1 mm / min at room temperature.

[0104]

1280 Two support rods 62 having a diameter of 2 mm were placed on the sample table 61 of the jig 6 shown in FIG. 9, and the tip portion 21 of Example 1 cut to a fixed size was placed and supported on the support rod 62.

1283 The distance between the support rods 62 (distance between fulcrums) was 10 mm. In this state, a pusher 64 having a fulcrum ball 63 having a diameter of 2 mm is connected to a load cell (not shown) of the testing machine, and the pusher 64 is moved in the direction of the arrow in the figure to perform a three-point bending test. rice field. The same test as above was performed on the tubes of Comparative Examples 1 to 3.

[0105]

1291 By the above bending test, the stress strain curve shown in FIG. 10 was obtained.

1292 The initial slope in this stress-strain curve is defined as the bending stress W, and this bending stress W represents the force required to simply bend each sample by 1 mm. bottom. The results are shown in Table 1 below.

[0106]

1298 [Experiment 2] The inner pressure resistance test shown below was performed on the tip portion 12 of Example 1 and the tubes of Comparative Examples 1 to 3 to evaluate the pressure resistance to pressure from the inside.

1301 As shown in FIG. 11, the tip of the tip portion 12 of Example 1 was sealed with an epoxy resin 71, and the connector 72 was connected to the base end. These were placed in a hot water bath at 37 ° C., and nitrogen gas was sent from the injection port 73 of the connector 72 to the inside of the tip portion 12 using a nitrogen gas cylinder, and the pressure was applied at a rate of 1.0 kg / cm2 per minute. By visually observing the bubbles generated in the water, the pressure value at which the leak or rupture occurred was measured. In addition, the same measurements as above were performed for the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0107]

1312 [Experiment 3] The outer pressure resistance test shown below was performed on the tip portion 12 of Example 1 and the tubes of Comparative Examples 1 to 3 to evaluate the pressure resistance against crushing from the outside.

1315 As shown in FIG. 12, the tip portion 12 of Example 1 was covered with a metallic sheath 82 having an injection port 81, and the tip 83 and the base end 84 of the sheath 82 were sealed with epoxy resin, respectively. At this time, the tip portion 12 was made longer than the total length of the sheath 82 and protruded from the tip end 83 and the base end 84. In this state, the whole was placed in a hot water bath at 37 ° C. The lumen 85 composed of the tip portion 12 and the sheath 82 was pressurized with nitrogen gas, and the outside of the tip portion 12 was pressurized by 1.0 kg / cm2.

[0108]

1325 At the time when the pressurization was started, a straight core rod 86 made of stainless steel (SUS304) was passed through the inner lumen 14 of the tip portion 12, and the passability of the core rod 86 was confirmed.

1328 The outer diameter of the core rod 86 was set to 0.38 mm, which is 0.05 mm smaller than the inner diameter of the tip portion 12. The pressure value when the lumen 14 was crushed by the deformation of the tip portion 12 due to pressurization and the core rod became immobile was obtained, and the crush resistance due to the pressure from the outside was evaluated. In addition, the pressure value at the time of leakage or rupture was also obtained by visually observing the bubbles generated in the water, but in most cases, the occurrence of crushing occurred earlier. In addition, the same measurements as above were performed for the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0109]

1340 [Experiment 4] The kinkability test shown below was performed on the tips 12 of Example 1 and the tubes of Comparative Examples 1 to 3 using the device 9 shown in FIG.

1342 The kink resistance test was performed using an autograph (AUTOGRAPH AGS-100A manufactured by Shimadzu Corporation) at a test speed of 10 mm / min. At room temperature. As shown in FIG. 13, core rods 91 are inserted into both ends of the tip portion 12 of the first embodiment cut to 65 mm, the space between the two core rods 91 is set to 25 mm, and the gap between the core rod 91 and the tip portion 12 is set. Was filled with epoxy resin. Both ends of the tip portion 12 into which the core rod 91 is inserted are sandwiched between chucks 92, and the chuck 92 on the upper side is lowered at a constant speed to narrow the interval. The moving distance of the chuck 92 on the upper side at this time was measured. It can be said that the smaller this measured value is, the worse the kink resistance is. In addition, the same measurements as above were performed for the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0110]

1357 [Experiment 5] The tip portion 12 of Example 1 and the tubes of Comparative Examples 1 to 3 were subjected to the tensile test shown below, the breaking strength and the breaking elongation were measured, and the strength of the tubes was compared.

1360 The tensile test was performed using an autograph (AUTOGRAPH AGS-100A manufactured by Shimadzu Corporation) at a test speed of 100 mm / min. At room temperature, and the breaking strength and breaking elongation were determined. In this test, using the same equipment as in Experiment 4, the chuck 92 was widened between the two chucks 92 at a constant speed, contrary to Experiment 4, and the chuck 92 when the tip portion 12 of Example 1 was broken. The distance traveled was measured. The same measurement was performed on the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0112]

1371 As shown in Table 1 above, from the measured values of flexural modulus, the hardness of the tube is the hardest in the reinforced tube of Comparative Example 2, and it is composed only of a flexible resin material, and has the same dimensions. It can be said that the tube of Example 1 is more flexible than the tube of Comparative Example 1.

1375 Further, it can be seen from the measured values of bending stress that the tube of Example 1 is more flexible than that of Comparative Examples 1 and 2. Furthermore, it is clear from the measured values of kink resistance that the tube of Example 1 is less likely to cause kink and is excellent in flexibility. From the above, it is understood that the medical tube of the present invention is excellent in flexibility and kink resistance.

[0113]

1383 Regarding the inner and outer pressure resistance, from the measured values shown in Table 1, the tube of Example 1 is superior to the tube of Comparative Example 1 in both inner pressure resistance and outer pressure resistance. Understand.

1386 Further, the tube of Comparative Example 2 is excellent in pressure resistance, but is a hard tube as described above. Further, comparing Example 1 and Comparative Example 3, Example 1 in which the inner layer 21 is provided inside the coil layer 3 has an inner pressure resistance as compared with Comparative Example 3 in which the inner layer 21 is not provided inside the coil layer 3. It has been shown that the sex is significantly improved. That is, it can be seen that the pressure resistance is remarkably improved by forming the structure in which the flexible layer is covered with the coil layer. Conventionally, for tubes of the same inner and outer diameters, the pressure resistance depends on the hardness of the material of the tube. Therefore, it was conventionally thought that the pressure resistance would be lost if the tube was softened. It is understood that the medical tube of the present invention satisfies both the flexibility and pressure resistance of the tube.

[0114]

1401 Further, from the results of the tensile test of the tube, it is shown that the tube of Example 1 is superior in strength to the tube of Comparative Examples 1 and 2.

1403 Further, the tube of Comparative Example 2 has a remarkably low breaking elongation, and such a tube tends to break suddenly, so that it is not preferable for safety as a tube used by inserting it into a body cavity. From the above, it is understood that the medical tube of the present invention has both satisfactory flexibility, pressure resistance and strength.

[0115]

1410 When the tubes of Example 1 and Comparative Examples 1 and 2 were bent at right angles and the presence or absence of kink was observed, the tubes of Example 1 maintained the inner holes and did not break, but Comparative Examples 1 to 2. The tube 2 was broken and the inner hole was crushed.

[0116]

1417 [Example 2] The medical tube 10 shown in FIG. 5 was manufactured.

1418 The chip 15 was manufactured using polyurethane.

1419 When the same test as above was performed on this tube 10, the flexibility, pressure resistance and strength were all excellent as in Example 1. Further, the tip of this tube 10 was very flexible as compared with Example 1.

[0117]

1425 [Example 3] Using the medical tube 1 of Example 1 as a member, a catheter 4 for cerebrovascular embolization shown in FIG. 6 was manufactured.

1427 Specifically, after cutting the medical tube 1 of Example 1 to a fixed size with an excimer laser, the tube 1 is provided with a reinforcing tube 41 (material: polyethylene resin) and a hub 42 (material: nylon 12 resin).), The tip soft tip 43 (material; polyurethane), and the contrast marker 44 made of a platinum coil were attached using a urethane adhesive. The marker 44 was wrapped around the outer surface of the chip 43, and a urethane adhesive was applied on the marker 44 so that the outer surface of the catheter 4 was smooth.

[0118]

1436 The catheter 4 is a catheter having a taper of 1.7 Fr at the tip and 1.9 Fr at the base, the total length of the catheter is 1500 mm, and the effective length of the catheter (length excluding the hub and the reinforcing tube) is 1400 mm.

1439 At the time of assembly, a cyanoacrylate-based instant adhesive was impregnated into the gap between the first and second coils 31 and 32 on the proximal end side of the medical tube 1 by utilizing the capillary phenomenon. The instant adhesive penetrated to about 1/3 of the base 11 of the medical tube 1, and the portion became hard. Further, the tip portion 12 having a small diameter was coated with a P (GMA-DMAA) block copolymer which is a hydrophilic polymer substance, and a surface treatment having lubricity when wet was performed.

[0119]

1449 When cerebral vascular treatment (cerebral artery embolization) for embolizing a cerebral aneurysm was performed using this catheter 4, the bending followability and torque controllability for a winding blood vessel were very good, and the catheter operability was improved. It was excellent.

[0120]

1456 [Example 4] The vasodilator catheter 5 shown in FIG. 7 was manufactured using the multilayer medical tube 1 of Example 1 as a member.

1458 Specifically, the medical tube 1 of Example 1 is cut to a fixed size, and this is used as an inner tube 51, which is made of an outer tube 52 (material: polypropylene resin), an expansion body 53 (material: polycarbonate sulfide resin), and platinum. The contrast marker 54, the tip soft tip 55 made of polyurethane, the reinforcing tube 56 (material: polyethylene resin), the inner tube hub 58 (material: polycarbonate resin), and the outer tube hub 59 (material: polycarbonate resin) were attached.

1464 The entire obtained catheter 5 was a tapered catheter with an outer diameter of 2.7 Fr (outer diameter of about 0.9 mm), and the total length of the catheter was 1550 mm and the

effective length of the catheter was 1350 mm.

[0121]

1470 When the PTCA procedure was performed using this catheter 5, the catheter was excellent in flexion followability, stenosis passage, pushability, and guide wire mobility, and the catheter was easy to operate.

1473 In addition, during the PTCA procedure, a contrast medium with high viscosity was used as the expansion fluid of the expansion body 53, and the pressurizing pressure of the expansion body 53 was increased to 16 kg / cm2, but the inner tube 51 was not crushed or ruptured at all. I couldn't.

[0122]

1480 INDUSTRIAL APPLICABILITY As described above, the medical tube of the present invention is rich in flexibility and kink resistance, has good torque transmissibility and push-in property, and is also excellent in pressure resistance on the inside and outside. ..

1483 Therefore, it can be suitably used as a member of a catheter having excellent operability, and is particularly effective as a member of a small-diameter catheter used by inserting it into a body cavity having a small diameter. Therefore, it is possible to provide a catheter useful for, for example, angioplasty, drug infusion therapy, angiography, and embolization therapy.

[0123]

1491 In addition, the catheter for cerebrovascular embolization of the present invention composed of the above-mentioned medical tube is rich in flexibility and kink resistance, has good torque transmissibility and push-in property, and has inner and outer pressure resistance. Are better.

1495 Therefore, it has excellent operability, can reach the target site of the fine and complicated cerebral blood vessels along the guide wire well, minimizes damage to the tubular tissue and organs of the human body, and is safe. Very expensive.

[0124]

1501 Further, the vasodilator catheter of the present invention composed of the above-mentioned medical tube is rich in flexibility and kink resistance, has good torque transmissibility and push-in property, and has excellent inner and outer pressure resistance. There is.

1504 Therefore, it has excellent operability, can reach the target member well along the guide wire, and can minimize damage to the tubular tissue and organs of the human body. In addition, there is very little risk of explosion even if a high pressure is applied when expanding the expanded body, and the safety is very high.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 May 2022 (27.05.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/109034 A1

(51) International Patent Classification:
A61M 25/00 (2006.01)

(21) International Application Number:
PCT/US2021/059735

(22) International Filing Date:
17 November 2021 (17.11.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/115,515 18 November 2020 (18.11.2020) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventors: **DOLENDO, Edward Enriquez**; 9 Parker, Suite #100, Irvine, California 92618 (US). **BRODT, Thomas Robert**; 9 Parker, Suite #100, Irvine, California 92618 (US). **TU, Thomas M.**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(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, IT, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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,

(54) Title: CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

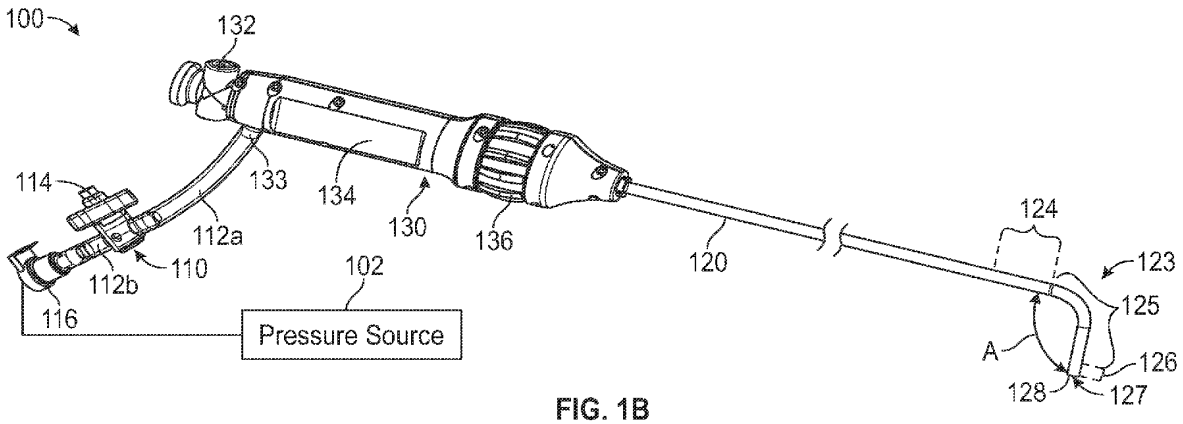


FIG. 1B

(57) Abstract: Disclosed herein are clot removal systems including steerable catheters, and associated systems and methods. In some embodiments, a clot removal system includes (i) an aspiration catheter having a proximal region and a distal region and (ii) a handle coupled to the proximal region of the catheter and having an actuator. The distal region of the catheter can include a deflectable member, and the clot removal system can include a pull wire extending between the actuator and the deflectable member. Actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region relative to the proximal region. The deflection can facilitate steering of the catheter to hard-to-reach (e.g., tortuous) portions of the anatomy of a patient.

[Continued on next page]

WO 2022/109034 A1

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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))*

CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/115,515, filed November 18, 2020, and titled "CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to clot removal systems including catheters (e.g., large bore aspiration catheters) having a steerable distal portion to, for example, facilitate positioning of the catheter in hard-to-reach regions of the vasculature of a patient.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. Infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT causes harm by: (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain, and infection, and (2) serving as a reservoir for blood clots to travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body, and result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. One common surgical technique, an embolectomy, involves incising a blood vessel and introducing a balloon-tipped device (such as the Fogarty catheter) to the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to translate the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the inner lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and the vessel will re-stenos after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage and in many patients the agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack sufficient retaining structure and thus cannot be appropriately fixed against the vessel to perform adequately. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters.

Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all the clot material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0011] Figures 1A and 1B are partially schematic side and isometric views, respectively, of a clot removal system in accordance with embodiments of the present technology.

[0012] Figure 2 is an enlarged, partially cut-away side view of a portion of a proximal region of a catheter of the clot removal system of Figures 1A and 1B in accordance with embodiments of the present technology.

[0013] Figure 3A is an enlarged, partially cut-away side view, and Figure 3B is an enlarged, partially cut-away isometric view, of a portion of an intermediate region of the catheter of Figures 1A and 1B in accordance with embodiments of the present technology.

[0014] Figures 4A and 4B are a distally-facing isometric view and an enlarged proximally-facing isometric view, respectively, of a deflectable member of a deflectable region of the catheter of Figures 1A and 1B in accordance with embodiments of the present technology.

[0015] Figures 4C and 4D are isometric views of a proximal ring and a distal ring, respectively, of the deflectable member of Figures 4A and 4B in accordance with embodiments of the present technology.

[0016] Figure 5A is a partially cross-sectional side view of a handle and a portion of the proximal region of the catheter of the clot removal system of Figures 1A and 1B in accordance with embodiments of the present technology; and Figure 5B is an enlarged cross-sectional isometric view of a portion of the handle shown in Figure 5A.

[0017] Figures 6A and 6B are a distally-facing isometric view and a side view, respectively, of a deflectable member in accordance with additional embodiments of the present technology.

[0018] Figure 6C is top view of a flat pattern that can be cut to integrally form a proximal ring and a tube portion of the deflectable member of Figures 6A and 6B in accordance with

embodiments of the present technology; and Figure 6D is an enlarged top view of a portion of the pattern shown in Figure 6C.

[0019] Figures 7A–7C are side views of a portion of the catheter of the clot removal system of Figures 1A and 1B during a procedure for removing clot material from within a blood vessel of a patient in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0020] The present technology is generally directed to clot removal systems including aspiration catheters having a deflectable/steerable distal portion for improved flexibility through hard-to-reach (e.g., tortuous) vascular anatomy of a patient, and associated systems and methods. In some embodiments, a clot removal system in accordance with embodiments of the present technology includes (i) an aspiration catheter having a proximal region and a distal region and (ii) a handle coupled to the proximal region of the catheter and having an actuator. The distal region of the catheter can include a deflectable member, and the clot removal system can include a pull wire extending between the actuator and the deflectable member. Actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region relative to the proximal region. The deflection can facilitate steering of the catheter to the hard-to-reach portions of the anatomy of the patient.

[0021] In some embodiments, the deflectable member includes a proximal ring, a distal ring, and a tube portion extending between the proximal and distal rings. The proximal ring can include an annular member coupled (e.g., welded) thereto and configured to slidably receive the pull wire. The distal ring can be configured to be fixedly attached (e.g., welded) to the pull wire. The tube portion can include a plurality of openings (e.g., circumferentially extending openings) that define a plurality of ribs. The ribs can flex away from each other when the actuator is actuated to pull the pull wire. In some embodiments, the tube portion further includes a spine extending between the proximal and distal rings and generally aligned with the pull wire.

[0022] In some embodiments, the catheter further includes an intermediate region between the proximal and distal regions. The catheter can include a braid of wires extending along the proximal and distal regions, and a coil extending over the braid along the intermediate region.

[0023] In some aspects of the present technology, the catheter is configured to be steered to and positioned in difficult-to-reach regions of the anatomy of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). More particularly, the

catheter can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid can provide good torque response along the proximal and intermediate regions of the catheter. Additionally, the deflectable region can be configured (e.g., shaped, sized) to be positioned within and steered/flexed into the difficult-to-reach regions of the anatomy. Further, the coil can provide increased hoop strength at the intermediate region while still allowing the catheter to flex. For example, the coil can inhibit or even prevent kinking or other unwanted movement of the catheter when the catheter is aspirated during a clot removal procedure.

[0024] Certain details are set forth in the following description and in Figures 1–7C to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

[0025] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0026] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further

embodiments of the present technology can be practiced without several of the details described below.

[0027] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures. The systems of the present technology can be used in any orientation suitable to the user.

[0028] Figures 1A and 1B are partially schematic side and isometric views, respectively, of a clot removal system 100 in accordance with embodiments of the present technology. The clot removal system 100 can also be referred to as an aspiration assembly, a clot treatment system, and/or a thrombectomy system. Referring to Figures 1A and 1B together, the clot removal system 100 includes a tubing assembly 110 coupled to a catheter 120 via a handle 130. In general, the clot removal system 100 (i) can include features generally similar or identical to those of the clot removal systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

[0029] Referring to Figure 1A, the catheter 120 can include (i) a proximal region or portion 121, (ii) an intermediate region 122 adjacent to and distal of the proximal region 121, and (iii) a distal region 123 adjacent to and distal of the intermediate region 122. Referring to Figure 1B, the distal region 123 can further include a transition region 124, a deflectable region 125 (e.g., a flexible region, steerable region, deformable region) distal of the transition region 124, and a tip region 126 distal of the deflectable region 125. Referring again to Figures 1A and 1B together, the catheter 120 further defines a lumen 127 extending therethrough from the proximal region 121 to the tip region 126. The proximal region 121 defines a proximal terminus (obscured by the handle 130 in Figures 1A and 1B; e.g., a proximal terminus 529 shown in Figure 5A) of the catheter 120 that can be positioned within the handle 130, and the tip region 126 defines a distal terminus 128 of the catheter 120.

[0030] In some embodiments, the proximal region 121 has a first length, the intermediate region 122 has a second length less than the first length, and the distal region 123 has a third length less than the first and second lengths. For example, the first length can be between about 50–100 millimeters (e.g., about 80 millimeters), the second length can be between about 10–50 millimeters (e.g., about 25 millimeters), and the third length can be between about 1.0–10 millimeters (e.g., about 4.2 millimeters). In some embodiments, the transition region 124 can have a length of between about 0.1–5.0 millimeters (e.g., about 0.6 millimeters), the deflectable region 125 can have a length of between about 1.0–10 millimeters (e.g., about 3.0 millimeters), and the tip region 126 can have a length of between about 0.1–5.0 millimeters (e.g., about 0.6 millimeters). In other embodiments, the lengths of one or more of the regions 121–126 can be different. In some embodiments, the catheter 120 can have varying flexibilities, shapes, thicknesses, and/or other properties in/along the various regions 121–126.

[0031] In the illustrated embodiment, the handle 130 includes and/or is coupled to a valve 132. The valve 132 can include a branch or side port 133 configured to fluidly couple the lumen 127 of the catheter 120 to the tubing assembly 110, and can be integral with or coupled to the proximal region 121 of the catheter 120. In some embodiments, the valve 132 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by inhibiting or even preventing fluid flow in the proximal direction through the valve 132 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 132 to be delivered through the catheter 120 to a treatment site in a blood vessel. In some embodiments, the valve 132 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

[0032] In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 102, such as a syringe. The tubing assembly 110 can include one or more tubing sections 112 (individually labeled as a first tubing section 112a and a second tubing section 112b), at least one fluid control device 114 (e.g., a valve), and at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 102 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 133 of the valve 132 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid control device 114 is externally operable by a user to regulate the flow of fluid therethrough and,

specifically, from the lumen 127 of the catheter 120 to the pressure source 102. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 102.

[0033] In the illustrated embodiment, the handle 130 includes a housing 134 and an actuator 136. The actuator 136 can be operably coupled to the catheter 120 and movable (e.g., rotatable) relative to the housing 134 to deflect (e.g., steer, flex) the deflectable region 125 from (i) a first position (e.g., an unflexed position, an aligned position) shown in Figure 1A in which the deflectable region 125 is generally aligned with the intermediate region 122 and/or the proximal region 121 to (ii) a second position (e.g., a flexed position) shown in Figure 1B in which the deflectable region 125 is deflected relative to the intermediate region 122 and/or the proximal region 121. That is, the actuator 136 can be configured to deflect the deflectable region 125 away from a longitudinal axis generally aligned with the proximal region 121 and/or the intermediate region 122. In some embodiments, the deflectable region 125 can have a bend angle A in the second position (Figure 1B) of greater than about 30 degrees, greater than about 50 degrees, greater than about 70 degrees, greater than about 90 degrees, or greater. In some embodiments, the bend angle A is about 90 degrees.

[0034] Figure 2 is an enlarged, partially cut-away side view of a portion of the proximal region 121 of the catheter 120 in accordance with embodiments of the present technology. Figure 3A is an enlarged, partially cut-away side view, and Figure 3B is an enlarged, partially cut-away isometric view, of a portion of the intermediate region 122 of the catheter 120 in accordance with embodiments of the present technology. Referring to Figures 1–3B together, the catheter 120 includes an outer sheath 240 and an inner liner 242 extending through/defining each of the regions 121–126. The outer sheath 240 is positioned over (e.g., radially outside of) the inner liner 242. The outer sheath 240 can also be referred to as an outer jacket, an outer shaft, or an outer layer, and the inner liner 242 can also be referred to as an inner layer, an inner sheath, or an inner shaft.

[0035] In some embodiments, the outer sheath 240 can be formed from a plastic material, elastomeric material, and/or thermoplastic elastomer (TPE) material. In some embodiments, the outer sheath 240 can be formed from a TPE manufactured by Arkema S.A., of Colombes, France, such as the TPEs manufactured under the trademark "Pebax." In some embodiments, the outer sheath 240 can have a varying hardness (e.g., durometer), thickness, flexibility, rigidity, and/or

other property in one or more of the different regions 121–126. For example, the outer sheath 240 can have (i) a first hardness along the proximal region 121 of between about 65D–75D (e.g., about 72D), (ii) a second hardness along the intermediate region 122 of between about 30D–40D (e.g., about 35D), (iii) a third hardness along the transition region 124 of between about 50D–60D (e.g., about 55D), (iv) a fourth hardness along the deflectable region of between about 20D–30D (e.g., about 25D), and (v) a fifth hardness along the tip region 126 of between about 50D–60D (e.g., about 55D). In other embodiments, the outer sheath 240 can have a different hardness or other property along one or more of the regions 121–126.

[0036] The inner liner 242 can be formed of a lubricious material that facilitates the movement (e.g., distal advancement, proximal retraction) of various components through the lumen 127, such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and the like. In some embodiments, the inner liner 242 can be formed from a polymer material, a fluoropolymer material (e.g., polytetrafluoroethylene (PTFE)), and/or another material having a high degree of lubricity. In some embodiments, the inner liner 242 can define a diameter D (Figure 2) of the lumen 127, and the diameter D can be greater than about 6 French, greater than about 10 French, greater than about 16 French, greater than about 20 French, greater than about 24 French, or greater. In some embodiments, the diameter D is about 8 French, about 16 French, about 20 French, or about 24 French. In certain embodiments, the diameter D of the inner liner 242 is the same in each of the regions 121–126 while, in other embodiments, the diameter D can vary along one or more of the regions 121–126.

[0037] The catheter 120 can further include a braid 244 extending along the proximal region 121 and the intermediate region 122 between the outer sheath 240 and the inner liner 242. In some embodiments, the braid 244 terminates at or before the distal region 123 such that the braid 244 does not extend along the transition region 124, the deflectable region 125, or the tip region 126. In the illustrated embodiment, the catheter 120 further includes a coil 346 (Figures 3A and 3B) extending at least partially along the intermediate region 122 between the braid 244 and the outer sheath 240. In some embodiments, the coil 346 extends only along the intermediate region 122 and does not extend into the proximal region 121 or the distal region 123.

[0038] The braid 244 can include wires, filaments, threads, sutures, fibers, or the like (collectively "wires 248") that have been woven or otherwise coupled, attached, formed, and/or joined together at a plurality of interstices 249. Accordingly, the braid 244 can also be referred to as a braided structure, a braided filament structure, a braided filament mesh structure, a mesh

structure, a mesh filament structure, and the like. In some embodiments, the wires 248 can comprise metals, polymers, and/or composite materials. In some embodiments, individual ones of the wires 248 can be rolled flat wires having a cross-sectional dimension of between about 0.0005–0.005 inch (e.g., about 0.002 inch) by about 0.002–0.005 inch (e.g., about 0.0033 inch).

[0039] In the illustrated embodiment, the coil 346 is a single wire wound around the braid 244 and the inner liner 242 along the intermediate region 122. In other embodiments, the coil 346 can include more than one wire wound about the braid 244. For example, the coil 346 can include multiple wires wound over one another and/or multiple wires wound to at least partially overlap one another to form a braided or overlapping coil structure on the braid 244. In other embodiments, the coil 346 can be formed directly over the inner liner 242, and the braid 244 can be formed over the coil 346. The coil 346 can be formed from a metallic or other suitably strong material, such as nickel-titanium alloys (e.g. nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium.

[0040] Figures 4A and 4B are a distally-facing isometric view and an enlarged proximally-facing isometric view, respectively, of a deflectable member 450 of the deflectable region 125 of the catheter 120 in accordance with embodiments of the present technology. The deflectable member 450 can be positioned between the outer sheath 240 and the inner liner 242 (Figures 2–3B), which are both omitted in Figures 4A and 4B for clarity. In the illustrated embodiment, the deflectable member 450 includes a proximal ring 452, a distal ring 454, and a tube portion 456 extending between the proximal ring 452 and the distal ring 454. The deflectable member 450 can be formed from a flexible metallic material—such as nickel-titanium alloys (e.g. nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium—or another suitably strong and flexible material. Similarly, the deflectable member 450 can be manufactured (e.g., laser cut) as a single integral piece, or one or more of the proximal ring 452, the distal ring 454, and the tube portion 456 can be separately manufactured and then coupled (e.g., welded, tack welded, adhered, fastened) together.

[0041] Figures 4C and 4D are isometric views of the proximal ring 452 and the distal ring 454, respectively, in accordance with embodiments of the present technology. Referring to Figures 4A–4C together, the proximal ring 452 can include an annular body 462 having an outer surface 461 and an inner surface 463. An annular member 464 can be coupled (e.g., welded, tack welded, adhered, fastened) to the inner surface 463 of the annular member 464 and can define/include a lumen 465. Referring to Figures 4A and 4D together, the distal ring 454 can

include an annular body 468 having an outer surface 467 and an inner surface 469. Referring to Figures 4A–4D together, the lumen 465 of the annular body 462 is configured to slidably receive a pull wire 458 (Figure 4D). The pull wire 458 can be coupled (e.g., welded, tack welded, adhered, fastened) to the inner surface 469 of the distal ring 454 and can extend from the distal ring 454 to the handle 130 (Figure 1), as described in greater detail below with reference to Figures 5A and 5B.

[0042] Referring again to Figures 4A and 4B together, the tube portion 456 can include a plurality of openings 451 extending partially about a circumference of the tube portion 456 to define a spine 453 and a plurality of ribs 455. In the illustrated embodiment, the spine 453 extends generally parallel to a longitudinal axis L (Figure 4A) of the deflectable member 450 and is generally aligned with the annular member 464 and the pull wire 458 (Figure 4D). That is, the pull wire 458 can extend through the tube portion 456 generally parallel to the spine 453. In some embodiments, the openings 451 are generally elongate openings that extend (i) generally parallel to one another and (ii) circumferentially about the longitudinal axis L such that, for example, the ribs 455 have a generally similar or identical shape. The openings 451 and/or the ribs 455 can all have the same dimensions as shown in Figures 4A and 4B while, in other embodiments, some or all of the openings 451 and/or the ribs 455 can have different dimensions and/or arrangements about the tube portion 456. In some embodiments, the tube portion 456 can be a laser-cut hypo tube.

[0043] Referring to Figures 2–4D together, in some embodiments the deflectable member 450 can be positioned between the outer sheath 240 and the inner liner 242 such that (i) the outer sheath 240 extends over/along the outer surface 461 of the proximal ring 452, an outer surface of the tube portion 456, and the outer surface 467 of the distal ring 454 and (ii) the inner liner 242 extends over/along the inner surface 463 of the proximal ring 452, an inner surface of the tube portion 456, and the inner surface 469 of the distal ring 454. In some embodiments, some or all of the pull wire 458 can be coated with PTFE or another suitable material (e.g., a fluoropolymer material). For example, the PTFE material can be omitted where the pull wire 458 is attached to the distal ring 454. The PTFE or other coating material can help inhibit the outer sheath 240 from adhering to the pull wire 458—thereby allowing the pull wire 458 to be moved relative to the deflectable member 450 after the outer sheath 240 is applied thereover.

[0044] Referring to Figures 1–3B together, in some embodiments the transition region 124 and the tip region 126 can include only the outer sheath 240 and the inner liner 242. In some

embodiments, the transition region 124 and/or the tip region 126 can include a marker band (not shown), such as a radiopaque marker configured to facilitate visualization of the position of the catheter 120 during a medical procedure (e.g., a clot removal procedure) using the catheter 120. For example, the transition region 124 and the tip region 126 can each include a radiopaque marker to facilitate visualization of the deflectable region 125 of the catheter 120.

[0045] Referring to Figures 1–4D together, in some embodiments, the catheter 120 can be formed about a mandrel or other elongate member. For example, the inner liner 232 can first be positioned about the mandrel. Then, the braid 244 can be formed (e.g., wound, braided) about the inner liner 242 around the mandrel (e.g., along the proximal and intermediate regions 121, 122) and/or the deflectable member 450 can be positioned about the inner liner 242 around the mandrel (e.g., along the deflectable region 125). Next, the coil 346 can be wound around the mandrel about the braid 244 over the intermediate region 122. Next, the outer sheath 240 can be positioned over the inner liner 242, the braid 244, the coil 346, and the deflectable member 450, and then heat shrunk or otherwise secured thereto. In some embodiments, the outer sheath 240 can be fused to the inner liner 242, the braid 244, the coil 346, and/or the deflectable member 450 to secure these components of the catheter 120 together.

[0046] Figure 5A is a partially cross-sectional side view of the handle 130 and a portion of the proximal region 121 of the catheter 120 in accordance with embodiments of the present technology. Figure 5B is an enlarged cross-sectional isometric view of a portion of the handle 130 shown in Figure 5A. Referring to Figures 5A and 5B, together, the housing 134 defines a proximal chamber 570 (e.g., a volume, lumen, compartment) and a distal chamber 572 that can be separated by the actuator 136. The valve 132 can be coupled to the housing 134 (e.g., a proximal portion of the housing 134) and positioned at least partially within the proximal chamber 570.

[0047] In the illustrated embodiment, the handle 130 includes a hollow tube member 574 positioned at least partially within the proximal chamber 570. The tube member 574 can include a proximal end portion 571a and a distal end portion 571b coupled to (e.g., secured to) the actuator 136. The tube member 574 can define a lumen 573 extending between the proximal and distal end portions 571a-b, and the tube member 574 can have a threaded inner surface 575 extending at least partially along the lumen 573. The actuator 136 can be a rotatable member, such as a wheel, grip wheel, or dial that is rotatable relative to the housing 134 to rotate the tube member 574 within the proximal chamber 570.

[0048] In the illustrated embodiment, the handle 130 further includes a catheter support or guide 576 extending at least partially through (i) the distal chamber 572, (ii) the actuator 136 (e.g., through a lumen in the actuator), (iii) the lumen 573 of the tube member 574, and (iv) the proximal chamber 570. In some embodiments, the catheter guide 576 defines a lumen 577 extending therethrough and includes a proximal flange portion 578 that can be secured to the housing 134. In some embodiments, the catheter guide 576 is fixed to the housing 134 such that the catheter guide 576 does not rotate when the actuator 136 is actuated to move the tube member 574. The proximal region 121 of the catheter 120 can extend into the handle 130, through the lumen 577 in the catheter guide 576, and to the valve 132. The proximal terminus 529 of the catheter 120 can be fluidly coupled to the valve 132. Accordingly, the catheter 120, the catheter guide 576, and the tube member 574 can be coaxially aligned. In other embodiments, the catheter guide 576 can be omitted.

[0049] The handle 130 can further include a shuttle member 580 positioned at least partially in the lumen 573 of the tube member 574 over the catheter guide 576 (e.g., over an outer surface thereof). In some embodiments, the shuttle member 580 is a hollow member slidably positioned over the catheter guide 576 and movable relative to the catheter 120. In the illustrated embodiment, the shuttle member 580 includes a threaded portion 582 having a threaded outer surface 583 and an anchor portion 584 extending from the threaded portion 582. The threaded outer surface 583 is configured to engage the threaded inner surface 575 of the tube member 574 such that, for example, movement of the tube member 574 drives the shuttle member 580 to move through the lumen 573 over the catheter guide 576 and relative to the catheter 120.

[0050] In the illustrated embodiment, the pull wire 458 extends along the catheter 120 into the handle 130 where it secured to the anchor portion 584 of the shuttle member 580. More specifically, the pull wire 458 can extend from the distal ring 454 of the deflectable member 450 (Figure 4D) and through/along the transition, intermediate, and proximal regions 124, 122, 121 of the catheter 120 (Figures 1A and 1B) to the handle 130. For example, the pull wire 458 can be routed (i) through a lumen formed in the wall of the catheter 120 or (ii) simply between the outer sheath 240 and inner liner 242 (Figures 2–3B). In the illustrated embodiment, the pull wire 458 exits the catheter 120 and the catheter guide 476 (e.g., via openings therein) and enters the distal chamber 572. From the distal chamber 572, the pull wire 458 can extend through the actuator 136 and through the lumen 573 of the tube member 574 to the anchor portion 584. As best seen in Figure 5B, in some embodiments the pull wire 458 can be secured to anchor portion

584 via a screw 581 or other fastener. In some embodiments, the handle 130 can further include a biasing member 585, such as a coil spring, coupled to and/or over the pull wire 458. The biasing member 585 can be configured to smooth/distribute tension loads on the pull wire 458 during operation that might otherwise damage the pull wire 458 and/or various components of the handle 130.

[0051] Referring to Figures 1A, 1B, and 4A–5B together, the deflectable region 125 (and correspondingly the deflectable member 450) is in the first position and the handle 130 is in a corresponding first position in which the shuttle member 580 is positioned distally within the lumen 473 of the tube member 574 proximate to the actuator 136 and/or the distal end portion 571b of the tube member 574. To move the deflectable region 125 to the second (e.g., bent) position, a user can rotate the actuator 136 in a first direction to rotate the tube member 574. The rotation of the tube member 574 can drive the shuttle member 580 to move proximally through the lumen 573 in a direction toward the proximal end portion 571a of the tube member 574 via the engagement of the threaded outer surface 583 with the threaded inner surface 575. That is, the handle 130 is configured to translate the rotational movement of the actuator 136 into linear movement of the shuttle member 580. As the shuttle member 580 moves proximally, the shuttle member 580 pulls the pull wire 458 proximally and increases the tension therein. The pull wire 458 thus moves (e.g., slides) proximally through the lumen 465 in the annular member 464 of the deflectable member 450 and, because the pull wire 458 is fixedly attached to the distal ring 454 of the deflectable member 450, the pull wire 458 urges the distal ring 454 proximally relative to the proximal ring 452. This differential force causes the tube portion 456 of the deflectable member 450 to bend toward the second position shown in Figure 1B. More specifically, because the pull wire 458 is aligned with the spine 453 of the deflectable member 450, the spine 453 can define an inner radius of the bend while the ribs 455 flex away from one another, thereby increasing a size of the openings 451. To return the deflectable region 125 from the second position to the first position, the user can rotate the actuator 136 in a second direction opposite the first direction to translate the shuttle member 580 distally through the lumen 573 to decrease the tension in the pull wire 458, thereby allowing the deflectable member 450 to return to the relaxed position shown in Figures 4A and 4B.

[0052] In other embodiments, the handle 130 can include other features for moving/driving the shuttle member 580 through the housing 134 to tension the pull wire 458. For example, the actuator 136 can be a slider, clip, or other actuator movable relative to the housing 134.

[0053] Referring to Figures 1A–5B together, in some aspects of the present technology, the catheter 120 is configured to be steered to and positioned in difficult-to-reach regions of the anatomy of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). More particularly, the catheter 120 can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid 234 can provide good torque response along the proximal and intermediate regions 121, 122 of the catheter 120. Moreover, the varying hardness (e.g., distally decreasing hardness) of the outer sheath 240 can provide (i) good torque response and/or pushability at the proximal region 121 and (ii) increased flexibility at the intermediate and distal regions 122, 123. Additionally, the deflectable region 125 is configured (e.g., shaped, sized) to be positioned within and steered/flexed into the difficult-to-reach regions of the anatomy. Further, the coil 346 can provide increased hoop strength at the intermediate region 122 while still allowing the catheter 120 to flex. For example, the coil 346 can inhibit or even prevent kinking or other unwanted movement of the catheter 120 when the lumen 127 is aspirated during a clot removal procedure.

[0054] Figures 6A and 6B are a distally-facing isometric view and a side view, respectively, of a deflectable member 650 in accordance with additional embodiments of the present technology. The deflectable member 650 is configured to be positioned in the deflectable region 125 of the catheter 120 (Figure 1) and can include some features generally similar or identical to the deflectable member 450 described in detail above with reference to Figures 4A–4D. For example, in the illustrated embodiment the deflectable member 650 includes a proximal ring 652, a distal ring 654, and a tube portion 656 extending between the proximal ring 652 and the distal ring 654. The proximal ring 652 includes an annular member 664 coupled thereto and configured to slidably receive the pull wire 458. The pull wire 458 can extend through the tube portion 656 and be fixedly secured (e.g., welded) to the distal ring 654.

[0055] In the illustrated embodiment, the tube portion 656 includes a plurality of openings 651 (identified individually as first openings 651a and second openings 651b) extending partially about a circumference of the tube portion 656 to define a plurality of ribs 655 (identified individually as first ribs 655a and second ribs 655b). In some embodiments, the first openings 651a are generally elongate openings that extend (i) generally parallel to one another and (ii) circumferentially about a longitudinal axis M of the deflectable member 650 such that, for example, the first ribs 655a have a generally similar or identical shape. Similarly, the second openings 651b can each have an elongate tapered shape and can extend (i) generally parallel to one another and (ii) circumferentially about the longitudinal axis M of the deflectable member

650 such that, for example, the second ribs 655b have a generally similar or identical shape. In the illustrated embodiment, the second ribs 655b have a smaller dimension (e.g. width) in a direction along the longitudinal axis M than the first ribs 655a. Accordingly, the second ribs 655b can be relatively more flexible than the first ribs 655a.

[0056] In some embodiments, the pull wire 458 can extend over/adjacent to the first ribs 655a. Accordingly, referring to Figures 5–6B together, actuation of the actuator can 136 pull the pull wire 458 to urge the distal ring 654 proximally relative to the proximal ring 652. This differential force causes the tube portion 656 of the deflectable member 650 to bend such that, for example, a portion of the first ribs 655a define an inner radius of the bend while the second ribs 655b flex away from one another, thereby increasing a size of the second openings 651b (e.g., and conversely decreasing a size of the first openings 651a).

[0057] In some embodiments, all or a portion of the deflectable member 650 can be manufactured as a single integral piece. For example, Figure 6C is top view of flat pattern that can be cut to integrally form the proximal ring 652 and the tube portion 656 of the deflectable member 650 in accordance with embodiments of the present technology. Figure 6D is an enlarged top view of a portion of the pattern shown in Figure 6C. Referring to Figures 6C and 6D together, the pattern can be laser cut from a single piece of material (e.g., stainless steel), formed to have the three-dimensional tubular shape shown in Figures 6A and 6B, and then welded or otherwise adhered together to form the deflectable member 650.

[0058] Figures 7A–7C are side views of a portion of the catheter 120 of the clot removal system 100 during a procedure for removing clot material PE (e.g., a pulmonary embolism) from within a blood vessel BV (e.g., a pulmonary blood vessel) of a patient (e.g., a human patient) in accordance with embodiments of the present technology. As noted above, in some embodiments the clot removal procedure illustrated in Figures 7A–7C can be generally similar or identical to any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0059] With reference to Figures 1A–7A together, the catheter 120 can be advanced through the patient toward and/or proximate to the clot material PE within the blood vessel BV (e.g., advanced to a treatment site within the blood vessel BV). In some embodiments, however, the blood vessel BV can include a hard-to-reach (e.g., tortuous) region, such as a region beyond a bend 790 in the blood vessel BV that can have a relatively small radius of curvature. The

region of the blood vessel BV distal of the bend 790 can be difficult to reach due to the required approach angle, varying anatomy of the blood vessel BV, and/or irregularities due to illness of the patient.

[0060] Accordingly, with reference to Figures 1A–5B and 7B together, the deflectable region 125 can be moved fully or partially from the first position (Figure 1A) to the second position (Figure 1B) before and/or during further advancement of the catheter 120 toward the clot material PE. More specifically, the user can actuate (e.g., rotate) the actuator 136 of the handle to pull the pull wire 458 to deflect the deflectable member 450 to deflect the deflectable region 125, as described in detail above. In some embodiments, the catheter 120 can be advanced through the blood vessel BV until the distal terminus 128 of the catheter 120 is positioned proximate to a proximal portion of the clot material PE. In some embodiments, the position of the distal terminus 128 can be confirmed or located via visualization of a marker band (not shown; e.g., in/along the tip region 126) using fluoroscopy or another imaging procedure (e.g., a radiographic procedure). In other embodiments, the distal terminus 128 can be positioned at least partially within the clot material PE or distal of the clot material PE.

[0061] In some aspects of the present technology, moving the deflectable region 125 to the second position helps the catheter 120 flex/bend around the bend 790 and into the hard-to-reach region of the blood vessel BV distal thereof. In some embodiments, before advancing the catheter 120 to the position shown in Figure 7B, the catheter 120 can be rotated to align the deflectable region 125 with the bend 790. In contrast, conventional catheters of the same size may be too stiff to easily position proximate the clot material PE. For example, such conventional catheters may "rainbow" over the clot material PE by following or tracking along the wall of the blood vessel BV at the outside of the bend 790. In addition to the deflectable region 125, both (i) the varying hardness of the outer sheath 240 (Figures 2–3B) and (ii) the flexibility of the braid 244 (Figures 2–3B) and the coil 346 (Figures 3B and 3C) can help the catheter 120 flex through the anatomy of the blood vessel BV to the desired position proximate the clot material PE.

[0062] Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the clot removal system 100 can include an introducer (e.g., a Y-connector with a hemostasis valve; not shown) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right

ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the clot material PE, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire can be extended to a location just proximal of the clot material PE. After positioning the guidewire, the catheter 120 can be placed over the guidewire and advanced to the position proximate to the clot material PE as illustrated in Figure 7B. In some embodiments, the guidewire can then be withdrawn while, in other embodiments, the guidewire can remain and can be used to guide other catheters (e.g., delivery catheters, additional aspiration guide catheters, etc.), interventional devices, etc., to the treatment site. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein, or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the clot material PE.

[0063] With reference to Figures 1A, 1B, and 7C together, the pressure source 102 is configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative pressure) and store the vacuum for subsequent application to the catheter 120. For example, after positioning the catheter 120 proximate the clot material PE, a user can first close the fluid control device 114 before generating the vacuum in the pressure source 102 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 102 (e.g., a negative pressure is maintained) before the pressure source 102 is fluidly connected to the lumen 127 of the catheter 120. To aspirate the lumen 127 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 102 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 102 to the lumen 127 of the catheter 120.

[0064] Opening of the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120. In particular, the suction is applied at the tip region 126 of the catheter 120 to suck/aspirate at least a portion of the clot material PE into the lumen 127 of the catheter 120, as shown in Figure 7C. In one aspect of the present technology, pre-charging or storing the vacuum in the pressure source 102 before applying the

vacuum to the lumen 127 of the catheter 120 is expected to generate greater suction forces and corresponding fluid flow velocities at and/or near the tip region 126 of the catheter 120 compared to simply activating the pressure source 102 while it is fluidly connected to the catheter 120.

[0065] Sometimes, as shown in Figure 7C, discharging the vacuum stored in the pressure source to aspirate the lumen 127 of the catheter 120 may remove substantially all (e.g., a desired amount) of the clot material PE from the blood vessel BV. That is, a single aspiration pulse may adequately remove the clot material PE from the blood vessel BV. In other embodiments, a portion of the clot material PE may remain in the blood vessel BV. In such instances, the user may wish to again apply vacuum pressure (conduct an "aspiration pass") to remove all or a portion of the remaining clot material PE in the blood vessel BV. In such instances, the pressure source 102 can be disconnected from the tubing assembly 110 and drained (e.g., aspirated clot removal removed) before the pressure source 102 is reconnected to the tubing assembly 110 and activated once again. After removing a desired amount of the clot material PE, the catheter 120 can be withdrawn from the patient.

[0066] In some aspects of the present technology, the relatively great flexibility and torquability of the catheter 120 allow the catheter 120 to be positioned in difficult-to-reach areas of the blood vessel BV (or elsewhere in the vasculature of the patient) without decreasing the size of the lumen 127 and while keeping the lumen 127 of constant diameter throughout. It is expected that the increased size of the lumen 127 will provide greater suction forces over a smaller period of time (e.g., will provide a larger vacuum impulse). In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot). Accordingly, in contrast to conventional catheters, the catheter 120 can be used to generate greater aspirational forces for improved clot removal in hard-to-reach places of the vasculature. In additional aspects of the present technology, the coil 336 (Figures 3B and 3C) can provide a high hoop strength that inhibits or even prevents kinking or other unwanted movement of the catheter 120 when the pressure source 102 is used to generate a suction pulse at the distal region 123 of the catheter 120.

[0067] Although described in the context of removing clot material from pulmonary blood vessels, in other embodiments the clot removal system 100 can be used to remove clot from other locations in the body of the patient. For example, the clot removal system 100 can used to aspirate or otherwise remove clot material (e.g., stationary or in transit) and/or vegetation from

the heart (e.g., the right atrium, tricuspid valve, pulmonary valve), the vena cava, the renal arteries, and so on.

[0068] Several aspects of the present technology are set forth in the following examples:

1. An aspiration catheter, comprising:

a proximal region; and

a distal region including a deflectable member, wherein the deflectable member includes—

a proximal ring;

a distal ring configured to be fixedly attached to a pull wire; and

a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally.

2. The aspiration guide catheter of example 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings, wherein the ribs extend away from the spine, and wherein the spine is configured to extend generally parallel to and over the pull wire.

3. The aspiration catheter of example 1 or example 2 wherein the proximal region and the distal region define a lumen having a diameter of 20 French or greater.

4. The aspiration catheter of any one of examples 1–3, further comprising an intermediate region between the proximal and distal regions, wherein the proximal region and the intermediate region include a braid of wires extending therethrough.

5. The aspiration catheter of example 4 wherein the intermediate region includes a wire coiled around the braid.

6. The aspiration catheter of any one of examples 1–5 wherein the tube portion extends along a longitudinal axis in a relaxed state, and wherein the openings extend

circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state.

7. The aspiration catheter of any one of examples 1–6 wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough.

8. A clot removal system, comprising:

an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member;

a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and

a pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region.

9. The clot removal system of example 8 wherein the aspiration catheter extends along an axis, and wherein the actuation of the actuator is configured to deflect the distal region of the aspiration catheter away from the axis by about 90 degrees or greater.

10. The clot removal system of example 8 or example 9 wherein the aspiration guide catheter has a size of 20 French or greater.

11. The clot removal system of any one of examples 8–10 wherein the deflectable member has a tubular shape that extends along a longitudinal axis, and wherein the deflectable member includes (a) a spine extending parallel to the longitudinal axis and (b) a plurality of ribs extending from the spine and circumferentially about the longitudinal axis.

12. The clot removal system of example 11 wherein the deflectable member has a distal portion and a proximal portion, and wherein the pull wire is attached to the distal portion of the deflectable member.

13. The clot removal system of example 12 wherein the actuation of the actuator is configured pull the distal portion proximally relative to the proximal portion.

14. The clot removal system of example 12 or example 13 wherein the ribs define a plurality of openings therebetween, and wherein the actuation of the actuator is configured pull the distal portion of the deflectable member proximally relative to the proximal portion to bend the spine and increase a size of the openings.

15. The clot removal system of any one of examples 8–14 wherein the aspiration catheter further includes—

an intermediate region between the proximal and distal regions;

an inner liner extending through the proximal, intermediate, and distal regions;

a braid of wires extending through the proximal and intermediate regions over the inner liner;

a wire extending through the intermediate region and coiled around the braid; and

an outer liner extending through the proximal, intermediate, and distal regions over the inner liner, the braid, and the wire, wherein the deflectable member is positioned between the inner and outer liners in the distal region.

16. The clot removal system of example 15 wherein—

the distal region further includes a proximal transition region, a distal tip region, and a deflectable region between the proximal transition region and the distal tip region;

the deflectable member is positioned in the deflectable region;

the outer liner has a first hardness in the proximal transition region, a second hardness in the deflectable region, and a third hardness in the distal tip region; and

the second hardness is less than the first hardness and less than the third hardness.

17. A method of removing clot material from a blood vessel, the method comprising:

advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion;

actuating a handle coupled to the aspiration catheter to deflect the distal portion of the aspiration catheter away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate to the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

18. The method of example 17 wherein actuating the handle to deflect the distal portion of the aspiration catheter includes deflecting the distal portion of the aspiration catheter away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

19. The method of example 17 or example 18 wherein the aspiration catheter has a size of 20 French or greater.

20. The method of any one of examples 17–19 wherein the aspiration catheter includes a deflectable member positioned in the distal portion, and wherein actuating the handle includes rotating an actuator of the handle to pull a pull wire coupled to the deflectable portion proximally to deflect the deflectable member to deflect the distal portion of the aspiration catheter.

[0069] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0070] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the

description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0071] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An aspiration catheter, comprising:

a proximal region; and

a distal region including a deflectable member, wherein the deflectable member includes—

a proximal ring;

a distal ring configured to be fixedly attached to a pull wire; and

a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally.

2. The aspiration guide catheter of claim 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings, wherein the ribs extend away from the spine, and wherein the spine is configured to extend generally parallel to and over the pull wire.

3. The aspiration catheter of claim 1 wherein the proximal region and the distal region define a lumen having a diameter of 20 French or greater.

4. The aspiration catheter of claim 1, further comprising an intermediate region between the proximal and distal regions, wherein the proximal region and the intermediate region include a braid of wires extending therethrough.

5. The aspiration catheter of claim 4 wherein the intermediate region includes a wire coiled around the braid.

6. The aspiration catheter of claim 1 wherein the tube portion extends along a longitudinal axis in a relaxed state, and wherein the openings extend circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state.

7. The aspiration catheter of claim 1 wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough.

8. A clot removal system, comprising:

an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member;

a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and

a pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region.

9. The clot removal system of claim 8 wherein the aspiration catheter extends along an axis, and wherein the actuation of the actuator is configured to deflect the distal region of the aspiration catheter away from the axis by about 90 degrees or greater.

10. The clot removal system of claim 8 wherein the aspiration guide catheter has a size of 20 French or greater.

11. The clot removal system of claim 8 wherein the deflectable member has a tubular shape that extends along a longitudinal axis, and wherein the deflectable member includes (a) a spine extending parallel to the longitudinal axis and (b) a plurality of ribs extending from the spine and circumferentially about the longitudinal axis.

12. The clot removal system of claim 11 wherein the deflectable member has a distal portion and a proximal portion, and wherein the pull wire is attached to the distal portion of the deflectable member.

13. The clot removal system of claim 12 wherein the actuation of the actuator is configured pull the distal portion proximally relative to the proximal portion.

14. The clot removal system of claim 12 wherein the ribs define a plurality of openings therebetween, and wherein the actuation of the actuator is configured pull the distal portion of the deflectable member proximally relative to the proximal portion to bend the spine and increase a size of the openings.

15. The clot removal system of claim 8 wherein the aspiration catheter further includes—

an intermediate region between the proximal and distal regions;

an inner liner extending through the proximal, intermediate, and distal regions;

a braid of wires extending through the proximal and intermediate regions over the inner liner;

a wire extending through the intermediate region and coiled around the braid; and

an outer liner extending through the proximal, intermediate, and distal regions over the inner liner, the braid, and the wire, wherein the deflectable member is positioned between the inner and outer liners in the distal region.

16. The clot removal system of claim 15 wherein—

the distal region further includes a proximal transition region, a distal tip region, and a deflectable region between the proximal transition region and the distal tip region;

the deflectable member is positioned in the deflectable region;

the outer liner has a first hardness in the proximal transition region, a second hardness in the deflectable region, and a third hardness in the distal tip region; and

the second hardness is less than the first hardness and less than the third hardness.

17. A method of removing clot material from a blood vessel, the method comprising:

advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion;

actuating a handle coupled to the aspiration catheter to deflect the distal portion of the aspiration catheter away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate to the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

18. The method of claim 17 wherein actuating the handle to deflect the distal portion of the aspiration catheter includes deflecting the distal portion of the aspiration catheter away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

19. The method of claim 17 wherein the aspiration catheter has a size of 20 French or greater.

20. The method of claim 17 wherein the aspiration catheter includes a deflectable member positioned in the distal portion, and wherein actuating the handle includes rotating an actuator of the handle to pull a pull wire coupled to the deflectable portion proximally to deflect the deflectable member to deflect the distal portion of the aspiration catheter.

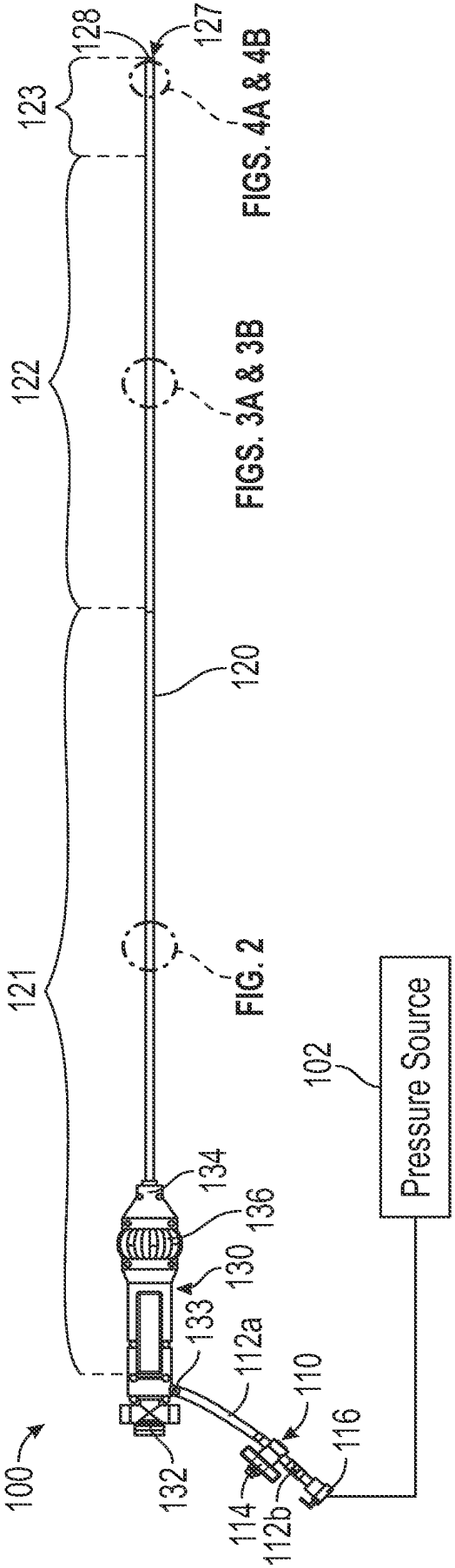

100
132
114
112b
112a
110
116
133
130
134
136
120
121
122
123
128
127
102
Pressure Source
FIGS. 4A & 4B
FIGS. 3A & 3B
FIG. 2

FIG. 1A

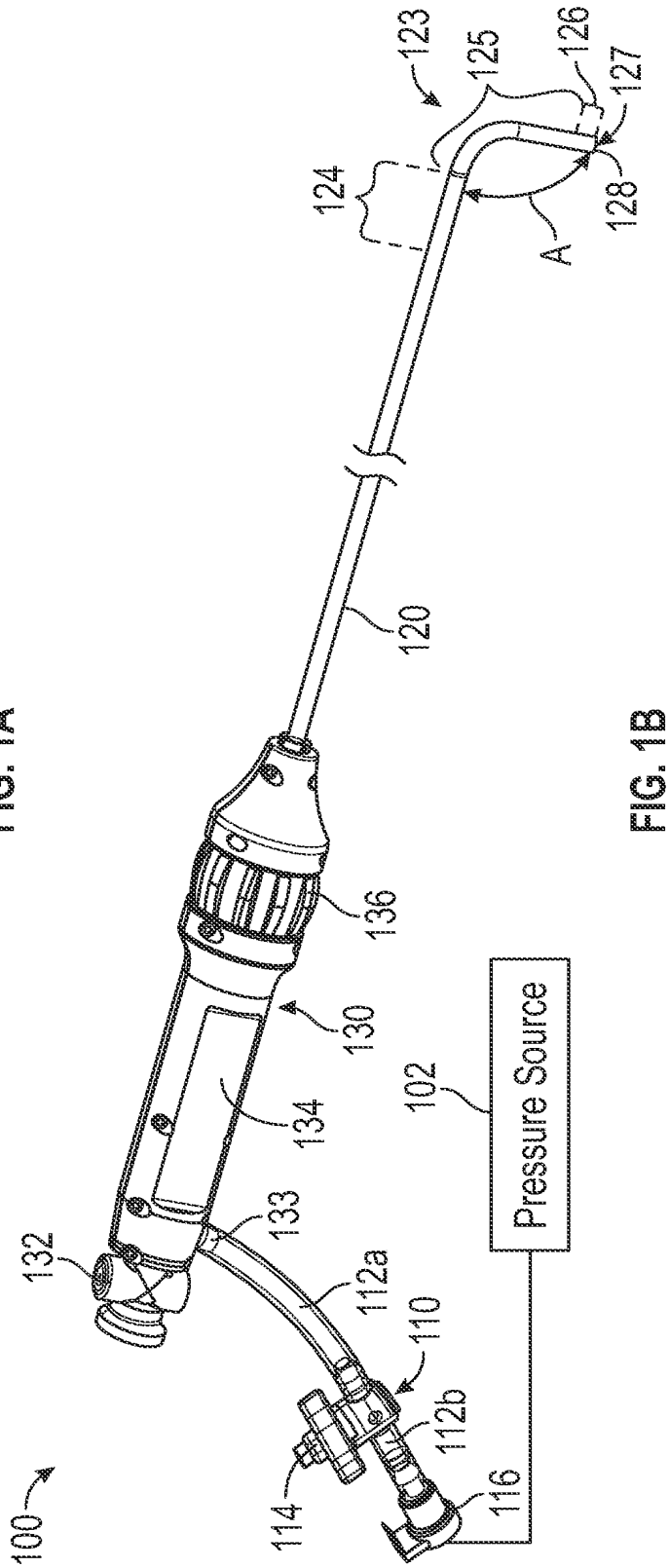

100
132
114
112b
112a
110
116
133
130
134
136
120
123
124
125
126
127
128
A
102
Pressure Source

FIG. 1B

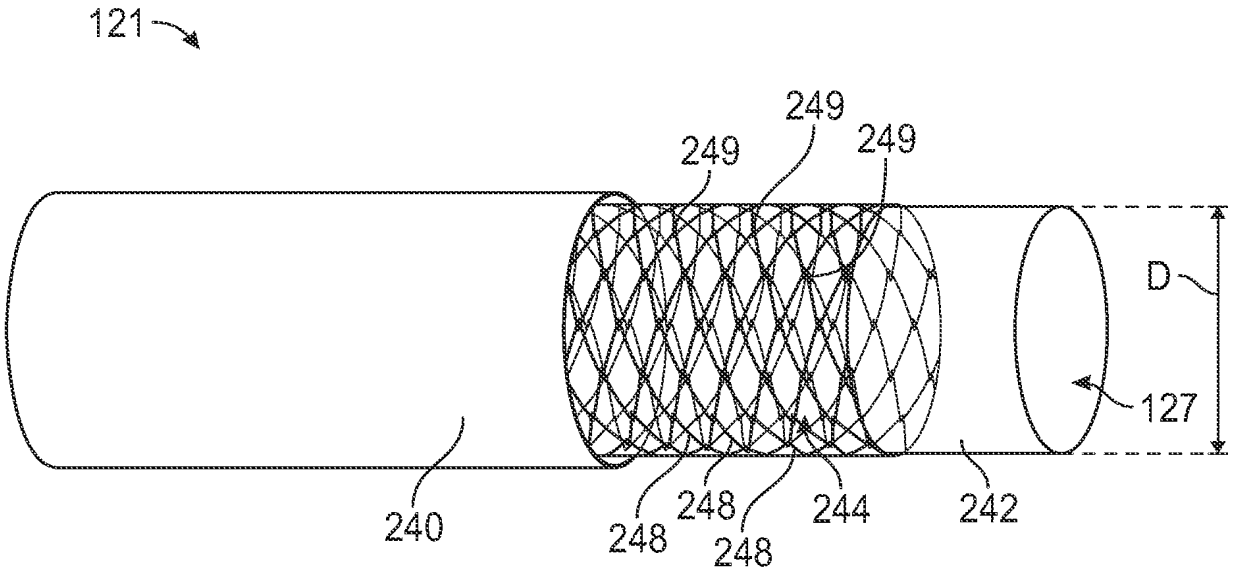

121
249
249
249
D
127
240
248
248
248
244
242

FIG. 2

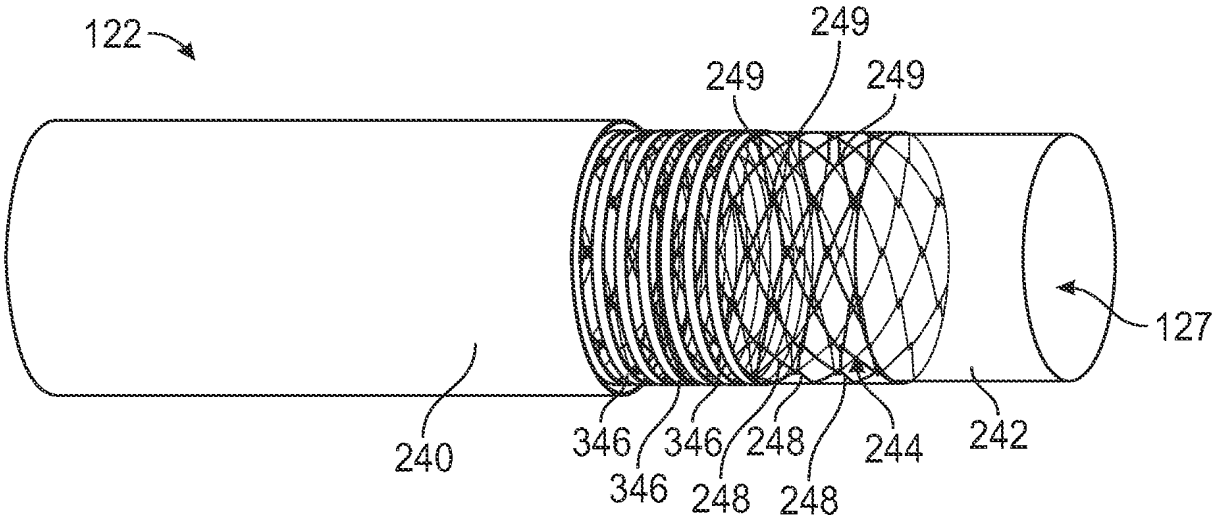

122
249
249
249
127
240
346
346
346
248
248
248
244
242

FIG. 3A

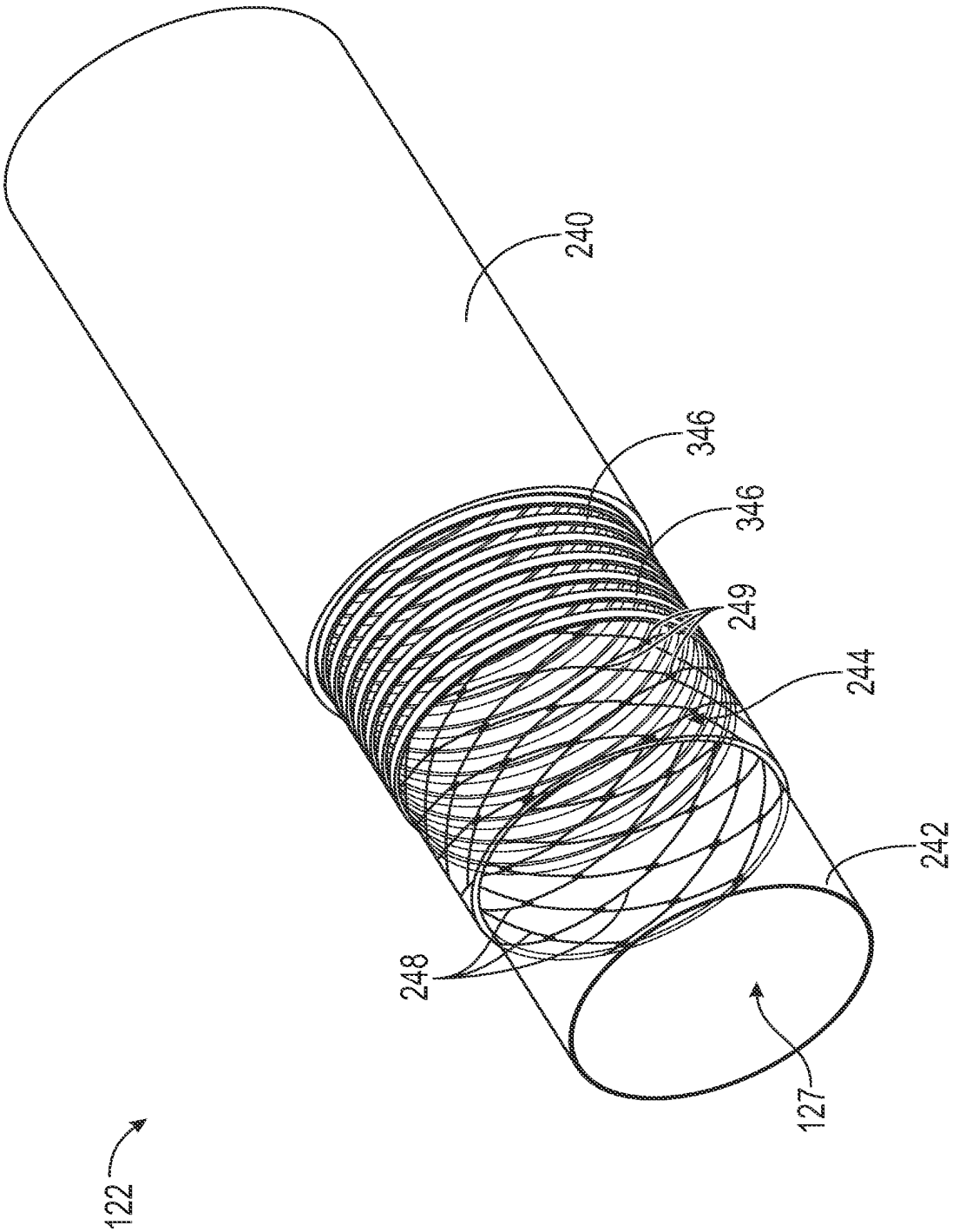


FIG. 3B

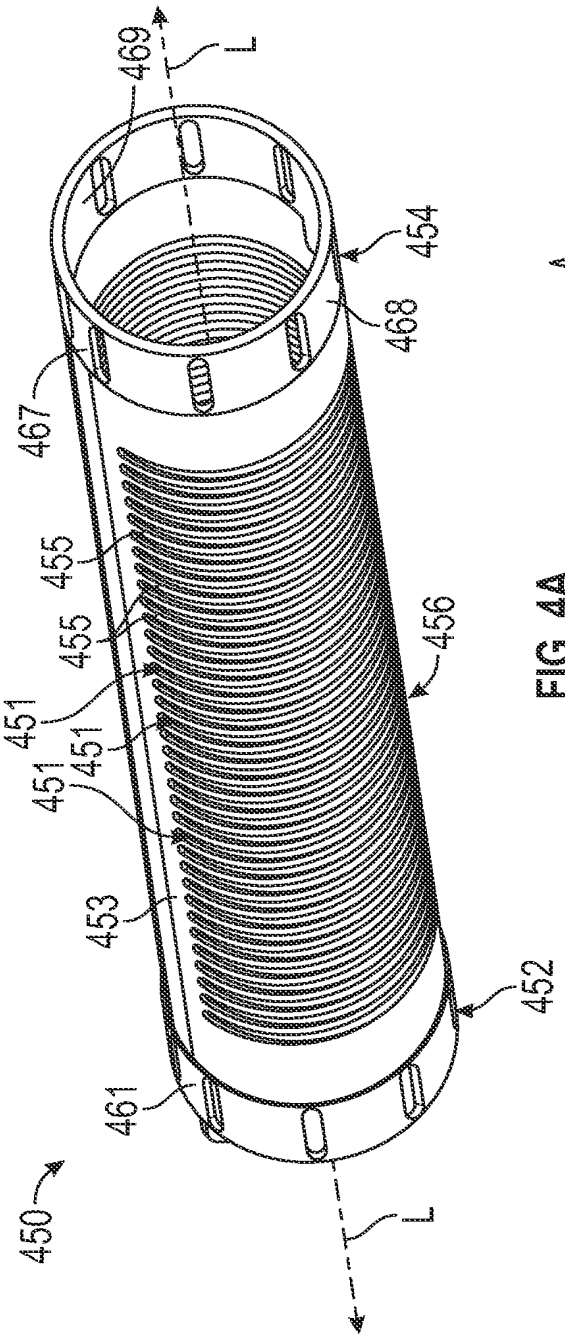

469
L
454
468
467
455
455
451
451
451
456
453
452
461
450
L

FIG. 4A

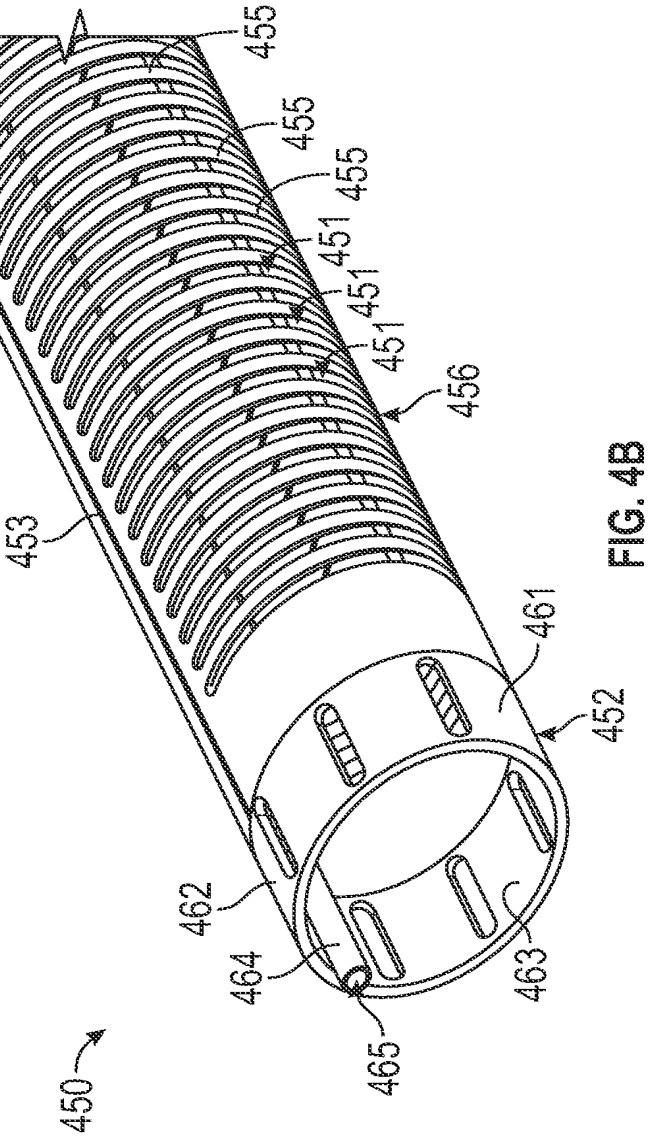

455
455
455
451
451
451
456
453
461
452
462
464
463
465
450

FIG. 4B

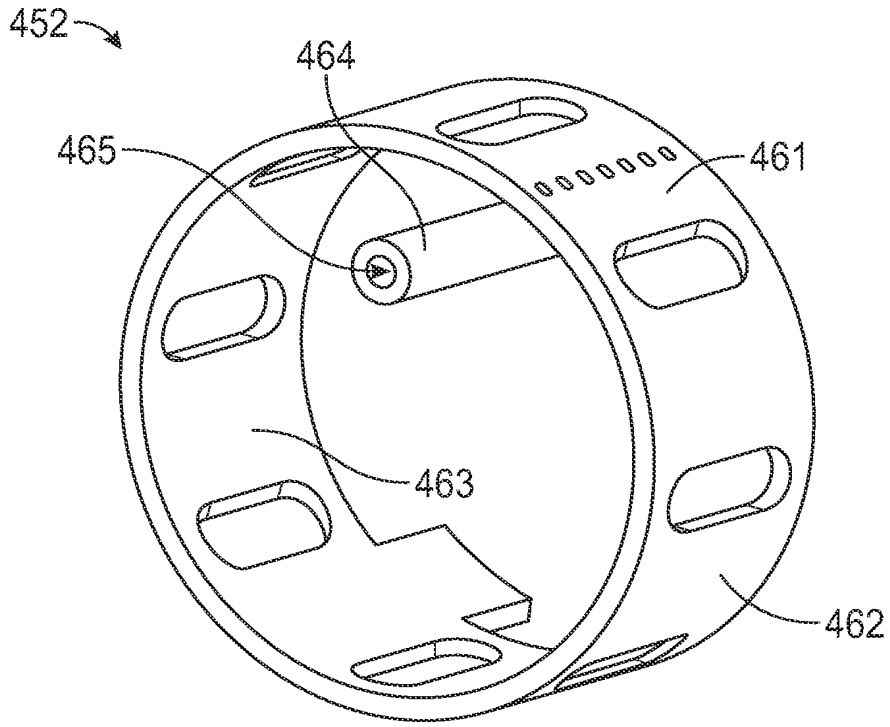


FIG. 4C

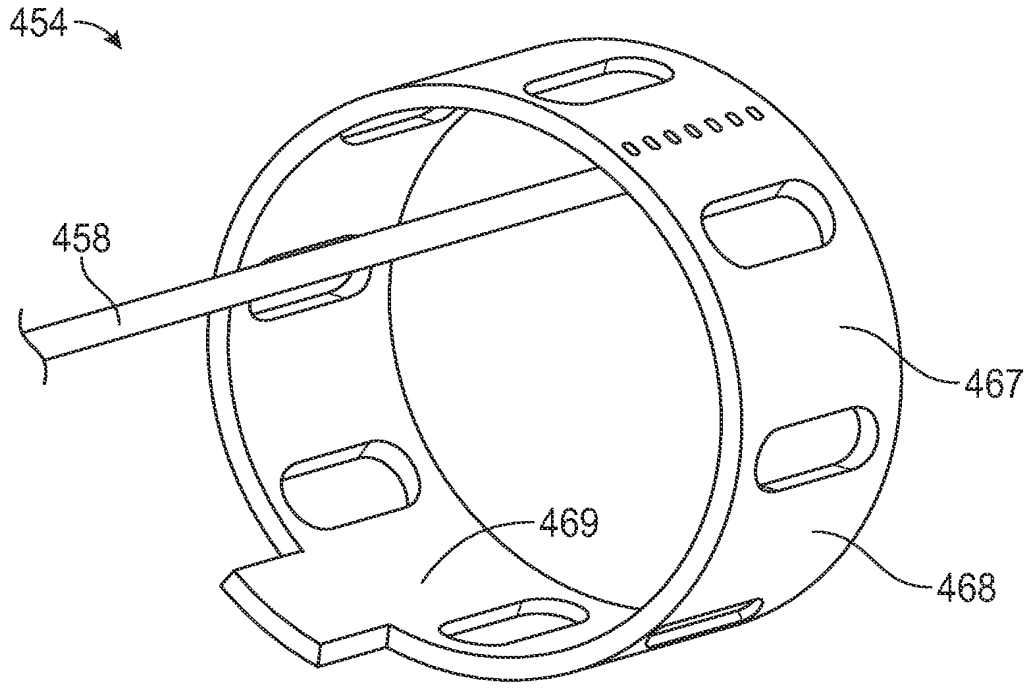


FIG. 4D

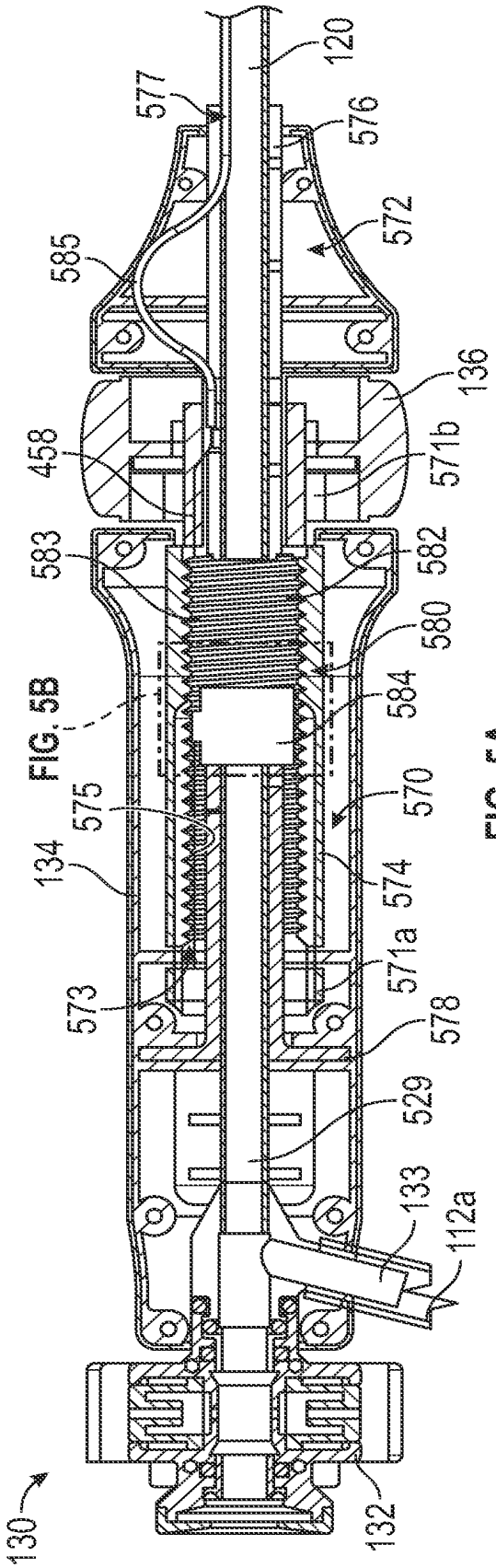


FIG. 5B

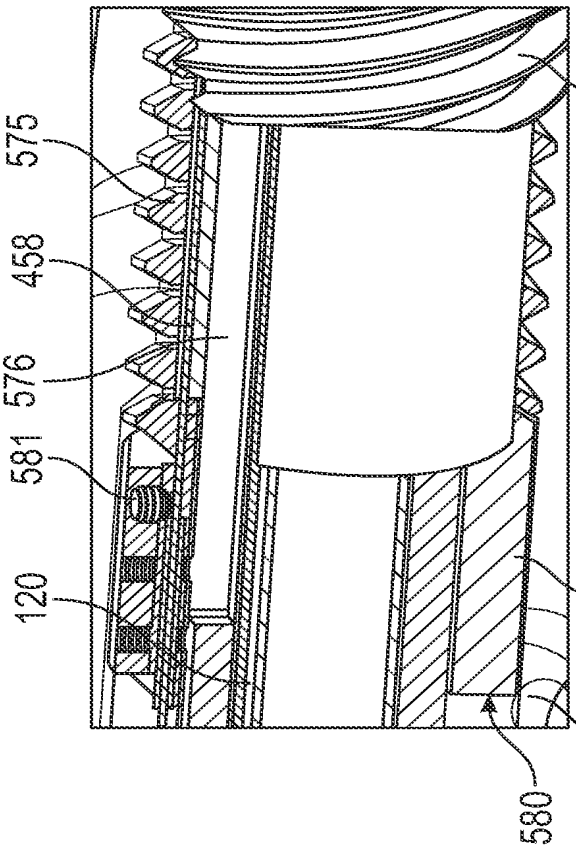


FIG. 5A

FIG. 5B

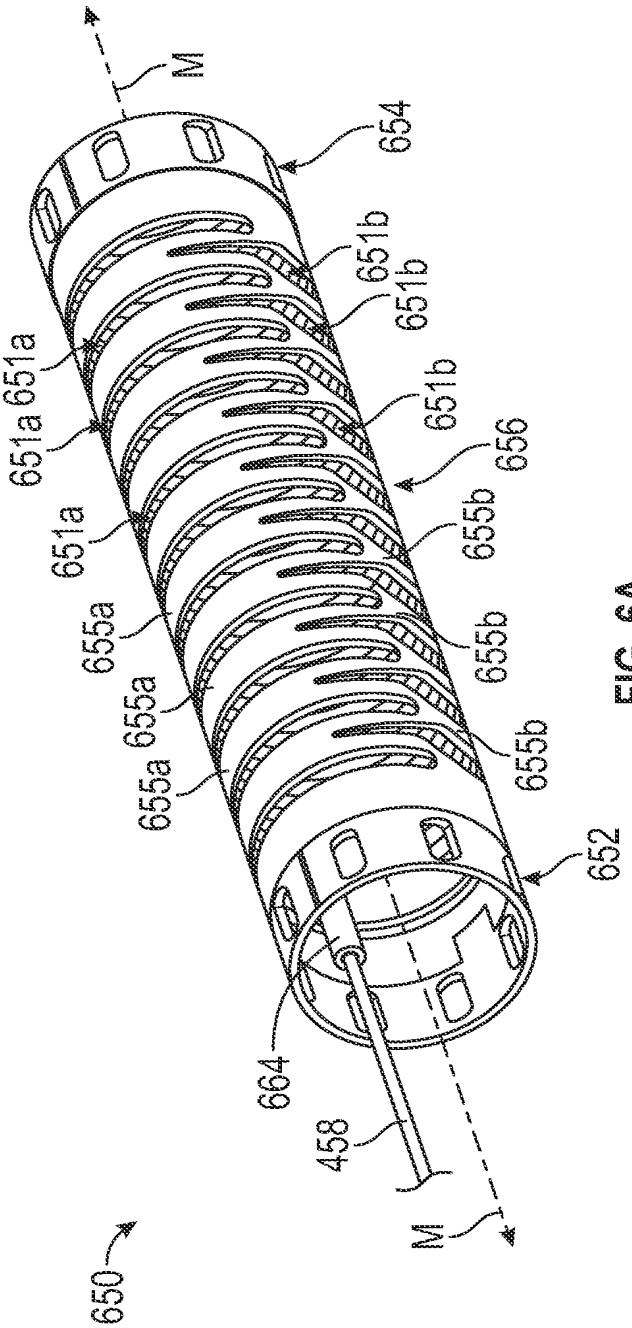

M
654
651b
651b
651a
651a
651b
656
651a
655b
655a
655b
655a
655b
652
664
458
M
650

FIG. 6A

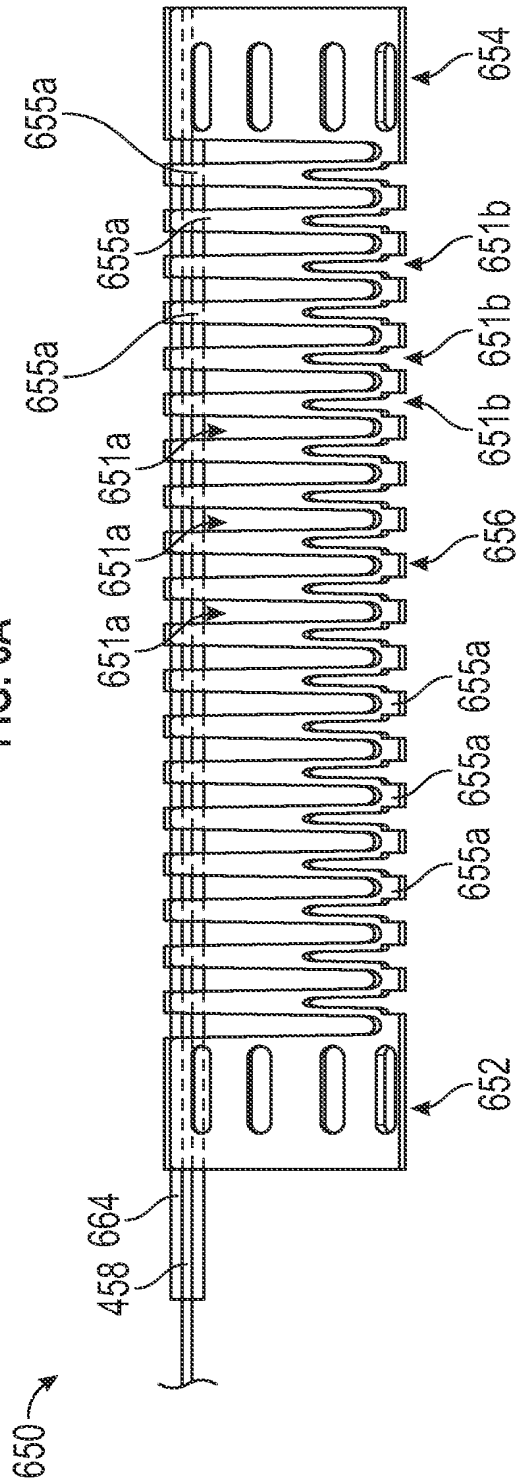

654
655a
655a
651b
651b
655a
651b
651b
651a
651a
656
651a
655a
655a
655a
652
664
458
650

FIG. 6B

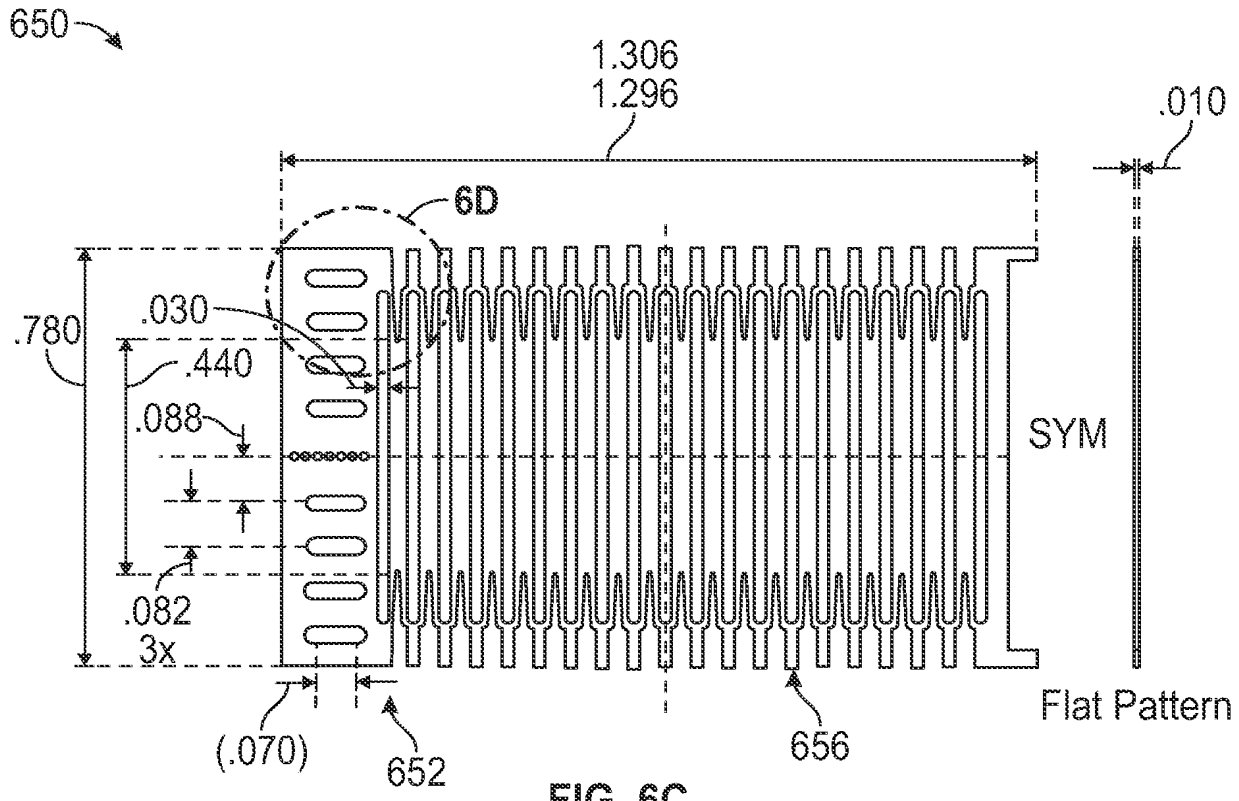

650
1.306
1.296
.010
6D
.780
.030
.440
.088
.082
3x
SYM
(.070)
652
656
Flat Pattern

FIG. 6C

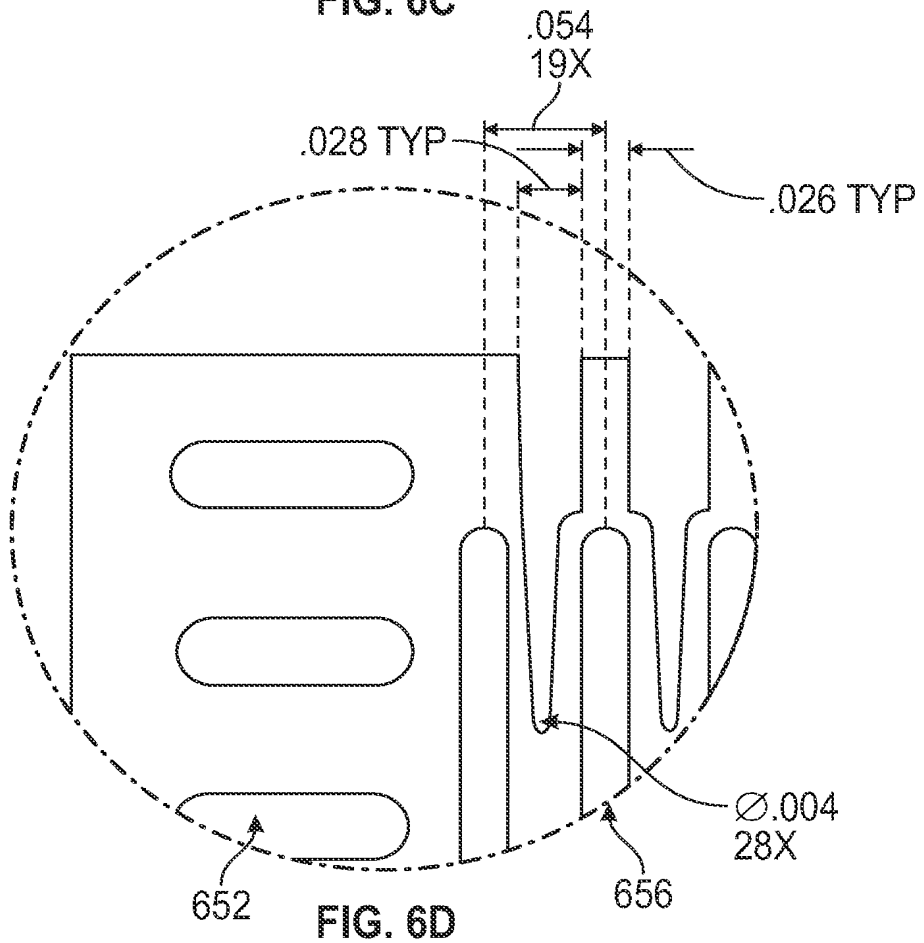

.054
19X
.028 TYP
.026 TYP
∅.004
28X
652
656

FIG. 6D

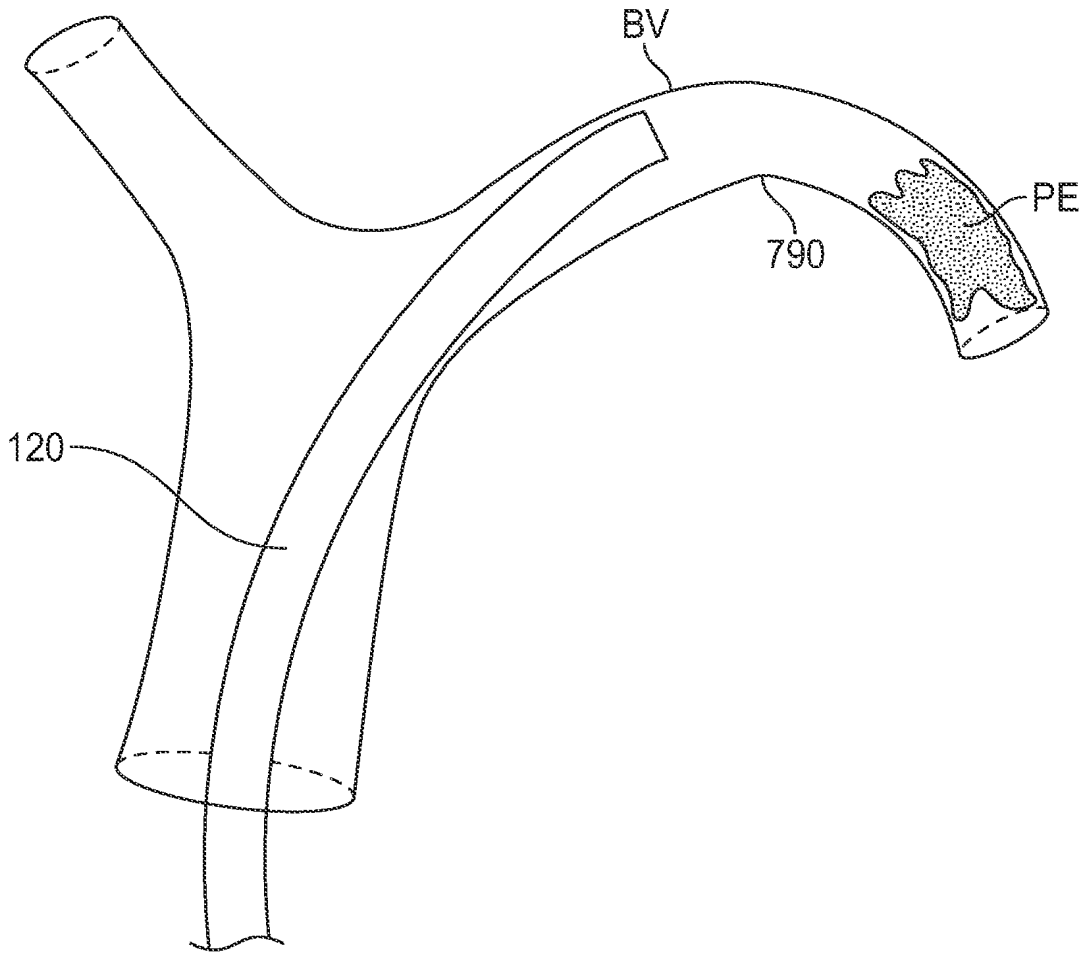


FIG. 7A

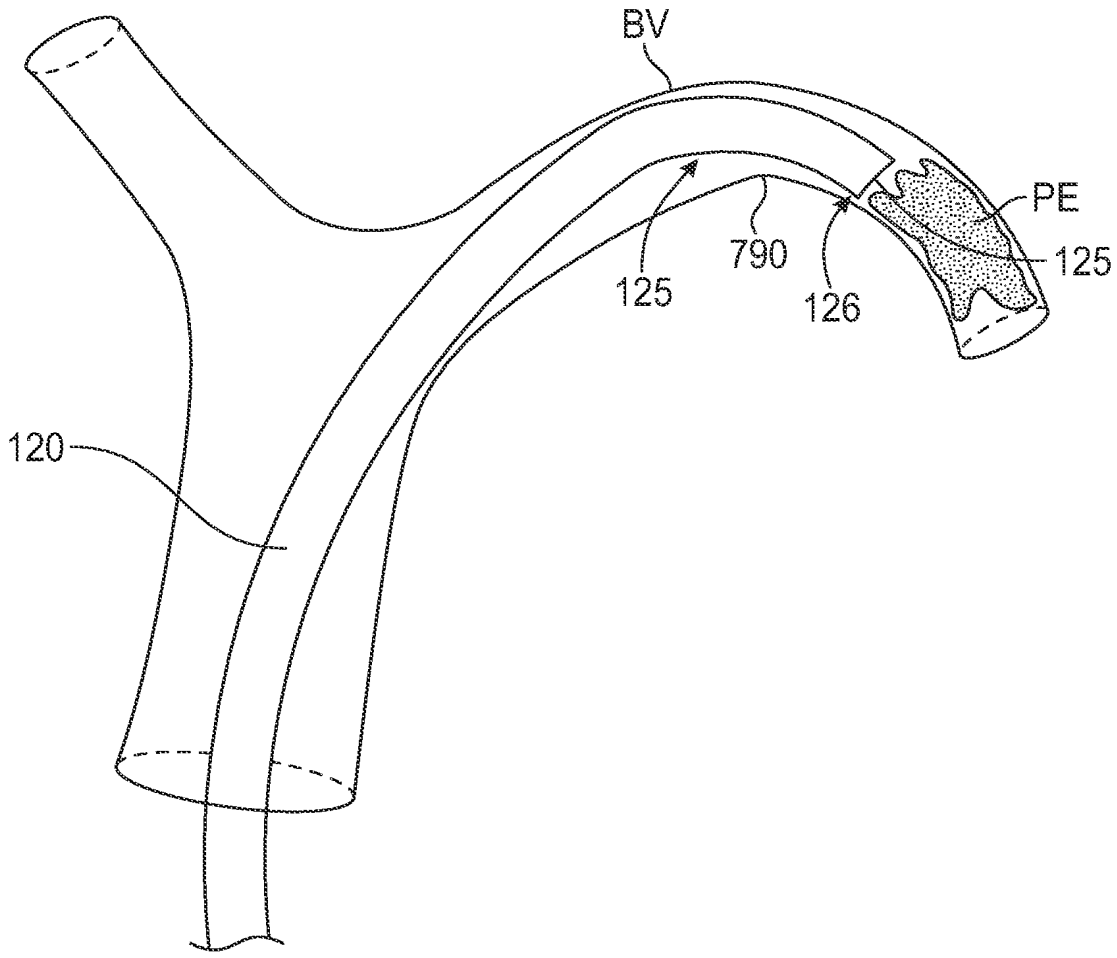


FIG. 7B

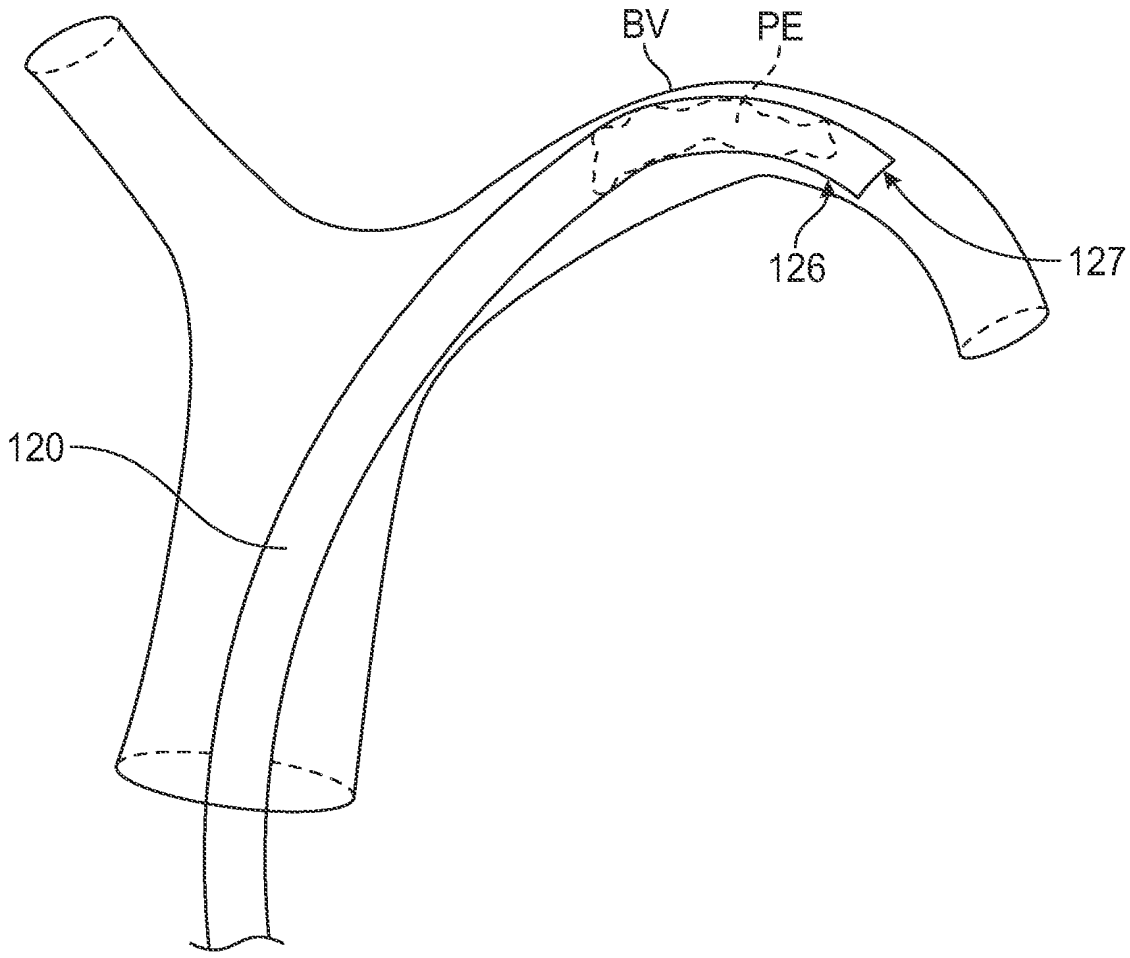


FIG. 7C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59735

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:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 directed to a proximal ring; a distal ring and a tube portion.

Group II: Claims 8-20 directed to a handle and an actuator.

-*-Continued in Supplemental Box-*-

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.:
1-7

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)) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59735

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 25/00 (2022.01)
CPC - A61M 25/0147; A61M 25/0138

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)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2019/246240 A1 (INTUITIVE SURGICAL OPERATIONS, INC.) 26 December 2019 (26.12.2019), entire document, especially Fig 4A, 4C; para [0071]-[0084]	1-3, 6-7
Y		4-5
Y	US2010/0016837 A1 (Howat) 21 January 2010 (21.01.2010), entire document, especially Fig 1-8; para [0034]-[0042]	4-5
A	US 2004/0138525 A1 (Saadat et al.) 15 July 2004 (15.07.2004), entire document	1-7
A	US 2020/0113412 A1 (AMBU A/S) 16 April 2020 (16.04.2020), entire document	1-7
A	US 2009/0192495 A1 (Ostrovsky et al.) 30 July 2009 (30.07.2009), entire document	1-7

☐ 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
"D" document cited by the applicant in the international application
"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 February 2022	MAR 22 2022
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. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59735

-*-Box No. III - Observations where unity of invention is lacking-*-

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The Invention of Group I includes the special technical feature of a proximal ring; a distal ring configured to be fixedly attached to a pull wire; and a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally, not required by Group II.

The invention of Group II includes the special technical feature of a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member; and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2004/0138525 A1 to Saadat et al. (hereinafter "Saadat"), which discloses an aspiration catheter (30; Fig 21A-21B; para [0097]; see analogous Fig 41, para [0125] describing tool arm 30 used for aspiration, wherein the tool arm 30 is interpreted as an aspiration catheter) including a proximal region (proximal half of 30; Fig 21A-21B; para [0097]; the proximal half of 30 being the bottom-most half of the entire tool arm 30 in the orientation shown in Fig 21A) and a distal region (distal half of 30; Fig 21A-21B; para [0097]; the distal half of 30 being the top-most half of the entire tool arm 30 in the orientation shown in Fig 21A), wherein the distal region includes a deflectable member (portion of 30 from bottom slot 132 to the distal-most end of 30; Fig 21A-21B; para [0097]); and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region (96; Fig 21A-21B; para [0097]; pullwire 96 is shown to be attached to the portion of 30 extending distally from distal-most slot 132 via fixation point 104 wherein pulling the pullwire 96 causes the distal tip of tool arm 30 to deflect relative to the proximal region of tool arm 30).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
GWM-02-PCT3		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2017/029440	25 April 2017 (25-04-2017)	25 April 2016 (25-04-2016)
Applicant		
STRYKER CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [X] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 8A

[ ] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[X] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/029440

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.: 7-24
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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:

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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/029440

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.
A	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 16	1
A	US 2013/096571 A1 (MASSICOTTE ET AL.) 18 April 2013 (2013-04-18) abstract; figures	1
A	US 2006/089533 A1 (ZIEGLER ET AL.) 27 April 2006 (2006-04-27) figures	1

-/--

[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
30 June 2017	07/07/2017

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)

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 00/32118 A1 (ATROPOS LIMITED) 8 June 2000 (2000-06-08) figures	1
A,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document	1

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/029440

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012009675 A2	19-01-2012	US 2014005712 A1	02-01-2014
		WO 2012009675 A2	19-01-2012
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
US 2013096571 A1	18-04-2013	US 2007038227 A1	15-02-2007
		US 2013096571 A1	18-04-2013
		WO 2007022055 A1	22-02-2007
US 2006089533 A1	27-04-2006	BR PI0617790 A2	09-08-2011
		EP 1945091 A2	23-07-2008
		IL 191079 A	31-01-2012
		JP 2009513250 A	02-04-2009
		US 2006089533 A1	27-04-2006
		US 2008045790 A1	21-02-2008
		US 2010198011 A1	05-08-2010
		WO 2007050370 A2	03-05-2007
WO 0032118 A1	08-06-2000	AU 1405400 A	19-06-2000
		AU 1405600 A	19-06-2000
		EP 1135071 A1	26-09-2001
		IE 991011 A1	12-07-2000
		IE 991013 A1	12-07-2000
		US 2002016607 A1	07-02-2002
		WO 0032118 A1	08-06-2000
		WO 0032119 A1	08-06-2000
WO 2017058280 A1	06-04-2017	US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		WO 2017058280 A1	06-04-2017

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 7-24

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2017/029440	25.04.2017	25.04.2016

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/22 A61B17/221

Applicant
STRYKER CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Giménez Burgos, R Telephone No. +31 70 340-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☑ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 7-24

because:

☒ the said international application, or the said claims Nos. 7-24 relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 7-24

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☒ See Supplemental Box for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-6
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-6
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-6
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The methods according to claims 7- 24 are methods of treatment of the living human or animal body by surgery.

The surgical methods claimed, at least implies the surgical step of positioning a distal end of the thrombectomy apparatus adjacent to the clot within the vessel.

Therefore, no preliminary international examination is required to the subject matter of these method claims (see Article 34(4) and Rule 67.1 PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 WO 2012/009675 A2 (LAZARUS EFFECT, INC.)

D2 GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC)

D3 US 2013/096571 A1 (MASSICOTTE ET AL.)

D4 US 2006/089533 A1 (ZIEGLER ET AL.)

2 Independent claim 1, positive assessment.

Document **D1** (Figs.: 13G) is regarded as being the prior art closest to the subject matter of claim 1, and discloses a mechanical thrombectomy system for removing a clot (2) from within a vessel, the apparatus comprising:

a tractor (370) comprising a flexible tube that extends distally in an un-inverted configuration at its proximal end, inverts over at its middle portion and extends proximally in an inverted configuration proximally,

a puller (354) connected to the first end of the tractor (370) extending proximally;

a clot engaging member (200) on the distal end of an elongate manipulator; and

a lumen extending continuously through the puller (354) and the tractor (370) and configured to pass the expandable elongate manipulator.

The subject matter of claim 1 therefore differs from this known mechanical thrombectomy system in that it further comprises:

a flexible catheter having a distal end and a distal end opening;

a tractor comprising a flexible belt that extends within the catheter, inverts over the distal end opening of the catheter and extends along the outer diameter of the catheter, and

a power drive at a proximal end of the flexible catheter configured to drive the tractor around the catheter.

The problem to be solved by the present invention may be regarded as the need to improve the manoeuvrability and positioning of the clot capturing tractor within the vessel.

Document **D2** (Figs.: 1- 3; page 8, line 12- page 11, line 5) discloses a mechanical thrombectomy apparatus for removing a clot from within a vessel, the apparatus comprising:

an elongate catheter (12) having a proximal end and a distal end and a distal end opening;

a tractor (14) comprising a flexible tube that extends within the catheter (12), inverts over the distal end opening of the catheter (12) and extends over the distal end of the catheter (12), wherein the tractor (14) is configured to invert by rolling over the distal end opening of the catheter (12) when a first end (16) of the tractor (14) is pulled proximally within the catheter (12); and

a puller (wire; 20) coupled to the first end (16) of the tractor (14), wherein the puller (20) extends within the catheter (12) to the proximal end of the catheter (12).

Document **D3** (Figs.) discloses a self propelled, endoscopic apparatus formed of a flexible, fluid filled toroid and motorized or powered frame.

The solution proposed in claim 1 of the present application meets the requirements under Articles 33(2) and 33(3) PCT because the prior art does not teach or fairly suggests the mechanical thrombectomy apparatus claimed.

3 Claims 2- 6 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date *(day/month/ year)*	Filing date *(day/month/ year)*	Priority date *(valid claim)* *(day/month/year)*
WO 2017/058280	06/04/1017	15/02/2016	28/09/2015

Re Item VII

Certain defects in the international application

4 Independent claim 1 is not in the two part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art **D1** being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

5 The features of claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

6 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in **D1**- **D3** is not mentioned in the description, nor are these documents identified therein.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
GWM-03-PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2018/040937	5 July 2018 (05-07-2018)	6 July 2017 (06-07-2017)
Applicant		
STRYKER CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [X] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 5

[X] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[ ] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A mechanical thrombectomy apparatus for removing a clot from a vessel includes an elongate inversion support catheter having a distal end opening, an elongate puller extending within the support catheter, and a knitted tractor tube (501) extending over an outer surface of the support catheter, inverting into the distal end opening of the support catheter, and attached to the elongate puller at a first end within the support catheter, wherein the portion of the knitted tractor tube extending over the support catheter comprises a wire forming a helical spiral of alternating teardrop shaped-links (503) each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, wherein the links flare outward from an outer wall of the support catheter when the puller is pulled proximally within the support catheter.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/040937

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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/040937

A. CLASSIFICATION OF SUBJECT MATTER
INV. 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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2017/086864 A1 (GREENHALGH E SKOTT [US] ET AL) 30 March 2017 (2017-03-30) paragraph [0021]; figures 1-6 paragraph [0064] paragraph [0121] - paragraph [0125] paragraph [0164]	1-22
Y	US 2013/226196 A1 (SMITH JAMES [ZA]) 29 August 2013 (2013-08-29) paragraph [0112] - paragraph [0114]; figures 4, 10	1-10
A	US 2010/249815 A1 (JANTZEN ALEXANDRA E [US] ET AL) 30 September 2010 (2010-09-30) abstract; figures 1, 2	1,10

-/--

[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
25 October 2018	14/11/2018

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	Moers, Roelof

2

Form PCT/ISA/210 (second sheet) (April 2005)

International application No
PCT/US2018/040937

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2016/074627 A1 (COTTONE ROBERT J [US]) 17 March 2016 (2016-03-17) paragraph [0095] - paragraph [0100]; figures 7A-8D	11-22
A	AU 2015 210 338 A1 (SHIFAMED HOLDINGS LLC) 27 August 2015 (2015-08-27) paragraph [0087] - paragraph [0092]; figures 3-7b	11-22
A	US 2005/177132 A1 (LENTZ DAVID J [US] ET AL) 11 August 2005 (2005-08-11) paragraph [0027]; figures 1-7	11,22

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/040937

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2017086864 A1	30-03-2017	CN 108348319 A	31-07-2018
		EP 3355829 A1	08-08-2018
		JP 2018529495 A	11-10-2018
		US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		WO 2017058280 A1	06-04-2017
US 2013226196 A1	29-08-2013	US 2013226196 A1	29-08-2013
		WO 2012049652 A1	19-04-2012
		ZA 201302264 B	30-04-2014
US 2010249815 A1	30-09-2010	NONE	
US 2016074627 A1	17-03-2016	CN 107148289 A	08-09-2017
		EP 3194003 A1	26-07-2017
		JP 2017532104 A	02-11-2017
		US 2016074627 A1	17-03-2016
		WO 2016044211 A1	24-03-2016
AU 2015210338 A1	27-08-2015	AU 2015210338 A1	27-08-2015
		AU 2018203003 A1	17-05-2018
US 2005177132 A1	11-08-2005	EP 1768732 A2	04-04-2007
		US 2005177132 A1	11-08-2005
		US 2010100073 A1	22-04-2010
		WO 2006009588 A2	26-01-2006

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10

Thrombectomy apparatus having knitted tractor tube.

---

2. claims: 11-22

Thrombectomy apparatus having slotted inversion support catheter.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2018/040937	05.07.2018	06.07.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/221

Applicant
STRYKER CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Moers, Roelof Telephone No. +31 70 340-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☑ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-22
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-22
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV

Lack of unity of invention

This Authority considers that the application does not meet the requirements of unity of invention and that there are 2 inventions.

The reasons, for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The common subject-matter of independent claims 1 and 10 and independent claims 11 and 22 is:

A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising: an elongate inversion support catheter; an elongate puller extending within the elongate inversion support catheter; and a tractor tube extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter.

This common subject-matter is known in the prior art, see for instance **US 2017/086864 A1 (D1)** (see claims 1, 11; fig. 1).

Therefore, these common features cannot form "special technical features" according to Rule 13(2) PCT.

D1 further discloses that the tractor tube can be knitted. Therefore, the remaining technical features of the first subject (claims 1 and 10) are formed by: the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter comprises a wire forming a helical spiral of alternating teardrop shaped-links each having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of the tractor tube, wherein the links flare outward from an outer wall of the elongate inversion support catheter when the puller is pulled proximally within the elongate inversion support catheter.

The remaining technical features of the second subject (claims 11 and 22) are formed by: the inversion support catheter being slotted comprising a spiral pattern having a plurality of slots arranged approximately transversely to a long axis of the elongate slotted inversion support catheter, wherein the slots have an open diameter of about 0.001 inches or less and wherein there are between 2 and 4 slots per circumferential turn of the spiral pattern.

Since these features are different and they solve different problems (I: how to provide improved retrieval of a clot; II: how to provide a catheter with buckling resistance and sufficient flexibility), there is a case of non-unity.

Hence, the following separate inventions or groups of inventions are not so linked as to form a single general inventive concept:
I claims 1-10: Thrombectomy apparatus having knitted tractor tube.
II claims 11-22: Thrombectomy apparatus having slotted inversion support catheter.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

SUBJECT I

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-10 does not involve an inventive step in the sense of Article 33(3) PCT.

Document **US 2017/086864 A1 (D1)** discloses (see paragraph [0021]; figures 1-6; paragraph [0064]; paragraph [0121] - paragraph [0125]; paragraph [0164]):
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 146 extending within the elongate inversion support catheter; and
a knitted tractor tube 244' extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter,
wherein the portion of the knitted tractor tube extending over the outer surface of the elongate inversion support catheter comprises a wire.

The shape of the knitted fibers is not defined further in D1. A knitted pattern normally includes loops. It is furthermore known to the skilled person that a pattern having a helical spiral of alternating teardrop shaped-links having a rounded apex, wherein each link is connected to two adjacent links so that the apex of each link is on an outward-facing surface of a tractor tube, wherein the links flare outward from when a puller is pulled proximally has a beneficial effect on grasping a clot to be removed.
Document **US 2013/226196 A1 (D2)** (see paragraph [0112] - paragraph [0114]; figures 4, 10) discloses a gripping device having an inversible member with such an arrangement.

The skilled person would provide the device of D1 with such a known pattern in order to increase the gripping properties and thus arrive at the subject matter of claim 1 without using any inventive skill.

From fig. 9 of D2 it can be seen that the grab width W of the links flaring outward is between 30-90% of the length L of the links.
Therefore, the subject matter of independent claim 10 also lacks inventive step.

Dependent claims 2-9 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, these features are either known from D1 or D2 or merely relate to minor modifications.

SUBJECT II

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 11-22 does not involve an inventive step in the sense of Article 33(3) PCT.

Document **US 2017/086864 A1 (D1)** discloses (see paragraph [0021]; figures 1-6; paragraph [0064]; paragraph [0121] - paragraph [0125]; paragraph [0164]):
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 146 extending within the elongate inversion support catheter; and a tractor tube 244' extending over an outer surface of the elongate inversion support catheter, inverting into the distal end opening of the elongate inversion support catheter, and attached to the elongate puller at a first end within the elongate inversion support catheter.

In paragraph [0157] it is further mentioned that the catheter may be constructed such that the tip does not buckle under the pull forces.
The skilled person, searching for a suitable non-buckling and flexible catheter would be aware that a plurality of thin slots in a spiral or non spiral pattern provides such flexibility. For instance document **US 2016/074627 A1 (D3)** (see paragraph [0095] - paragraph [0100]; figures 7A-8D) discloses such a slotted catheter, also having different sections for different flexibilities.
The skilled person would provide the apparatus of D1 with such a slotted catheter without using any inventive skill. The term "open diameter" is not clear (see point VIII below) but the dimension of 0.001 inches appears to be a normal value for a slotted

catheter having a size for entry in small blood vessels. See for instance also **US 2005/177132 A1 (D4)** (paragraph [0027]; figures 1-7).
Therefore, the subject matter of independent claims 11 and 22 lacks inventive step.

Dependent claims 12-21 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, these features are either known from D3 or D4 or merely relate to minor modifications.

Re Item VII

Certain defects in the international application

The independent claims are not in the **two part** form and the claims are not provided with **reference numerals**.

The application contains **non-SI** units and citations without also citing the published documents.

Re Item VIII

Certain observations on the international application

Although claims 1 and 10 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

In claims 11, 12 and 22 it is not clear what is meant by slots having an open diameter of about 0.001 inches. It would appear that slots have a width and a length.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 January 2002 (10.01.2002)

PCT

(10) International Publication Number
WO 02/02162 A2

(51) International Patent Classification[7]: A61M

(21) International Application Number: PCT/US01/20509

(22) International Filing Date: 28 June 2001 (28.06.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

09/605,143	29 June 2000 (29.06.2000)	US
09/756,476	8 January 2001 (08.01.2001)	US
09/891,141	25 June 2001 (25.06.2001)	US

(71) Applicant *(for all designated States except US)*: **CONCENTRIC MEDICAL, INC.** [US/US]; 2585 Leghorn Street, Mountain View, CA 94043 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SEPETKA, Ivan** [US/US]; 346 Costello Court, Los Altos, CA 94024 (US). **DIECK, Martin** [US/US]; 21105 Hazelbrook Drive, Cupertino, CA 95014 (US). **GIA, Son** [US/US]; 5065 Bengal Drive, San Jose, CA 95111 (US). **MILLER, John** [US/US]; 603 Vera Avenue, Redwood City, CA 94061 (US). **NGO, Tiffany, Tran** [US/US]; 2108-D Galveston Avenue, San Jose, CA 95122 (US). **PIERCE, Ryan** [US/US]; 728 Calderon Avenue, Mountain View, CA 94041 (US).

(74) Agent: **HOEKENDIJK, Jens**; 433 Airport Blvd., Suite 432, Burlingame, CA 94010 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

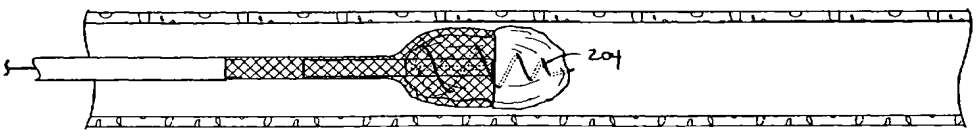
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SYSTEMS, METHODS AND DEVICES FOR REMOVING OBSTRUCTIONS FROM A BLOOD VESSEL



(57) Abstract: A system for removing an obstruction from a blood vessel includes an obstruction engaging element and an expandable capture element. The capture element preferably has a flexible cover and an expandable support structure. The engaging element engages the obstruction and moves the obstruction into the capture element. The capture element protects the obstruction when the obstruction is moved into the catheter.

WO 02/02162 A2

SYSTEMS, METHODS AND DEVICES FOR REMOVING OBSTRUCTIONS FROM A BLOOD VESSEL

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation in part of Serial No. 09/756,476, filed January 8, 2001, which is a continuation-in-part of Application Serial No. 09/605,143, filed June 29, 2000, entitled, "Methods and Devices for Removing an Obstruction From a Blood Vessel," by inventors Sepetka, et al., the full disclosures of which are incorporated herein by reference for all purposes.

BACKGROUND OF THE INVENTION

The present invention is directed to methods and devices for removing obstructions from blood vessels. The device may be used to retrieve and remove clots and other biological obstructions. The device may also be used to retrieve embolic coils and the like which have been misplaced or have migrated to an undesirable location.

One such obstruction removal device is disclosed in U.S. Patent No. 5,895,398 which is hereby incorporated by reference. The device has an expandable engaging member which is introduced into the blood vessel to engage the obstruction for removal.

The present invention is also directed to devices, systems and methods which use an expandable capture element when removing obstructions from a blood vessel. One such system for removing obstructions in a blood vessel is described in U.S. Patent No. 5,102,415 to Guenther et al. The system described in U.S. Patent No. 5,102,415 has a balloon catheter and a catheter having an expandable tip which receives the obstruction. The balloon catheter is passed through the obstruction while the balloon is deflated. The balloon is then inflated and the tip of the catheter is expanded. The balloon is then moved proximally so that the obstruction is pulled into the expanded tip of the catheter. A problem with the system of U.S. Patent No. 5,102,415 is that the interaction between the balloon catheter and the leading edge of the catheter may tend to shear off portions of the obstruction. This can cause obvious problems when working in sensitive vascular areas.

The present invention is directed to additional devices and methods for removing obstructions in a blood vessel.

SUMMARY OF THE INVENTION

In accordance with the present invention, device and methods for removing obstructions are provided. In a first aspect of the invention, an obstruction removal device is provided which has an obstruction engaging element extending from an insertion element. The engaging element is movable from a collapsed position to an expanded position. The engaging element forms coils having varying diameter wherein the coils at a distal portion are larger than coils at an intermediate portion. The distal portion forms a relatively closed structure which prevents the obstruction, or any part thereof, from migrating downstream. The distal portion is expanded distal to the obstruction while the proximal portion engages and holds the obstruction.

In another aspect of the present invention, another obstruction removal device is provided which has at least one closed loop and preferably two closed loops. The closed loop provides an advantage when advanced through a catheter or sheath in that the closed loop produces opposing radial forces on the catheter or sheath through which the loop is advanced. In this manner, the obstruction removal device can be advanced more easily through the catheter or sheath to prevent binding or kinking of the device during advancement. In a preferred embodiment, the obstruction removal device has two loops of varying diameter with the distal loop having a larger diameter. Each of the loops lie in a plane with the planes of the two loops preferably being perpendicular to one another.

In another aspect of the invention, another obstruction removal device is provided which has wound sections formed by one or more filaments which are separated by sections substantially free of the filaments. The intermittent wound sections provide discrete portions where the obstruction can be engaged. In an embodiment, the wound sections can slide on the core element to provide flexibility when advancing the obstruction removal device. The wound sections and sections free of filament are preferably about 1-5 mm long. The obstruction removal device preferably has at least three wound sections and more preferably at least five wound sections.

In still another aspect of the invention, another obstruction removal device is provided which has alternating large and small diameter portions. In a preferred embodiment, the obstruction removal device has at least four large diameter sections and three smaller diameter portions. The alternating large and small diameter portions may help to engage certain types of obstructions and can also help to prevent parts of the obstruction from breaking off and migrating downstream.

Any of the obstruction removal devices described herein may also be used with a source of power coupled to the obstruction removal device for use as described below. The source of power may simply produce a positive or negative charge or may be an RF energy source. The source of power may be used to help the obstruction removal device penetrate and engage the obstruction and may also be used to adhere the obstruction to the obstruction removal device as will be described. In a preferred embodiment, a negative charge is provided when advancing the obstruction removal device into the obstruction and a positive charge, or RF energy, is supplied to adhere the device to the obstruction.

The devices of the present invention may be manufactured in any suitable manner. In another aspect of the present invention, the obstruction removal device has a core element surrounded by a sheath. A strand, preferably about four strands, are positioned between the core element and the tube. The strand and the tube prevent any part of the obstruction removal device from breaking free should the core element fail. The strand and tube will hold the obstruction removal device together even if the core element breaks. The sheath is preferably flexible so that the sheath can undergo much larger deflections than the core element.

The obstruction removal devices of the present invention may also be advanced through a guide catheter having a flow restricting element which is preferably a balloon but may be any other suitable structure. The flow restricting element is expanded to reduce blood flow through the obstructed vessel to minimize the likelihood that the obstruction will migrate downstream.

In another aspect of the invention, a system is provided which has an expandable capture element and an obstruction engaging device which together work to remove an obstruction from a blood vessel. The capture element is advanced through the patient in a collapsed position and is expanded when at the desired location. The obstruction engaging device preferably has one or more filaments which provide a relatively flexible interaction between the engaging device and the capture element. This provides advantages over the use of a balloon catheter as described in greater detail below. The obstruction engaging device preferably has 1-4 filaments and more preferably 1-2 filaments. Of course, the obstruction engaging device may have more filaments without departing from various aspects of the invention and, in fact, the device may form a filter which further helps to prevent portions of the obstruction from being carried downstream.

The capture element is preferably naturally biased toward the expanded position although the capture element may also be manually actuated as described below. The capture element has a support structure with a flexible cover attached thereto. The support structure preferably has a closed loop which opens the distal end of the cover. The loop is preferably integrally formed and has a number of integrally formed hinges which deflect when the loop is expanded and collapsed. The hinges are preferably V-shaped although other shapes may be used. A plurality of struts extend proximally from the loop.

The capture element may also be expanded by the user so that the user may select the appropriate time for expansion of the capture element. In this manner, the user may advance the capture element to a suitable location for expansion. The user may also collapse the capture element before withdrawing the capture element into a catheter. The capture element has an actuator for opening and closing the capture element. The actuator may have a control arm and a stable arm although any suitable actuator may be used. The control arm is manipulated to expand and contract a loop at the distal end of the capture element. Alternatively, the actuator may be a tube which cinches the loop closed. In a specific embodiment, the capture element may also evert when moving to the expanded position.

The device of the present invention may be used in various different locations and for various different purposes. In one embodiment, the device may be used in connection with a guide catheter. When used with the guide catheter, the device may be expanded to slow or even stop blood flow when performing other procedures downstream of the guide catheter such as removing a clot or placing a stent.

Alternatively, the device may be passed through a conventional guide catheter so that the device may be introduced further into the vasculature. In this system, the capture element passes through the guide catheter. The obstruction engaging device is then used to engage the obstruction and move the obstruction into the capture element.

The present invention is also directed to methods and devices for removing an obstruction where the obstruction engaging element has a shape which traps the obstruction. In one aspect, the element extends proximally and then distally to ensnare the obstruction. The element may have such a shape naturally or may be moved into this shape by manipulating the element. For example, the element may be rotated in one or both directions to ensnare the obstruction. The element may have a portion which prolapses to capture the element as the element is manipulated.

In still another aspect of the invention, the capture element inverts when the obstruction is moved into the capture element. The obstruction is preferably engaged with an engaging element having a filament which ensnares the obstruction. The obstruction engaging element may be independent from the capture element or may be connected to the engaging element. The capture element inverts upon application of a compressive force to the inverting portion or upon any other suitable actuation force. The capture element preferably inverts when the compressive force is applied by either the obstruction or the engaging element.

The present invention is also directed to actuators for medical devices. In a first aspect, an actuator is provided which has an outer member and a plurality of fingers extending from the outer member. The fingers form an end that can be opened and closed by bending and straightening the fingers. The fingers may be bent by moving an inner member coupled to the fingers or by tensioning or releasing tension on a filament. The medical devices described above may be used for any suitable purpose including capture or containment of obstructions. For this purpose, the fingers or frame may be covered with the cover that forms an enclosure to hold the obstruction.

In another aspect, the medical device may have a frame that extends from inner and outer members. The frame forms an end that also opens and closes. The frame has a first set of connectors coupled to the outer member and a second set of connectors coupled to the inner member. The inner and outer members are movable relative to one another to open and close the end. The frame may be an integral structure with the structure being deformed when the end opens and closes. In still another aspect, the frame may be made of a shape memory material which regains either the closed or open position when heated or cooled. For example, the frame may be heated using electrical energy or other suitable source to actuate the frame.

These and other advantages of the invention will become apparent from the following description, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a system for removing an obstruction.

Figure 2 shows the obstruction removal device in a collapsed condition.

Figure 3 shows the obstruction removal device with a distal portion of the obstruction removal device expanded.

Figure 4 shows the obstruction removal device with a proximal portion expanded to engage an obstruction.

Figure 5 shows another obstruction removal device.

Figure 6 shows yet another obstruction removal device.

Figure 7 shows still another obstruction removal device.

Figure 8 is an end view of the obstruction removal device of Figure 7.

Figure 9 is an exploded view showing a method of constructing an obstruction removal device.

Fig. 10 shows another system for removing an obstruction from a blood vessel.

Fig. 11 shows a capture element in an expanded position with an obstruction engaging element engaging an obstruction

Fig. 12 shows the obstruction moved into the capture element with the obstruction engaging element.

Fig. 13 shows the capture element collapsed and contained within a catheter.

Fig. 14 shows an alternative structure for the capture element.

Fig. 15 shows another capture element.

Fig. 16 shows a distal end of the capture element of Fig. 15.

Fig. 17 shows the support structure for the capture element of Figs. 15 and 16.

Fig. 18 shows the capture element collapsed around the obstruction prior to withdrawal.

Fig. 19 shows the capture element contained within the catheter in an inverted position when collapsed.

Fig. 20 shows another support structure for the capture element with the support structure in an expanded position.

Fig. 21 shows the support structure of Fig. 20 in a collapsed position.

Fig. 22 shows still another support structure for the capture element.

Fig. 23 shows another capture element having a support structure which bows outward to preferentially close the distal end.

Fig. 24 shows the capture element of Fig. 23 with an obstruction contained within the capture element.

Fig. 25 shows another capture element.

Fig. 26 shows yet another capture element in an expanded position.

Fig. 27 shows the capture element of Fig. 26 in a collapsed position.

Fig. 28 shows another device for capturing an obstruction.

Fig. 29 shows the capture device of Fig. 28 advanced at least partially into engagement with the obstruction.

Fig. 30 shows an obstruction engaging element advanced through the capture element.

Fig. 31 shows the element engaging the obstruction.

Fig. 32 shows the obstruction partially contained within the capture element.

Fig. 33 shows the obstruction completely contained within an inverted portion of the capture element.

Fig. 34 shows still another device for capturing an obstruction.

Fig. 35 shows the element engaging the obstruction.

Fig. 36 shows the inverting portion beginning to invert to capture the obstruction.

Fig. 37 shows the obstruction partially contained within the capture element.

Fig. 38A shows the obstruction completely contained within the capture element.

Fig. 38B shows the inverting portion contained within another catheter such as the guide catheter for removal from the patient.

Fig. 39 shows the distal end of the device of Figs. 34-38 with the engaging element expanded.

Fig. 40 shows the distal end of the device of Figs. 34-38 with the engaging element collapsed.

Fig. 41A shows an actuator for a medical device having which has a deformable frame being used as an obstruction capture device.

Fig. 41B shows the capture device with an obstruction contained therein.

Fig. 42A shows the actuator of Fig. 40 with the distal end closed.

Fig. 42B shows the capture device withdrawn into another catheter.

Figs. 43A-D show the frame coupled to inner and outer members.

Fig. 44 shows another actuator having a frame made of a shape memory material.

Fig. 45 shows the actuator of Fig. 43 with the distal end closed.

Fig. 46 shows still another actuator for a medical device.

Fig. 47 shows the actuator of Fig. 46 with a plurality of fingers in a closed position.

Fig. 48 shows an alternate embodiment of the medical device of Figs. 45 and 46.

Fig. 49 shows the medical device of Fig. 48 with the fingers in a closed position.

Fig. 50 shows the actuator of Figs. 46-49 used to capture or remove an obstruction.

Fig. 51 shows the actuator of Figs. 46-49 with the distal end closed to capture the obstruction.

Fig. 52 shows another obstruction engaging element.

Fig. 53 shows the obstruction engaging element of Fig. 52 with the element engaging an obstruction.

Fig. 54 shows the obstruction engaging element of Figs. 52 and 53 with the element having a prolapsed portion.

Fig. 55 shows another obstruction engaging element in an expanded position.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figs. 1-4, a system 2 for removing an obstruction is shown. A guide catheter 4 is advanced to a location proximal to an obstruction. When accessing the cerebral vasculature, for example, the guide catheter 4 is often positioned in the carotid or vertebral artery. Of course, the guide catheter 4 may not be necessary or may be positioned in any other suitable location depending upon the location of the obstruction. The guide catheter 4 preferably has a flow restricting element 6 which restricts or even stops blood flow through the vessel as described below. The flow restricting element 6 is preferably a balloon 5 coupled to a source of inflation fluid 7 which is used to inflate the balloon 5.

An obstruction removing device 8 is advanced through the guide catheter 4 to the obstruction. A microcatheter 10 may also be positioned within the guide catheter 4 to deliver the obstruction removing device 8 further into the vasculature. The obstruction removing device may be advanced by itself through the microcatheter 10 or may be contained within a sheath 12 which is advanced through the microcatheter 10. A source power 14 may also be coupled to the obstruction removal device 8 for use in the manner explained below.

The power source 14 may simply produce a positive or negative charge or may be an RF or other suitable power source.

The obstruction removing device 8 has an engaging element 16 extending from an insertion element 18. The engaging element 16 is movable from a collapsed position (Fig. 2) to an expanded position (Figs. 3 and 4). When the engaging element 16 is contained within the sheath 12 or microcatheter 10, the engaging element 16 is in a relatively straight configuration. The engaging element 16 has a distal portion 20, 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 16 has a proximal portion 22 which is formed with smaller coils than the distal portion 20. The proximal portion 22 engages the obstruction as described below.

The engaging element 16 preferably has a number of markers 23, 25, 27 which provide an indication as to how much of the engaging element 16 extends from the sheath 12 or microcatheter 10. For example, markers 23, 25, 27 may indicate when the engaging element 16 is ½, ¾ or fully exposed. In this manner, the user may quickly advance the engaging element engaging element 16 through the sheath 12 or microcatheter 10 without inadvertently exposing and advancing the engaging element 16 out of the sheath 12 or microcatheter. The markers 23, 25, 27 can also be used to provide a controlled diameter of the engaging element 16 since the diameter of the engaging element 16 is known for the various positions corresponding to the markers 23, 25, 27. The markers 23, 25, 27 may also be used to size the vessel in which the engaging element 16 is positioned by observing when the engaging element 16 engages the vessel walls and determining the size of the engaging element 16 using the markers 23, 25, 27.

The insertion element 18 is preferably made of a superelastic material or stainless steel having a diameter of 0.004 to 0.038 inch and preferably about 0.010 inch. Although the insertion element 18 is preferably a solid, elongate element, the insertion element 18 may take any other suitable structure such as a hollow tube. The engaging element 16 is preferably made of a superelastic material, such as nitinol, and has a diameter of 0.005-0.018 inch, more preferably 0.005-0.010 inch and most preferably about 0.008 inch. The engaging element 16 has a rounded, atraumatic tip 24 to prevent damage to the vessel and facilitate advancement through the vessel, microcatheter 10 and/or sheath 12. A radiopaque wire 26, such as platinum ribbon 28 having a width of 0.004 inch and a thickness of 0.002 inch, is preferably wrapped around the engaging element 16 to improve radiopacity.

The device 8 is preferably self-expanding but may also be expanded with an actuator 29. The actuator 29 is preferably a thin filament which is tensioned to move the device 8 to the expanded position. An advantage of the invention is that the filament 29 extends through the same lumen as the device 8 thereby minimizing the overall size of the device. It is understood that throughout discussion of the devices and methods herein that any of the devices may be expanded using the actuator 29 rather than being self-expanding without departing from the scope of various aspects of the invention.

The device 8 may also include a cover 9 which extends between adjacent coils. The cover 9 may be a number of individual strands 11 which extend between the coils or may be an elastic membrane which covers the coils. The strands 11 are preferably elastic to stretch when the device 8 is expanded.

Use of the obstruction removing device 8 is now described. The guide catheter 4 is introduced into the patient and delivered proximal to the target vessel such as to the carotid or vertebral artery. The microcatheter 10 is then advanced through the guide catheter 4 further into the vasculature to a position proximal to, within or distal to the obstruction. The obstruction removal device 8 is then advanced through the microcatheter 10 either by itself or pre-loaded within the sheath 12. The obstruction removal device 8 is then advanced to the obstruction. Before advancing the obstruction removal device 8 further, the flow restricting element 6 on the guide catheter 4 is expanded to reduce and even stop flow through the vessel. Stopping flow in the vessel may help prevent the obstruction, or any parts thereof, from migrating downstream. Reducing flow through the vessel may also reduce the likelihood that the obstruction is disrupted by a combination of flow and the obstruction removal device 8.

The obstruction removal device 8 is then placed into the obstruction and preferably through the obstruction. The engaging element 16 is then advanced out of the microcatheter 10 or sheath 12 to permit the distal portion 20 of the engaging element 16 to expand at a location beyond the obstruction. In this manner, the relatively closed distal portion 20 prevents the obstruction, or any part thereof, from migrating downstream. The proximal portion 22 is then advanced out of the sheath 12 or microcatheter 10 so that the smaller coils of the proximal portion 22 engage the obstruction as shown in Fig. 4.

Referring to Fig. 5, another obstruction removal device 8A is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8A has a first section 30 with larger diameter coils than a second section 32.

A third section 34 also has larger coils than the second section 32 with the second section 32 positioned between the first and third sections 30, 34. The obstruction removal device 8A may have a number of alternating small and large sections 30, 32, 34 which can enhance the ability of the obstruction removal device 8A to engage various obstructions. In the preferred embodiment of Fig. 5, the obstruction removal device 8A has four large sections 32, 34 with relatively large coils and three sections 30 having smaller coils.

The obstruction removal device 8A may be used in any suitable manner to engage the obstruction. For example, the microcatheter 10 or sheath 12 may be advanced through the obstruction and then retracted to expose the obstruction removal device 8A. The obstruction removal device 8A is then retracted into the obstruction to engage the obstruction. The obstruction removal device 8A may be rotated when moved into the obstruction to take advantage of the generally helical shape of the obstruction removal device. The obstruction removal device 8A may also be used to engage the obstruction by simply retracting the microcatheter 10 or sheath 12 with the obstruction removal device 8A expanding within the obstruction. Finally, the engaging element 16A may be exposed and expanded proximal to the obstruction and then advanced into the obstruction. When advancing the obstruction removal device 8A into the obstruction, the user may also twist the obstruction removal device 8A to take advantage of the generally helical shape. The alternating large and small sections 30, 32, 34 enhance the ability of the engaging element 16A to engage varying shapes and sizes of obstructions.

Referring to Fig. 6, still another obstruction removal device 8B is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8B has the insertion element 18 with an engaging element 16B extending therefrom. The engaging element 16B forms a helical coil 38 with a generally frustoconical shape, however, the engaging element 16B may take any other shape without departing from the scope of the invention including any shape disclosed in this application or any patent incorporated by reference herein.

A filament 40, preferably a radiopaque filament, is wrapped around the engaging element 16B. The filament 40 is wrapped somewhat loosely around the engaging element 16B so that the filament 40 provides additional surface area to engage the obstruction. The filament 40 forms a wound section 42, and more preferably at least five wound sections 42, which are separated by substantially exposed sections 44 of the engaging element 16B. The wound and exposed sections 42, 44 may be 1-5 mm long. Stated another

way, the wound and exposed sections 42, 44 are at least 1 mm, more preferably at least 3 mm long, and no more than 8 mm long. The wound sections 42 may be formed by a single filament 40 which extends continuously between the wound sections 42 or may be formed by independent filaments 40 at each wound section 42 which are attached to the engaging element 16B.

The wound sections 40 may be movable along the engaging element 16B to provide flexibility when advancing the obstruction removal device 8B through small and tortuous vessels. The movable wound sections 40 may also allow different parts of the obstruction removal device 8B to grip different parts of the obstruction to hold the obstruction together or engage different parts of the obstruction. The obstruction removal device 8B is used in substantially the same manner as the other obstruction removal devices described herein. The obstruction removal device 8B has a handle 41 with a lead screw 43 which engages threads 55. The handle 41 is rotated to advance and retract the engaging element 16B.

Referring to Fig. 7, still another obstruction removal device 8C is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8C has an engaging element 16C , which forms a first closed loop 50, and a second closed loop 52. The first loop 50 is preferably somewhat larger than the second closed loop 52 with the first loop 50 having a diameter of about 1.5-8.0 mm and the second loop 52 having a diameter of about 1.5-6.0 mm. A tip 54 extends from the first loop 50 for a distance of about 5 mm. A radiopaque element 56, such as platinum ribbon, is preferably wrapped around the loops 50, 52 to improve radiopacity and to enhance the ability of the engaging element 16C to hold the obstruction. The radiopaque element 56 also may provide advantages when engaging an obstruction in a manner similar to the obstruction removal devices described above with reference to Fig. 6.

An advantage of the obstruction removal device 8C is that the loops 50, 52 exert substantially equal and opposing forces on the sheath 12 or microcatheter 10 through which the obstruction removal device 8C is advanced. In this manner, kinking or binding of the obstruction removal device 8C during advancement can be minimized or reduced altogether. Referring to the end view of Fig. 8, the first and second loops 50, 52 preferably lie in first and second planes 58, 60, respectively, which are preferably perpendicular to one another.

Another method of aiding mechanical capture of an obstruction is to coat the

device and elements of the present invention with a material 61 which helps to adhere the obstruction, and in particular thrombus, to the device or element. The material 61 is preferably fibrin but may be any other suitable material. Use of the material 61 may be incorporated into any of the devices described herein or other suitable device such as the devices shown in Figs. 2-8, 22 or 30.

Referring to Fig. 9, an exploded view of a construction of the obstruction removal device 8, 8A, 8B, 8C is shown. A tube 62, which is preferably a thermoplastic polymer such as polyester or urethane is positioned over a core element 64. As mentioned above, the core element 64 is preferably a superelastic or stainless steel element at either the insertion element 18 or the engaging element 16 (Figs. 2-7). A reinforcing strand 66 is trapped between the tube 62 and the core element 64 to reinforce the obstruction removal device. The strand 66 is preferably small and has a diameter or thickness of less than 0.005 inch, more preferably less than 0.0001 inch, so that the overall size of the obstruction removal device is not increased significantly with use of the strand 66. The strand 66 may be made of any suitable material including VECTRAN made by Celanese Acetate LLP or DACRON or KEVLAR which are both manufactured by Dupont. VECTRAN is a thermoplastic multifilament yarn spun from a liquid crystal polymer.

The strand 66 provides a degree of safety in that the strand 66 and tube 62 together prevent any part of the obstruction removal device from breaking free from the rest of the device. The tube 62 will resist breaking since it is more flexible than the core element 64 and can undergo larger deflections and displacements without breaking. In a preferred embodiment, 2-8 strands 66, preferably about 4 strands 66, are used. The overall size of the device is also relatively small with the outer diameter of the resulting structure being no more than 0.020 inch and more preferably no more than 0.012 inch.

The power source 14 may be also be used with any of the obstruction removal devices in the following manner, however, the methods and devices of the present invention may, of course, be practiced without the power source 14. As mentioned above, the power source 14 may simply produce a charge at the engaging element 16 or may be a source of RF energy. In one particular method of the present invention, the power source 14 produces a negative charge while advancing the engaging element 16 through the obstruction. The negative charge may aid in passing the engaging element 16 through the obstruction and may help to dissolve part of the obstruction. The power supply is then changed to produce a positive charge to adhere the obstruction to the engaging element 16. Alternatively, the

power source 14 may be an RF energy source, which delivers RF to the engaging element 16 which also adheres the obstruction to the engaging element 16 and may help provide a controlled penetration into the obstruction. The obstruction is then removed by moving the obstruction into the guide catheter 4, which is then withdrawn to remove the obstruction. Use of the power source 14 is particularly useful when the obstruction is a biologic structure such as a clot.

Referring to Figs. 10-14, another system 100 for removing an obstruction is shown. The system 100 is particularly useful for removing clots and thrombus from blood vessels but may also be used to remove other obstructions such as embolic coils and the like. The system 100 includes an expandable capture element 102 and an obstruction engaging device 106 which work together to capture the obstruction. The obstruction engaging device 106 engages the obstruction and moves the obstruction into the capture element 102 as described below. After the obstruction has been captured, the capture element 102 may then be used in various ways for ultimate removal of the obstruction. The capture element 102 may be advanced through the guide catheter 4 or through another catheter 107 which is advanced through the guide catheter 4. As will be explained below, the capture element 102 is preferably advanced over the obstruction engaging device 106.

The obstruction engaging device 106 may be any of the engaging or removal devices described herein or any other suitable device. Various aspects of the invention preferably include one or more features of the obstruction removing devices described herein and all aspects, features, dimensions, and characteristics of the obstruction removing and engaging devices described herein are incorporated here. It is understood that the term obstruction removal device and obstruction engaging device are interchangeable. The obstruction engaging device 106 may be contained within the sheath 12 or may be advanced by itself through the guide catheter 4 and/or catheter 107.

The engaging device 106 may have one or more filaments 108, preferably 1-4 and more preferably 1-2 filaments, which engage the obstruction. The filament 108 forms a relatively small, flexible interaction between the engaging device 106, capture element 102 and obstruction which provides advantages over the prior art method of using a balloon catheter. The filament 108 may deflect and displace to accommodate the geometry and orientation of the obstruction when the obstruction enters the capture element 102. The interaction between the balloon catheter and the expandable catheter of the prior art tends to shear off portions of the obstruction due to the relatively rigid interaction between the balloon

catheter and expanded catheter. The filament 108 also has a relatively small size which further enhances the flexibility of the obstruction engaging device 108. The filament 108 may also form one or more loops 110 which further serve to create a soft, flexible interaction between the obstruction engaging device 106 and capture element 102. The filaments 108 may also form a filter which further prevents the obstruction or portions thereof from travelling downstream.

The capture element 102 preferably has a support structure 112 with a flexible cover 114 attached thereto. The support structure 112 is preferably self-expanding although the support structure 112 may also be selectively expanded by the user as explained below. The support structure 112 preferably has a loop 116 having integrally formed hinges 117. The hinges 117 are preferably formed by V-shaped interconnecting elements 120 although other shapes, such as U-shaped, may be used. The loop 116 is preferably formed as an integral structure with the loop 116 being formed from a tube of material which is cut, etched, treated or otherwise formed into the loop 116 with hinges 117. The loop is preferably made of a superelastic material although any suitable material may be used.

Struts 122 extend proximally from the loop 116. The struts 122 do not intersect and generally form a cone 124 when expanded. The struts 122 are coupled to a lumen 121 which receives the engaging device 106 so that the capture element 102 can be advanced over the engaging device 106 as described below. Referring also to Fig. 14, the struts 122 may also be coupled together at a hub 126 at the proximal end. The hub 126 has a lumen 127 which receives the engaging device 106. A shaft 128 extends from the hub 126 and is used to manipulate the capture element 102. The struts 122 are preferably made of a superelastic material or stainless steel and are attached to the closed loop 116 by soldering, welding, glue or any other suitable attachment method. The struts 122 may also be integrally formed with the loop 116. Of course, the supporting structure 112 may be made of any other suitable material and may be formed in any other suitable manner. The struts 122 may also be bowed outward so that the distal end of the device is preferentially closed before the entire device has been withdrawn as shown in Figs. 23 and 24.

The cover 114 is preferably attached to the support structure 112 with glue, thread, suture or any other suitable method. The cover 114 preferably lies over the support structure 112 but may also be contained within the support structure 112. The cover 114 is relatively long to ensure that the entire obstruction is captured. The cover 114 is preferably at least three times, more preferably at least five times, and most preferably at least seven times

larger than the maximum expanded diameter of the support structure 112 or cover 114. Of course, the capture element 102 may have any other suitable dimensions depending upon the particular application. The cover 114 is preferably made of ePTFE but may be made of any other suitable material. The cover 114 may also be a mesh-like structure, or any other suitable expandable structure which can contain the obstruction and parts thereof, without departing from the scope of the invention.

Various methods of the present invention are now described. The methods are described in connection with system 100 of Figs. 10-14 but may be practiced with other suitable devices and systems. The present invention is well-suited for use in the cerebral vasculature and a cerebral application is described, however, the invention may be practiced in other vascular locations as well.

The guide catheter 4 is advanced to a suitable location. The obstruction engaging device 106 is then advanced through the guide catheter 4. Referring to Figs 11 and 12, the obstruction engaging device 106 is then used to engage the obstruction in any manner described herein. For example, the sheath 10 (see Fig. 10) may be advanced through the obstruction and then retracted so that a proximal portion 111 of the device 106 is contained within the obstruction. The device 106 is then moved proximally, and is preferably twisted, so that the loops 110 engage the obstruction. In the specific embodiment of Figs. 11-14, the device 106 ensnares the obstruction with the loops 110 when twisted and moved proximally.

The capture element 102 is then advanced over the engaging device 106. The capture element 102 may be advanced through the guide catheter 4 or may be advanced through the catheter 107 which is advanced through the guide catheter 4 further into the cerebral vasculature. The capture element 102 is then moved out the catheter 107 or guide catheter 4 so that the capture element 102 expands. The obstruction is then moved into the capture element 102 with the device 106 as shown in Fig. 13. When the obstruction is contained within the capture element 102, the capture element 102 is then withdrawn into the catheter 107 or guide catheter 4 as shown in Fig. 14. The catheter 107 and/or guide catheter 4 are then withdrawn from the patient thereby withdrawing the obstruction.

It may be desirable to reduce or even stop blood flow through the blood vessel during the procedure to reduce flow forces on the obstruction when manipulating the obstruction. Reducing flow in the vessel may also prevent some parts of the obstruction from breaking off and flowing downstream before entering the capture element 102. Referring again to Figs. 10 and 22, blood flow may be reduced by inflating a balloon 131 on the guide

catheter 4 or the catheter 107. The balloon 131 is inflated using a suitable source of inflation fluid 133. Alternatively, the capture element 102 itself may also be used to reduce blood flow through the vessel. The capture element 102 naturally impedes blood flow since it expands within the blood vessel. The capture element 102 may also be designed to only partially occlude the vessel so that some blood flow is provided to the area downstream from the capture element 102. The device 102 may be modified to include a second loop130 extending between the struts 122 to enhance the ability of the device 102 to occlude the vessel. The loop 130 preferably has the features of the loop 116. Although it is preferred to reduce or even stop flow in the vessel, the invention may also be practiced without reducing blood flow.

The devices and methods of the present invention may also be practiced with a source of vacuum 135 providing suction during capture of the obstruction. The source of vacuum 135 may be activated during engagement of the obstruction with the device 106, movement of the obstruction into the capture element 102, and/or withdrawal of the capture element 102 into the catheter 107 or guide catheter 4. The source of vacuum 135 is coupled to the guide catheter, 4, catheter 107 and lumen 121 for these purposes.

Referring to Figs. 10 and 15-17, another capture element 132 for removing an obstruction is shown wherein the same or similar reference numbers refer to the same or similar structure. The capture element 132 is selectively expandable by the user which provides various advantages described below. The cover 114 is attached to a catheter 134 near or at the distal end 135. The catheter 134 may be the guide catheter 4 or the catheter 107 in the system 100 described above. An expandable and collapsible loop 136 is attached to the distal end of the cover 114 to expand and collapse the distal end of the cover 114. The loop 136 is expanded and collapsed by manipulating an actuator 138 which includes a control arm 140 and a stable arm 142. The control arm 140 extends and slides through an eyelet 144 when expanding and collapsing the loop 136. The stable arm 142 extends from the loop 136 at or near the eyelet 144 to stabilize the loop 136 when moving the control arm 140. The cover 114 is attached to the loop 136 using any suitable method. For example, the distal end may be inverted to create a fold 141 which surrounds the loop 136.

Another advantage of the capture element 132 is that the capture element 132 may be selectively expanded and contracted by the user. The capture element 132 may be fully or partially collapsed to trap the obstruction prior to withdrawal of the capture element 132 into the catheter 107 or guide catheter 4 as shown in Fig. 18. In fact, the capture element

132 may be withdrawn by itself by simply closing the distal end and withdrawing the capture element 132. In this manner, the capture element 132 protects the obstruction during withdrawal and prevents the obstruction from escaping. This provides obvious advantages over the system of Guenther described above.

Referring to Figs. 10 and 19, still another capture element 150 is shown in which the same or similar reference numbers refer to the same or similar structure. The capture element 150 has the cover 114 and the actuator 138 which includes the stable arm 142, control arm 140, and loop 136 although other actuating structures may be used. The capture element 150 is contained within the catheter 107 or the guide catheter 4 during introduction and is then everted out of the catheter 107 or catheter 4 when deployed. The capture element 150 may be used in substantially the same manner as the other capture elements described herein and in particular the capture element 132 of Figs 15-17. The capture element 150 may also be used to further collapse the cover 114 since the actuator 138 may be used to close the distal end with the cover 114 deployed. After the obstruction is contained within the capture element 150, the capture element 150 is withdrawn into the catheter 107 or catheter 4. Although it is preferred to withdraw the capture element 150 into the catheter 4 or catheter 107, the capture element 150 may be collapsed and then inverted back into the catheter 4, 107 thereby trapping the obstruction in the catheter 4, 107 itself.

Referring to Figs. 20 and 21, the distal end of yet another capture element 152 is shown in which the same or similar reference numbers refer to the same or similar structure. The capture element 152 has a self-expanding support structure 154 with an expandable loop 156 at the distal end. The loop 156 has a tube 158 which receives a wire 160 at both ends. The slidable connection between the tube 158 and wire 160 permits the loop 156 to contract and expand between the positions of Figs. 20 and 21. Struts 162 extend from the loop which engage the catheter to collapse the loop 156. The cover 114 is attached to the loop 156 by any suitable method. The capture element 152 is used in any manner described herein. The capture element 152 is used in any manner described herein and those methods are incorporated here.

Referring to Fig. 25, still another device 170 is shown wherein the same or similar reference numbers refer to the same or similar structure. The device 170 is similar to the device of Fig. 15 in that the device 170 may be selectively expanded and collapsed by the user. The device 170 has a collar 172, which may also be a continuous sheath or tube, which slides over the catheter 107 or sheath 12. The engaging device 106 passes through the

catheter 107 or sheath 12 (Fig. 10) and is used in the manner described herein. A 174 wire, or other elongate member, is coupled to the collar 172 for advancing and manipulating the collar 172.

The cover 114 is coupled to a loop 176 which is selectively expanded by the user as now explained. The loop 176 is manipulated with the actuator 138 which may be any suitable mechanism. The actuator 138 has a wire 139 passing through an actuator tube 178 and may also include the stable arm 142. The wire 139 is coupled to the loop so that movement of the wire 139 opens and closes the loop 176. The actuator tube 178 may be simply advanced to cinch the loop 176 closed. The loop 176 is preferably naturally biased toward the open position and is held closed by the tube 178.

The device 170 is used in substantially the same manner as the other devices described herein and discussion of those methods are specifically incorporated here. The device 170 may be advanced by itself through the vasculature with the tube 178 holding the loop 176 in the closed position. The cover 114 is advanced by manipulating the tube 178, wire 139 and wire 174. The cover 114 is advanced over the catheter 107 or sheath 12 and the tube 178 is retracted to permit the loop 176 to expand. The obstruction is then introduced into the cover 114 and the cover 114 is then closed by advancing the tube 178 to cinch the loop 176 closed. The actuator 138 may also be manipulated to open or close the loop 176 together with the tube 178 or independently of the tube 178.

Referring to Figs. 26 and 27, still another device 180 is shown wherein the same or similar reference numbers refer to the same or similar structure. The device 180 has the cover 114 and a loop 182 coupled to the distal end of the cover 114. Stabilizing struts 184 extend from an end 186 of a tubular body 188 to the loop 182. Actuating arms 190 extend through the body 188 and are also attached to the loop 182. The arms 190 are manipulated to move the loop 182 between the collapsed and expanded positions of Figs. 26 and 27. The engaging device 106 passes through the body 188 and may be delivered through the catheter 107 or sheath 12. The device 180 is used in substantially the same manner as the device of Fig. 15 and discussion of those methods are incorporated here.

Referring to Figs. 28-33, another capture element 200 is shown for capturing an obstruction. The capture element 200 has an inverting portion 202 that inverts to entrap the obstruction. The capture element 200 is then withdrawn into the guide catheter 4 (Fig. 1) for removal of the obstruction from the patient.

Referring to Fig. 31, the engaging element 204 is shown engaging the obstruction. The element 204 may be any suitable element such as the obstruction engaging elements and removal devices described herein. The element 204 passes through a lumen 205 in the capture element 200. The engaging element 204 may be advanced through the capture element 200 by itself or may be contained within the microcatheter 10 or sheath 12 (Figs. 1 and 2) which is advanced through the capture element 200.

The capture element 200 has a distal portion 207 which is flexible and which may be partially contained, engaged or otherwise in contact with the obstruction as shown in Fig. 29. The distal portion 207 may also invert but preferably does not invert. The distal portion 207 necks-down at a distal end 209 to a size smaller than the guidewire GW so that the capture element 200 is advanced together with the guidewire. Of course, the capture element 200 may also be advanced by itself after introduction of the guidewire and may be contained within or advanced over another catheter without departing from the invention.

The element 204 engages the obstruction in any suitable manner. The inverting portion 202 is then inverted by applying a compressive force to the inverting portion 202. The compressive force is applied by moving the capture element 200 relative to the engaging element 204 which causes the element 200 and/or obstruction to compress the inverting portion. Continued relative movement moves the obstruction into the inverted capture element 200 as shown in Figs. 32 and 33 to capture the obstruction. The capture element 200 is then moved into the guide catheter 4 (Fig. 1) for removal from the patient. The capture element 200 may be made of any suitable materials. For example, the distal portion 207 may be made of any suitable polymeric material such as those described herein and the inverting portion 202 may be made of a braided or woven material or fabric made of fibers or filaments of nitinol, stainless steel, polymer or other material.

Referring to Figs. 34-40, another capture element 210 for removing an obstruction is shown wherein the same or similar reference numbers refer to the same or similar structure. The capture element 210 also has an inverting portion 212 connected to an end 213 of a delivery element 214 which may be a hollow tube, sheath or catheter. The distal end of the capture element 210 has a collar 214 attached to a proximal end 216 of an engaging element 218. A distal end 220 of the obstruction engaging element 218 is attached to an inner element 222 such as a wire, mandrel or guidewire. The collar 214 slides over the inner element 222 so that when the inner element 222 and delivery element 214 are movable relative to one another. Relative movement between the inner element 222 and delivery

element 214 moves the obstruction engaging element 218 between the expanede and collapsed positions (Figs. 39 and 40) and also can collapse the capture element 210. The engaging element 218 is similar to the other elements and devices described herein in that the element has a filament 224 which is tensioned to collapse the filament 224. The filament 224 forms coils 226 around the inner element 222.

The capture element 210 and obstruction engaging element 218 are advanced through the patient in either the sheath 12 or microcatheter 10 (Figs. 1 and 2). The capture element 210 and obstruction engaging element 218 are then positioned distal to the obstruction and the obstruction is engaged with the element 218. The capture element 210 and engaging element 218 are then moved relative to one another to invert the capture element 210 as described above.

Referring to Figs. 41-43, another aspect of the present invention is shown which provides an actuator 228 for a medical device 230. The actuator 228 may be used for actuating any medical device and a specific example is a capture element or an obstruction removal device. The medical device 230 has a frame 232, an outer member 234 and an inner member 236 positioned within the outer member 234. The frame 232 extends distally from the inner and outer members 236, 234.

The frame 232 has a distal end 238 which moves between the open (Figs. 41A and B) and closed (Figs. 42A and B) positions. The frame 232 has a first set of connectors 240 coupled to the outer member 234 and a second set of connectors 242 coupled to the inner member 236. The inner and outer members 236, 234 are moved relative to one another so that the frame 232 is deformed to open and close the distal end between the positions of Figs. 41A and B and 42A and B. The inner and outer members 236, 234 are preferably tubes but may be any other suitable structure that permits longitudinal movement of the connectors 240, 242 in the manner described. The connectors 240, 242 extend longitudinally to a ring 241 formed of V-shaped elements 243. The connectors 240 attached to the inner member 236 are coupled to intersections 245 of the ring 241 and the other connectors 240 are attached to the other intersections 247 of the ring. Stated another way, the connectors 240, 242 are attached at spaced apart positions on the ring with one connector 240 between each pair of connectors 242. The frame 232 is preferably integrally formed in a manner similar to a stent. For example, the frame 232 may be formed by removing material from a tube to provide the frame structure.

A cover 233 may be provided over or under the frame 232 so that the frame 232 acts as an actuator 244 to open and close the cover 233. The cover 233 may be used in the same manner as any of the capture elements described herein. To this end, any of the obstruction engaging elements described herein may be used with the device to trap and remove obstructions.

Referring to Figs. 44 and 45, still another medical device 250 is shown which is similar to the medical device 230 of Figs. 41-43. The medical device also has a frame 252 having a distal end 254 which opens and closes. The frame 252 is made of a shape memory material which either recovers the open or closed position when heated. The shape memory material may be heated in any suitable manner including use of a heated fluid or by applying electrical energy which heats the frame 252 to cause the frame to assume the recovered shape. Fig. 45 shows the frame 252 assuming the collapsed shape upon application of electrical energy from an energy source 253. The cover 233 may also be provided so that the frame acts as an actuator for still another capture device. Figs. 45 show the medical device 250 being used to capture an obstruction. The device 250 is then withdrawn into the guide catheter or other suitable catheter for removal of the obstruction.

Referring to Figs. 46-51, still another actuator for a medical device 256 is shown. The characteristics of the medical device 256 may be used to form any device. The medical device 256 has a plurality of longitudinally extending fingers 258. The fingers 258 are normally in a relatively straight configuration. The fingers 258 are bent inward so that a distal end 260 closes (Fig. 47). The fingers 258 may be attached to the cover 233 to open and close the cover 233 with the fingers 258. The fingers 258 are preferably bent by tensioning flexible, elongate members 262. The elongate members 262 may be attached to an inner member 264 (Figs. 46 and 47) or an outer member 265 (Figs. 48 and 49). Any of the obstruction engaging elements may be used with the medical device to remove an obstruction in any manner described herein. For example, Figs. 50 and 51 show the medical device 256 being used to capture or remove an obstruction. The device 256 may be used to capture or engage the obstruction by itself or in cooperation with any a suitable engaging element 257.

Referring to Figs. 52-55, another obstruction engaging element 270 is shown. The obstruction engaging element 270 includes a filament 272 which forms windings or coils 274. The windings 274 may take any suitable shape such as helical. The obstruction engaging element 270 is advanced to an obstruction in any manner described herein. For example, the obstruction engaging element 270 may be contained within the sheath 12 or

catheter 10 (Figs. 1 and 2) and advanced through the obstruction. The obstruction engaging element 270 is then advanced out of the sheath 12 or catheter 10 (Figs. 1 and 2) to permit the obstruction engaging element 270 to expand.

When the element initially expands, the coils 274 do not overlap when viewed along a longitudinal axis L. The element 270 is then engaged by manipulating the element 270. After the obstruction has been engaged, the element 270 is rotated which tends to open the coils 274. This causes one or more proximal coils 274 to prolapse over other coils to ensnare the obstruction. Stated another way, the element 270 initially extends distally in a relatively continuous manner. After rotating the element 270, the element extends distally, then proximally, then distally again. Stated yet another way, the coils are manipulated so that they appear to overlap when viewed along the longitudinal axis L. The prolapsed or overlapping coils 274 may provide an even more secure engagement to the obstruction. The element 274 may also be formed to have the overlapping or prolapsed sections when in the natural, unbiased and expanded position as shown in Figs. 54.

While the above is a description of the preferred embodiments of the invention, various alternatives, substitutions and modifications may be made without departing from the scope thereof, which is defined by the following claims. Thus, the preferred embodiments should not be taken as limiting the scope of the invention. For example, although all of the obstruction removal devices described herein are self-expanding structures, the obstruction removal devices may also have actuating mechanisms for moving the engaging element between the expanded and collapsed positions. Furthermore, the present invention is directed to a number of separate inventions and each of these inventions may be claimed independently of one another. Each feature, aspect and advantage of the invention may be claimed independent of one another without departing from the scope of the invention. For example, use of the power source 14 is independent of the using the intermittent wound sections 42 but may be used with any of the devices and methods described herein. As a further example, any engaging device, even a balloon, may be used with some of the inventive aspects of the capture element and any capture element may be used with inventive aspects of the engaging device.

The obstruction engaging element may be used in any manner described herein and all such methods, devices and systems form part of the present invention. It can be appreciated that various aspects of each of the obstruction engaging elements may be practiced with various aspects of the capture element and, thus, all such combinations are, of

course, contemplated whether or not all such combinations are specifically identified herein. Finally, the devices of the present invention may also be used in connection with simply controlling blood flow through an area and not necessarily with removal of an obstruction. Thus, it is understood that various aspects of the present invention are not limited to removal of obstructions. Thus, the invention does not include a single essential feature, aspect or advantage and the invention should not be limited as such.

WHAT IS CLAIMED IS:

1. A method of removing an obstruction, comprising the steps of:

providing an obstruction removing device, the obstruction removing device having an element movable from a collapsed position to an expanded position, the element being contained within a lumen in a delivery device in the collapsed position;

advancing the delivery device through the patient's vascular system to an obstruction in a vessel;

expanding at least part of the engaging element toward the expanded position;

coupling the engaging element to a supply of power;

moving the engaging element into contact with the obstruction; and

supplying power to the element when the engaging element is in contact with the obstruction.

2. A method of constructing an obstruction removing device, comprising the steps of:

providing an elongate element;

positioning at least one strand against the elongate element; and

positioning a tube over the fiber to trap the fiber.

3. An obstruction removal device, comprising:

an insertion element having an expandable element extending from the insertion element;

at least one strand extending along at least the expandable element; and

a tube of material which traps the at least one strand.

4. The device of claim 2, wherein:

the strand has a diameter of less than 0.005 inch.

5. The device of claim 4, wherein:

the strand is a thermoplastic multifilament yarn spun from a liquid crystal polymer.

6. The device of claim 2, wherein:

the elongate element being made of superelastic material.

7. The device of claim 2, wherein:
the elongate element having a diameter of 0.005-0.018 inch.

8. The device of claim 2, wherein:
the elongate element being biased toward an expanded position.

9. The device of claim 2, wherein:
the elongate element has an diameter of 0.005-0.010 inch.

10. A kit for removing an obstruction in a blood vessel, comprising:
an obstruction removing device having an elongate insertion element and an expandable obstruction engaging element extending from the elongate insertion element; and
a catheter having an expandable balloon mounted thereto, the catheter having at least one lumen sized to receive the obstruction removal device.

11. A method of removing an obstruction in a blood vessel, comprising the steps of:
providing an obstruction removal device and a guide catheter, the obstruction removing device having an elongate insertion element and an expandable obstruction engaging element extending from the elongate insertion element, the guide catheter having a flow restricting element mounted thereto, the delivery catheter having at least one lumen sized to receive the obstruction removal device;
advancing the obstruction removal device through the guide catheter to an obstruction in a blood vessel;
expanding the flow restricting element to at least reduce blood flow in the blood vessel;
engaging the obstruction with the obstruction removal device while the flow restricting element is expanded; and
removing the obstruction.

12. An obstruction removal device, comprising:
an elongate element extending from an insertion element, the elongate element being movable from a collapse position to an expanded position, the elongate element

forming helical coils having varying diameter, wherein the coils at a distal portion are larger than the coils at an intermediate portion.

13. The device of claim 12, wherein:

the elongate element has a proximal portion which has coils which are larger than the coils at the intermediate portion.

14. A method of removing an obstruction from a patient, comprising the steps of:

providing an obstruction removal device, the obstruction removal device having an engaging element extending from an insertion element, the engaging element being movable from a collapsed condition to an expanded condition, the engaging element having a proximal portion and a distal portion;

passing the obstruction removal device through an obstruction in a vessel with the engaging element in the collapsed position;

expanding the distal portion at a location distal to the obstruction so that the distal portion forms a trap to prevent the obstruction from traveling downstream; and

engaging the obstruction with the proximal portion of the obstruction removal device after the expanding step.

15. An obstruction removal device, comprising:

an elongate insertion element; and

an obstruction engaging element extending from the insertion element, the obstruction removing element being movable from a collapsed position to an expanded position, the obstruction removing device forming at least one closed loop in the expanded position, the closed loop exerting substantially equal and opposing radial forces when collapsed.

16. The device of claim 15, wherein:

the obstruction engaging element forms at least two loops in the expanded position, a first loop lying in a first plane when expanded and a second loop lying in a second plane when expanded.

17. The device of claim 16, wherein:

the first plane is substantially perpendicular to the first plane.

18. The device of claim 16, wherein:
the first loop is larger than the second loop, the first loop being positioned distal to the second loop.

19. The device of claim 15, wherein:
the engaging element is formed by a core element and a filament wrapped around the core element.

20. An obstruction removal device, comprising:
an elongate insertion element; and
an obstruction engaging element movable from a collapsed position to an expanded condition, the engaging element having at least two wound sections having a filament wound around a core element, the wound sections being separated by a section substantially free of the filament.

21. The device of claim 20, wherein:
the section which is substantially free of the filament is at least 1 mm long.

22. The device of claim 20, wherein:
the section which is substantially free of the filament is at least 3 mm long.

23. The device of claim 20, wherein:
the section which is substantially free of the filament is no more than 6 mm long.

24. An obstruction removing device, comprising:
an elongate insertion element; and
an obstruction engaging element movable from a collapsed position to an expanded condition, the engaging element having a first section, a second section, and a third section, the second section being positioned between the first and third sections, the second section forming coils having a smaller diameter than coils formed by the first and third sections.

25. The device of claim 24, wherein:

the obstruction engaging element has a fourth section and a fifth section, the fourth section being positioned between the third and fifth sections, the fourth section forming coils having a smaller diameter than coils formed by the third and fifth sections.

26. A system for removing an obstruction from a blood vessel, comprising:

a catheter having a lumen;

an expandable capture element which is contained within the lumen of the catheter, the capture element being slidable within the lumen of the catheter between a collapsed position contained within the lumen and an expanded position in which the capture element is positioned outside the lumen; and

an obstruction engaging device having a filament, the filament being movable from a collapsed position to an expanded position, the obstruction engaging element passing through the catheter.

27. The system of claim 26, wherein:

the expandable capture element is naturally biased toward the expanded position when positioned outside the lumen.

28. The system of claim 26, wherein:

the expandable capture element has a support structure with a flexible cover attached to the support structure.

29. The system of claim 28, wherein:

the self-expanding support structure has a closed loop having integrally formed hinges.

30 . The system of claim 29, wherein:

the hinges are V-shaped interconnecting elements.

31 . The system of claim 28, wherein:

the support structure has a plurality of longitudinal struts extending from the loop.

32. The system of claim 26, wherein:

the capture element has an expandable loop at the distal end.

33. The system of claim 32, wherein:
the loop is formed by an eyelet with a control arm extending through the eyelet.

34. The system of claim 26, wherein:
the capture element has a flexible cover, the cover having a length which is at least three times an expanded diameter of the capture element.

35. The system of claim 34, wherein:
the length of the cover is at least five times the expanded diameter of the capture element.

36. The system of claim 26, wherein:
the engaging device has 1-4 filaments.

37. A method of removing an obstruction from a blood vessel comprising the steps of:
providing a catheter, an obstruction engaging device and an expandable capture element, the capture element being contained within a lumen of the catheter in a collapsed position, the capture element moving to an expanded position when positioned outside the lumen, the obstruction engaging device having a filament which is movable from a collapsed position to an expanded position;
introducing the catheter into a blood vessel of a patient;
engaging an obstruction with the filament;
expanding the capture element; and
moving the obstruction into the capture element with the engaging device after the engaging and expanding steps.

38. A system for removing an obstruction from a blood vessel, comprising:
a catheter having a lumen;
an expandable capture element contained within the lumen of the catheter, the capture element being in a collapsed position when contained within the lumen and being in an expanded position when positioned outside the lumen, the expandable capture element

having a support structure forming a closed loop having a plurality of integrally formed hinges; and

an obstruction engaging device which extends through the expandable capture element, the engaging device having a collapsed shape and an expanded shape.

39. The system of claim 38, wherein:

the capture element has a flexible cover attached to the support structure, the cover having a distal end which is positioned at the loop so that the loop opens the distal end of the cover.

40. The system of claim 38, wherein:

the support structure has a plurality of longitudinal struts which extend proximally from the loop.

41. The system of claim 40, wherein:

the struts do not intersect and form a form a conical shape when the capture element is in the expanded.

42. The system of claim 38, wherein:

the loop has integrally formed hinges.

43. The system of claim 42, wherein:

the hinges are formed by V-shaped elements.

44. The system of claim 38, wherein:

the obstruction engaging device has a filament configured to penetrate and engage an obstruction.

45. A system for removing an obstruction from a blood vessel, comprising:

a catheter having a lumen;

an expandable capture element which is contained within the lumen of the catheter, the capture element being slidable within the lumen of the catheter, the capture element having an actuator for manually expanding and contracting the capture element; and

an obstruction engaging device which passes through the capture element.

46. The system of claim 45, wherein:

the obstruction engaging devices includes a filament for engaging the obstruction.

47. The system of claim 45, wherein:
the actuator has a control arm and a stable arm, the control arm being manipulated to expand and collapse the capture element.

48. The system of claim 45, wherein:
the actuator has a loop and a control arm which is manipulated to open and close the loop.

49. The system of claim 45, wherein:
the capture element everts when moving outside the lumen.

50. The system of claim 45, wherein:
the actuator includes a tube and a wire extending through the tube.

51. The system of claim 45, wherein:
the actuator includes at least two wires.

52. The system of claim 51, wherein:
the actuator includes first and second stabilizing wires and at least one actuating wire.

53. A catheter for capturing an obstruction, comprising:
a catheter having a lumen;
a capture element positioned in the lumen of the catheter, the capture element being expandable, the capture element having an expandable support structure and a cover attached to the support structure, the cover having a length which is at least three times a diameter of the support structure in the expanded position.

54. The catheter of claim 53, wherein:
the cover has a length which is at least five times a diameter of the support structure in the expanded position.

55. A device for removing an obstruction from a blood vessel, comprising:

an expandable loop which is movable from a collapsed position to an expanded position;

a cover coupled to the loop, the distal end of the cover being moving from a closed position to an open position when the loop moves from the collapsed to expanded positions; and

a tube having an actuator extending therethrough, the actuator being coupled to the loop so that relative movement between the tube and the actuator causes the loop to move between the expanded and collapsed positions.

56. The device of claim 55, wherein:

the tube is positioned outside the cover.

57. The device of claim 55, further comprising:

a catheter passing through the cover; and

an obstruction engaging device passing through the catheter.

58. A device for removing an obstruction from a blood vessel, comprising:

a tube;

a support structure movable between a collapsed position and an expanded position, the support structure extending through the tube and being naturally biased toward the expanded position, wherein the support structure expands when moved out of the distal end of the tube and is in the collapsed position when contained within the tube, the support structure being bowed outward;

a cover coupled to the structure, the cover moving from a closed position to an open position when the loop moves from the collapsed position to the expanded position.

59. A method of removing an obstruction from a blood vessel, comprising the steps of:

providing a obstruction engaging element having a collapsed position and an expanded position, the obstruction engaging element having at least one filament, the filament being in a substantially straight configuration when collapsed;

advancing the obstruction engaging element through a patient's vascular system to an obstruction with the obstruction engaging element in the collapsed position; and

engaging the obstruction with the obstruction engaging element, the filament engaging the obstruction with a shape which extends from a proximal end toward a distal end, turns back toward the proximal end and again turns back and extends toward the distal end.

60. A device for removing an obstruction from a blood vessel, comprising:

a delivery element having a lumen; and

an obstruction engaging element positioned in the lumen, the obstruction engaging element having a filament which has a collapsed position and an expanded position, the filament being in a substantially straight configuration when collapsed within the lumen of the delivery element, the filament being movable to a shape which extends from a proximal end toward a distal end, turns back toward the proximal end and again turns back and extends toward the distal end.

61. The device of claim 60, wherein:

the filament is naturally biased into the shape.

62. The device of claim 60, wherein:

the distal end of the filament is a free end and the obstruction engaging element has only one filament.

63. The device of claim 60, wherein:

the obstruction engaging element forms the shape by manipulating the obstruction engaging element.

64. The device of claim 63, wherein:

the obstruction engaging element is rotated to form the shape.

65. The device of claim 64, wherein:

the obstruction engaging element is rotated so that coils prolapse over other coils.

66. A method of removing an obstruction from a blood vessel, comprising the steps of:

providing a obstruction engaging element having a collapsed position and an expanded position, the obstruction engaging element having at least one filament which is coated with fibrin;

advancing the obstruction engaging element through a patient's vascular system to an obstruction with the obstruction engaging element in the collapsed position;

positioning the obstruction engaging element to engage the obstruction; and

removing the obstruction with the obstruction engaging element.

67. A device for removing an obstruction from a blood vessel, comprising:

a delivery element having a lumen; and

a obstruction engaging element having a collapsed position and an expanded position, the obstruction engaging element having at least one filament which is coated with fibrin, the obstruction engaging element being contained within the lumen of the delivery element.

68. The device of claim 67,

the obstruction engaging element is in a substantially straightened configuration when collapsed.

69. The device of claim 67, wherein:

the obstruction engaging element has a filament.

70. The device of claim 67, wherein:

the obstruction engaging element has only one filament which extends to a free end.

71. A method of removing an obstruction from a blood vessel, comprising the steps of:

providing a capture element and an obstruction engaging element;

moving the obstruction with the obstruction engaging element into the capture element, wherein the capture element has an inverting portion which inverts when the obstruction is moved into the capture element; and

removing the obstruction from the patient.

72. A device for removing an obstruction from a blood vessel, comprising:

a capture element having an inverting portion which inverts to capture an obstruction, the inverting portion inverting upon application of a compressive force to the inverting portion.

73. The device of claim 72, further comprising:
an obstruction engaging element extending through the capture element.

74. The device of claim 72, wherein:
the obstruction engaging element has a filament which is manipulated to ensnare the obstruction.

75. The device of claim 72, wherein:
the filament extends through the capture element.

76 . The device of claim 72, wherein:
the obstruction engaging element is movable relative to the capture element.

77. The device of claim 76, wherein:
the obstruction engaging element is movable relative to the capture element to invert the capture element.

78. The device of claim 76, wherein:
the obstruction engaging element is coupled to the capture element.

79. The device of claim 78, wherein:
the obstruction engaging element is wound around a central wire with a distal end of the obstruction engaging element attached to the central wire.

80. The device of claim 78, wherein:
the obstruction engaging element is connected to the capture element.

81. The device of claim 78, wherein:
the obstruction engaging element contacts the capture element to invert the capture element.

82. The device of claim 72, wherein:
the inverting portion is a braided structure.

83. A medical device, comprising:

an outer member;

a plurality of fingers extending distally from the outer member, the plurality of fingers forming an end, the end being movable between an open position to a closed position, the plurality of fingers being bent when moving from the open position to the closed position.

84. The medical device of claim 83, further comprising:

an inner member positioned in the outer member;

the plurality of fingers being moved between the open and closed positions by relative movement of the inner and outer members.

85. The medical device of claim 83, wherein:

each of the plurality of fingers has a flexible actuator attached thereto, wherein the actuator is manipulated to move the fingers between the open and closed positions.

86. The medical device of claim 83, further comprising:

a sheath positioned to cover at least one of an inner and outer surface of the frame.

87. The medical device of claim 83, further comprising:

an obstruction engaging element extending through the outer member.

88. The medical device of claim 39, wherein:

the fingers are independent from one another and extend independently from the outer member

89. A medical device, comprising:

an outer member;

an inner member positioned within the outer member;

a frame extending distally from the inner and outer members, the frame having an end which is movable from an open position to a closed position, the frame having a first set of connectors coupled to the outer member and a second set of connectors coupled to the inner member;

wherein the inner and outer members are movable relative to one another to move the open end between the open and closed positions.

90. The medical device of claim 89, further comprising:
a cover positioned to cover at least one of an inner and outer surface of the frame.

91. The medical device of claim 89, further comprising:
an obstruction engaging element extending through the inner member.

92. The medical device of claim 89, wherein:
the frame is integrally formed.

93. The medical device of claim 89, wherein:
the frame has a ring at the distal end.

94. The medical device of claim 89, wherein:
the ring is formed by v-shaped elements.

95. The medical device of claim 89, wherein:
the first set of connectors and second set of connectors are connected to the ring at space-apart locations one after the other.

96. A medical device, comprising:
an outer member;
a frame extending distally from the outer member, the frame having an end which is movable from an open position to a closed position;
wherein the frame moves between the open and closed positions by applying electrical energy to the frame.

97. The medical device of claim 94, further comprising:
a cover positioned to cover at least one of an inner and outer surface of the frame.

98. The medical device of claim 94, further comprising:
an obstruction engaging element extending through the inner member.

99. The medical device of claim 94, wherein:
the frame is integrally formed.

100. The medical device of claim 94, wherein:
the frame comprises a shape-memory material, wherein application of the electrical energy causes the shape-memory material to change shape

101. The medical device of claim 98, wherein:
the frame moves to the closed position upon application of the electrical energy.

102. A method for removing an obstruction from a blood vessel using the devices of claims 83-98.

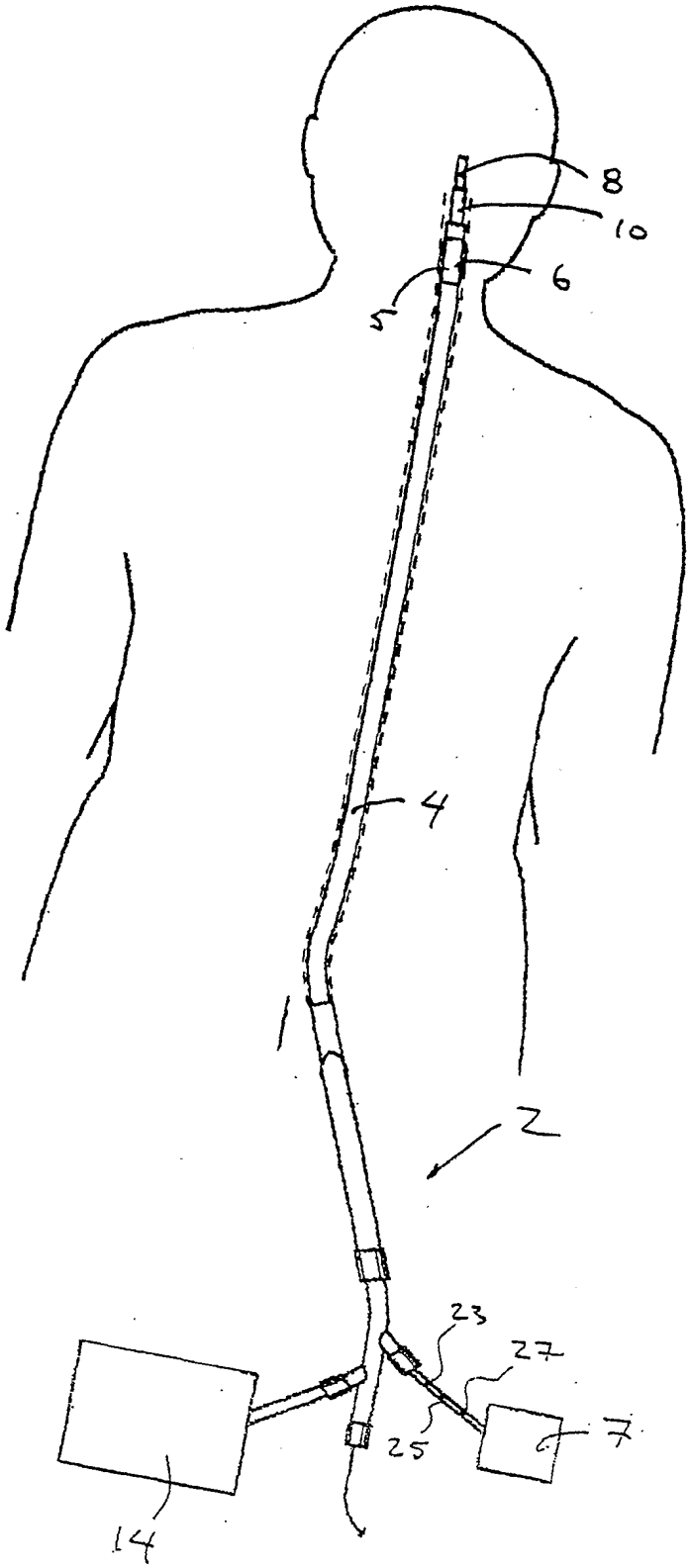


FIG. 1

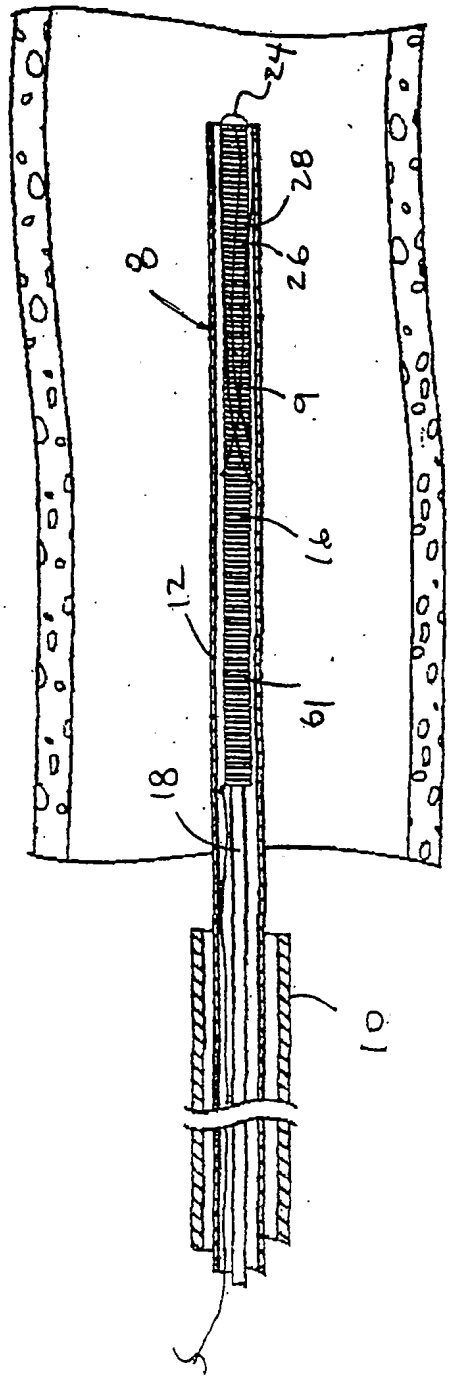


FIG. 2

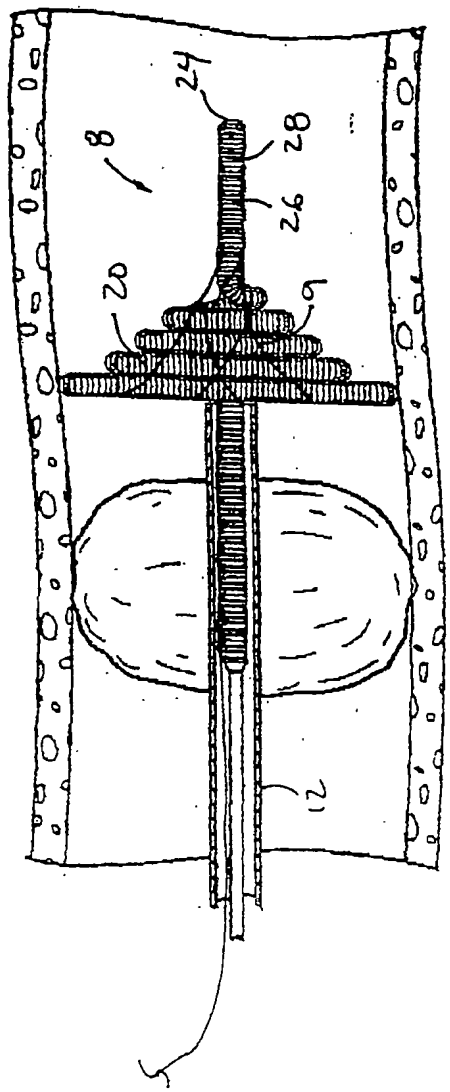


FIG. 3

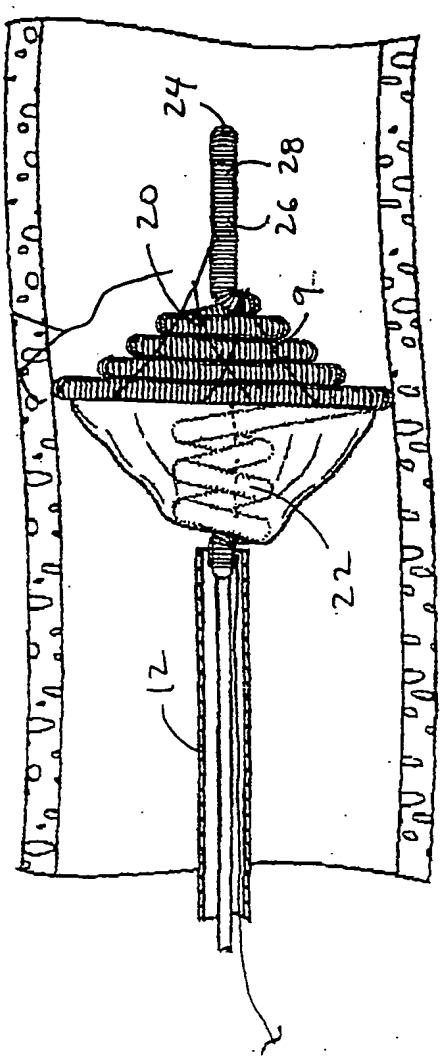


FIG. 4

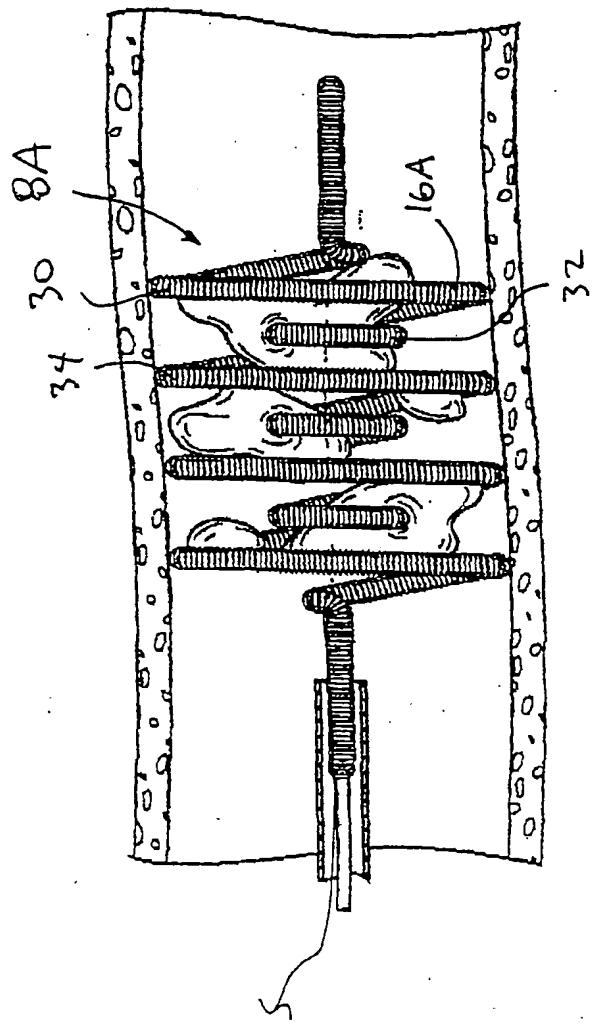


FIG. 5

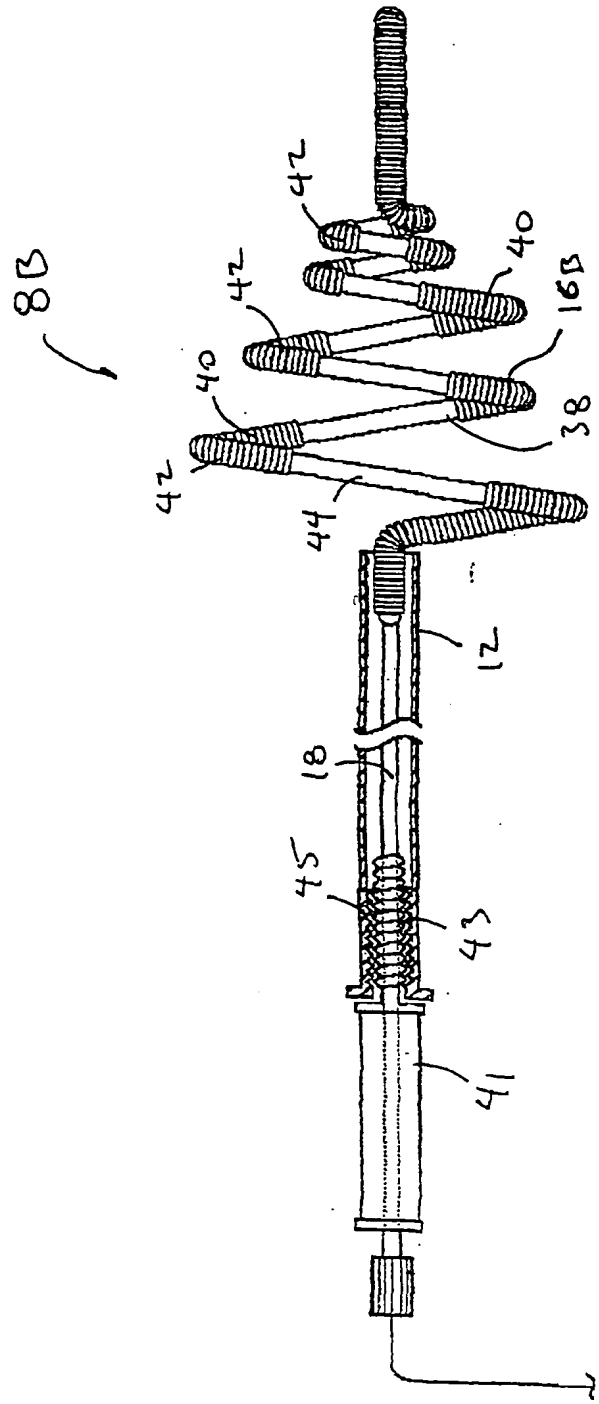


FIG. 6

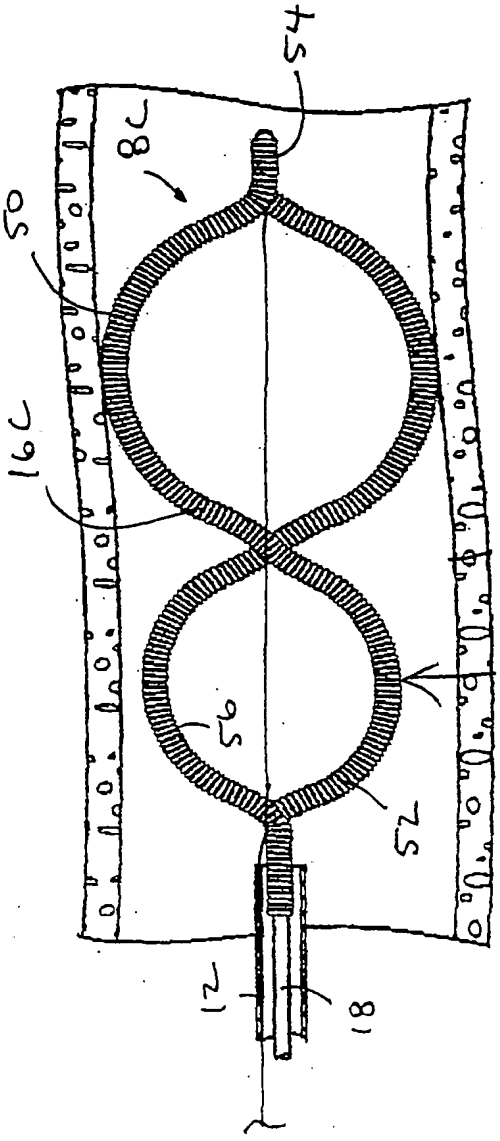


FIG. 7

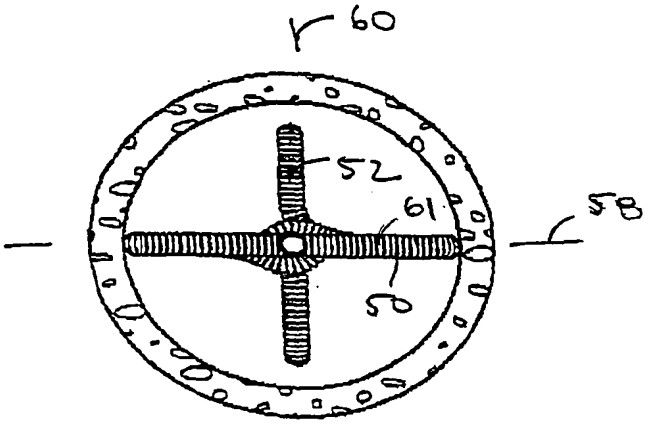


FIG. 8

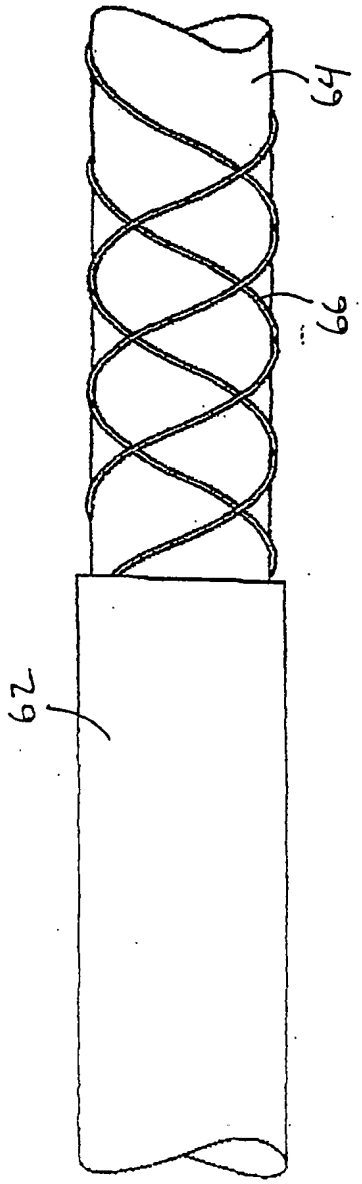


FIG. 9

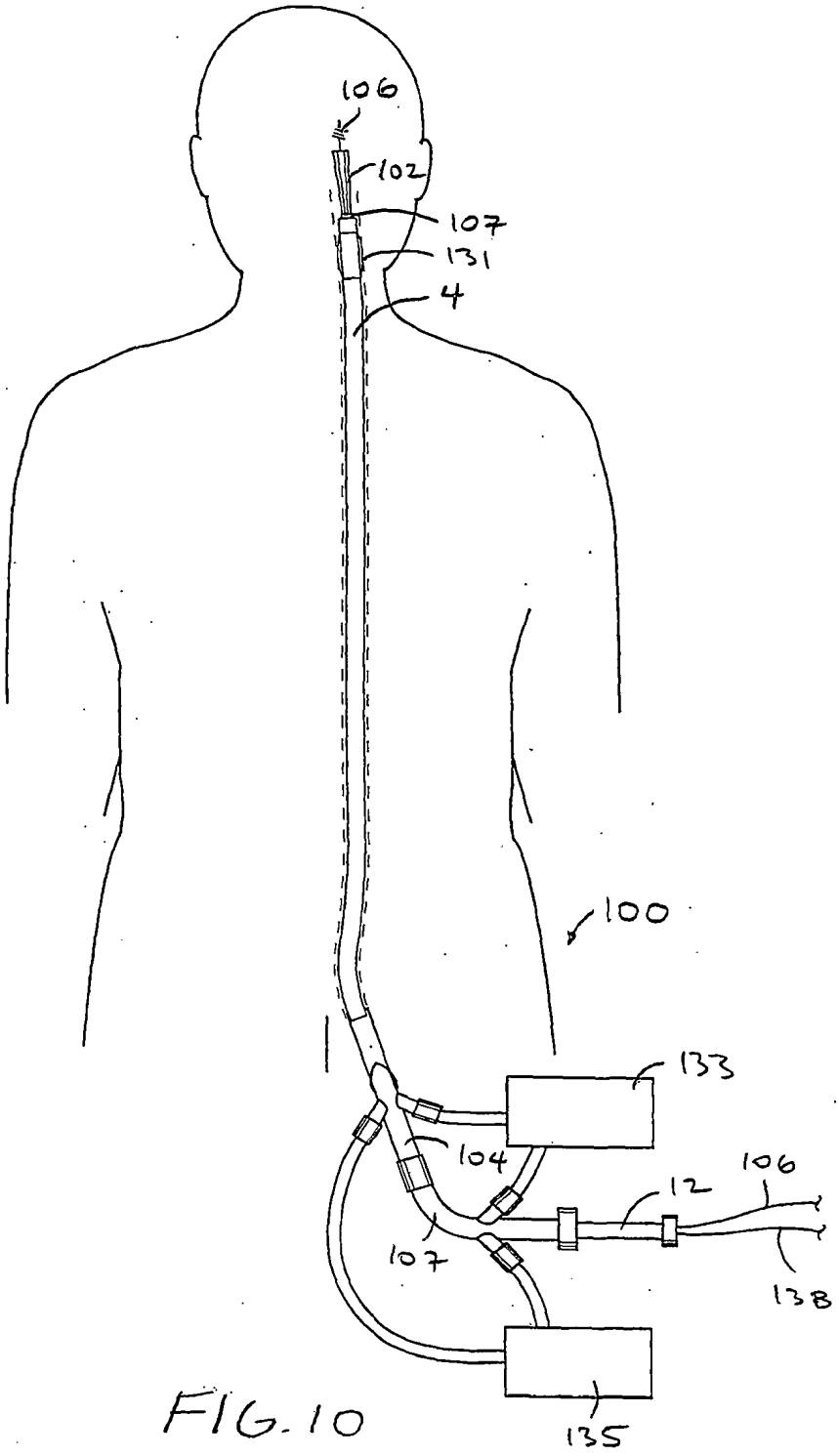


FIG. 10

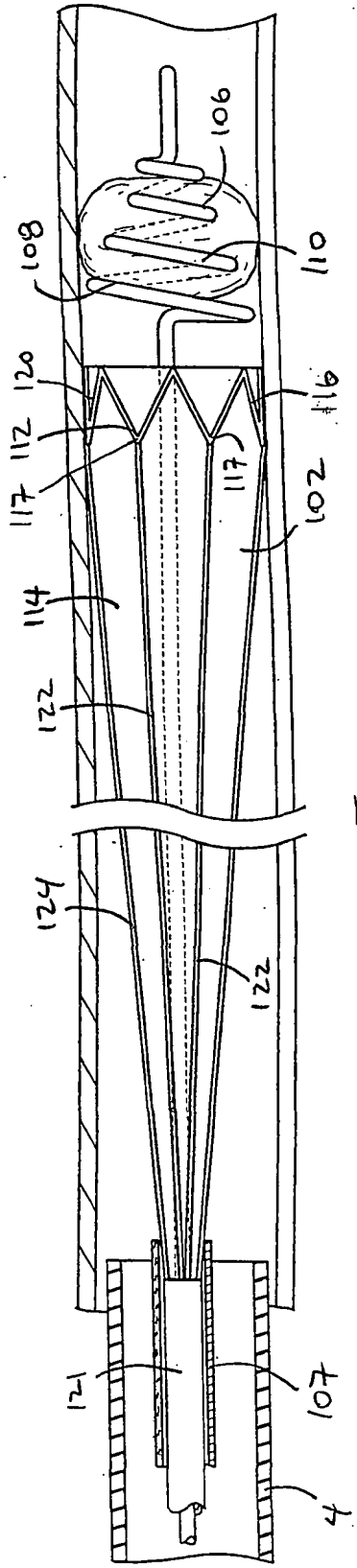

106
108
110
120
116
112
117
117
102
114
122
124
122
121
107
4

FIG. 11

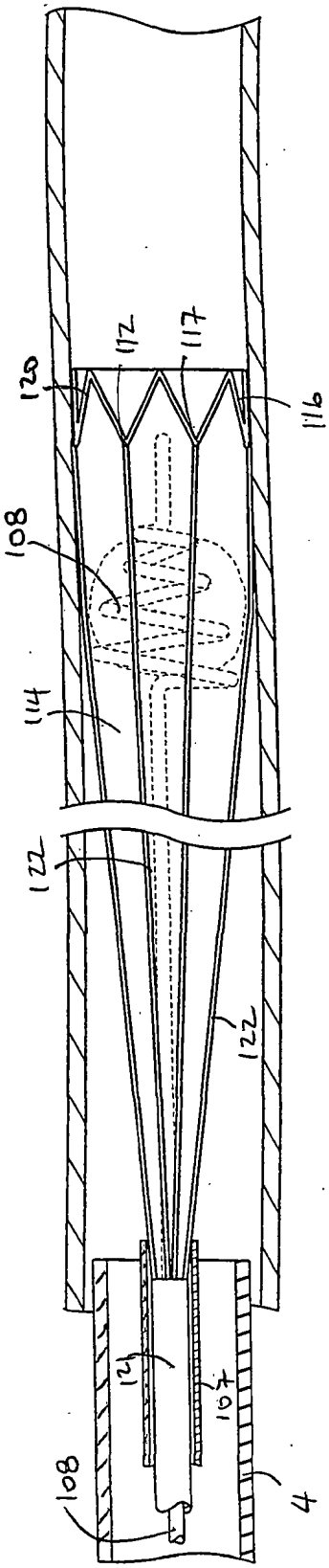

112
117
120
116
108
114
122
122
121
107
108
4

FIG. 12

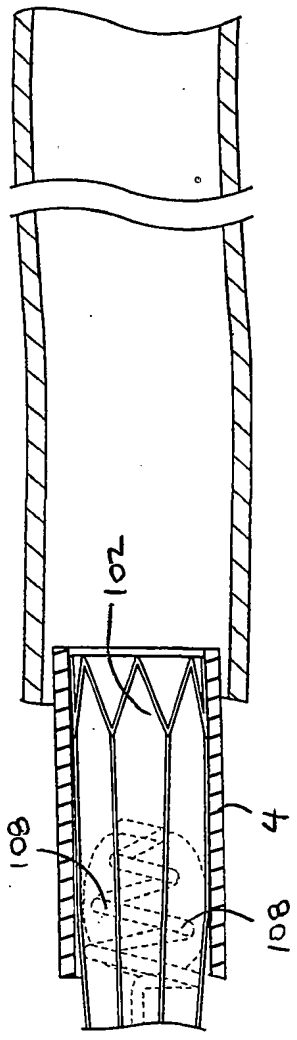


FIG. 13

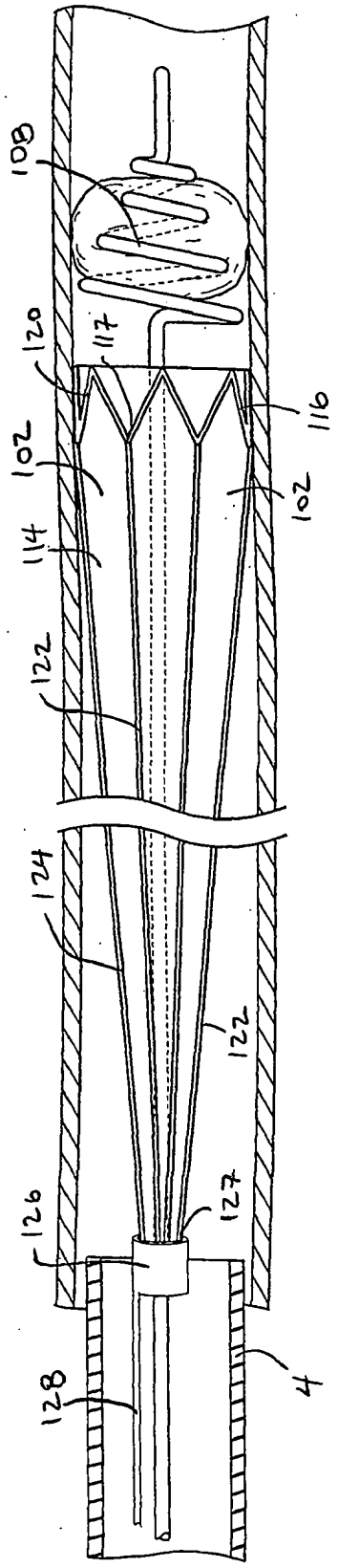


FIG. 14

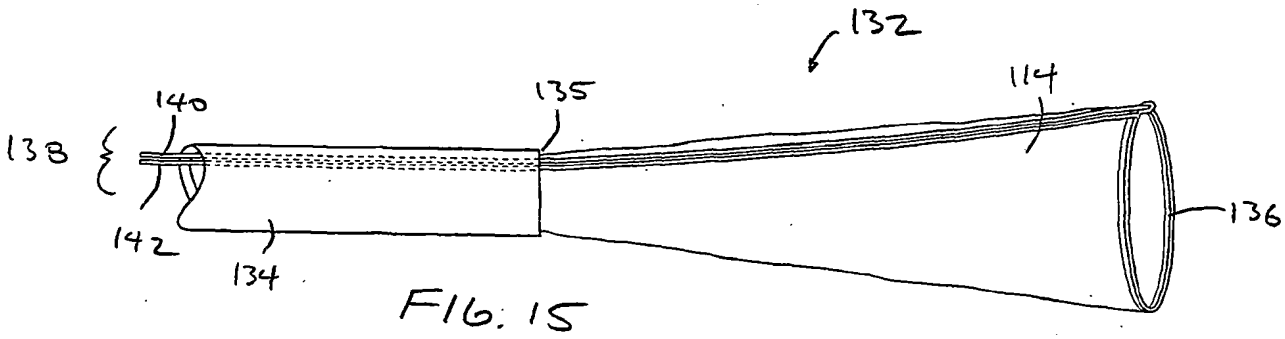


FIG. 15

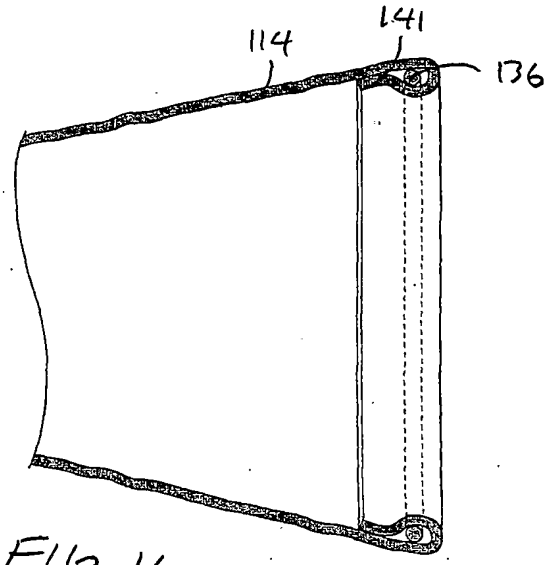


FIG. 16

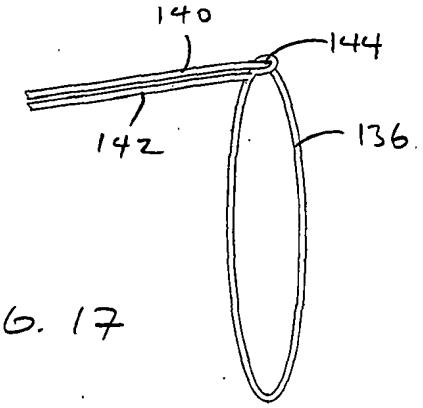


FIG. 17

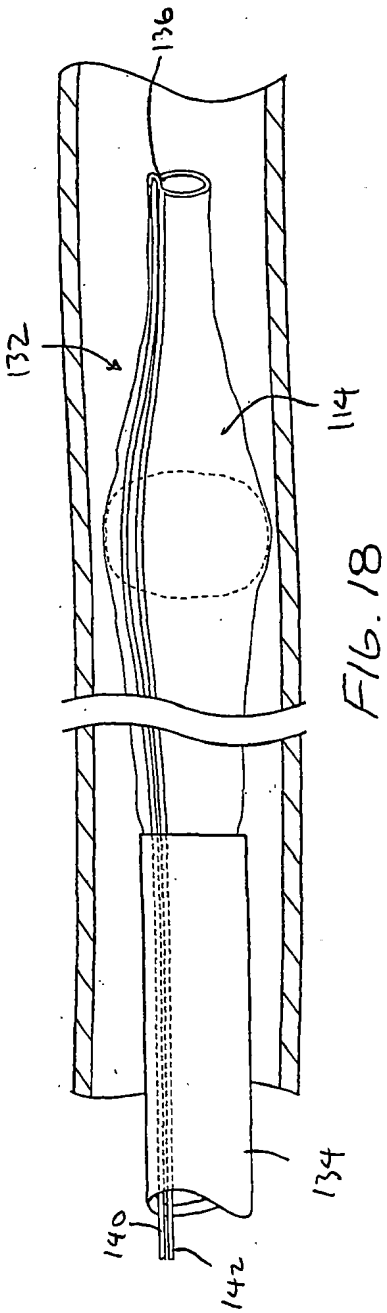


FIG. 18

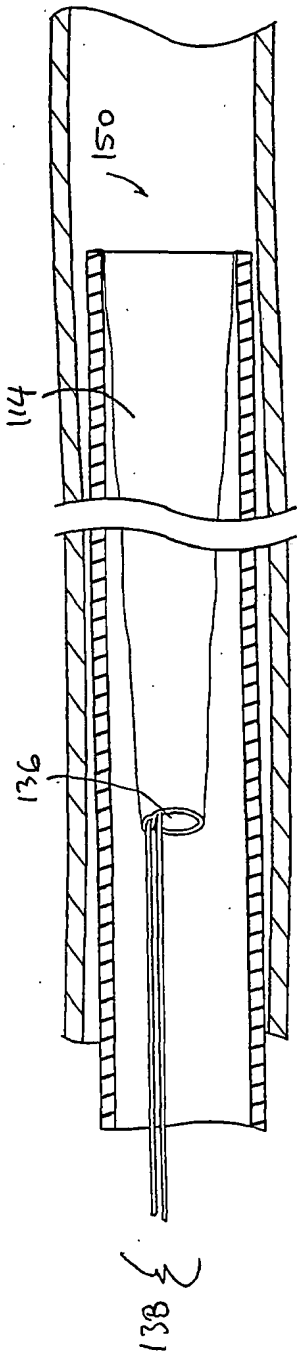


FIG. 19

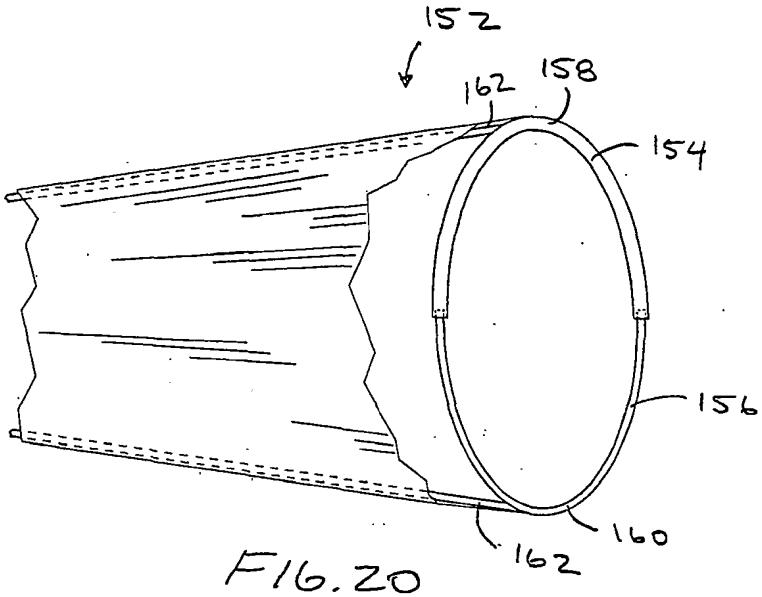


FIG. 20

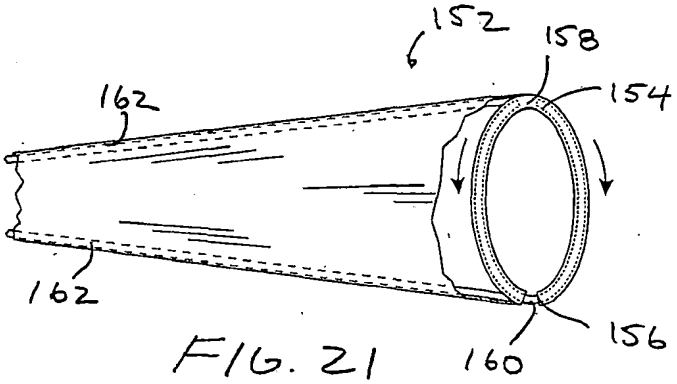


FIG. 21

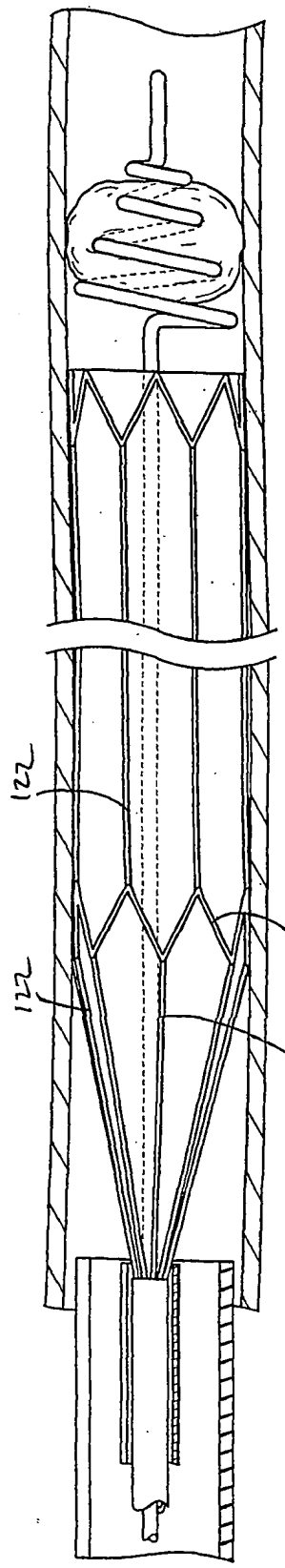


FIG. 22

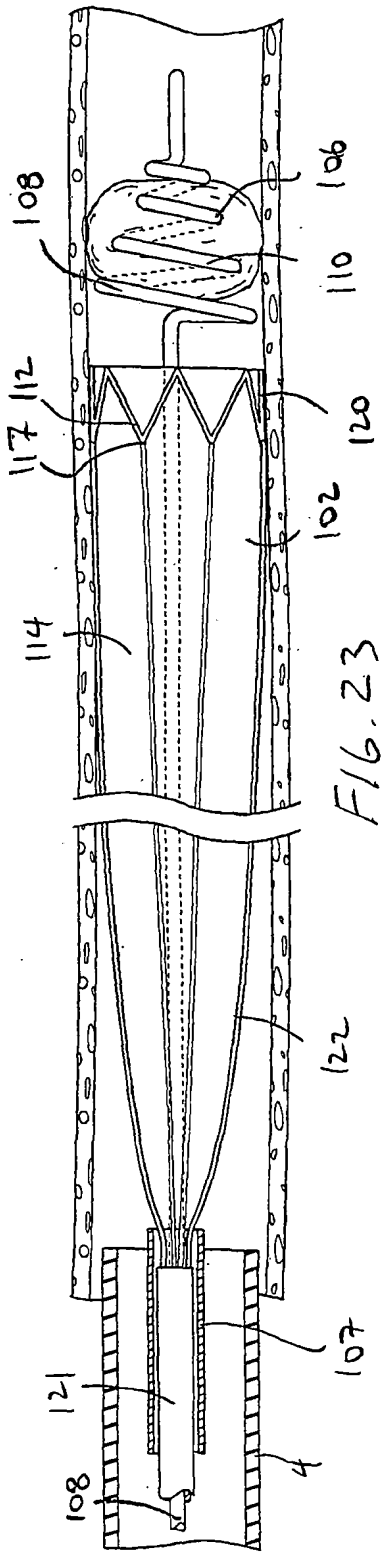

108
106
110
112
117
120
102
114
122
107
121
108
4

FIG. 23

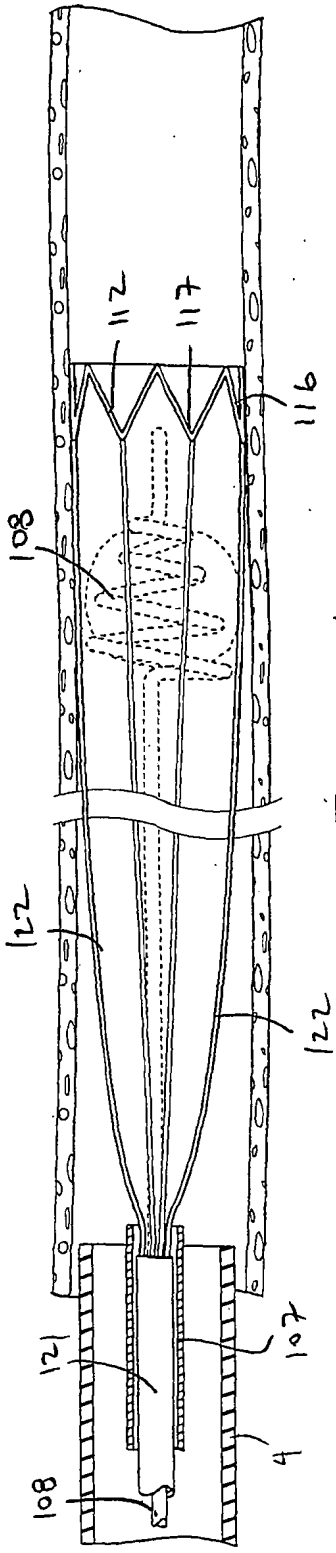

112
117
116
108
122
122
107
121
108
4

FIG. 24

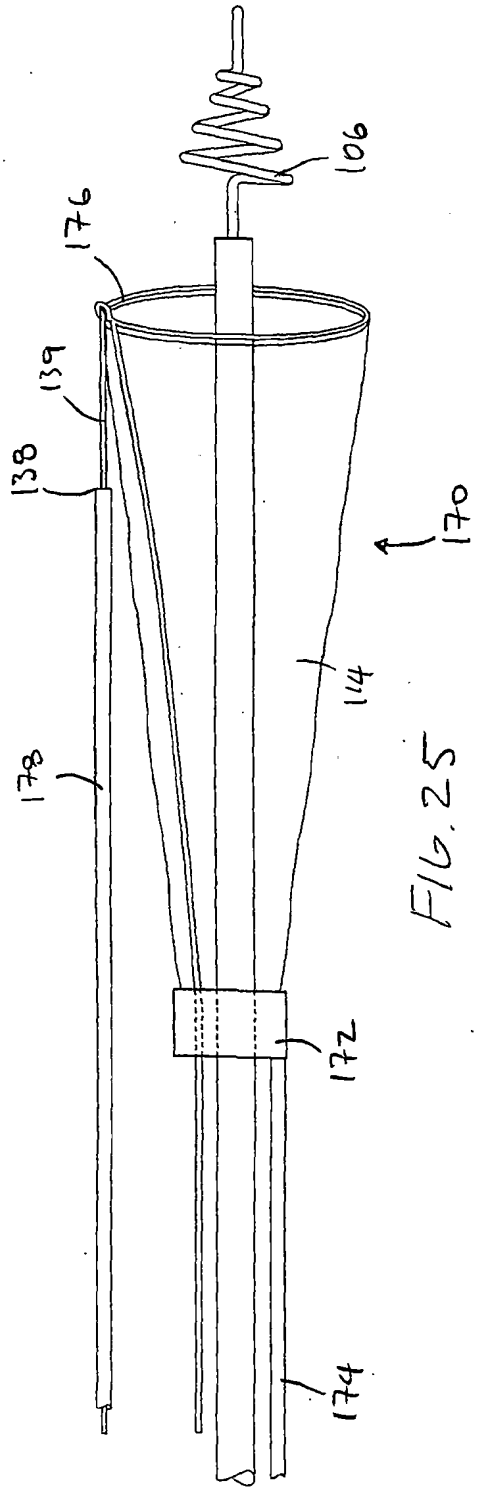


FIG. 25

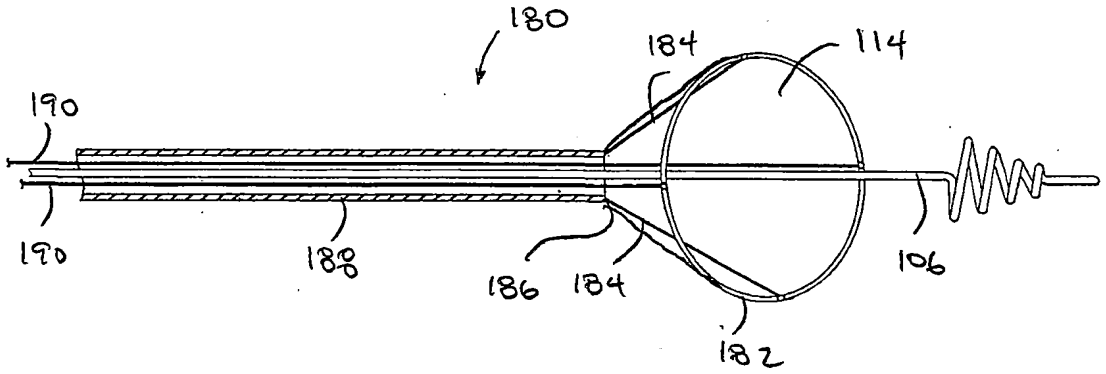

180
184
114
190
190
188
186
184
182
106

FIG. 26

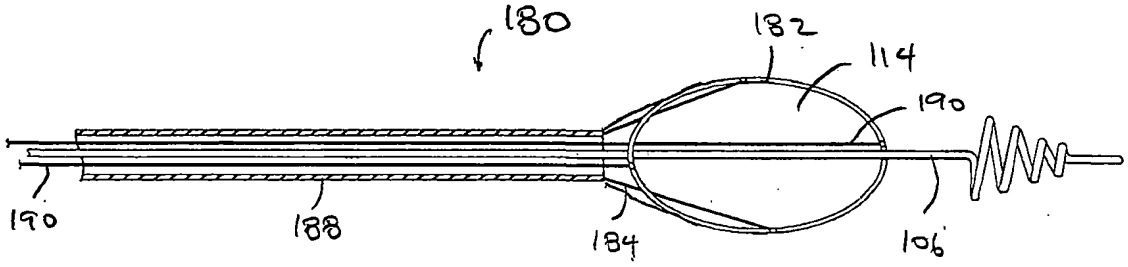

180
182
114
190
190
188
184
106

FIG. 27

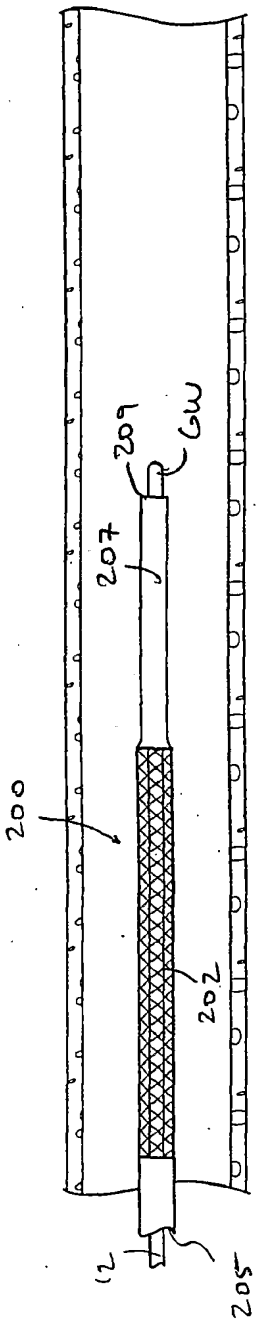


FIG 28

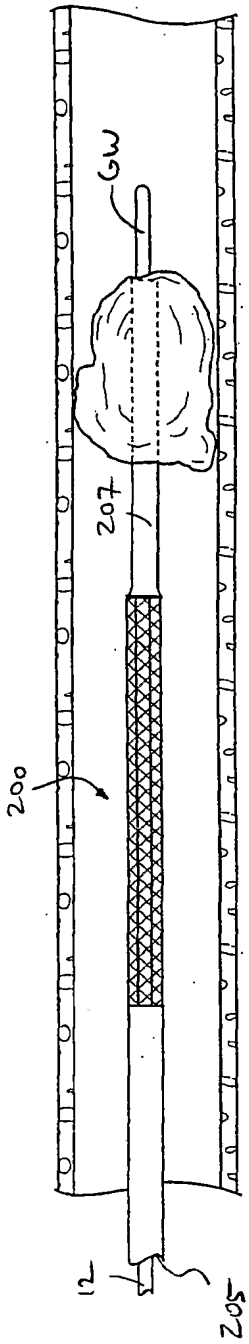


FIG 29

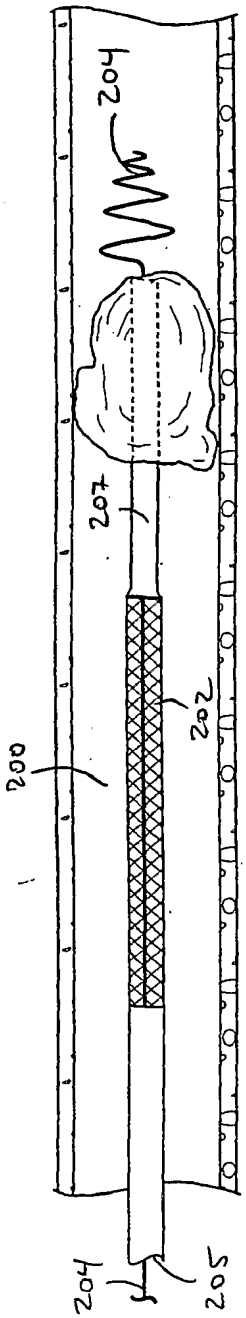


FIG 30

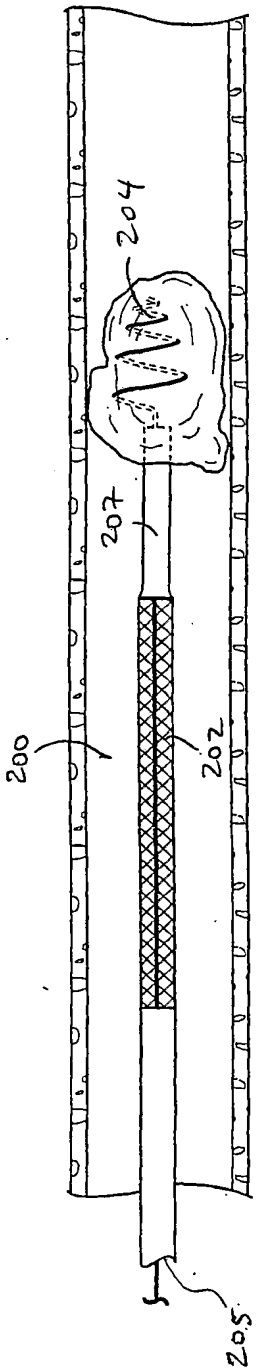


FIG 31

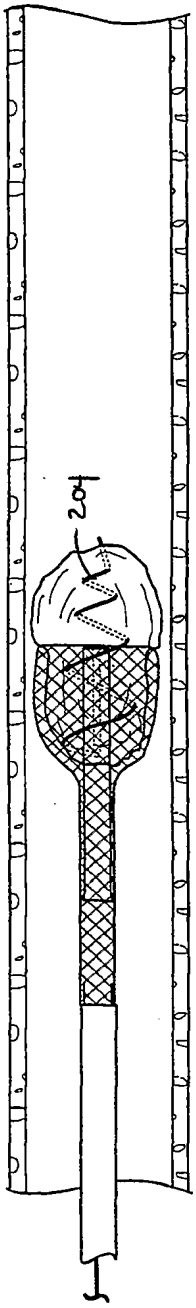


FIG 32

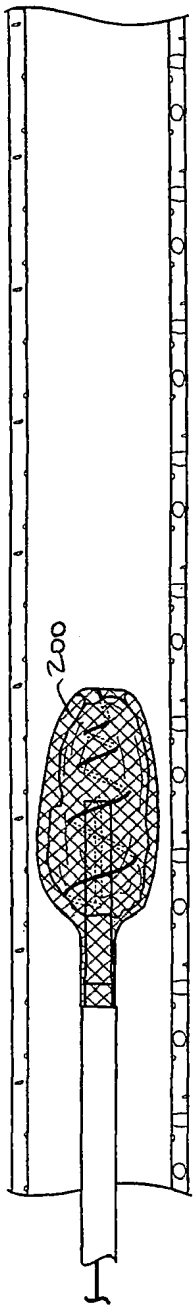


FIG 33

FIG 34

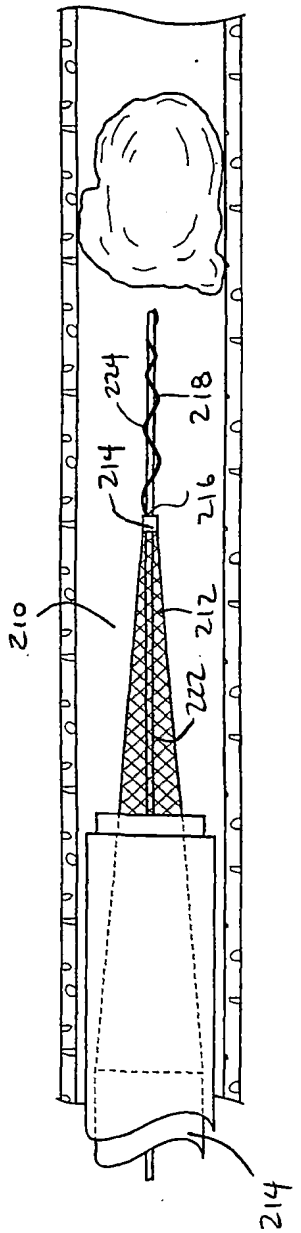


FIG 35

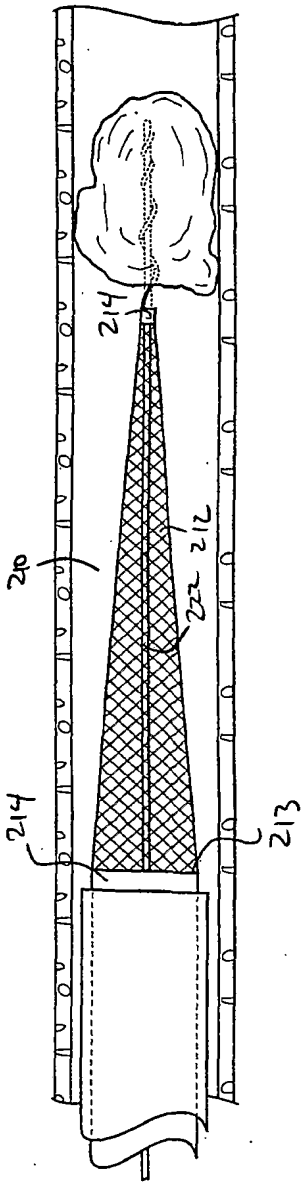


FIG 36

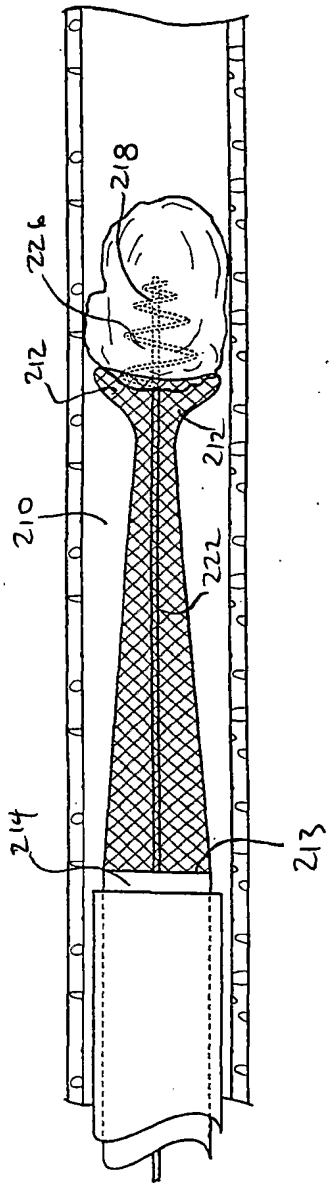


FIG 37

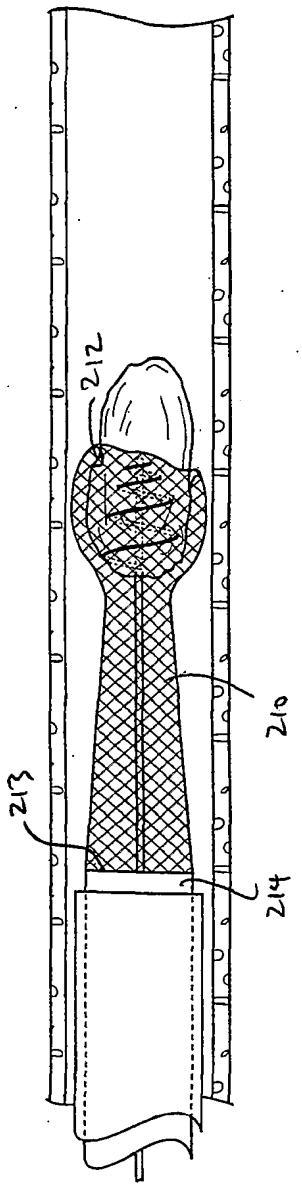


FIG 38A

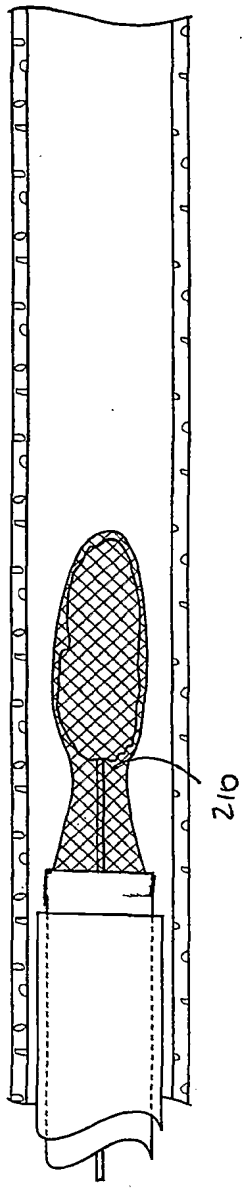
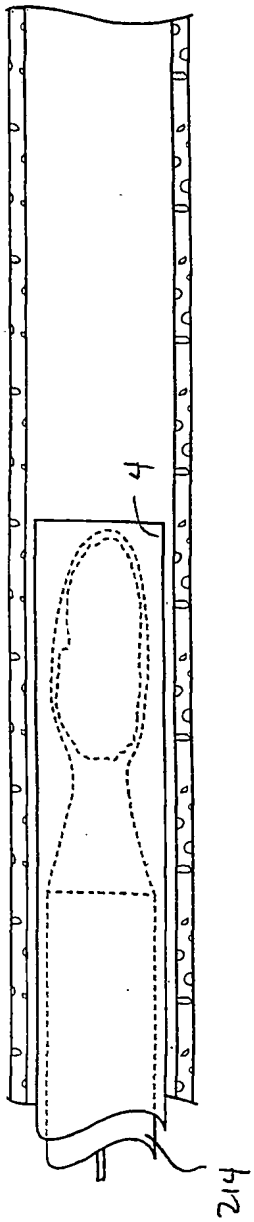


FIG. 38B



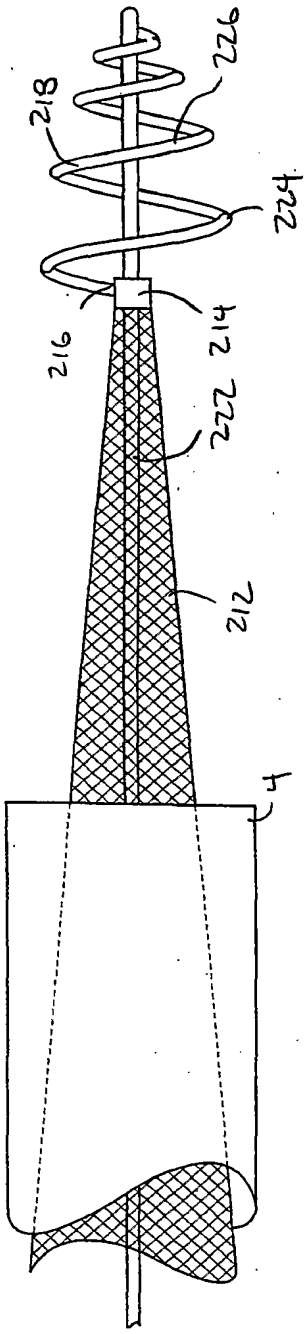


FIG 39

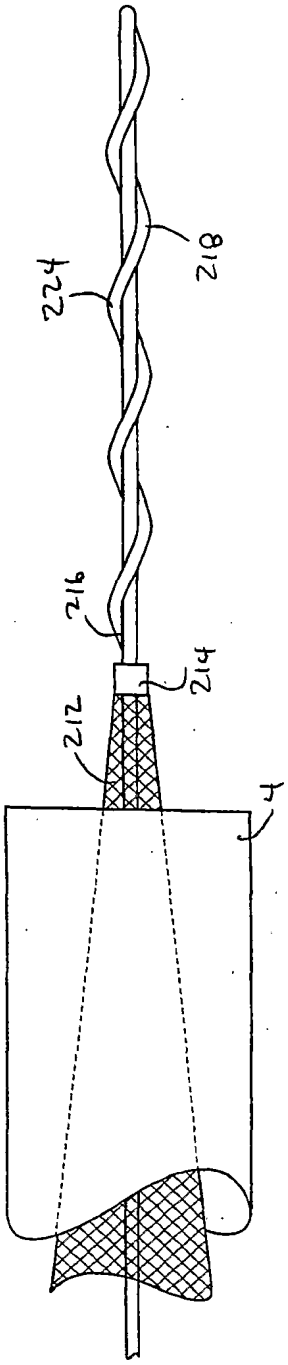


FIG 40

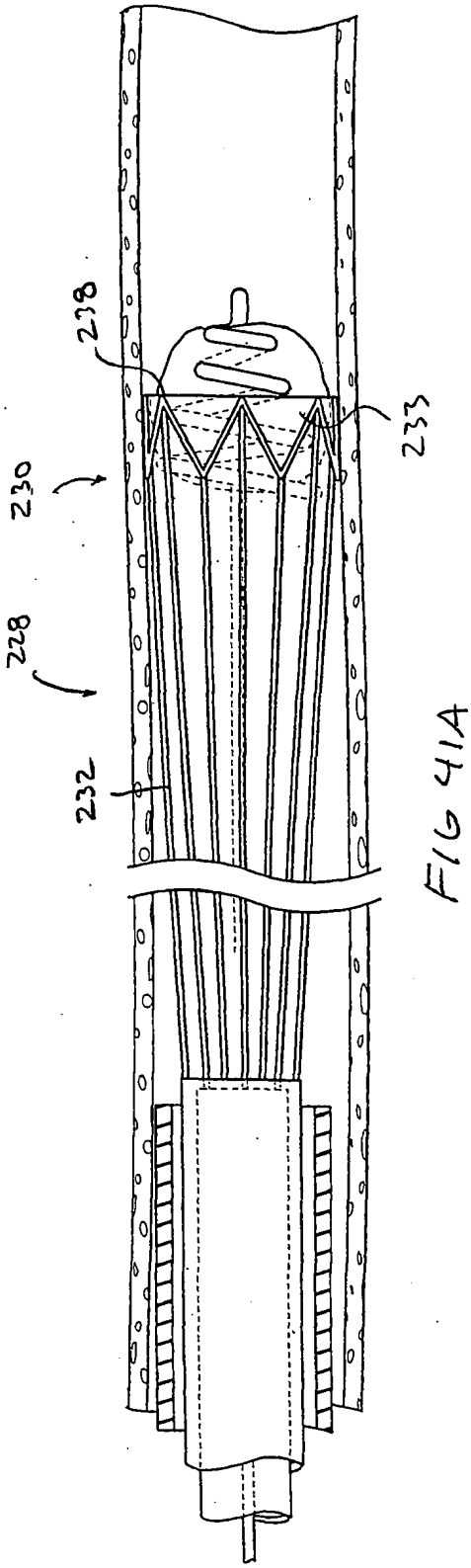


FIG 41A

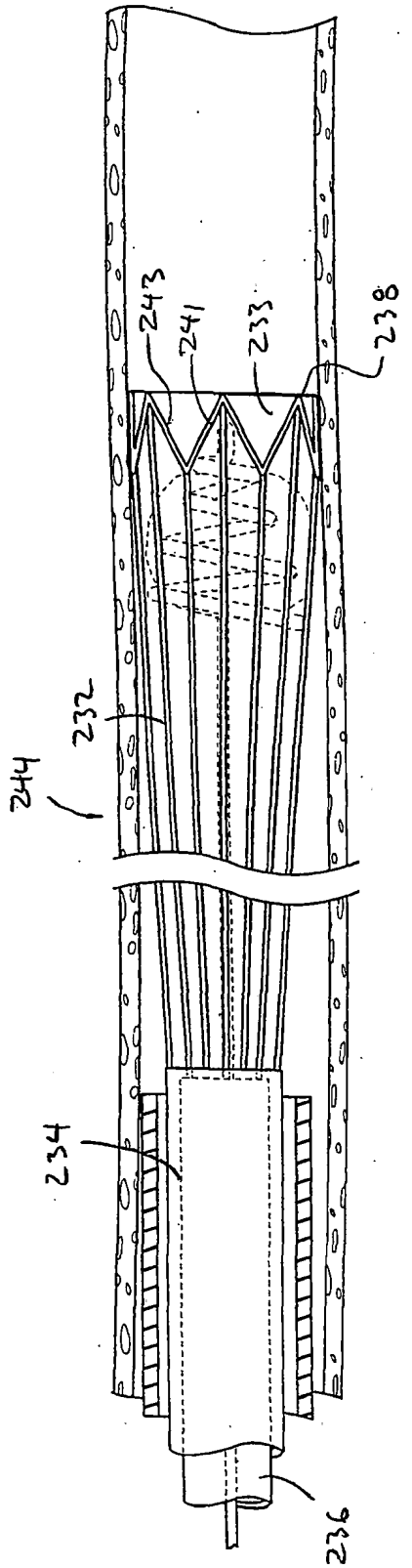


FIG. 41B

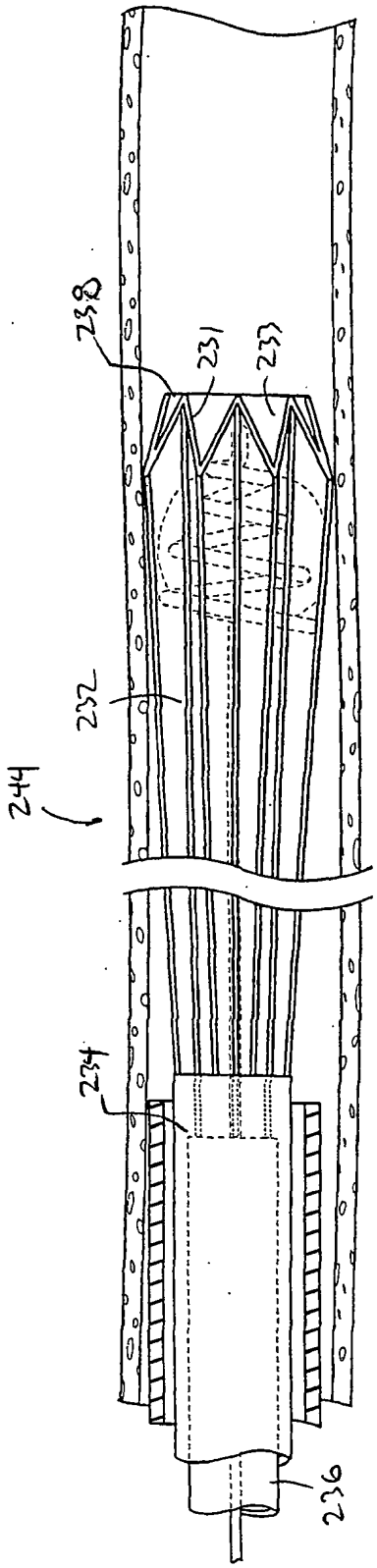


FIG 42A

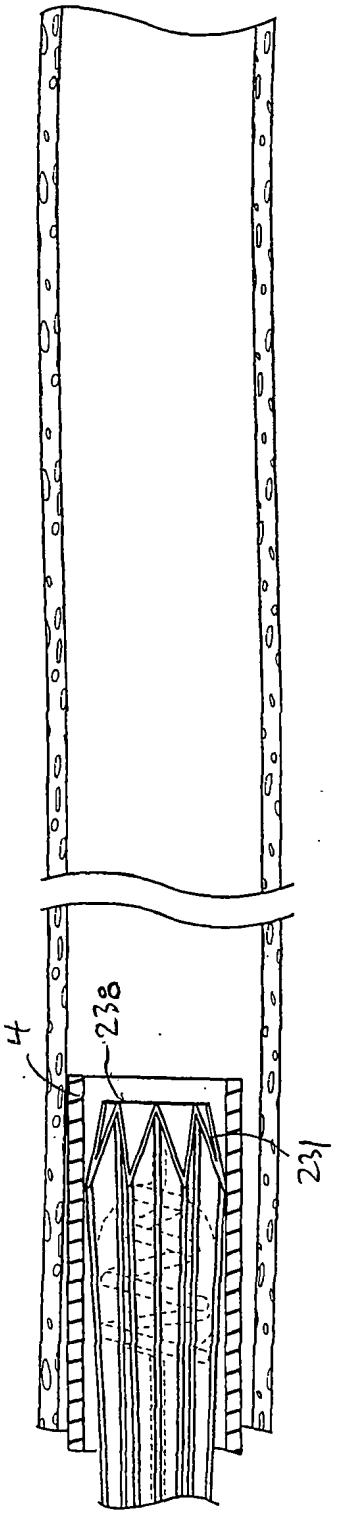


FIG 42B

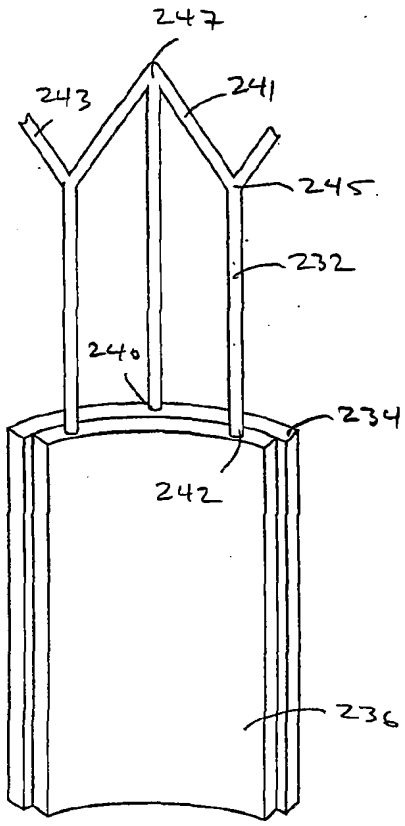


FIG 43A

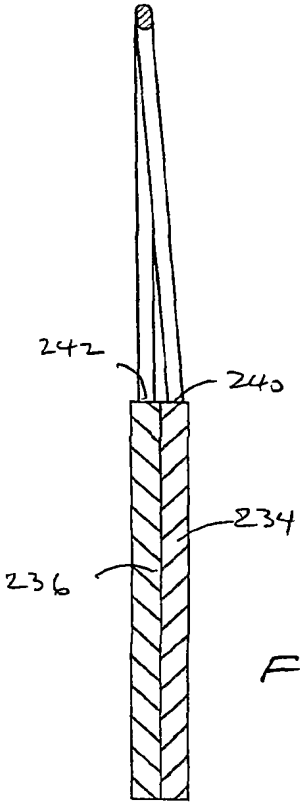


FIG 43C

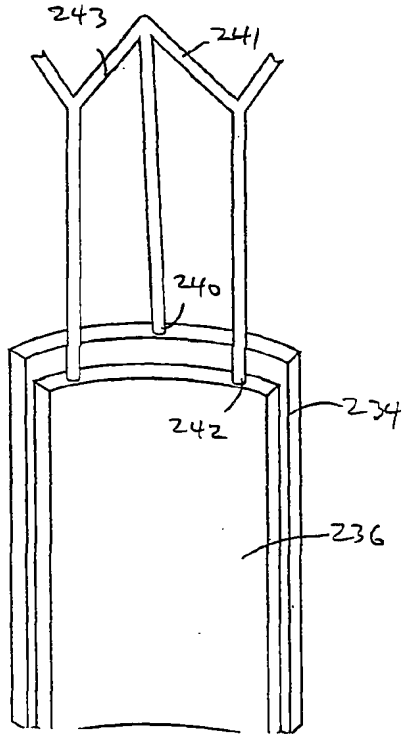


FIG 43B

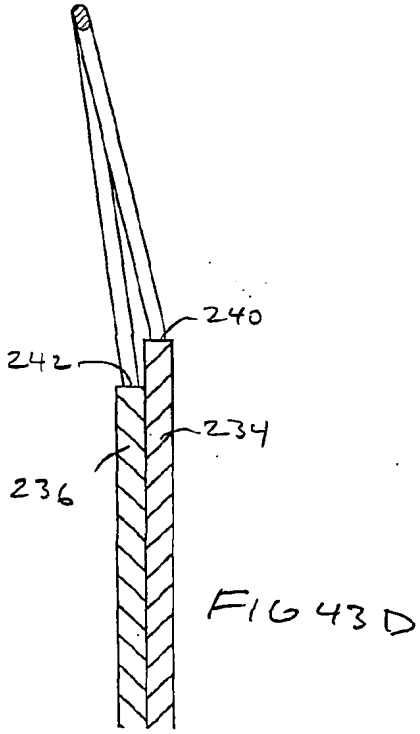


FIG 43D

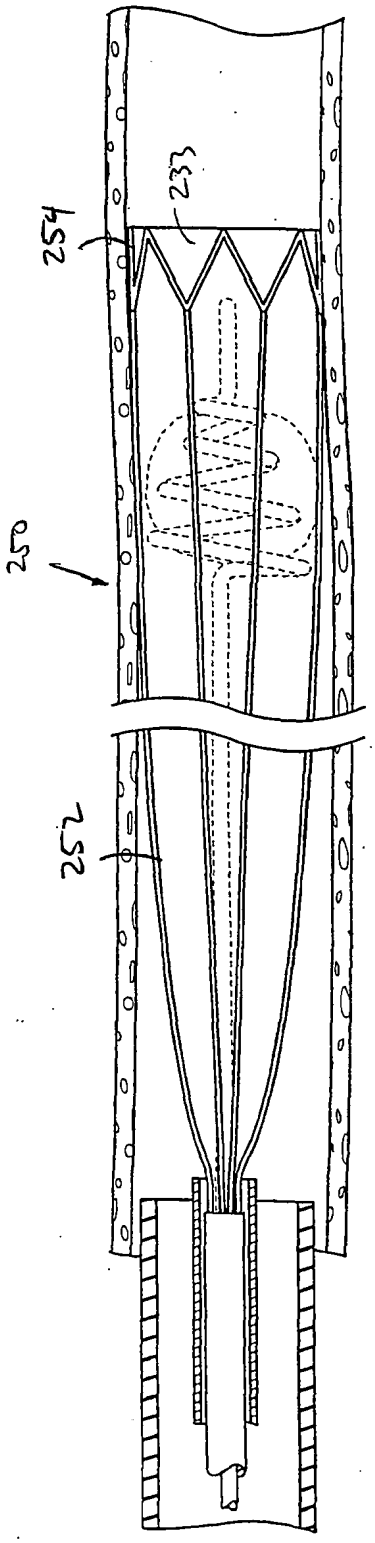


FIG 44

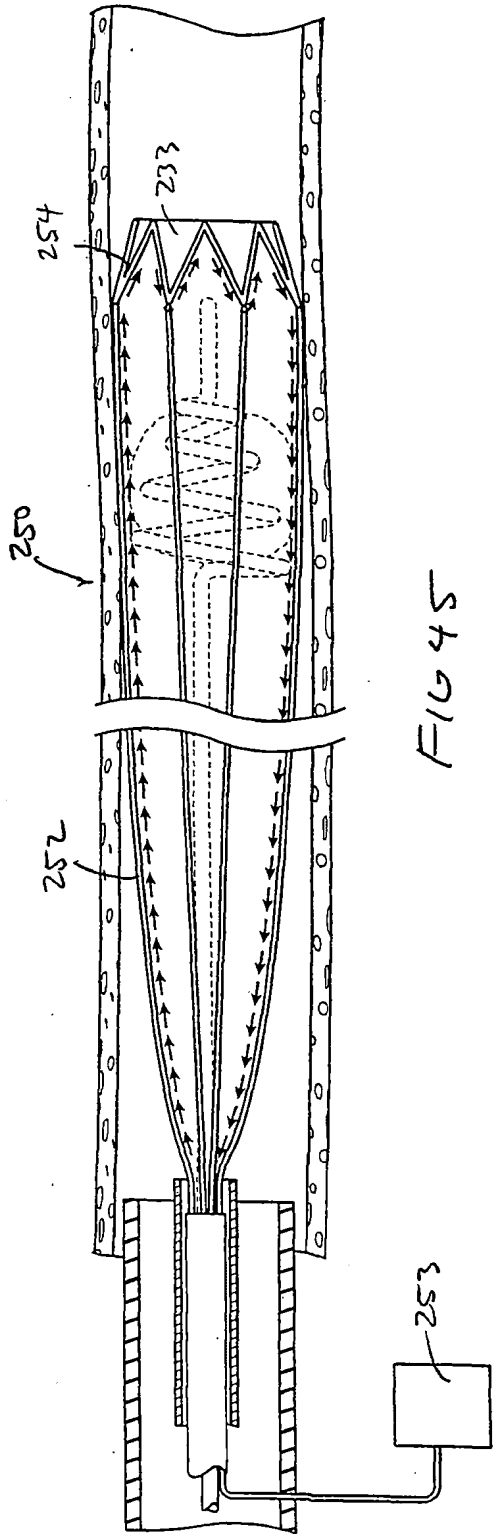


FIG 45

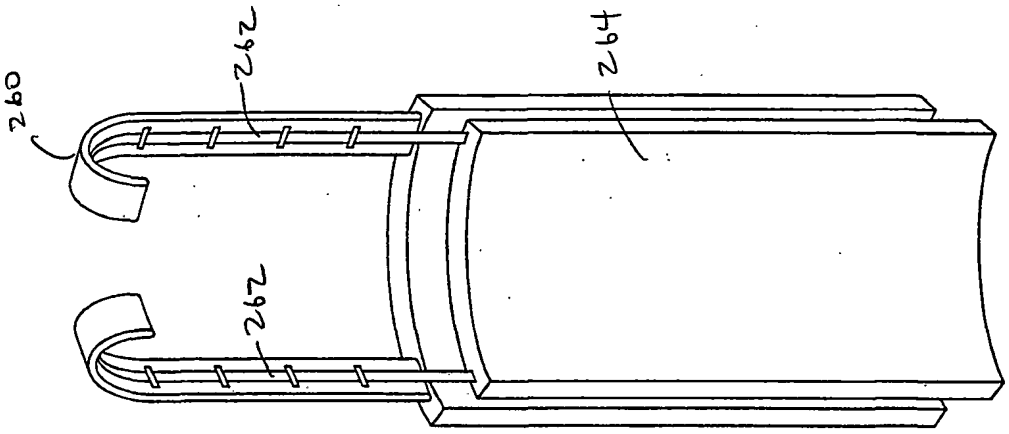


FIG. 47

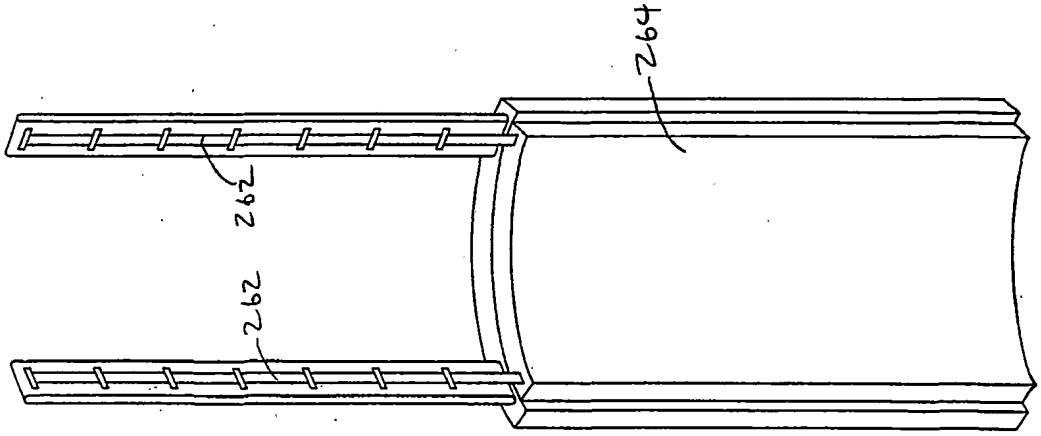


FIG 46

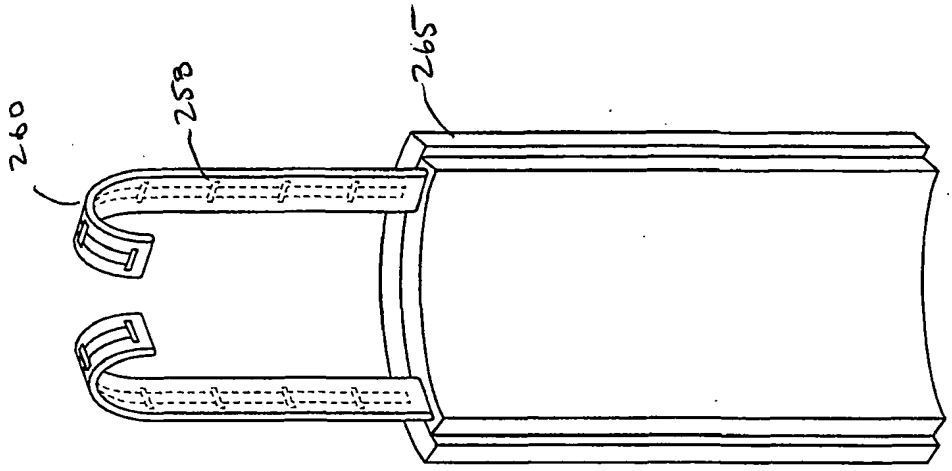


FIG 49

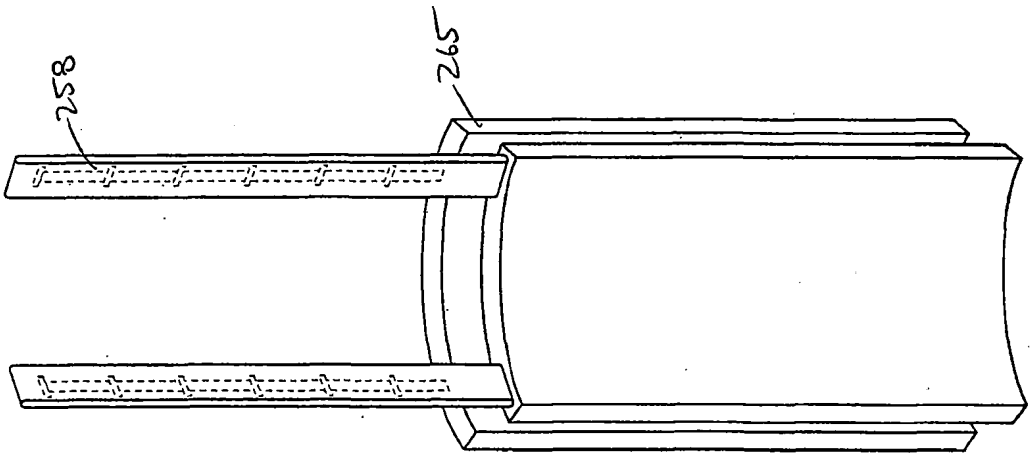


FIG 48

FIG. 50

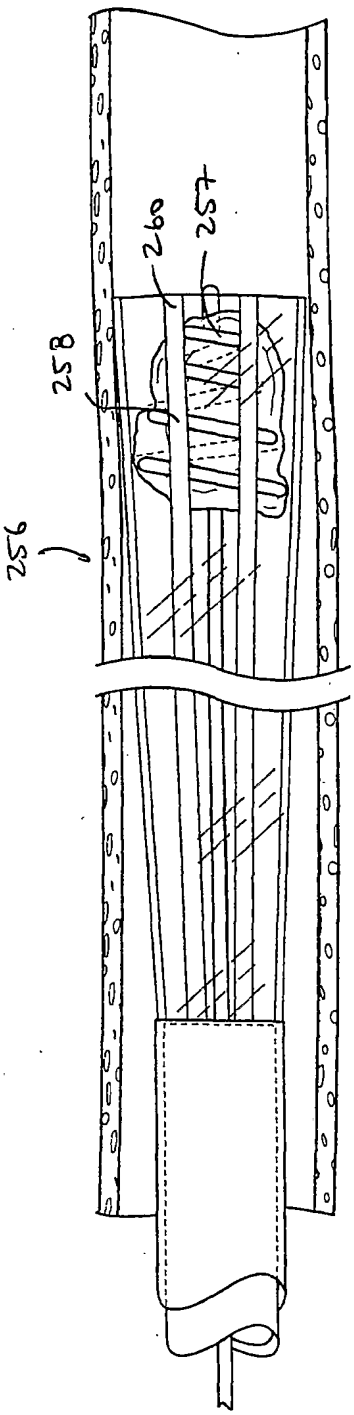


FIG. 51

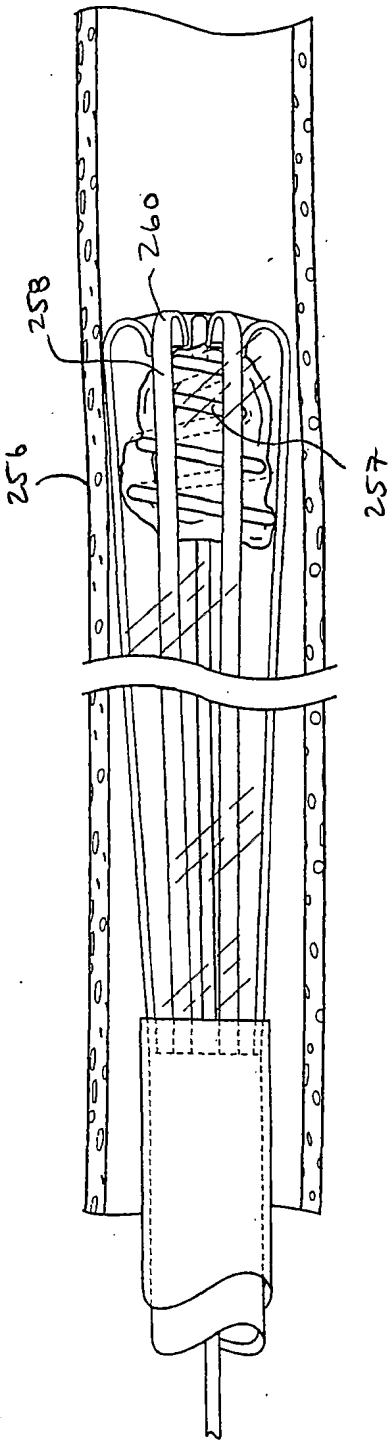


FIG. 52

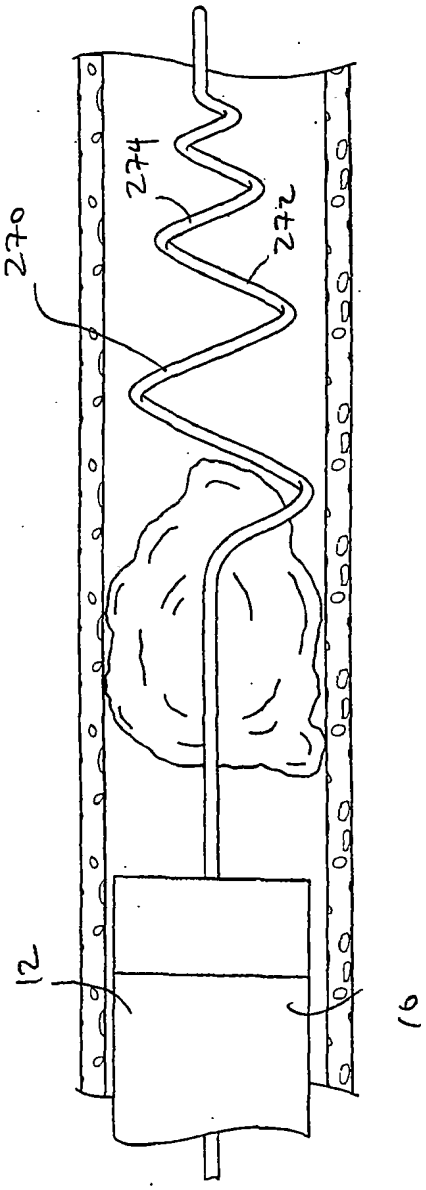


FIG. 53

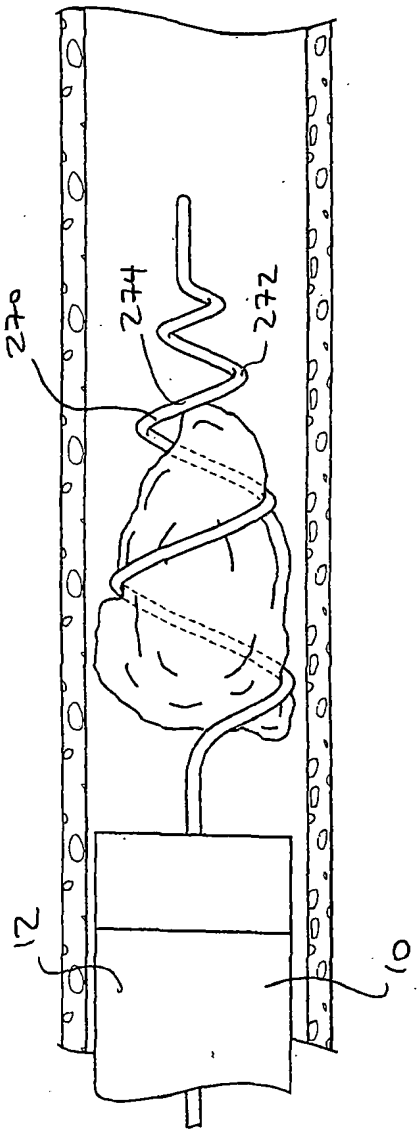


FIG. 54

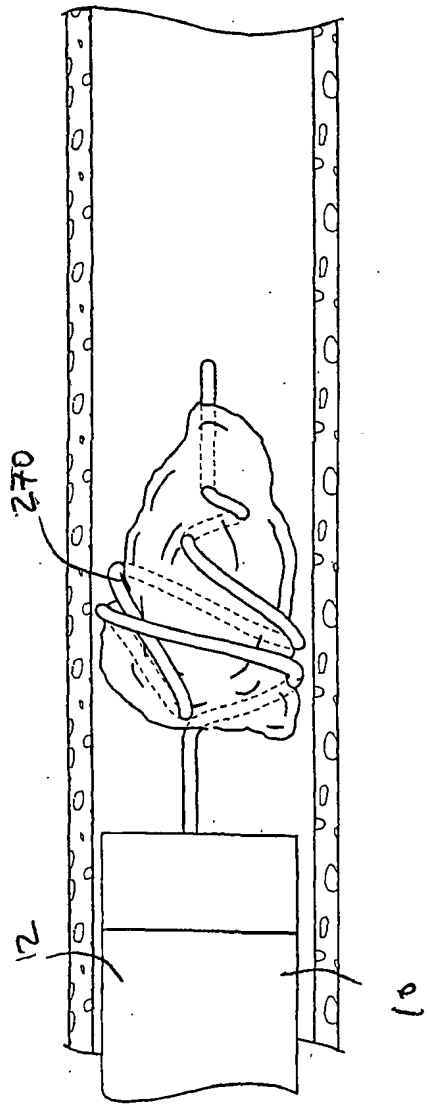
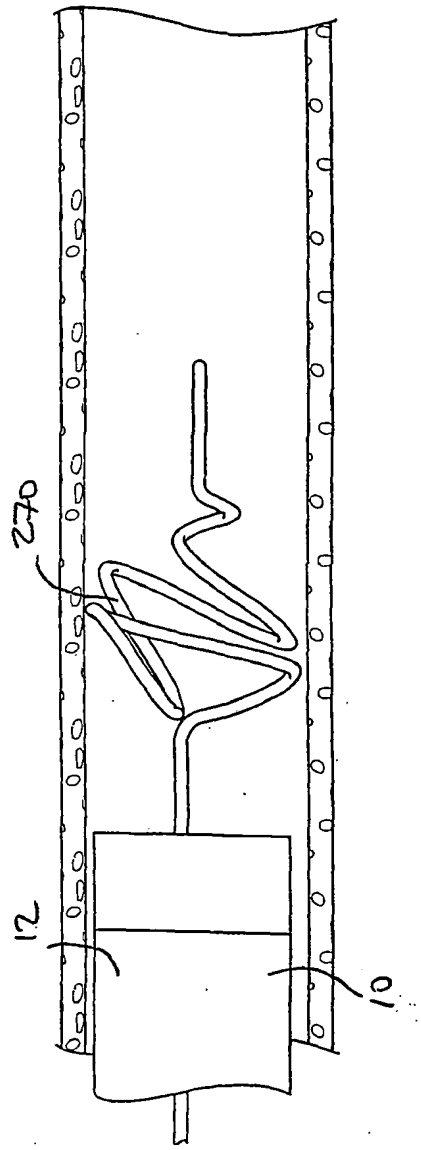


FIG. 55



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 June 2021 (24.06.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/127202 A1

(51) International Patent Classification:
A61B 17/221 (2006.01) *A61B 17/34* (2006.01)
A61B 17/22 (2006.01) *A61F 2/01* (2006.01)
A61B 17/3207 (2006.01) *A61F 2/86* (2013.01)

(21) International Application Number:
PCT/US2020/065645

(22) International Filing Date:
17 December 2020 (17.12.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/949,967 18 December 2019 (18.12.2019) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventor: **THRESS, John Coleman**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(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, IT, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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).

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))*

(54) **Title:** DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION

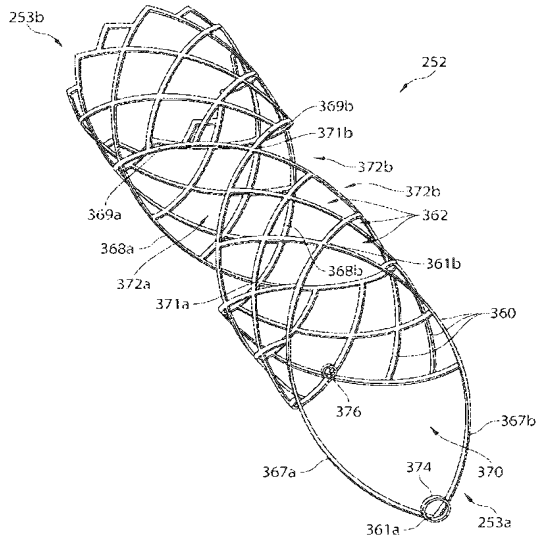


FIG. 3A

(57) **Abstract:** Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. In one embodiment, a system includes a coring element for coring and separating the clot material. The coring element can comprise a unitary structure having a first region, a second region, a third region, and a fourth region. The first region is adjacent to a proximal portion of the unitary structure and includes a first mouth configured to core and separate the clot material. The second region is distal of the first region, generally tubular, and includes a first plurality of interconnected struts. The third region is distal of the second region and includes a second mouth configured to core and separate the vascular thrombus. The fourth region is distal of the third region, generally tubular, and includes a second plurality of interconnected struts.

WO 2021/127202 A1

DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/949,967, filed December 18, 2019, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to systems, methods, and devices for extracting thrombi from blood vessels of human patients. In particular, some embodiments of the present technology relate to systems for thrombus extraction from the peripheral vasculature of a human patient.

BACKGROUND

[0003] Thrombosis is the local coagulation or clotting of the blood in a part of the circulatory system, and a thrombus is a blood clot formed in situ within the vascular system. A venous thrombus is a blood clot that forms within a vein. A common type of venous thrombosis is a deep vein thrombosis (DVT), which is the formation of a blood clot within a deep vein (e.g., predominantly in the legs). Nonspecific signs of a thrombosis may include pain, swelling, redness, warmness, and engorged superficial veins.

[0004] If the thrombus breaks off (embolizes) and flows towards the lungs, it can become a life-threatening pulmonary embolism (PE) (e.g., a blood clot in the lungs). In addition to the loss of life that can arise from PE, DVT can cause significant health issues such as post thrombotic syndrome, which can cause chronic swelling, pressure, pain, and ulcers due to valve and vessel damage. Further, DVT can result in significant health-care costs either directly or indirectly through the treatment of related complications and inability of patients to work.

[0005] Three processes are believed to result in venous thrombosis. First is a decreased blood flow rate (venous stasis), second is an increased tendency to clot (hypercoagulability), and the third is changes to the blood vessel wall. DVT formation typically begins inside the valves of the calf veins where the blood is relatively oxygen deprived, which activates certain biochemical pathways. Several medical conditions increase the risk for DVT, including diabetes, cancer,

trauma, and antiphospholipid syndrome. Other risk factors include older age, surgery, immobilization (as with bed rest, orthopedic casts, and sitting on long flights), combined oral contraceptives, pregnancy, the postnatal period, and genetic factors. The rate of DVT increases dramatically from childhood to old age and, in adulthood, about 1 in 1,000 adults develop DVT annually.

[0006] Although current devices and methods of prevention and/or treatment of DVT exist, there are a number of shortcomings that have yet to be resolved, such as high incidence of DVT re-occurrence, use of devices not designed to remove large clot volumes, and/or complicated treatments involving multiple treatment devices and/or pharmaceuticals. Accordingly, new devices, systems, and methods of treating thrombus, and particularly DVT are desired.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0008] Figure 1 is a side view of a thrombectomy system configured in accordance with an embodiment of the present technology.

[0009] Figures 2A and 2B are side views of a thrombus extraction assembly of the thrombectomy system including a thrombus extraction device in a partially-expanded configuration and a fully-expanded configuration, respectively, configured in accordance with embodiments of the present technology.

[0010] Figures 3A–3D are an isometric view, a side view, a top view, and a rear view, respectively, of a coring element of the thrombus extraction device configured in accordance with embodiments of the present technology.

[0011] Figure 4 is an enlarged side view of the thrombus extraction device coupled to a distal portion of the thrombus extraction assembly and in the fully-expanded configuration in accordance with an embodiment of the present technology.

[0012] Figures 5A and 5B are side views of a dilator assembly of the thrombectomy system in a first configuration and a second configuration, respectively, configured in accordance with embodiments of the present technology.

[0013] Figure 6 is an enlarged cross-sectional side view of a portion of the thrombectomy system including a self-expanding funnel configured in accordance with an embodiment of the present technology.

[0014] Figures 7A–7D are side views of the dilator assembly positioned within an introducer assembly of the thrombectomy system and illustrating various stages in a process or method for deploying the self-expanding funnel in accordance with embodiments of the present technology.

[0015] Figures 8A, 8C, and 8D are cross-sectional side views, and Figure 8B is an enlarged cross-sectional isometric view, of a control assembly of the dilator assembly configured in accordance with embodiments of the present technology.

[0016] Figures 9A–9C, are cross-sectional side views of a control assembly configured in accordance with another embodiment of the present technology.

[0017] Figures 10A and 10B are partially cross-sectional side views of a control assembly configured in accordance with another embodiment of the present technology.

[0018] Figure 11 is a schematic view of an introduction technique for accessing a thrombus for treatment with the thrombectomy system in accordance with an embodiment of the present technology.

[0019] Figures 12A–12C are side views, and Figures 12D–12K are enlarged side views, of the thrombectomy system positioned within a blood vessel during a thrombectomy procedure in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0020] The present technology is generally directed to methods and systems for removing clot material (e.g., a thrombus) from a blood vessel of a human patient. In some embodiments, a system for removing clot material (e.g., a thrombectomy system) includes a thrombus extraction device including (i) a coring element configured to core and separate the clot material from the vessel wall and (ii) a capture element configured to capture the cored and separated clot material. In some embodiments, the coring element comprises a unitary structure having a first region adjacent to a proximal portion of the unitary structure, a second region distal of the first region, a third region distal of the second region, and a fourth region distal of the third region. The first region can include a first mouth configured to core and separate the clot material and the third region can include a second mouth configured to core and separate the clot material. The second

and fourth regions can each be generally tubular and can include a plurality of interconnected struts. In one aspect of the present technology, the first and second mouths are radially offset such that at least one of the first and second mouths is positioned and oriented to effectively core and separate the clot material from within the blood vessel during a thrombus extraction procedure using the thrombus extraction device.

[0021] In some embodiments, the thrombectomy system includes a dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath. The dilator assembly can include a first shaft defining a lumen, a second shaft slidably positioned within the lumen of the first shaft, and a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein. A control assembly including an actuator is operably coupled to the first and second shafts. Movement of the actuator to a first position is configured to distally advance the first and second shafts together to deploy the funnel from the retention sheath. Movement of the actuator to a second position is configured to distally advance the first shaft relative to the second shaft such that first shaft and the retention sheath define a generally uniform (e.g., constant diameter) outer surface. In one aspect of the present technology, the generally uniform outer surface of the dilator assembly is unlikely to snag or otherwise damage the funnel or vessel as the dilator assembly is retracted through the introducer sheath. In another aspect of the present technology, the dilator assembly can be coupled to the introducer sheath to inhibit or even prevent unintentional, premature deployment of the funnel.

[0022] Although many of the embodiments are described below with respect to devices, systems, and methods for treating vascular thrombi (e.g., deep vein thrombosis (DVT)), other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating pulmonary embolism). In general, for example, the devices, systems, and methods of the present technology can be used to extract any formation of material in a vessel (e.g., a venous or arterial vessel), such as cancerous growths, vegetation, and the like. Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–12K can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–12K can be used as standalone

and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–12K.

[0023] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0024] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Thrombectomy Systems

[0025] Figure 1 is a side view of a thrombectomy system 100 (which can also be referred to as a thrombus extraction system, clot removal system) configured in accordance with an embodiment of the present technology. In the illustrated embodiment, the thrombectomy system 100 includes an introducer assembly 102, an obturator or dilator assembly 104 (shown positioned within the introducer assembly 102), and a thrombus extraction assembly 106. In general, the thrombectomy system 100 can be used to (i) access a portion of a blood vessel (e.g., a venous vessel of a human patient) containing a thrombus (e.g., clot material) and (ii) remove all or portions of that thrombus from the blood vessel. More specifically, for example, the introducer assembly 102 and the dilator assembly 104 can be partially advanced into the vasculature of the patient (e.g., a blood vessel or venous vessel of the patient). The dilator assembly 104 can be actuated to deploy a self-expanding funnel (e.g., as shown in Figures 7A–7C) and then removed from the introducer assembly 102. Next, the thrombus extraction assembly 106 and an attached thrombus extraction device can be partially inserted through the introducer assembly 102 and deployed at and/or near the location of a thrombus for capturing the thrombus. Finally, the thrombus extraction assembly 106 and/or the introducer assembly 102 can be removed from the patient along with the captured thrombus. In some embodiments, the thrombectomy system 100 and/or methods of operating the thrombectomy system 100 to remove a thrombus from a patient can include some features the same as or similar to the thrombectomy systems described in detail

in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," and/or (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," both of which are incorporated herein by reference in their entirety.

[0026] In the illustrated embodiment, the introducer assembly 102 includes an elongate sheath 112, which can also be referred to as a shaft, catheter, and the like. The sheath 112 defines a lumen (obscured in Figure 1; e.g., identified as lumen 688 in Figure 6) and includes a proximal portion 113a and a distal portion 113b. The proximal portion 113a can terminate at a proximal end, and the distal portion 113b can terminate at a distal end. The lumen of the sheath 112 is sized to slidably receive the dilator assembly 104 and the thrombus extraction assembly 106. For example, the dilator assembly 104 is shown partially positioned within the sheath 112 in Figure 1. The sheath 112 can be elastic and/or flexible and can have any suitable length and diameter. In some embodiments, the sheath 112 can have an outer diameter of at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, at least 26 French, greater than 26 French, between 10 French and 26 French, between 14 French and 24 French, between 15 French and 21 French, between 16 French and 22 French, and/or any other or intermediate size. In some embodiments, the lumen of the sheath 112 can have an internal diameter of at least 2 French, at least 10 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 11 French and 12 French, between 10 French and 22 French, between 14 French and 21 French, between 16 French and 20 French, and/or any other or intermediate size. In some embodiments, the sheath 112 can include a radiopaque marker (not shown) positioned, for example, at the distal portion 113b thereof.

[0027] The introducer assembly 102 further includes a sealable hub 114 coupled to the proximal portion 113a of the sheath 112. The sealable hub 114 is configured to allow access to the lumen of the sheath 112 and can be self-sealing and/or can comprise a self-sealing seal. For example, in the illustrated embodiment the sealable hub 114 is a hemostasis valve that is configured to maintain hemostasis during a thrombus extraction procedure by preventing fluid flow in the proximal direction through the sealable hub 114 as various components—such as portions of the dilator assembly 104 and/or the thrombus extraction assembly 106—are inserted through the sealable hub 114 to be delivered through the sheath 112 to a treatment site in a blood vessel. More specifically, the sealable hub 114 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND

METHODS OF USE," which is incorporated herein by reference in its entirety. The sealable hub 114 can include one or more buttons or actuators that enable an operator to selectively seal/unseal the sealable hub 114.

[0028] The introducer assembly 102 can further include an aspiration port 116 connected to the sealable hub 114 (e.g., to a side port of the sealable hub 114) and/or the sheath 112 (e.g., to the proximal portion 113a of the sheath 112) via, for example, a connecting tube 118. The aspiration port 116 can be connected to a syringe connector 117 that can be selectively coupled to a syringe or other aspiration device, or the aspiration port 116 can be connected to other suitable elements. In some embodiments, the introducer assembly 102 includes a fluid control device 119 configured to selectively fluidly connect the aspiration port 116 to the lumen of the sheath 112. In the illustrated embodiment, the fluid control device 119 is a stopcock operably coupled to the connecting tube 118 between the lumen of the sheath 112 and the aspiration port 116. In other embodiments, the fluid control device 119 can be a clamp or another suitable valve.

[0029] The dilator assembly 104 can include a control assembly 120 operably coupled to a retention sheath 122 via a first shaft (obscured in Figure 1; e.g., identified as first shaft 580 in Figures 5A and 5B). In the illustrated embodiment, the first shaft of the dilator assembly 104 extends through the sealable hub 114 and the sheath 112 such that the retention sheath 122 is positioned distal of the distal portion 113b of the sheath 112. Moreover, the control assembly 120 is releasably coupled to (e.g., mated to, fixed to) the sealable hub 114. Accordingly, the introducer assembly 102 can carry or hold the dilator assembly 104. As described in greater detail below with reference to Figures 5A–7D, the dilator assembly 104 (e.g., the retention sheath 122) is configured to (i) hold/constrain a self-expanding funnel (obscured in Figure 1; e.g., identified as funnel 690 in Figure 6) that is attached to the distal portion 113b of the sheath 112, and (ii) release/deploy the self-expanding funnel. More specifically, for example, the control assembly 120 can include an actuator 124 that is movable (e.g., in the direction of arrow A in Figure 1) to advance the retention sheath 122 relative to the sheath 112 (and the self-expanding funnel) attached thereto to deploy/release the self-expanding funnel.

[0030] In some embodiments, the thrombectomy system 100 can further include a loading tool 108 (e.g., a loading funnel) for use in loading the self-expanding funnel into the dilator assembly 104 (e.g., into the retention sheath 122). In the illustrated embodiment, the loading tool 108 defines a lumen 127 therethrough and includes a first portion 126 of varying diameter (e.g., a tapered portion such as a funnel portion) and a second portion 128 of generally constant diameter

(e.g., a shaft portion). In other embodiments, the second portion 128 can have a partially varying diameter. The first portion 126 is configured (e.g., sized and shaped) to receive the self-expanding funnel and to move the self-expanding funnel to the constrained configuration as the self-expanding funnel is advanced through the first portion 126. The lumen 127 of the loading tool 108 can be sized to allow the retention sheath 122 to pass completely through the loading tool 108.

[0031] In the illustrated embodiment, the thrombus extraction assembly 106 includes a catheter portion 130 and a handle portion 140 ("handle 140") operably coupled to the catheter portion 130. In operation, the handle 140 is configured to be actuated/manipulated by a user to control (e.g., deploy) one or more components of the catheter portion 130 and/or a thrombus extraction device (not shown in Figure 1; e.g., identified as thrombus extraction device 250 in Figures 2A and 2B) coupled to the catheter portion 130.

[0032] In the illustrated embodiment the catheter portion 130 includes an outer shaft 132, an intermediate shaft 133, and an inner shaft 134 slidably and coaxially aligned relative to one another. For example, each of the shafts 132–134 can define a lumen (e.g., a central, axial lumen) and (i) the intermediate shaft 133 can be configured (e.g., sized and shaped) to slidably fit within the lumen of the outer shaft 132 and (ii) the inner shaft 134 can be configured to slidably fit within the lumen of the intermediate shaft 133. In some embodiments, the outer shaft 132 is configured (e.g., sized) to slidably fit within the sheath 112 of the introducer assembly 102 and can have, for example, a size of at least 8 French, at least 10 French, at least 11 French, at least 12 French, at least 14 French, at least 16 French, between 8 French and 14 French, between 11 French and 12 French, and/or any other or intermediate size. By this arrangement, each of the shafts 132–134 can be displaced longitudinally relative to one another and relative to the sheath 112 of the introducer assembly 102. In some embodiments, each of the shafts 132–134 can have the same length while, in other embodiments, one or more of the shafts 132–134 can have different lengths. For example, in some embodiments the intermediate shaft 133 can be longer than the outer shaft 132 and the inner shaft 134 can be longer than the intermediate shaft 133. In other embodiments, the catheter portion 130 can comprise any number of shafts (e.g., catheters, sheaths) that are slidable relative to one another and/or configured to be positioned coaxially relative to one another. For example, in some embodiments the catheter portion can include three intermediate shafts as described in detail in U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

[0033] The handle 140 includes a proximal portion 141a (e.g., a plunger portion) and a distal portion 141b (e.g., a locking portion). In the illustrated embodiment, the intermediate shaft 133 is coupled to and extends distally from the distal portion 141b of the handle 140. The distal portion 141b of the handle 140 can include a lock feature 142 such as, for example, a spinlock. The lock feature 142 is configured to selectively engage and/or lockingly engage with a mating feature 135 located near a proximal portion 136a of the outer shaft 132. In some embodiments, the outer shaft 132 can slide proximally over the intermediate shaft 133 until the lock feature 142 engages with the mating feature 135 to thereby secure the position of the outer shaft 132 relative to the intermediate shaft 133. In some embodiments, the intermediate shaft 133 is relatively longer than the outer shaft 132 such that a portion of the intermediate shaft 133 extends distally from a distal portion 136b of the outer shaft 132 when the outer shaft 132 is lockingly engaged with the lock feature 142.

[0034] In the illustrated embodiment, the handle 140 further includes a plunger 144 (e.g., an actuator) operably coupled to the inner shaft 134 and movable between a first, non-extended position (e.g., as shown in Figures 1 and 2A) and a second, extended position (e.g., as shown in Figure 2B). Thus, movement of the plunger 144 relative to the handle 140 displaces the inner shaft 134 relative to the handle 140, the outer shaft 132, and/or the intermediate shaft 133. For example, withdrawing the plunger 144 proximally from the first position to the second position can withdraw the inner shaft 134 through the intermediate shaft 133. In some embodiments, the inner shaft 134 can have a length such that the inner shaft 134 extends distally past a distal terminus of the intermediate shaft 133 when the plunger 144 is in both the first and second positions. In some embodiments, the plunger 144 can be lockable in the first position and/or the second position to lock the position of the inner shaft 134. In other embodiments, the plunger 144 can be operably coupled to other components of the catheter portion 130 such as, for example, the intermediate shaft 133 and/or one or more additional shafts (not shown).

[0035] In the illustrated embodiment, the thrombus extraction assembly 106 further includes a first flush port 138 connected to the outer shaft 132 and a second flush port 148 connected to the handle 140. The first flush port 138 can be fluidly connected to the lumen of the outer shaft 132 to allow flushing of the lumen of the outer shaft 132. The second flush port 148 can be fluidly connected to the lumen of the intermediate shaft 133 (e.g., via an internal portion of the handle 140) to allow flushing of the lumen of the intermediate shaft 133.

[0036] The thrombus extraction assembly 106 can include and/or be coupled to a thrombus extraction device configured to core and capture a thrombus from the patient. Figures 2A and 2B, for example, are side views of the thrombus extraction assembly 106 of Figure 1 operably coupled to a thrombus extraction device 250 configured in accordance with embodiments of the present technology. The thrombus extraction device 250 is shown in a deployed and partially-expanded configuration in Figure 2A and a deployed and fully-expanded configuration in Figure 2B. The thrombus extraction device 250 can be in an undeployed, constrained (e.g., unexpanded) position when positioned within the outer shaft 132.

[0037] Referring to Figures 2A and 2B together, the thrombus extraction device 250 includes an expandable coring element 252 and an expandable capture element 254 coupled to (e.g., attached to, connected to, integrally formed with) the coring element 252. The coring element 252 is positioned proximal of the capture element 254. In the illustrated embodiment, the coring element 252 includes (i) a proximal portion 253a coupled to the intermediate shaft 133 (e.g., to a distal portion of the intermediate shaft 133) and (ii) a distal portion 253b coupled to a proximal portion 255a of the capture element 254. Further, a distal portion 255b of the capture element 254 is coupled to the inner shaft 134 (e.g., to a distal portion of the inner shaft 134). As shown, the outer shaft 132 is proximally displaced relative to the handle 140 such that the mating feature 135 of the outer shaft 132 contacts/engages the lock feature 142 of the handle 140. Due to this positioning of the outer shaft 132 relative to the handle 140, each of the intermediate shaft 133, the inner shaft 134, and the thrombus extraction device 250 extend distally beyond the distal portion 136b of the outer shaft 132.

[0038] In some embodiments, the thrombus extraction device 250 can further include an atraumatic tip 258. In some embodiments, the atraumatic tip 258 can include a radiopaque marker to aid in intravascularly positioning the thrombus extraction device 250 within the patient. The thrombus extraction device 250 can additionally or alternatively include one or more radiopaque markers located on, for example, the outer shaft 132 (e.g., the distal portion 136b of the outer shaft 132) the intermediate shaft 133 (e.g., the distal portion of the intermediate shaft 133), and or other components of the thrombus extraction device 250. In some embodiments, the atraumatic tip 258 can define a channel configured to receive a guidewire therethrough.

[0039] In the partially-expanded configuration shown in Figure 2A, the plunger 144 of the handle 140 is in the first position. In contrast, in the fully-expanded configuration shown in Figure 2B, the plunger 144 is in the second position (e.g., proximally retracted away from the handle

140) such that the inner shaft 134 is proximally retracted relative to the intermediate shaft 133. This proximal retraction of the inner shaft 134 relative to the intermediate shaft 133 forces the coring element and capture element 254 to fully expand, as described in greater detail below with reference to Figure 4.

[0040] The thrombus extraction assembly 106 can comprise one or several features configured to secure the thrombus extraction device 250, and specifically the coring element 252 and/or the expandable capture element 254 in the fully-expanded position. As used herein, full expansion describes a condition in which the thrombus extraction device 250 is continually biased toward expansion by one or several forces in addition to the self-expanding forces arising from the thrombus extraction device 250. In some embodiments, full expansion occurs when the thrombus extraction device 250 is deployed and when the plunger 144 is in the second position (e.g., when the inner shaft 134 is proximally retracted relative to the intermediate shaft 133). Alternatively or additionally, full-expansion can occur when the thrombus extraction device 250 is deployed and biased towards expansion via a spring connected either directly or indirectly to the thrombus extraction device 250. Accordingly, when the thrombus extraction device 250 is fully expanded, forces less than a minimal radial compressive force do not change the diameter of the thrombus extraction device 250. Therefore, when fully-expanded, the thrombus extraction device 250 can maintain at least a desired radial force on a blood vessel when the thrombus extraction device 250 is drawn through that blood vessel. In some embodiments, the dimensions of the thrombus extraction device 250 can be selected such that the thrombus extraction device 250 apposes a wall of the blood vessel and/or applies a desired force to the wall of the blood vessel when fully expanded.

[0041] In some embodiments, the plunger 144 can be locked in the second position by, for example, rotating the plunger 144 with respect to the handle 140 to thereby engage one or several locking features on the plunger 144 and/or in the handle 140. Locking the plunger 144 in the second position secures the position of the inner shaft 134 relative to the intermediate shaft 133, thereby securing the thrombus extraction device 250 in the fully-expanded position. In other embodiments, the inner shaft 134 and the intermediate shaft 133 can be directly locked together via for example, (i) a static coupling in which the position of the inner shaft 134 is fixed relative to the position of the intermediate shaft 133 or (ii) a dynamic coupling in which the position of the inner shaft 134 relative to the intermediate shaft 133 is limited (rather than fixed). For example, the inner shaft 134 can be dynamically locked to the plunger 144 via a compliance spring

(e.g., a tension spring, compression spring), which allows limited movement of the inner shaft 134 relative to the intermediate shaft 133 when the plunger 144 is locked in the second position.

II. Selected Embodiments of Coring Elements

[0042] Figures 3A–3D are an isometric view, a side view, a top view, and a (proximally-facing) rear view, respectively, of the coring element 252 of the thrombus extraction device 250 of Figures 2A and 2B configured in accordance with embodiments of the present technology. Referring to Figures 3A–3D together, the coring element 252 comprises a plurality of struts 360 that together define a plurality of interstices or pores 362. The struts 360 can have a variety of shapes and sizes and, in some embodiments, the struts 360 can have a thickness and/or diameter between about 0.05–0.15 inch, between about 0.075–0.125 inch, between about 0.09–0.1 inch, about 0.096 inch, and/or other dimensions. In general, the struts 360 can together form a unitary fenestrated structure that is configured to core and separate a portion of a thrombus (e.g., a vascular thrombus) from a blood vessel containing the thrombus. In some embodiments, the coring element 252 can comprise a stent or stent-like device.

[0043] As best shown in Figures 3B and 3C, the coring element 252 includes a first region 363 including the proximal portion 253a, a second region 364 distal of the first region 363, a third region 365 distal of the second region 364, and a fourth region 366 distal of the third region 365 and including the distal portion 253b. The second region 364 and the fourth region 366 can be generally tubular. The first region 363 and the third region 365 have relatively fewer of the struts 360 compared to the second region 364 and the fourth region 366. For example, the first region 363 can include a pair of curved struts 367 (identified individually as first strut 367a and second strut 367a as best shown in Figures 3A and 3C) that curve in opposite directions around a central axis L of the coring element 252 and intersect and/or terminate at a pair of first junctions 361 (identified individually as a lower first junction 361a and an upper first junction 361b) to define a proximal, first mouth 370. The third region 365 can include (i) a pair of curved lower struts 368 (identified individually as a first lower strut 368a and a second lower strut 368b shown together in Figure 3A) that extend distally from a lower second junction 371a and curve around the central axis L and (ii) a pair of curved upper struts 369 (identified individually as a first upper strut 369a and a second upper strut 369b shown together in Figures 3A and 3C) that extend distally from an upper second junction 371b and curve around the central axis L. The lower and upper struts 368, 369 together define a distal first mouth portion 372a and a distal second mouth portion 372b (collectively "a second mouth 372"). In the illustrated embodiment, the first mouth portion 372a

is rotationally offset from the second mouth portion 372b. In other embodiments, the first mouth portion 372a can be positioned differently relative to the second mouth portion 372b (e.g., in a different rotational and/or longitudinal direction) and/or the second mouth 372 can comprise more than two separate portions (e.g., three, four, or more openings). In general, the first and second mouths 370, 372 can be defined by/in regions of the coring element 252 having different porosities.

[0044] In some embodiments, the coring element 252 is made from a shape memory material such as a shape memory alloy and/or a shape memory polymer. For example, the coring element 252 can comprise nitinol and/or a nitinol alloy. Similarly, the coring element 252 can be made using a variety of techniques including welding, laser welding, cutting, laser cutting, and/or expanding. For example, the coring element 252 can first be laser cut from a piece of nitinol (e.g., a nitinol tube) and then blown up and/or expanded. In general, the size (e.g., the length and diameter) of the coring element 252 can be selected based on the size (e.g., diameter) of the blood vessel from which thrombus is to be extracted. In some embodiments, the coring element 252 can have a length M of between about 0.2–5 inches (e.g., between about 1.5–2.5 inches, between about 1.75–2.25 inches, between about 1.9–2.0 inches, between about 1.5–1.8 inches, about 1.6 inches, about 1.7 inches, about 1.96 inches, about 3.0 inches, about 4.0 inches, smaller than 0.5 inch). In some embodiments, in the fully-expanded position unconstrained within a vessel, the coring element 252 can have a diameter D of between about 2–50 mm (e.g., between about 4–25 mm, between about 6 20 mm, between about 8–16 mm). In some embodiments, the length M of the coring element 252 can be selected based on the fully expanded and unconstrained diameter D of the coring element 252 to prevent undesired tipping and/or rotation of the coring element 252 within the blood vessel during operation. In general, the length M and the unconstrained diameter D of the coring element 252 will vary depending on the size of the vessel the coring element 252 is designed for. For example, the coring element 252 will generally have a smaller length M and diameter D when designed for smaller (e.g., 4 mm) vessels rather than larger (e.g., 25–35 mm) vessels.

[0045] The coring element 252 is configured to core (e.g., shear, separate) thrombus from within the blood vessel when the coring element is advanced/retracted through the thrombus in the fully-expanded configuration. For example, as described in greater detail below with reference to Figures 12D–12K, the coring element 252 can be withdrawn proximally through the thrombus to core the thrombus. As the coring element 252 is withdrawn through the thrombus the fully-expanded diameter of the coring element 252 will flexibly adapt to match the diameter of the

blood vessel. More particularly, the first and second mouths 370, 372 are configured (e.g., sized, shaped, and/or positioned) to provide most of the coring function (e.g., coring force) during operation of the coring element 252. For example, proximally-facing surfaces of the struts 367 can define a first leading edge that cuts through and cores the thrombus. Similarly, proximally-facing surfaces of the lower and upper struts 368, 369 can define a second leading edge that can also cut through and core the thrombus. In some embodiments, portions of the struts 367, the lower struts 368, and/or the upper struts 369 can be sharpened and/or can include a cutting element (e.g., a knife or knife edge) attached thereto or otherwise integrated with to further facilitate coring of the thrombus.

[0046] In one aspect of the present technology, the first mouth 370 and the second mouth 372 are longitudinally offset relative to one another. Moreover, the leading edges of the struts 367 and the leading edges of the lower and upper struts 368, 369 are oriented differently such that, for example, the first mouth 370 and the second mouth 372 are oriented at different angles when the coring element 252 is within the blood vessel. The arrangement can be more effective at coring thrombus compared to, for example, coring elements including only a single mouth (e.g., including only the first mouth 370). It is expected that the coring element 252 provides a greater coring length for engaging the wall of the blood vessel and coring (e.g., adherent) thrombus than coring elements with only a single mouth. Moreover, the coring element 252 can be relatively flexible at the first region 363 and third region 365 which include fewer struts 360 than the second region 364 and fourth region 366. For example, the coring element 252 can flex/bend at the first junctions 361 and/or the second junctions 371. In some embodiments, the first and second junctions 361, 371 enable the coring element 252 to flex in different directions (e.g., laterally and vertically). In one aspect of the present technology, this ability of the coring element 252 to flex can allow the coring element 252 to maintain a selected orientation—even when moved through tortuous vessels. In another aspect of the present technology, the arrangement of the first and second mouths 370 and 372 ensures that at least one of the first mouth 370, the first mouth portion 372a, and the second mouth portion 372b is positioned and oriented to effectively core thrombus from within the blood vessel during a thrombus extraction procedure using the coring element 252. In some embodiments, the first mouth 370 and/or the second mouth 372 can further facilitate the collapse of the coring element 252 to the non-expanded configuration.

[0047] In the embodiment illustrated in Figures 3A–3D, a first connection feature 374 and a second connection feature 376 are coupled to the coring element 252. As described in greater detail below with reference to Figure 4, the intermediate shaft 133 (Figure 1) can be operably

coupled to the first connection feature 374 and the inner shaft 134 can be operably coupled to the second connection feature 376 for controlling operation (e.g., movement and expansion) of the coring element 252. In the illustrated embodiment, the first connection feature 374 is a ring coupled to the proximal portion 253a of the coring element 252 and, more specifically, to the lower first junction 361a. In other embodiments, the first connection feature 374 can be positioned on a different portion of the coring element 252 (e.g., at the upper first junction 361b, on one of the struts 367). Similarly, the second connection feature 376 can also be a ring and can be coupled to one or more of the struts 360 in the second region 364 or another region of the coring element 252. As best seen in Figure 3D, in some embodiments the first connection feature 374 can have a diameter E_1 that is greater than a diameter E_2 of the second connection feature 376, and the first and second connection features 374, 376 can be axially aligned along an axis extending parallel to the central axis L of the coring element 252. In other embodiments, the first and second connection features 374, 376 can have other shapes and/or configurations and/or can be arranged differently relative to one another. The first and second connection features 374, 376 can be the same material as the coring element 252 or can be a different material than the coring element 252. Likewise, the first and second connection features 374, 376 can be integrally formed with the coring element 252 and/or can be attached to the coring element 252 via, for example, one or more of welds, adhesives, mechanical fasteners, and the like.

[0048] Figure 4 is an enlarged side view of the thrombus extraction device 250 coupled to a distal portion of the thrombus extraction assembly 106 and in the fully-expanded configuration in accordance with an embodiment of the present technology. In the illustrated embodiment, the coring element 252 is coupled to the intermediate shaft 133 (e.g., to a distal portion of the intermediate shaft 133) via the first connection feature 374. In some embodiments, the coring element 252 is fixedly coupled to the intermediate shaft 133 such that movement of the intermediate shaft 133 also moves the coring element 252. The proximal portion 255a of the capture element 254 is connected to the distal portion 253b of the coring element 252. In some embodiments, the capture element 254 is formed on the distal portion 253b of the coring element 252 such that the thrombus extraction device 250 is a unitary/integral structure. For example, the capture element 254 can comprise a mesh (e.g., a braided filament mesh structure) that is woven onto the distal portion 253b of the coring element 252. In some embodiments, the distal portion 255b of the capture element 254 is coupled to the to the inner shaft 134 (e.g., to a distal portion of the inner shaft 134).

[0049] In the illustrated embodiment, the inner shaft 134 slidably extends through the second connection feature 376. That is, the inner shaft 134 can have an outer diameter that is less than the diameter E_2 (Figure 4) of the second connection feature 376 such that the second connection feature 376 is slidable along the inner shaft 134. The inner shaft 134 can include a stop feature 478 configured to engage the second connection feature 376 of the coring element 252 to effect expansion of the coring element 252. In some embodiments, the stop feature 478 can comprise a polymeric member and/or a metallic member that is affixed to a portion of the inner shaft 134 that is distal of the second connection feature 376.

[0050] The stop feature 478 is configured (e.g., sized and shaped) to contact and engage the second connection feature 376 when the inner shaft 134 is withdrawn proximally relative to the coring element 252 via, for example, movement of the plunger 144 (Figures 1–3) from the first position to the second position. By this arrangement, the coring element 252 is selectively coupled to the inner shaft 134 such that the stop feature 478 can apply a proximally-directed force to the coring element 252 that can expand all or a portion of the coring element 252 to the fully-expanded configuration. For example, movement of the inner shaft 134 can forcibly expand at least the first region 363 (Figures 3B and 3C) of the coring element which is between the first and second connection features 374, 376. In some embodiments, the second connection feature 376 can be positioned differently with respect to the coring element 252 such that more or less of the coring element 252 is forcibly expanded when the stop feature 478 is pulled against the second connection feature 376.

[0051] In some embodiments, the capture element 254 can comprise a braided filament mesh structure, such as a braid of elastic filaments having a generally tubular, elongated portion 477 and a distal tapered portion 479. In other embodiments, the capture element 254 can be any porous structure and/or can have other suitable shapes, sizes, and configurations. Because the distal portion 255b of the capture element 254 is coupled to the inner shaft 134, axial movement of the inner shaft 134 expands/shortens and collapses/lengthens the capture element 254. For example, proximal movement of the inner shaft 134 can compress the capture element 254 along its longitudinal axis such that (i) a radius of the capture element 254 increases and (ii) the length of the capture element 254 decreases. Conversely, distal movement of the inner shaft 134 can stretch the capture element 254 along its longitudinal axis such that (i) the radius of the capture element 254 decreases and (ii) the length of the capture element 254 increases. In some embodiments, with reference to Figures 2A, 2B, and 4 together, distal movement of the plunger 144 can move the capture element 252 to a fully-collapsed position before the plunger 144 reaches

the fully-depressed first position shown in Figure 2A. Thus, continued distal movement of the plunger 144 (e.g., from the second position toward the first position) can pull the coring element 252 to cause the coring element 252 to collapse/longitudinally extend. That is, the plunger 144, the inner shaft 134, and the capture element 254 can collectively act to elongate/collapse the coring element 252 as the plunger 144 is distally depressed while the capture element 254 is fully collapsed. In other embodiments, the inner shaft 134 can be selectively decoupled from the capture element 254 such that proximal displacement of the inner shaft 134 expands the coring element 252 without effecting any movement of the capture element 254. In some embodiments, the capture element 254 can have a length (i) in the collapsed configuration of between about 5–30 inches (e.g., between about 10–20 inches, about 16 inches) and (ii) in the expanded configuration of between about 1–25 inches (e.g., between about 10–20 inches, about 11 inches).

[0052] In some embodiments, the capture element 254 can be formed by a braiding machine and/or a weaving machine while, in other embodiments, the capture element 254 can be manually braided and/or woven. In some embodiments, the capture element 254 is formed as a tubular braid and is then further shaped using a heat setting process. The braid can be a tubular braid of fine metal wires such as nitinol (nickel-titanium alloy), platinum, cobalt-chrome alloy, stainless steel, tungsten or titanium. In some embodiments, the capture element 254 can be formed at least in part from a cylindrical braid of elastic filaments. Thus, the braid may be radially constrained without plastic deformation such that it can self-expand on release of the radial constraint. Such a braid of elastic filaments can be referred to herein as a "self-expanding braid." In some embodiments, the thickness of the braid filaments can be less than about 0.15 mm. In some embodiments, the braid may be fabricated from filaments and/or wires with diameters ranging from about 0.05–0.25 mm. In some embodiments, braid filaments of different diameters may be combined to impart different characteristics including: stiffness, elasticity, structure, radial force, pore size, embolic capturing or filtering ability, and so on. In some embodiments the capture element 254 and/or the coring element 252 can be coated to reduce their surface friction/abrasiveness (e.g., for arterial applications). Likewise, the capture element 254 and/or the coring element 252 can be covered with a film (e.g., via dipping or spray coating) to create a non-permeable membrane to contain clot without allowing the clot to become embedded in the interstices of the capture element 254 and/or the coring element 252, thereby facilitating ease of cleaning. In some embodiments, the number of filaments used to form the capture element 254 can be between about 20–300 (e.g., including 144 filaments, 244 filaments). In some embodiments, the size of the pores formed by the capture element 254 (e.g., in the elongated

portion 477) can be between about 0.05–4.0 mm (e.g., between about 0.5 mm–2.5 mm, less than 0.4 mm).

III. Selected Embodiments of Dilator Assemblies and Associated Methods

[0053] Figures 5A and 5B are side views of the dilator assembly 104 of Figure 1 in a first configuration and a second configuration, respectively, configured in accordance with embodiments of the present technology. Referring to Figures 5A and 5B together, the dilator assembly 104 includes a first shaft or sheath 580 extending between and operably coupling the control assembly 120 and the retention sheath 122. The dilator assembly 104 can further include a second shaft or sheath 582 slidably positioned over the first shaft 580 and operably coupled to the control assembly 120. Put differently, the second shaft 582 can define a lumen sized to slidably receive the first shaft 580 such that the first and second shafts 580, 582 are axially displaceable relative to one another. In the illustrated embodiment, the first shaft 580 is longer than the second shaft 582 such that the retention sheath 122 is positioned distal of a distal portion 583b (opposite a proximal portion 583a) of the second shaft 582. The control assembly 120 further includes a housing 595 configured to engage (e.g., mate with) the sealable hub 114 of the introducer assembly 102 (Figure 1).

[0054] The retention sheath 122 includes a proximal portion 585a and a distal portion 585b. In the illustrated embodiment, the distal portion 585a includes an atraumatic tip 584 and the proximal portion 585a includes a first engagement feature 586. Similarly, the distal portion 583b of the second shaft 582 includes a second engagement feature 589. In some embodiments, the atraumatic tip 584 is radiopaque.

[0055] When the dilator assembly 104 is in the first configuration shown in Figure 5A, the second shaft 582 is proximally positioned (e.g., withdrawn) relative to the first shaft 580 such that the first engagement feature 586 does not engage the second engagement feature 589. As described in greater detail below with reference to Figure 7A, when the dilator assembly 104 is in the first configuration, the first engagement feature 586 is configured to engage (e.g., connect with, mate with) the distal portion 113b of the sheath 112 of the introducer assembly 102 (Figure 1). In some embodiments, the engagement of the first engagement feature 586 with the sheath 112 can form a seal.

[0056] When the dilator assembly 104 is in the second configuration (Figure 5B), the second engagement feature 589 of the second shaft 582 is configured to engage the first engagement feature 586 of the retention sheath 122. As shown, the second shaft 582 can have a diameter that

is equal to or substantially equal to the outer diameter of the retention sheath 122 such that the dilator assembly 104 has a uniform or substantially uniform (e.g., smooth) outer surface in the second configuration. That is, there is no step or discontinuity in the outer surface between, for example, the first shaft 580 and the retention sheath 122. In other embodiments, the second shaft 582 and the retention sheath 122 can have different diameters, and the first and second engagement features 586, 589 can be configured to provide a smooth transition between the second shaft 582 and the retention sheath 122. In some embodiments, the engagement of the first engagement feature 586 with the second engagement feature 589 can form a seal. In some embodiments, the operator can move the dilator assembly 104 from the first configuration to the second configuration by actuating the actuator 124 of the control assembly 120 (e.g., by advancing the actuator 124 in the direction of arrows A). More specifically, as described in greater detail below with reference to Figures 7A–7D, actuation of the actuator 124 can distally advance (i) the first and second shafts 580, 582 together relative to the sheath 112 and then (ii) the second shaft 582 relative to the first shaft 580.

[0057] Figure 6 is an enlarged cross-sectional side view of a portion of the thrombectomy system 100 shown in Figure 1. More particularly, Figure 6 shows a self-expanding funnel 690 coupled to the distal portion 113b of the sheath 112 of the introducer assembly 102 and restrained within the retention sheath 122 of the dilator assembly 104 in accordance with an embodiment of the present technology. In the illustrated embodiment, the retention sheath 122 includes a shell portion 692 coupled to the tip 584 and defining a lumen 693. In some embodiments, the shell portion 692 and the tip 584 are integrally formed together while, in other embodiments, the tip 584 can be a separate component that is coupled to the shell portion 692 by, for example, positioning at least a portion of the tip 584 in the lumen 693 and securing the shell portion 692 to the tip 584 (e.g., via an adhesive, friction fit).

[0058] The first shaft 580 of the dilator assembly 104 extends through a lumen 688 of the sheath 112 and at least partially through the lumen 693 of the shell portion 692. In the illustrated embodiment, a portion of the tip 584 snuggly receives a distal portion (e.g., a distal portion) of the first shaft 580 to secure the first shaft 580 to the retention sheath 122. In other embodiments, the first shaft 580 can be coupled to the retention sheath 122 in other manners. As further shown in Figure 6, the first shaft 580 and the tip 584 can define a continuous lumen 691 for receiving a guidewire (not shown). In some embodiments, the guidewire can have a diameter of about 0.038 inch, 0.035 inch, about 0.018 inch, 0.014 inch, greater than about 0.38 inch, less than about 0.1 inch, or less than about 0.05 inch.

[0059] In the illustrated embodiment, an inner diameter F_1 of the shell portion 692 is greater than an external diameter F_2 of the first shaft 580 such that an annular retaining/receiving space 694 is formed between the outer surface of the first shaft 580 and the inner surface of the shell portion 692. The receiving space 694 is configured (e.g., sized and shaped) to receive and/or retain the funnel 690 in a constrained configuration. Accordingly, in some embodiments the funnel 690 can have a diameter substantially matching the inner diameter F_1 of the shell portion 692 when the funnel 690 is in the constrained configuration. In some embodiments, the first engagement feature 586 of the retention sheath 122 can engage (e.g., sealingly engage) the distal portion 113b of the sheath 112 when the funnel 690 is retained within the retention sheath 122.

[0060] Figures 7A–7D are side views illustrating various stages in a process or method for deploying the funnel 690 in accordance with embodiments of the present technology. Referring first to Figure 7A, the dilator assembly 104 is initially positioned within the introducer assembly 102 in the first configuration (Figure 5A) such that (i) the housing 595 of the control assembly 120 is coupled to/engages the sealable hub 114 and (ii) the first engagement feature 586 of the retention sheath 122 sealingly engages the distal portion 113b of the sheath 112. In other embodiments, the first engagement feature 586 need not sealingly engage the sheath 112. In the initial position shown in Figure 7A, the actuator 124 of the control assembly 120 is in a first position (e.g., a fully-retracted position) and the funnel 690 is contained in the constrained configuration within the retention sheath 122, as shown in Figure 6.

[0061] In the arrangement shown in Figure 7A, the introducer assembly 102 and the dilator assembly 104 (collectively "assemblies 102, 104") can be used to percutaneously access a venous vessel of a patient through, for example an access site such as a popliteal access site, a femoral access site, an internal jugular access site, and/or other access site. In some embodiments, the assemblies 102, 104 are inserted through another introducer sheath (not shown). In some embodiments, the assemblies 102, 104 are advanced within the venous vessel to a treatment position in which the distal portion 113b of the sheath 112 is proximate to (e.g., proximal of) a thrombus in the venous vessel.

[0062] Referring to Figure 7B, after positioning the assemblies 102, 104, the funnel 690 (shown as transparent in Figures 7B and 7C for the sake of clarity) can be deployed by, for example, moving the actuator 124 from the first position (Figure 7B) to a second position (e.g., an intermediate position, a mid-stroke position, a drop-off position) to distally advance the first and second shafts 580, 582 together relative to the sheath 112. The distal advancement of the first

shaft 580 causes the retention sheath 122 to move distally over and away from the funnel 690. The funnel 690 self-expands to an expanded (e.g., unconstrained) configuration when the funnel 690 is no longer constrained by the retention sheath 122. In other embodiments, the control assembly 120 is configured such that moving the actuator 124 from the first position to the second position distally advances only the first shaft 580 of the dilator assembly 104 rather than both the first and second shafts 580, 582 together.

[0063] The funnel 690 can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, in the expanded configuration, the funnel 690 can have (i) a maximum diameter greater than and/or equal to the diameter D of the coring element 252 (Figures 3B and 3C) when the coring element 252 is in the fully-expanded configuration and (ii) a minimum diameter substantially equal to an outer diameter of the sheath 112. In some embodiments, the funnel 690 can have a length N that is greater than and/or equal to the length M of the coring element 252 (Figures 3A–3D) such that the coring element 252 can be received and contained within the funnel 690. In other embodiments, the length N of the funnel 690 can be less than the length M of the coring element 252. In some embodiments, the funnel 690 can have a conically shaped portion, and specifically, a truncated-conically shaped portion. In some embodiments, the funnel 690 can be formed from at least one of a castellated nitinol braid, a nitinol braided stent, a laser cut nitinol, a laser cut polymer tube, an injection molded polymeric structure, or an inflatable balloon. In some embodiments, the funnel 690 can comprise a mesh having a pore size sufficiently small to prevent the passage of thrombus through the pores of the mesh. In some embodiments, the funnel 690 can be permeable to blood.

[0064] Referring to Figure 7C, after the funnel 690 has been deployed, the dilator assembly 104 can be moved to the second configuration (Figure 5B). For example, the operator can move the actuator 124 of the control assembly 120 from the second position (Figure 7B) to a third position (e.g., a fully-advanced position) to distally advance the second shaft 582 relative to the first shaft 580 until the second engagement feature 589 of the second shaft 582 engages the first engagement feature 586 of the retention sheath 122. As shown in Figure 7D, after moving the dilator assembly 104 to the second configuration, the dilator assembly 104 can be fully retracted and withdrawn from the introducer assembly 102. For example, the dilator assembly 104 can be proximally retracted through the lumen of the sheath 112 and out of the sealable hub 114 of the introducer assembly 102.

[0065] Referring to Figures 7A–7D together, in one aspect of the present technology, moving the dilator assembly 104 to the second configuration before retracting the dilator assembly 104 from the introducer assembly 102 can inhibit or even prevent the dilator assembly 104 from damaging the funnel 690 or other components of the introducer assembly 102 during retraction of the dilator assembly 104. More specifically, if the dilator assembly 104 did not include the second shaft 582, proximal retraction of the retention sheath 122 into the sheath 112 could cause the retention sheath 122 (e.g., the first engagement feature 586) to snag or damage the deployed funnel 690. However, because the second shaft 582 has a diameter that is equal to or substantially equal to the outer diameter of the retention sheath 122, the dilator assembly 104 has a uniform or substantially uniform (e.g., smooth) outer surface in the second configuration, and is therefore less likely to snag or otherwise damage the funnel 690, the sealable hub 114, and/or other components of the introducer assembly 102 during retraction. In other embodiments, the second shaft 582 and the retention sheath 122 can have different diameters, and the first and second engagement features 586, 589 can be configured to provide a smooth transition between the second shaft 582 and the retention sheath 122.

[0066] In another aspect of the present technology, the movement of the actuator 124 from the first position to the third position both (i) advances the first and second shafts 580, 582 together to deploy the funnel 690 (e.g., as the actuator 124 moves from the first position to the second position) and (ii) advances the second shaft 582 relative to the first shaft 580 (e.g., as the actuator 124 moves from the second position to the third position) so that the dilator assembly 104 has a generally uniform outer diameter. This "dual-action" allows the control assembly 120 to be coupled to the sealable hub 114 during both the deployment of the funnel 690 and the advancement of the second shaft 582 toward the first shaft 580. This can advantageously inhibit or prevent the inadvertent advancement of the retention sheath 122 and therefore the premature deployment of the funnel 690. For example, the dilator assembly 104 and the introducer assembly 102 must often be fully removed from the patient for reloading of the funnel 690 if the funnel 690 is prematurely deployed—potentially increasing the trauma to the patient and the duration of the thrombectomy procedure. In contrast, some conventional dilator assemblies include a dilator that is "floating" (e.g., not locked to or engaged with an introducer assembly) such that an inadvertent bump or other force on the dilator assembly can cause corresponding movement of the dilator assembly.

[0067] Figures 8A, 8C, and 8D are cross-sectional side views, and Figure 8B is an enlarged cross-sectional isometric view, of the control assembly 120 configured in accordance with embodiments of the present technology. In Figures 8A and 8B the actuator 124 is in the first

position shown in Figure 7A, in Figure 8C the actuator 124 is in the second position shown in Figure 7B, and in Figure 8D the actuator 124 is in the third position shown in Figure 7C.

[0068] Referring first to Figure 8A, the control assembly 120 includes a proximal portion 801a and a distal portion 801b and defines a lumen 802 extending therethrough between the proximal and distal portions 801a, b. In the illustrated embodiment, the control assembly 120 includes a sealable member 804 at or proximate the proximal portion 801a and a connection portion 806 at or proximate the distal portion 801b. The sealable member 804 can be configured to selectively seal the lumen 802 of the control assembly 120 and, in some embodiments, can receive a guidewire (not shown) therethrough. The connection portion 806 is configured to mate/engage with the sealable hub 114 of the introducer assembly 102 to secure the control assembly 120 thereto, as described in detail above with reference to Figures 7A–7C. For example, in some embodiments the connection portion 806 can include a snap feature (e.g., having one or more teeth, flanges), a twist lock (e.g., a bayonet- or luer-type fitting), and/or other feature for engaging and/or locking to the sealable hub 114.

[0069] Referring to Figures 8A and 8B together, in the illustrated embodiment the control assembly 120 further includes a first shaft hub 810 and a second shaft hub 850. The first shaft hub 810 is configured to be coupled to the first shaft 580 of the dilator assembly 104, and the second shaft hub 850 is configured to be coupled to the second shaft 582 of the dilator assembly 104. The first and second shafts 580, 582 are not shown in Figures 8A–8D for the sake of clarity. In the illustrated embodiment, the second shaft hub 850 is connected to (e.g., integrally formed with) the actuator 124, which extends outside the housing 595 and is configured to be advanced distally and/or retracted proximally by the operator. The first shaft hub 810 includes a first body portion 812 and one or more first engagement or snap features 814 (only one first engagement feature 814 is visible in Figures 8A–8D) that extend radially and/or axially away from the first body portion 812 and into a corresponding first track 830 formed in the housing 595. The second shaft hub 850 similarly includes a second body portion 852 and second engagement or snap features 854 (e.g., a pair of similar or identical second engagement features 854) that extend radially and/or axially away from the second body portion 852 and into a corresponding second track 840 formed in the housing 595.

[0070] In the illustrated embodiment, the first track 830 includes one or more proximal detents 832 (obscured in Figures 8A and 8B; shown in Figure 8C), one or more distal detents 834, and a distal terminus 835. In some embodiments, the first track 830 can include a pair of opposing

(e.g., radially opposite) proximal detents 832 and a pair of opposing distal detents 834. The second track 840 includes a first portion 842 having a first track width or height G_1 (Figure 8A) and a second portion 844 having a second track width or height G_2 (Figure 8A) greater than the first track width G_1. In some embodiments, the transition (e.g., a slope or step) between the first and second portions 842, 844 of the second track 840 is generally aligned over and/or proximate to the distal detents 834 of the first tack 830.

[0071] In operation, the first and second shaft hubs 810, 850 are configured to slide within the lumen 802 along the first and second tracks 830, 840, respectively. In some embodiments, the first engagement features 814 and/or the second engagement features 854 are flexible such that they can flex/bend as the first and second shaft hubs 810, 850 move along the first and second tracks 830, 840. The configuration/arrangement of the first and second shaft hubs 810, 850 and the first and second tracks 830, 840—for example, the arrangement of the proximal and distal detents 832, 834, the first portion 842, and/or the second portion 844—can facilitate the movement of the dilator assembly 104 from the first configuration (Figure 5A) to the second configuration (Figure 5B).

[0072] More specifically, in the first position shown in Figures 8A and 8B, the actuator 124 is positioned at a most proximal position along the housing 595. For example, the first shaft hub 810 can abut a proximal wall portion 807 of the housing 595. In the first position, the first portion 842 of the second track 840 compresses (e.g., presses, constrains) the second engagement features 854 of the second shaft hub 850 radially inward toward and into engagement with the first shaft hub 810 (e.g., with the first body portion 812). Put differently, a distance (e.g., diameter) of the second shaft hub 850 between the second engagement features 854 can be greater than the first diameter G_1 when the second shaft hub 850 is in a relaxed state, unconstrained by the first portion 842 of the second track 840. By this arrangement, the second shaft hub 850 is secured to the first shaft hub 810 such that movement of the actuator 124 along the first portion 842 of the second track 840 moves both the first and second shaft hubs 810, 850. In some embodiments, the first body portion 812 of the first shaft hub 810 can include various features (e.g., grooves, channels, teeth) for mating with the second engagement features 854 of the second shaft hub 850 to thereby secure the first and second shaft hubs 810, 850 together.

[0073] Moreover, in the first position, at least a portion of the first engagement features 814 of the first shaft hub 810 can be positioned proximal of the proximal detents 832 (Figures 8C and 8D). The proximal detents 832 can thus retain the first shaft hub 810—and the second shaft hub

850 and the actuator 124 secured thereto—in the first position until a predetermined force is applied to the actuator 124 in the distal direction. In one aspect of the present technology, this arrangement can inhibit the unintended distal advancement of the first shaft 580—and thus the premature deployment of the funnel 690 (Figures 7A–7C). In some embodiments, when the predetermined force is applied to the actuator 124, the first engagement features 814 flex inwardly such that first shaft hub 810 can slide distally thereby.

[0074] Accordingly, referring to Figures 8A–8C together, the actuator 124 can be advanced distally from the first position to the second position shown in 8C after the first engagement features 814 disengage the proximal detents 832. As the actuator 124 is moved distally, the first and second shaft hubs 810, 850 move distally together—thereby advancing the first and second shafts 580, 582 together as shown in Figure 7B—until the first shaft hub 810 reaches the distal terminus 835 of the first track 830 and/or the second shaft hub 840 reaches the second portion 844 of the second track 840. More specifically, the distal terminus 835 and/or the distal detents 834 of the first track 830 can engage the first engagement features 814 to prevent the first shaft hub 810 (and thus the first shaft 580) from moving farther distally. At the same time, the greater-diameter second portion 844 of the second track 840 allows the second engagement features 854 to move radially outward (e.g., flex radially outward toward the relaxed state) and out of engagement with first shaft hub 810. That is, the control assembly 120 is configured such that the second engagement features 854 of the second shaft hub 850 reach the transition point between the first and second portions 842, 844 of the first track 840 at substantially the same time as the first engagement features 814 of the first shaft hub 810 reach/engage the distal detents 834 of the first track 830.

[0075] Accordingly, as shown in Figure 8D, the second shaft hub 850 can leave the first shaft hub 810 behind and advance further distally to the third position. As the second shaft hub 850 moves distally while the first shaft hub 810 remains stationary, the second shaft 582 is advanced distally toward the retention sheath 122 as shown in Figure 7C. In some embodiments, the second shaft hub 850 can abut a distal wall portion 809 of the housing 595 in the third position.

[0076] Referring to Figures 5A–8D together, in one aspect of the present technology, the control assembly 120 facilitates the movement of the dilator assembly 104 from the first configuration to the second configuration with only as a single movement of the actuator 124 from the first to third positions. As described above, this advantageously allows the control assembly 120 to be coupled to the sealable hub 114 at all times during deployment of the funnel 690, which

controls deployment of the funnel 690 and prevents the funnel 690 from inadvertently being deployed. This is expected to reduce the potential for the other components of the system, such as the retention sheath 122, from catching on the funnel 690 as the dilator is retracted through the sheath 112. Moreover, deployment of the funnel 690 and advancement of the second shaft 582 are achieved by a single stroke and are thus greatly simplified.

[0077] In some embodiments, the actuator 124 can be moved proximally (e.g., from the third position toward the first position) to facilitate loading of the funnel 690. For example, the dilator assembly 104 can be inserted into the sheath 112 when the control assembly 120 is in the third position such that the retention sheath 122 extends from the distal portion 113b of the sheath 112 and distally beyond the funnel 690. The operator can then move the actuator 124 to the second position, thereby forcing the second shaft hub 850 into engagement with the first shaft hub 810 via the narrowing of the second track 840 from the second portion 844 to the first portion 842. The loading tool 108 (Figure 1) can then be slid proximally over the retention sheath 122 and the funnel 690 until the funnel 690 is fully encapsulated by the loading tool 108 and/or until the funnel 690 is in the constrained configuration. The operator can then move the actuator 124 from the second position to the first position to retract the retention sheath 122 over the funnel 690 to thereby load/capture the funnel 690 within the receiving space 694 of the retention sheath 122. Finally, the loading tool 108 can be removed.

[0078] In other embodiments, control assemblies in accordance with the present technology can include other components and/or configurations for facilitating the dual-action of (i) advancing the first and second shafts 580, 582 to deploy the funnel 690 and (ii) advancing the second shaft 582 relative to the first shaft 580 to provide a uniform outer surface that facilitates retraction of the dilator assembly 104. Figures 9A–9C, for example, are cross-sectional side views of a control assembly 920 including the actuator 124 in the first position, the second position, and the third position (Figures 7A–7C) configured in accordance with another embodiment of the present technology.

[0079] The control assembly 920 can include some features generally similar to the control assembly 120 described in detail above with reference to Figures 8A–8D. For example, referring to Figures 9A–9C together, the control assembly 920 includes a first shaft hub 910 coupled to the first shaft 580 of the dilator assembly 104, and a second shaft hub 950 coupled to the second shaft 582 of the dilator assembly 104. In the illustrated embodiment, the second shaft hub 950 is connected to (e.g., integrally formed with) the actuator 124, which extends outside a housing 995

of the control assembly 920 and is configured to be advanced distally and/or retracted proximally by the operator. The first and second shaft hubs 910, 950 are configured to slide at least partially through a lumen 902 extending through the housing 995.

[0080] In the illustrated embodiment, the control assembly 920 further includes an elongate member 960 (shown as transparent in Figures 9A–9C for the sake of clarity) having (i) a proximal portion 961a positioned proximal of the first shaft hub 910 and (ii) a distal portion 961b positioned distal of the first shaft hub 910 and coupled to the second shaft hub 950. The first shaft hub 910 can be slidably positioned within the elongate member 960. A biasing member 964, such as a compression spring, extends between the proximal portion 961a of the elongate member 960 and the first shaft hub 910. In some embodiments, a proximal portion 965a of the biasing member 964 is connected to the proximal portion 961a of the elongate member 960 and a distal portion 965b of the biasing member 964 is connected to the first shaft hub 910.

[0081] The control assembly 920 can further include a stop member 970 coupled to the first shaft 580 (e.g., to a proximal portion of the first shaft 580). The stop member 970 is configured to slide at least partially through the lumen 902 of the housing during operation of the control assembly 920 and can be fully contained within the housing 995 (e.g., as shown in Figures 9B and 9C) and/or can extend fully or partially outside of the housing 995 (e.g., as shown in Figure 9A). As shown in Figure 9B, the stop member 970 has a dimension (e.g., diameter) H_1 that is greater than a dimension H_2 of a stop portion 972 of the housing 995. By this arrangement, the stop member 970 is configured to contact the stop portion 972 of the housing 995 to thereby prevent the first shaft 580 (and the retention sheath 122 attached thereto) from advancing farther distally.

[0082] Referring to Figure 9A, in the first position, the first shaft hub 910 engages (e.g., mates with) the second shaft hub 950 such that distal advancement of the actuator 124 moves both the first and second shaft hubs 910, 950. Moreover, the biasing member 964 is at equilibrium and thus does not exert any force on, for example, the first shaft hub 910. In some embodiments, the actuator 124 and/or the second shaft hub 950 can include first engagement features 954 (e.g., bumps, projections) that can engage (e.g., mate with) corresponding first detents 957 in the housing 995 to releasably secure the actuator 124 in the first position until a predetermined force is applied to the actuator in the distal direction. In some embodiments, when the predetermined force is applied to the actuator 124, the first engagement features 954 can flex outwardly and out of the first detents 957 to permit the first and second shaft hubs 910, 950 to move distally.

[0083] Accordingly, referring to Figures 9A and 9B together, the actuator 124 can be advanced distally from the first position to the second position after the first engagement features 954 disengage the first detents 957. As the actuator 124 is moved distally, the first and second shaft hubs 910, 950 move distally together—thereby advancing the first and second shafts 580, 582 together as shown in Figure 7B—until the stop member 970 reaches and contacts the stop portion 972 of the housing 995. More specifically, the biasing member 964 can exert a force against the first shaft hub 910 to move the first shaft hub 910 together with the second shaft hub 950. When the stop member 970 contacts the stop portion 972, the first shaft hub 910 is stopped from advancing farther distally.

[0084] Accordingly, referring to Figures 9B and 9C together, the second shaft hub 950 can leave the first shaft hub 910 behind as the actuator 124 is moved farther distally to the third position. As the second shaft hub 950 moves distally while the first shaft hub 910 remains stationary, the second shaft 582 is advanced distally toward the retention sheath 122 as shown in Figure 7C. In some embodiments, the second shaft hub 950 can abut a distal wall portion 909 of the housing 995 in the third position, which prevents the second shaft hub 950 from advancing farther. As further shown in Figure 9C, advancing the second shaft hub 950 to the third position compresses the biasing member 964 between the first shaft hub 910, which remains stationary, and the proximal portion 961a of the elongate member 960 which continues to move with the second shaft hub 950. In some embodiments, the bias force exerted by the biasing member 964 can facilitate the subsequent movement of the actuator 124 from the third position to the second position. In some embodiments, the actuator 124 can include second engagement features 958 (e.g., bumps, projections) that can engage (e.g., mate with) corresponding second detents 959 in the housing 995 to releasably secure the actuator 124 in the third position until a predetermined force is applied to the actuator in the proximal direction. In some embodiments, this force can be less than that required to disengage the first engagement features 954 from the first detents 957 due to the biasing force of the biasing member 964. In other embodiments, the detents 959 can comprise a track (e.g., an L-shaped track), and the second shaft hub 950 can be rotated to rotate the second engagement features 958 into the track to releasably secure the actuator 124 in the third position.

[0085] In other embodiments, the stop member 970 is not configured to stop distal advancement of the first shaft 580. Rather, the stop member 970 can instead be a luer flush port 970 (or another component) that simply moves together with the first shaft 580, or can be omitted altogether. In such embodiments, the first shaft hub 910 can move along a track (not shown)

formed in the housing 995 in a similar manner as the first shaft hub 810 described in detail with reference to Figures 8A–8D. For example, the first shaft hub 910 can include first engagement or snap features 914 (only one first engagement feature 914 is visible in Figures 9A–9C) that extend (i) radially and/or axially away from a body portion of the first shaft hub 910, (ii) out of the elongate member 960, and (iii) into the track in the housing 995. The track can include a detent or other feature (not shown) configured (e.g., positioned and shaped) to stop the first shaft hub 910 from moving farther distally when the first shaft hub 910 reaches the second position shown in Figure 9B.

[0086] Figures 10A and 10B are partially cross-sectional side views of a control assembly 1020 configured in accordance with another embodiment of the present technology. In general, the control assembly is movable between (i) the first position (shown in Figure 10A) in which the second shaft 582 is retracted proximally relative to the first shaft 580 as shown in Figures 5A and 7A and (ii) the third position (shown in Figure 10B) in which the second shaft 582 is advanced distally relative to the first shaft 580 to form a generally uniform outer surface of the dilator assembly 104 as shown in Figures 5B and 7C. In one aspect of the present technology, the control assembly 1020 does not include the intermediate second position (Figure 7B), but instead fluidly moves between the first and third positions.

[0087] The control assembly 1020 can include some features generally similar to the control assembly 120 and/or the control assembly 920 described in detail above with reference to Figures 8A–9C. For example, referring to Figures 10A and 10B together, the control assembly 1020 includes an actuator 1024 (e.g., a plunger 1024) that is movable relative to/through a lumen 1002 of a housing 1095. The plunger 1024 is coupled to (i) a first shaft hub 1010 that is coupled to the first shaft 580 of the dilator assembly 104 and (ii) a second shaft hub 1050 that is coupled to the second shaft 582 of the dilator assembly 104. The first and second shafts 580, 582 are not shown in Figures 10A and 10B for the sake of clarity.

[0088] In the illustrated embodiment, the second shaft hub 1050 includes engagement features 1054 that are configured (e.g., sized and shaped) to engage with a corresponding stop portion 1056 formed in the housing 1095 when the plunger 1024 is in the first position shown in Figure 10A. The first shaft hub 1010 is configured to slide along a track 1080 formed in/along a portion of the plunger 1024. In some embodiments, the track 1080 includes at least one detent 1084 at a distal portion thereof and configured to stop/block distal advancement of the first shaft

hub 1010. In other embodiments, the housing 1095 can include a flange or other component configured to stop distal advancement of the first shaft hub 1010.

[0089] A first biasing member 1064 (e.g., a compression spring) extends between and operably couples (e.g., connects) the first shaft hub 1010 and a proximal portion 1096 of the housing 1095. A second biasing member 1066 (e.g., a compression spring) extends between and operably couples (e.g., connects) the first and second shaft hubs 1010, 1050. In the first position shown in Figure 10A, both of the first and second biasing members 1064, 1066 are compressed and under load and therefore urge the first and second shaft hubs 1010, 1050, respectively, distally. In some embodiments, the first biasing member 1064 has a larger compression force than the second biasing member 1066.

[0090] In the first position shown in Figure 10A, the plunger 1024 is locked in a proximally retracted position by the engagement of the engagement features 1054 with the stop portion 1056 of the housing 1095. To move the control assembly 1020 to the third position shown in Figure 10B, the operator can rotate the plunger 1024 (e.g., as indicated by arrow I in Figure 10A) to unlock the second shaft hub 1050 and the plunger 1024. When the plunger 1024 is unlocked, the first biasing member 1064 is configured to drive the first shaft hub 1010 distally until the first shaft hub 1010 is stopped by/within the detent 1084. In one aspect of the present technology, because the first biasing member 1064 is stronger than the second biasing member 1066, the second biasing member 1066 remains substantially compressed until the first shaft hub 1010 engages the detent 1084. Therefore, both the first and second shaft hubs 1010, 1050—and thus both the first and second shafts 580, 582—move together until the first shaft hub 1010 reaches the detent 1084. Then, the second biasing member 1066 is configured to drive the second shaft hub 1050 distally relative to the first shaft hub 1010 (e.g., away from the first shaft hub 1010). In the third position shown in Figure 10B, the first and second biasing members 1064, 1066 can bias the first and second shaft hubs 1010, 1050 distally to maintain the control assembly 1020 in the third position. By this arrangement, the first and second shafts 580, 582 are automatically moved from the first configuration (Figure 5A) to the second configuration (Figure 5B)—deploying the funnel and readying the dilator assembly 104 for retraction as shown in Figures 7A–7D.

[0091] In other embodiments, the first and second biasing members 1064, 1066 can be arranged in an opposite configuration. For example, the first biasing member 1064 can extend between and operably couple the first and second shaft hubs 1010, 1050, and the second biasing member 1066 can extend between and operably couple the second shaft hub 1050 and a distal

portion 1098 of the housing 1096. Likewise, the second biasing member 1066 can have a larger compression force than the first biasing member 1064. Thus, the first and second biasing members 1064, 1066 can bias the control assembly 1020 to the first position. To move the control assembly 1020 to the third position, the user can advance the plunger 1024 against the compression forces of the first and second biasing members 1064, 1066 until the second shaft hub 1050 reaches the third position. In some embodiments, the user can then rotate the plunger 1024 to lock the control assembly 1020 in the third position.

IV. Selected Embodiments of Thrombectomy Methods

[0092] Figure 11 is a schematic view of an introduction technique for accessing a thrombus 1190 for treatment with the thrombectomy system 100 in accordance with an embodiment of the present technology. The thrombus 1190 (e.g., clot material) can be located in a blood vessel 1196 and accessed through an access site 1192 such as the popliteal access site, or other venous or arterial access sites. The introducer assembly 102 can extend from the popliteal access site 1192, or other venous or arterial access sites, to a deployment position 1194 at which the self-expanding funnel 690 can be deployed and which can be proximate to the thrombus 1190. As described in greater detail below with reference to Figures 12A–12K, the thrombus extraction device 250 can be passed through the thrombus 1190 in the direction of blood flow and then retracted through the thrombus 1190 in a direction with blood flow. During retraction, the coring element 252 can core/separate the thrombus 1190 and the capture element 254 can capture all or a portion of the thrombus 1190. In some embodiments, some or all of the thrombus extraction device 250 can extend into one of the iliac veins and/or the inferior vena cava.

[0093] More particularly, Figures 12A–12C are side views, and Figures 12D–12M are enlarged side views, of the thrombectomy system 100 positioned within the blood vessel 1196 during a thrombectomy procedure to treat (e.g., remove) the thrombus 1190 in accordance with embodiments of the present technology.

[0094] Figure 12A illustrates the thrombectomy system 100 intravascularly positioned within the blood vessel 1196 after (i) deploying the self-expanding funnel 690 (e.g., as described in detail with reference to Figures 5A–10B), (ii) removing the dilator assembly 104 from the introducer assembly 102, and (iii) advancing the outer shaft 132 of the thrombus extraction assembly 106 through the sheath 112 and the thrombus 1190. The distal advance of the outer shaft 132 through the thrombus 1190 can be either with or against the direction of blood flow.

[0095] Figure 12B illustrates the thrombectomy system 100 after advancing the thrombus extraction device 250 through the outer shaft 132 to a deployed position distal of the thrombus 1190. In some embodiments, the thrombus extraction device 250 can be constrained within the outer shaft 132 and inserted, together with the outer shaft 132, into the lumen of the sheath 112 via the sealable hub 114. In some embodiments, the thrombus extraction device 250 can be deployed by advancing the thrombus extraction device 250 beyond the distal portion 136b of the sheath 112 and/or by retracting the outer shaft 132 relative to the thrombus extraction device 250 until the thrombus extraction device 250 is beyond the distal portion 136b of the outer shaft 132.

[0096] Figure 12C illustrates the thrombectomy system 100 after fully-expanding the thrombus extraction device 250. In some embodiments, at least a portion of the coring element 252 and/or the capture element 254 contact a wall 1297 of the blood vessel 1196 in the fully-expanded position. As described in detail above with reference to Figures 2A and 2B, in some embodiments the thrombus extraction device 250 can be fully expanded by moving the plunger 144 from the first position to the second position and securing the plunger 144 in the second position to thereby fix the relative position of the inner shaft 134 with respect to the intermediate shaft 133.

[0097] In general, Figures 12D–12K illustrate the proximal retraction of the thrombus extraction device 250 through the thrombus 1190 to capture at least a portion of the thrombus 1190, and the subsequent joint retraction of the thrombus extraction device 250 and the captured thrombus 1190 into the funnel 690 and the sheath 112.

[0098] Referring first to Figure 12D, proximal retraction of the thrombus extraction device 250 causes the coring element 252 to separate and/or core a distal portion 1298b of the thrombus 1190 from the wall 1297 of the blood vessel 1196. As shown in Figure 12E, continued proximal retraction of the thrombus extraction device 250 through the thrombus 1190 causes the capture element 254 to capture the distal portion 1298b of the thrombus 1190 therein. Figures 12F–12H illustrate further proximal retraction of the thrombus extraction device 250 which causes further separation, coring, and/or capture of the thrombus 1190. As seen in Figure 12H, a proximal portion 1298a of the thrombus 1190 is cored and captured as the thrombus extraction device 250 is proximally retracted toward the funnel 690 and the sheath 112.

[0099] As described in detail above with reference to Figures 3A–4, the coring element 252 can include both the first mouth 370 and the second mouth 372 (identified in Figure 12D). Thus, the first mouth 370, the first mouth portion 372a, and/or the second mouth portion 372b can

facilitate the coring/separating of the thrombus 1190 during proximal retraction of the thrombus extraction device 250. In one aspect of the present technology, the first mouth 370 and the second mouth 372 are radially offset relative to one another which can increase the coring effectiveness—even when the blood vessel 1196 is very tortuous and/or the thrombus 1190 is strongly adhered to the wall 1297 of the blood vessel 1196—by ensuring that at least one of the first mouth 370 and the second mouth 372 is positioned and oriented to effectively core the thrombus 1190.

[0100] In some embodiments, as shown in Figures 12I and 12G, the thrombus extraction device 250 can be proximally retracted until the proximal portion 253a of the coring element 252 is contained (e.g., positioned) within the funnel 690. More specifically, the thrombus extraction device 250 can be proximally retracted until all or a portion of the first mouth 370 and/or the second mouth 372 of the coring element 252 are contained within the funnel 690. In some embodiments, when one or both of the first and second mouths 370, 372 are positioned within the funnel 690, the thrombus extraction device 250 can be moved or transformed from the expanded deployed state to the compressed state to compress and secure the thrombus 1190 captured by the thrombus extraction device 250. In some embodiments, for example, the intermediate shaft 133 (Figure 12H) can be unlocked and/or decoupled from the inner shaft 134 (e.g., via user actuation of the plunger 144 shown in Figures 1–2B) such that the inner shaft 134 can be advanced distally relative to the intermediate shaft 133 to collapse or compress the thrombus extraction device 250.

[0101] After the thrombus extraction device 250 has been collapsed, the thrombus extraction device 250 can be proximally retracted through the funnel 690 and into the sheath 112 as depicted in Figure 12K. The thrombus extraction device 250 can continue to be proximally retracted until the thrombus extraction device 250 and the captured thrombus 1190 are fully contained within the sheath 112. In some embodiments, the thrombus extraction device 250 and the captured thrombus 1190 can then be withdrawn through the sheath 112 and the sealable hub 114 (Figure 12B).

[0102] In some embodiments, a vacuum (e.g., a pre-charged vacuum) can be applied to the sheath 112 at any point during retraction of the thrombus extraction device 250. In some embodiments, application of the vacuum can generate instantaneous or nearly instantaneous suction at the distal portion of the sheath 112 that can aspirate any remaining portions of the thrombus 1190 into and/or through the sheath 112. For example, the generated suction can aspirate any of the thrombus 1190 that captured or extruded by the funnel 690. Moreover, in some embodiments, application of a vacuum can facilitate smooth retraction of the captured thrombus

1190 through the sheath 112. For example, a burst of suction generated by application of the vacuum can help inhibit clogging of the sheath 112, and/or help resolve (e.g., break apart) a clog formed in the sheath 112 during retraction.

V. Examples

[0103] Several aspects of the present technology are set forth in the following examples:

1. A coring element for coring a vascular thrombus within a blood vessel of a patient, the coring element comprising:

a unitary structure having—

a first region adjacent to a proximal portion of the unitary structure, wherein the first region includes a first mouth configured to core the vascular thrombus;

a second region distal of the first region, wherein the second region is generally tubular and includes a first plurality of interconnected struts;

a third region distal of the second region, wherein the third region includes a second mouth configured to core the vascular thrombus; and

a fourth region distal of the third region, wherein the fourth region is generally tubular and includes a second plurality of interconnected struts.

2. The coring element of example 1 wherein the first mouth is radially offset from the second mouth.

3. The coring element of example 1 or example 2 wherein the unitary structure extends along a longitudinal axis, and wherein the first region includes a pair of first curved struts that curve in opposite directions around the longitudinal axis and intersect at a pair of first junctions to define the first mouth.

4. The coring element of any one of examples 1–3 wherein the unitary structure extends along a longitudinal axis, wherein the third region includes (a) a pair of upper curved struts that curve around the longitudinal axis and intersect each other at an upper junction and (b) a pair of lower curved struts that curve around the longitudinal axis and intersect each other at a lower junction, and wherein the lower and upper curved struts define the second mouth.

5. The coring element of example 4 wherein the lower and upper curved struts define (a) a first mouth portion opening in a first direction generally orthogonal to the longitudinal axis and (b) a second mouth portion opening in a second direction generally orthogonal to the longitudinal axis, and wherein the first and second mouth portions define the second mouth.

6. The coring element of example 5 wherein the first direction is generally opposite to the second direction.

7. The coring element of any one of examples 1–6 wherein the coring element is expandable from a compressed delivery configuration to an expanded deployed configuration.

8. The coring element of example 7 wherein the coring element is configured to self-expand.

9. The coring element of example 8 wherein the coring element is made from a shape memory material.

10. The coring element of any one of examples 1–9 wherein the fourth region of the unitary structure is configured to be connected to a braided filament mesh structure.

11. A dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath, the dilator assembly comprising:

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft.

12. The dilator assembly of example 11 wherein the retention sheath has substantially a same outer diameter as the first shaft.

13. The dilator assembly of example 11 or example 13 wherein movement of the actuator from the second position to the third position brings a distal portion of the first shaft into contact with a proximal portion of the retention sheath.

14. The dilator assembly of any one of examples 11–13 wherein the control assembly includes—

a housing;

a first shaft hub slidably positioned within the housing and coupled to the first shaft; and

a second shaft hub slidably positioned within the housing and coupled to the second shaft.

15. The dilator assembly of example 14 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together.

16. The dilator assembly of example 14 or example 15 wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

17. The dilator assembly of any one of examples 14–16 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together, and wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

18. The dilator of assembly of any one of examples 14–17 wherein the second shaft hub includes a first engagement feature, wherein the housing includes a second engagement feature, and wherein the first engagement feature is configured to engage the second engagement feature at the second position to prevent movement of the second shaft hub when the actuator is moved from the second position to the third position.

19. The dilator assembly of example 18 wherein the first engagement feature is a snap feature, and wherein the second engagement feature is a detent formed in the housing.

20. The dilator assembly of any one of examples 14–19, further comprising a biasing member operably coupled to the first shaft hub, wherein the biasing member is configured to bias the first shaft hub from the third position toward the second position.

21. The dilator assembly of any one of examples 11–20 wherein the control assembly further includes a housing, wherein the actuator is movable relative to the housing, wherein the movement of the actuator from the first position to the second position is distal movement of the actuator relative to the housing, and wherein the movement of the actuator from the second position to the third position is further distal movement of the actuator relative to the housing.

22. The dilator assembly of any one of examples 11–21, further comprising the introducer sheath and the funnel.

23. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel, wherein the dilator assembly includes—

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position distally advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft; and

a clot removal device configured to be inserted through the introducer sheath to capture at least a portion of the vascular thrombus.

24. The system of example 23 wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element is configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

25. The system of example 23 or example 24 wherein the funnel has a first length when deployed from the retention sheath, and wherein the coring element has a second length when expanded that is less than the first length.

26. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel; and

a clot removal device configured to be inserted through the introducer sheath, wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element includes a first region including a first mouth and a second region including a second mouth, wherein the first and second mouths are configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

27. The system of example 26 wherein the first mouth is radially offset from the second mouth.

28. The system of example 27 wherein the coring element is formed from a unitary structure including a plurality of struts, wherein the struts define the first and second mouths,

wherein the struts further define a plurality of interstices, and wherein the first and second mouths are larger than each of the interstices.

VI. Conclusion

[0104] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0105] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0106] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A coring element for coring a vascular thrombus within a blood vessel of a patient, the coring element comprising:

a unitary structure having—

a first region adjacent to a proximal portion of the unitary structure, wherein the first region includes a first mouth configured to core the vascular thrombus;

a second region distal of the first region, wherein the second region is generally tubular and includes a first plurality of interconnected struts;

a third region distal of the second region, wherein the third region includes a second mouth configured to core the vascular thrombus; and

a fourth region distal of the third region, wherein the fourth region is generally tubular and includes a second plurality of interconnected struts.

2. The coring element of claim 1 wherein the first mouth is radially offset from the second mouth.

3. The coring element of claim 1 wherein the unitary structure extends along a longitudinal axis, and wherein the first region includes a pair of first curved struts that curve in opposite directions around the longitudinal axis and intersect at a pair of first junctions to define the first mouth.

4. The coring element of claim 1 wherein the unitary structure extends along a longitudinal axis, wherein the third region includes (a) a pair of upper curved struts that curve around the longitudinal axis and intersect each other at an upper junction and (b) a pair of lower curved struts that curve around the longitudinal axis and intersect each other at a lower junction, and wherein the lower and upper curved struts define the second mouth.

5. The coring element of claim 4 wherein the lower and upper curved struts define (a) a first mouth portion opening in a first direction generally orthogonal to the longitudinal axis and

(b) a second mouth portion opening in a second direction generally orthogonal to the longitudinal axis, and wherein the first and second mouth portions define the second mouth.

6. The coring element of claim 5 wherein the first direction is generally opposite to the second direction.

7. The coring element of claim 1 wherein the coring element is expandable from a compressed delivery configuration to an expanded deployed configuration.

8. The coring element of claim 7 wherein the coring element is configured to self-expand.

9. The coring element of claim 8 wherein the coring element is made from a shape memory material.

10. The coring element of claim 1 wherein the fourth region of the unitary structure is configured to be connected to a braided filament mesh structure.

11. A dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath, the dilator assembly comprising:

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft.

12. The dilator assembly of claim 11 wherein the retention sheath has substantially a same outer diameter as the first shaft.

13. The dilator assembly of claim 11 wherein movement of the actuator from the second position to the third position brings a distal portion of the first shaft into contact with a proximal portion of the retention sheath.

14. The dilator assembly of claim 11 wherein the control assembly includes—

a housing;

a first shaft hub slidably positioned within the housing and coupled to the first shaft; and

a second shaft hub slidably positioned within the housing and coupled to the second shaft.

15. The dilator assembly of claim 14 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together.

16. The dilator assembly of claim 14 wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

17. The dilator assembly of claim 14 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together, and wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

18. The dilator of assembly of claim 14 wherein the second shaft hub includes a first engagement feature, wherein the housing includes a second engagement feature, and wherein the first engagement feature is configured to engage the second engagement feature at the second position to prevent movement of the second shaft hub when the actuator is moved from the second position to the third position.

19. The dilator assembly of claim 18 wherein the first engagement feature is a snap feature, and wherein the second engagement feature is a detent formed in the housing.

20. The dilator assembly of claim 14, further comprising a biasing member operably coupled to the first shaft hub, wherein the biasing member is configured to bias the first shaft hub from the third position toward the second position.

21. The dilator assembly of claim 11 wherein the control assembly further includes a housing, wherein the actuator is movable relative to the housing, wherein the movement of the actuator from the first position to the second position is distal movement of the actuator relative to the housing, and wherein the movement of the actuator from the second position to the third position is further distal movement of the actuator relative to the housing.

22. The dilator assembly of claim 11, further comprising the introducer sheath and the funnel.

23. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel, wherein the dilator assembly includes—

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position distally advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft; and

a clot removal device configured to be inserted through the introducer sheath to capture at least a portion of the vascular thrombus.

24. The system of claim 23 wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element is configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

25. The system of claim 23 wherein the funnel has a first length when deployed from the retention sheath, and wherein the coring element has a second length when expanded that is less than the first length.

26. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel; and

a clot removal device configured to be inserted through the introducer sheath, wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element includes a first region including a first mouth and a second region including a second mouth, wherein the first and second mouths are configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

27. The system of claim 26 wherein the first mouth is radially offset from the second mouth.

28. The system of claim 27 wherein the coring element is formed from a unitary structure including a plurality of struts, wherein the struts define the first and second mouths, wherein the struts further define a plurality of interstices, and wherein the first and second mouths are larger than each of the interstices.

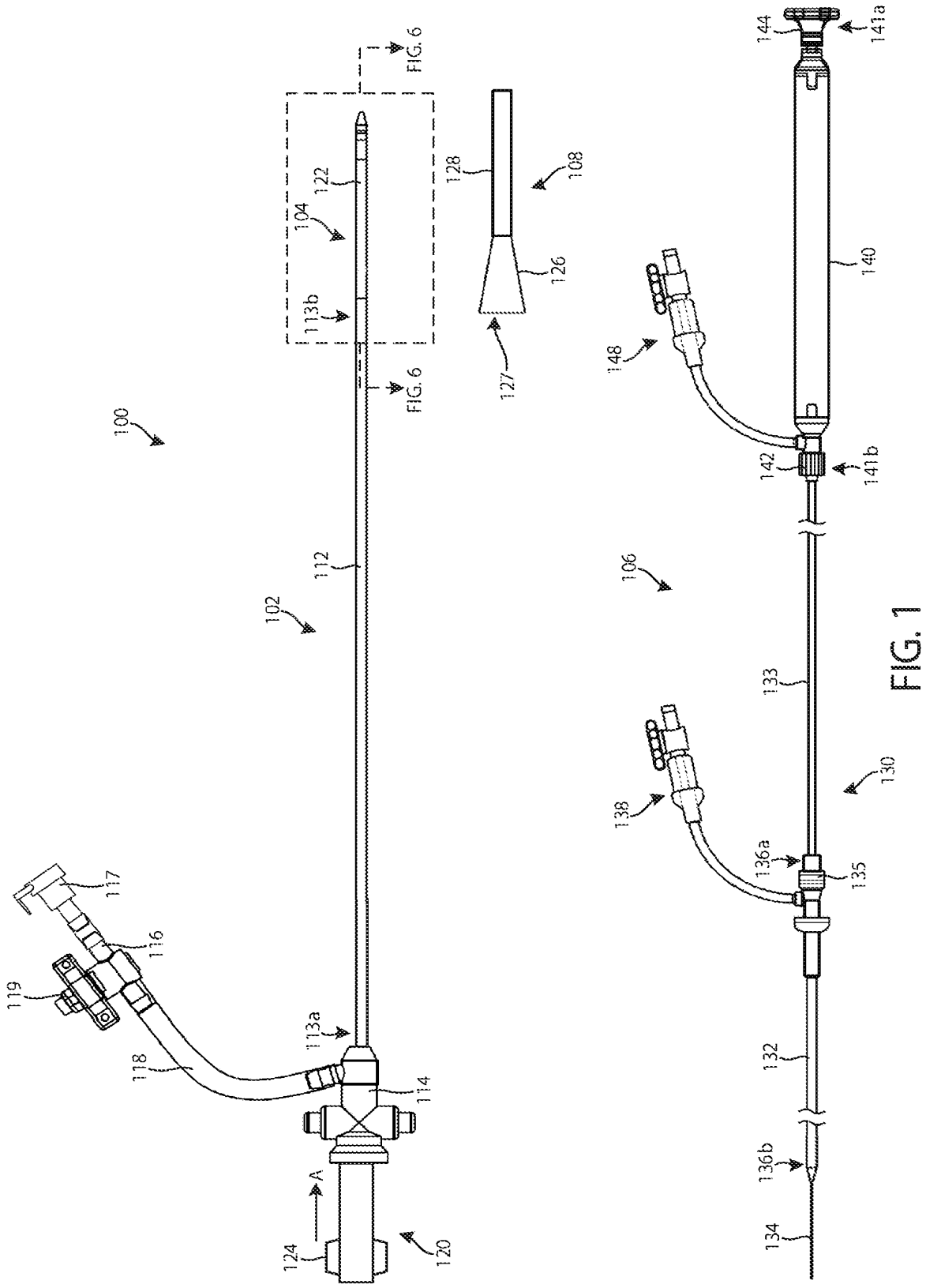

100
102
104
106
108
112
113a
113b
114
116
117
118
119
120
122
124
126
127
128
130
132
133
134
135
136a
136b
138
140
141a
141b
142
144
148
A
FIG. 6
FIG. 6

FIG. 1

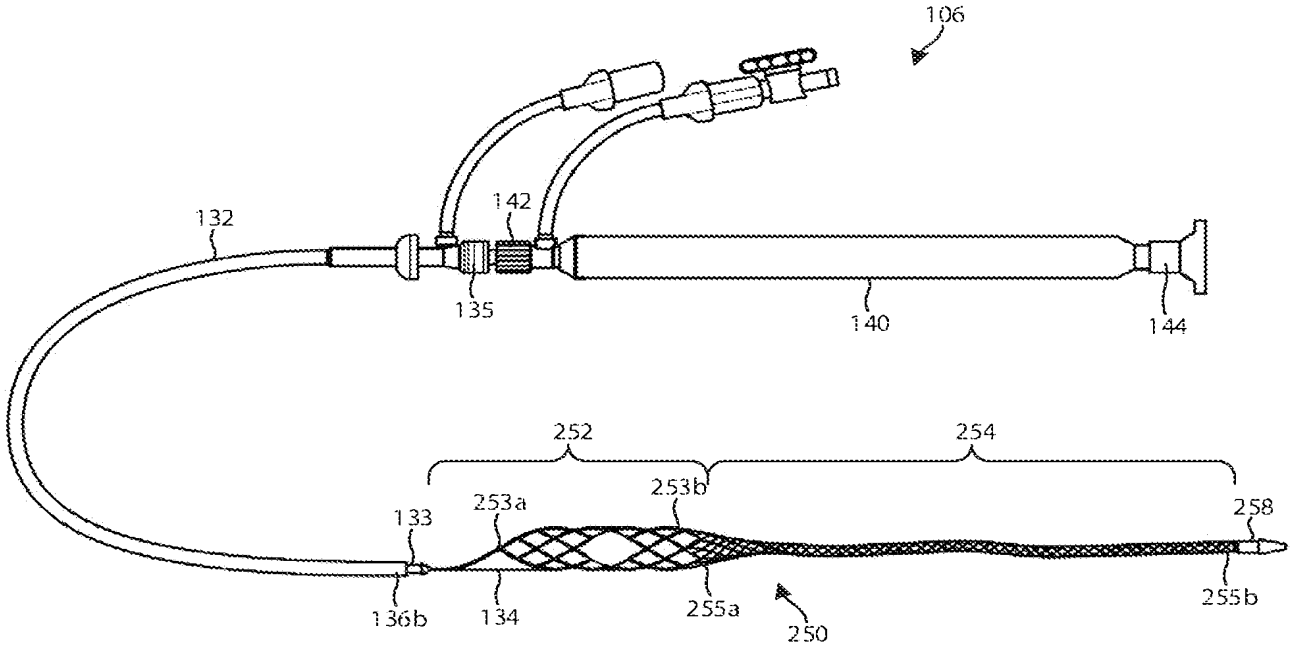

106
142
132
135
140
144
252
254
253a
253b
258
133
136b
134
255a
250
255b

FIG. 2A

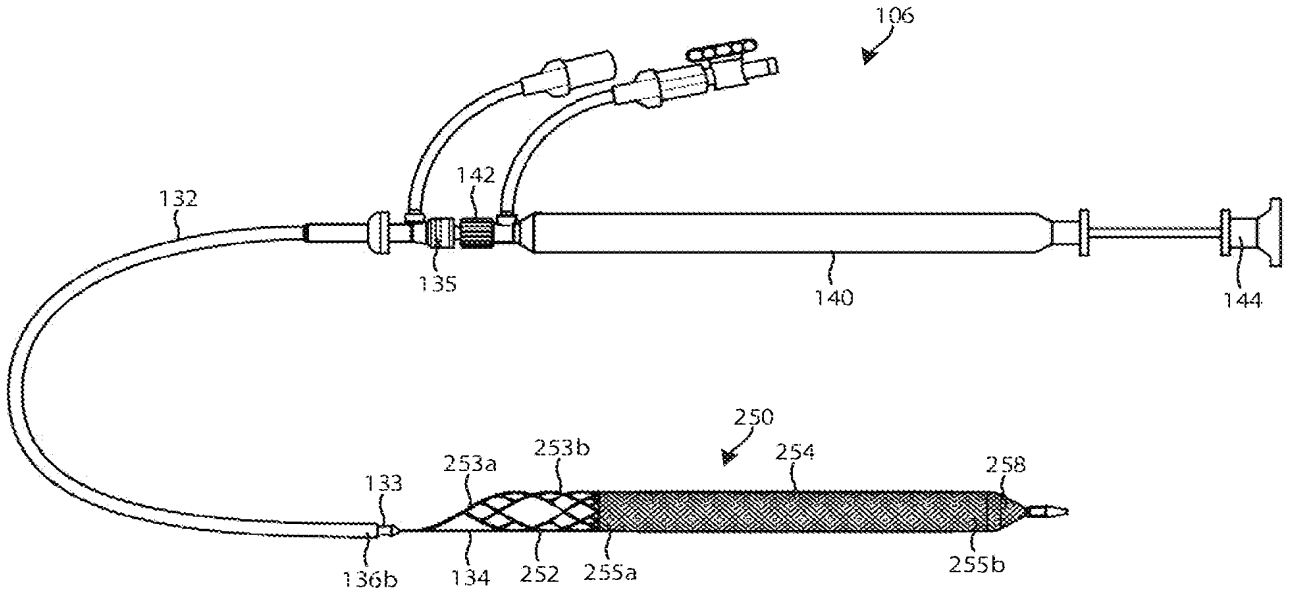

106
142
132
135
140
144
250
253a
253b
254
258
133
136b
134
252
255a
255b

FIG. 2B

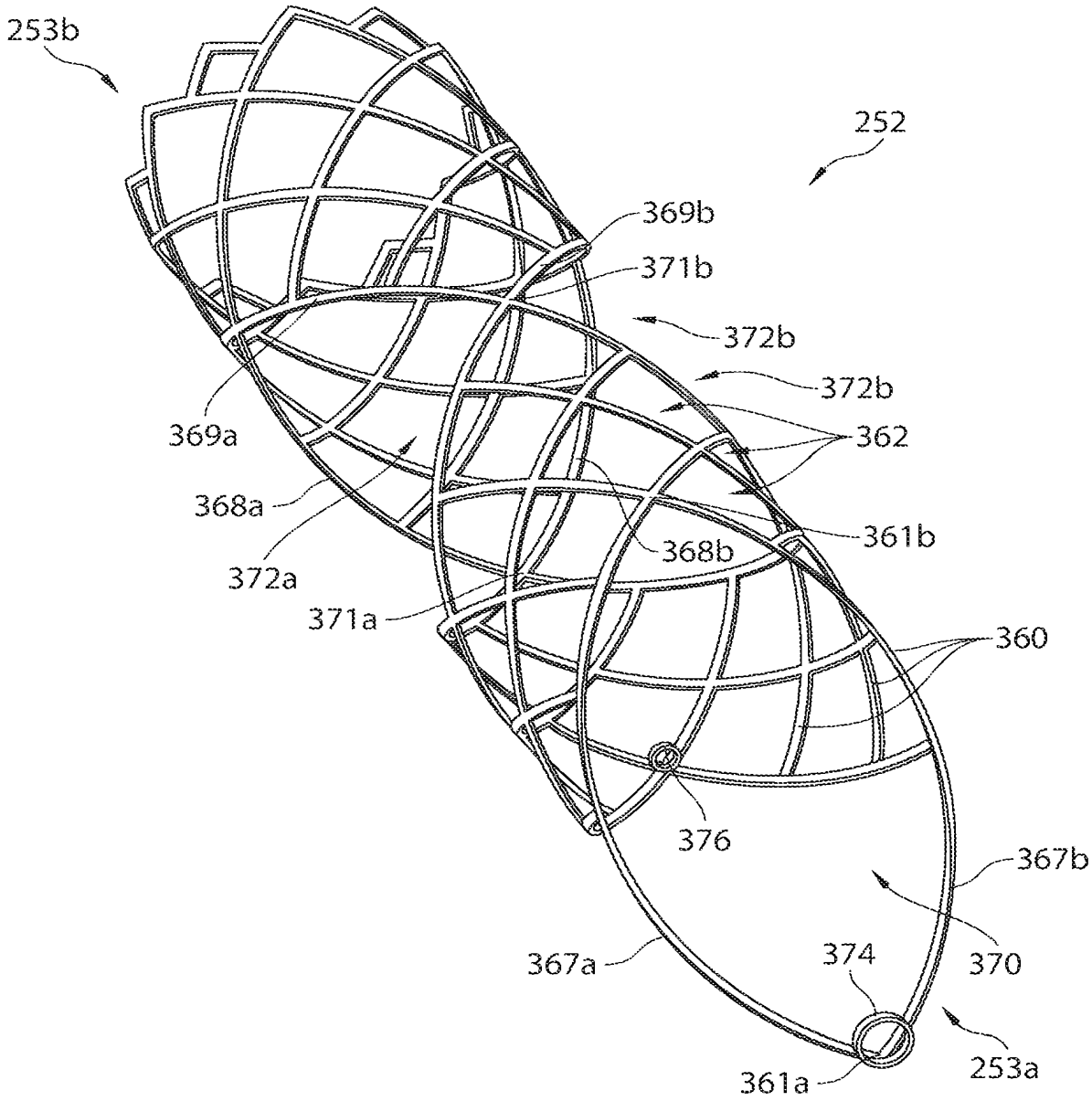

253b
252
369b
371b
372b
372b
362
369a
368a
372a
371a
368b
361b
360
376
367b
370
367a
374
361a
253a

FIG. 3A

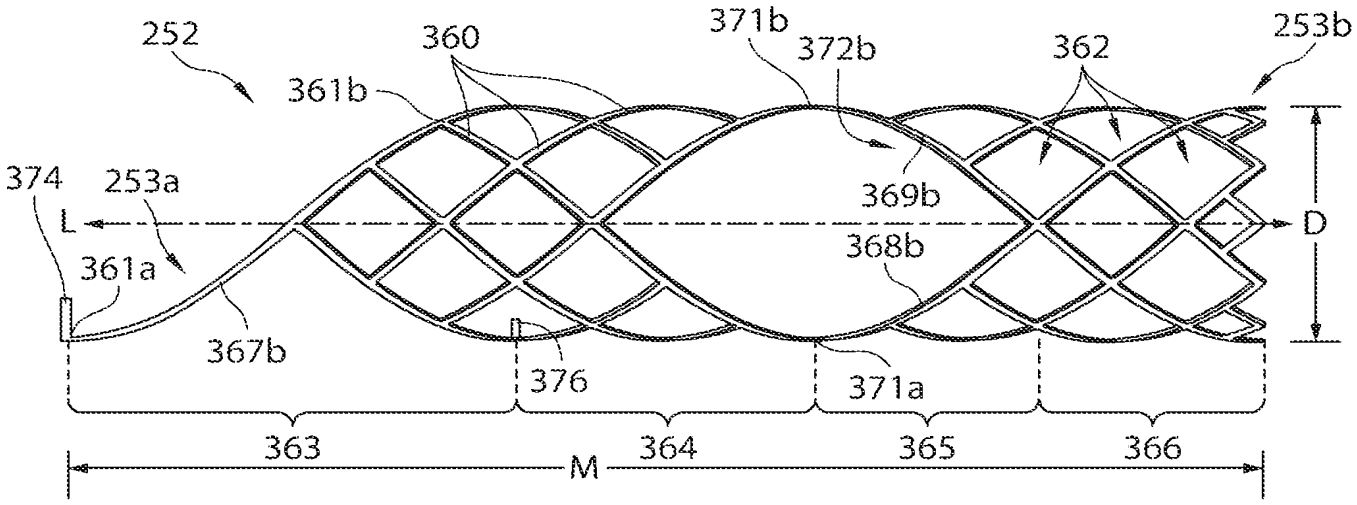

252
360
371b
372b
362
253b
361b
374
253a
L
369b
D
361a
368b
367b
376
371a
363
M
364
365
366

FIG. 3B

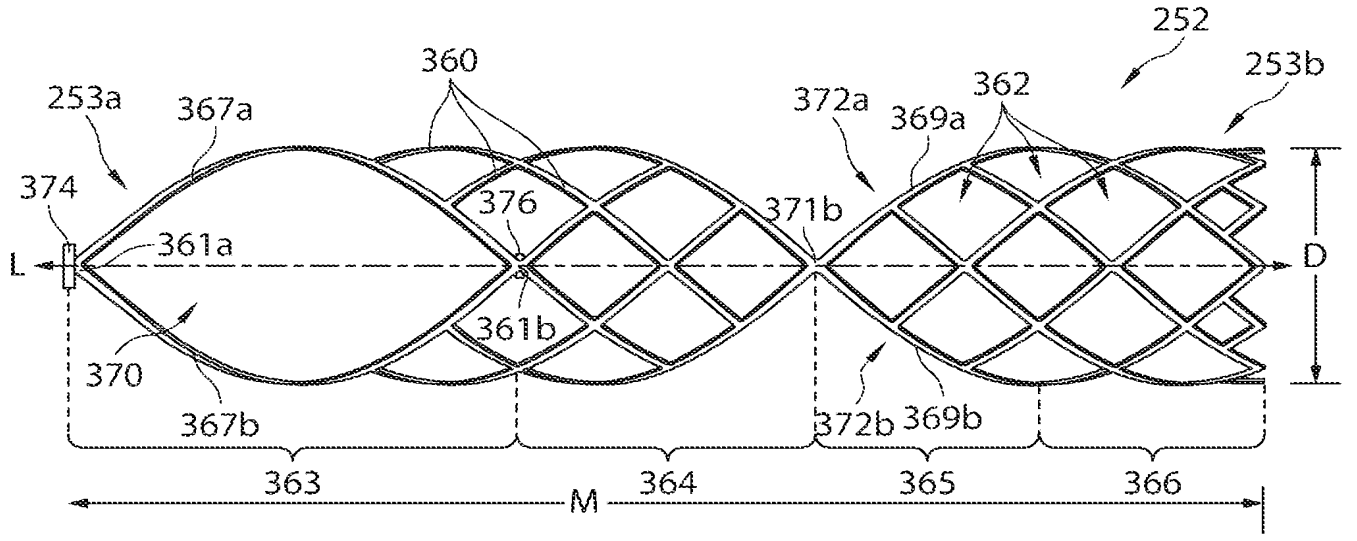

252
360
253b
253a
367a
372a
362
369a
374
376
371b
L
361a
D
361b
370
367b
372b
369b
363
M
364
365
366

FIG. 3C

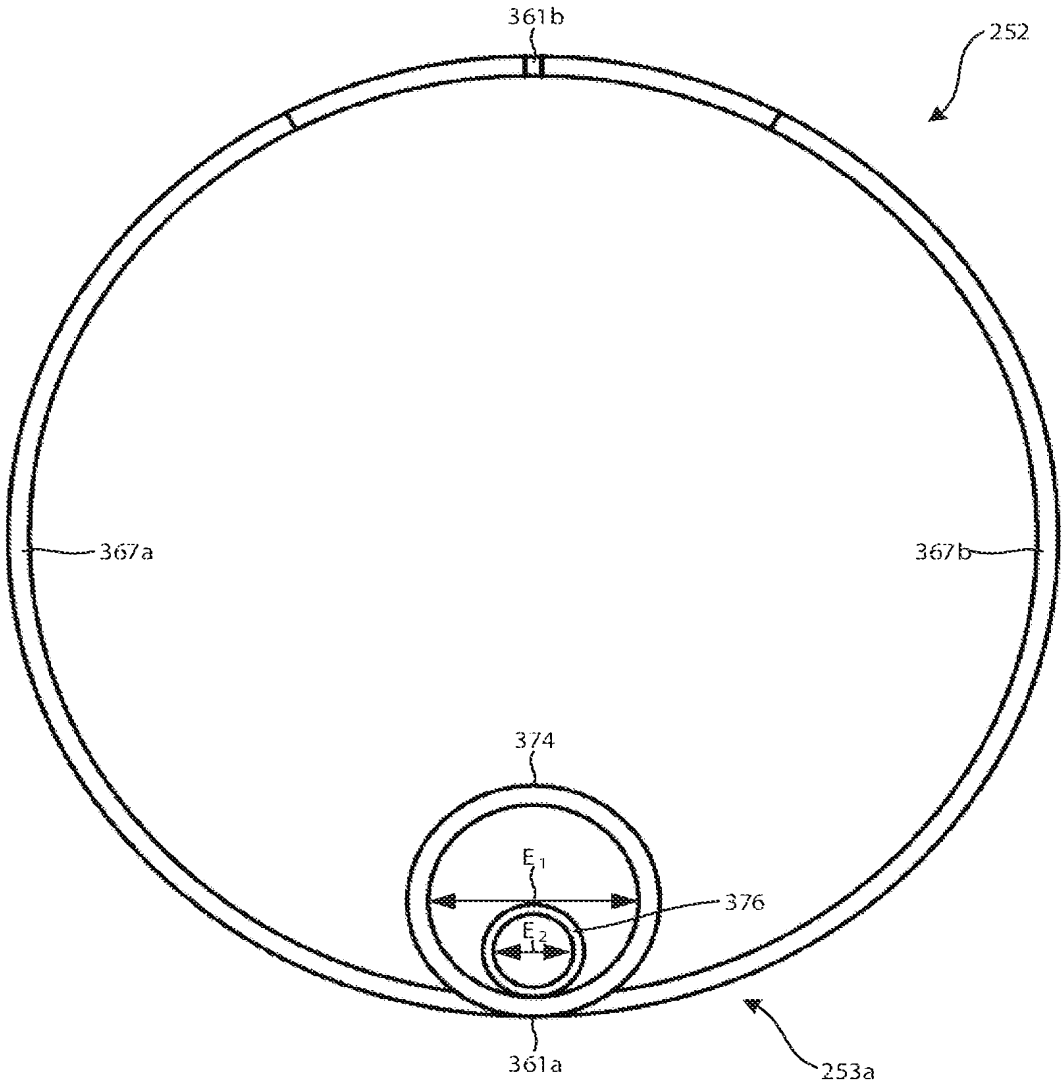


FIG. 3D

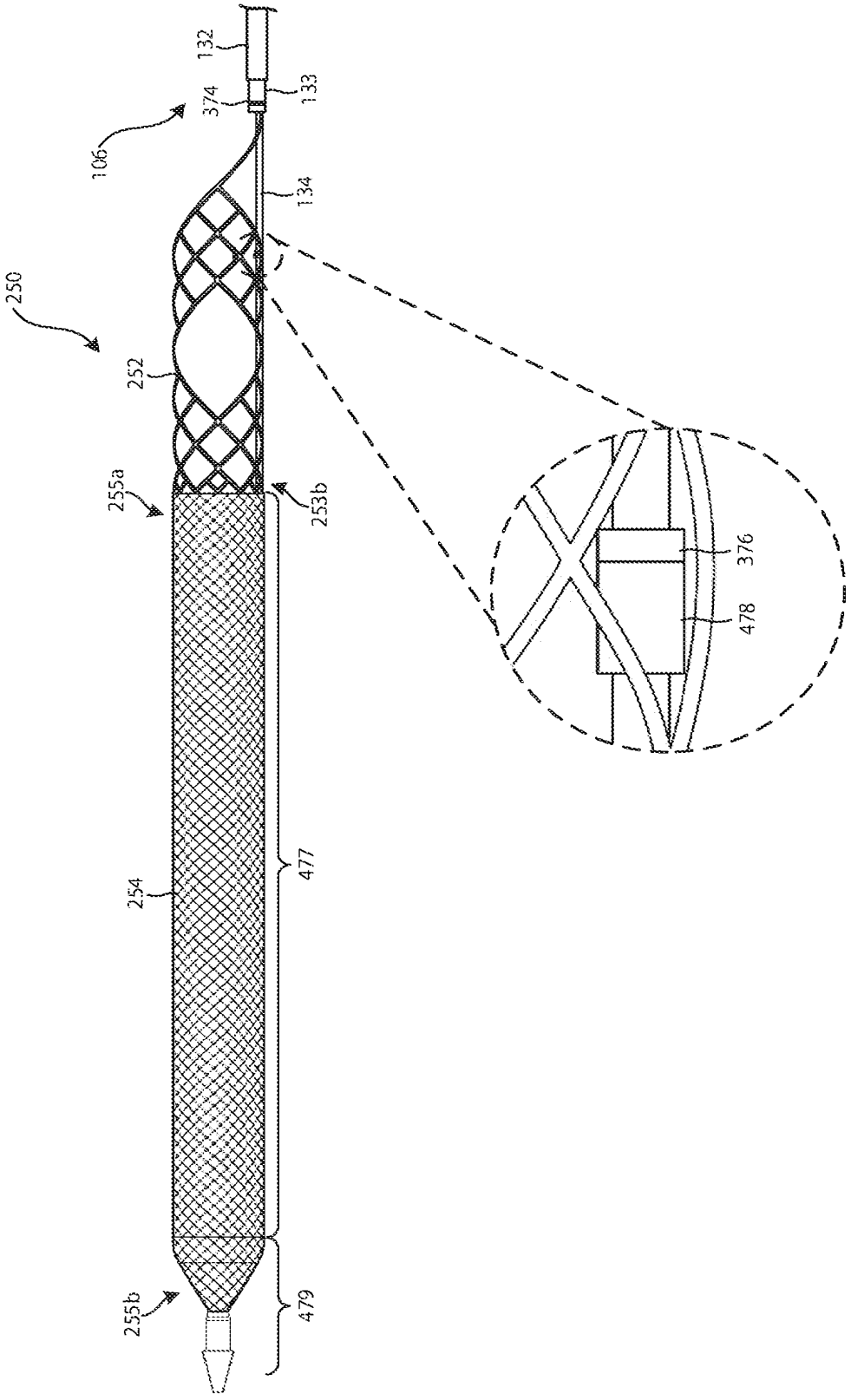


FIG. 4

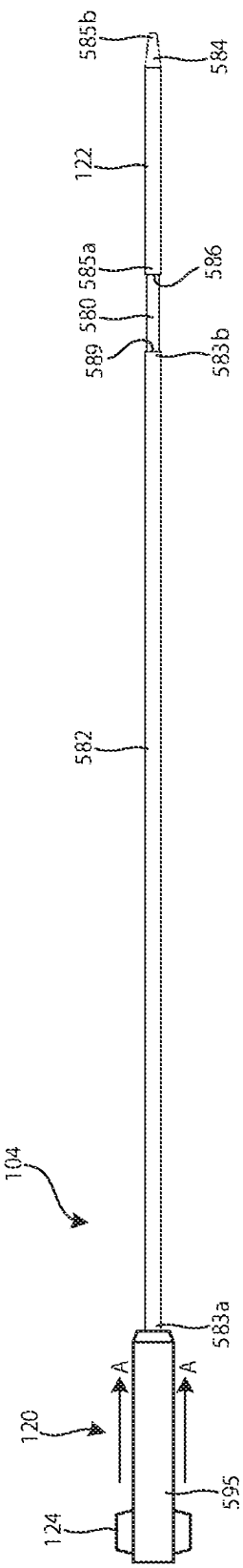


FIG. 5A

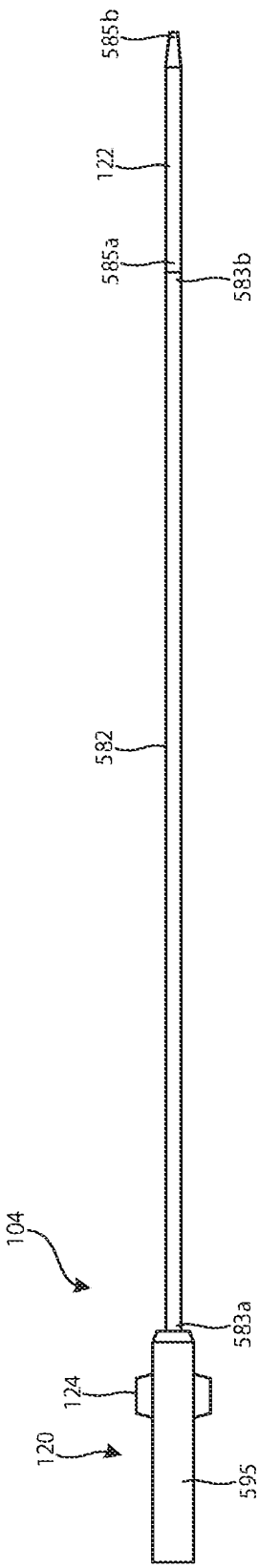


FIG. 5B

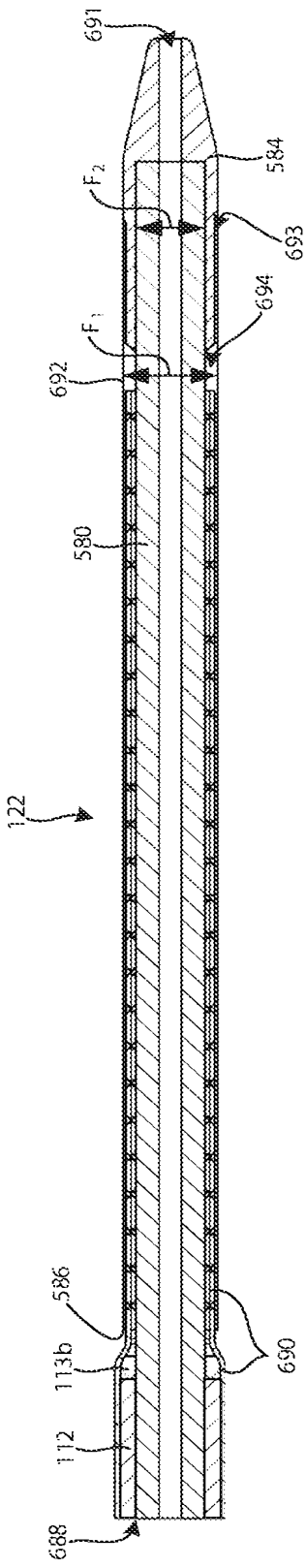


FIG. 6

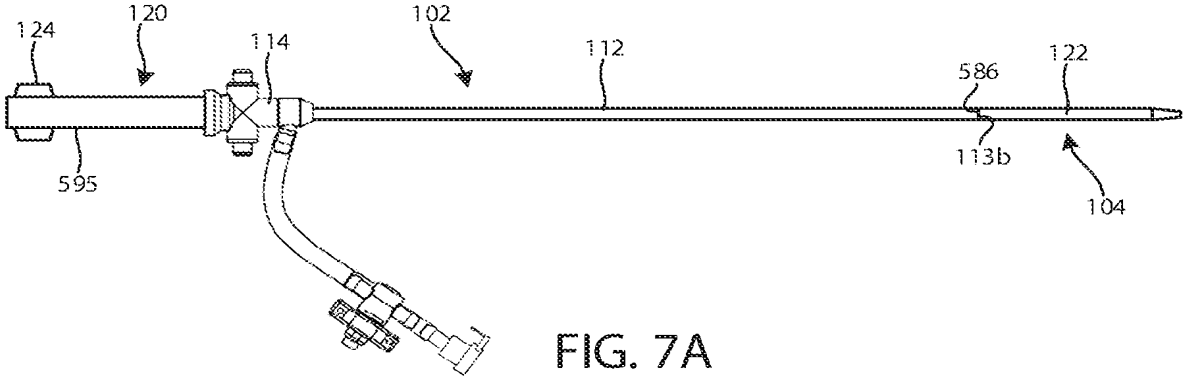


FIG. 7A

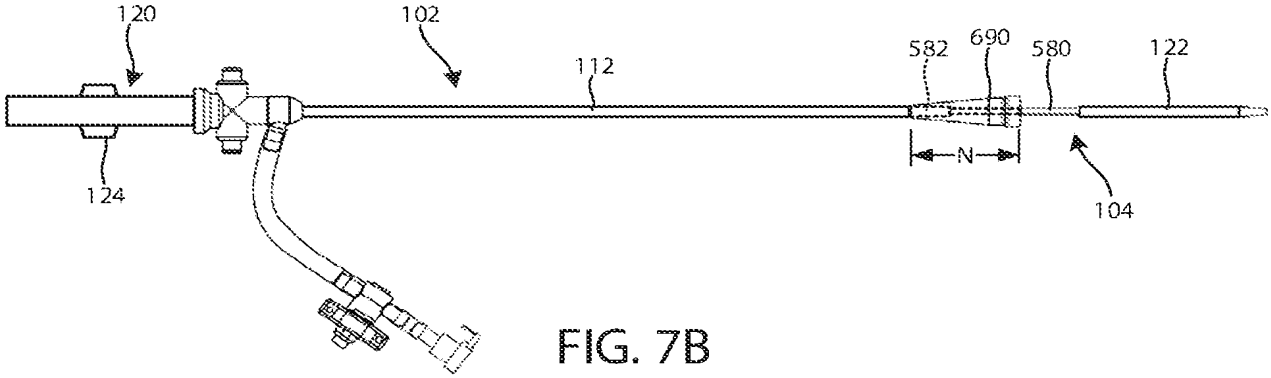


FIG. 7B

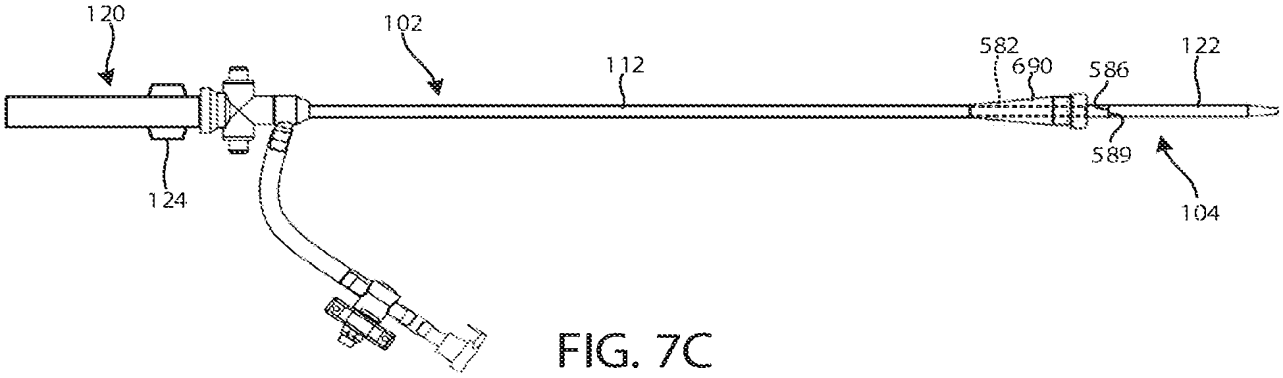


FIG. 7C

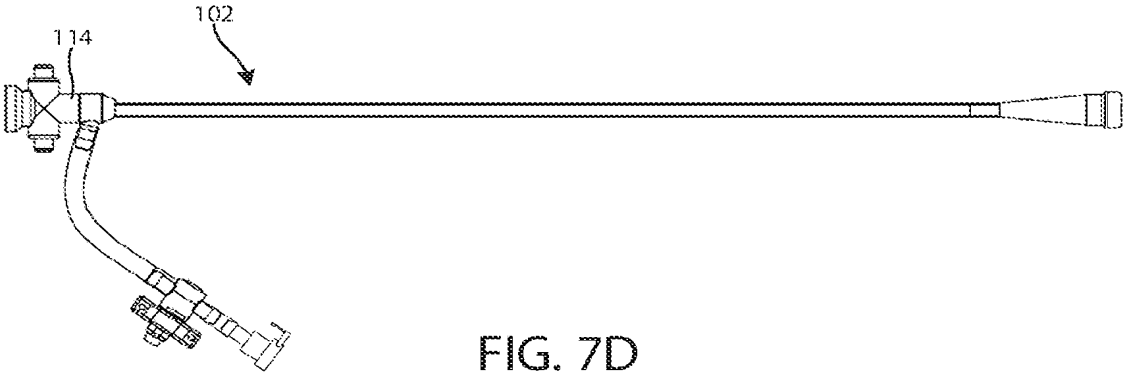


FIG. 7D

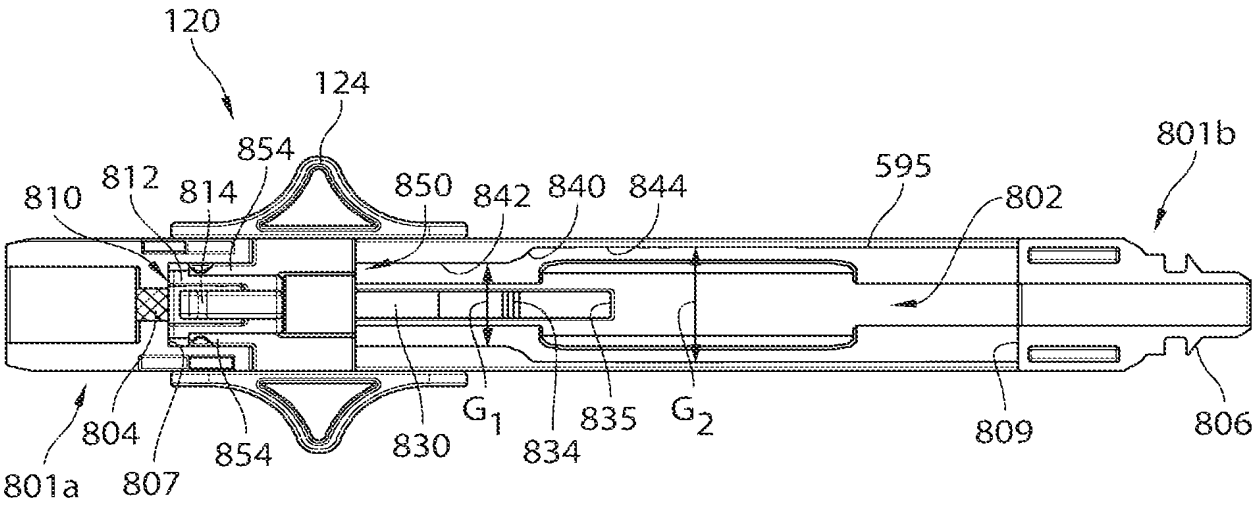

120
124
854
812
814
810
850
842
840
844
595
802
801b
804
807
854
830
G_1
834
835
G_2
809
806
801a

FIG. 8A

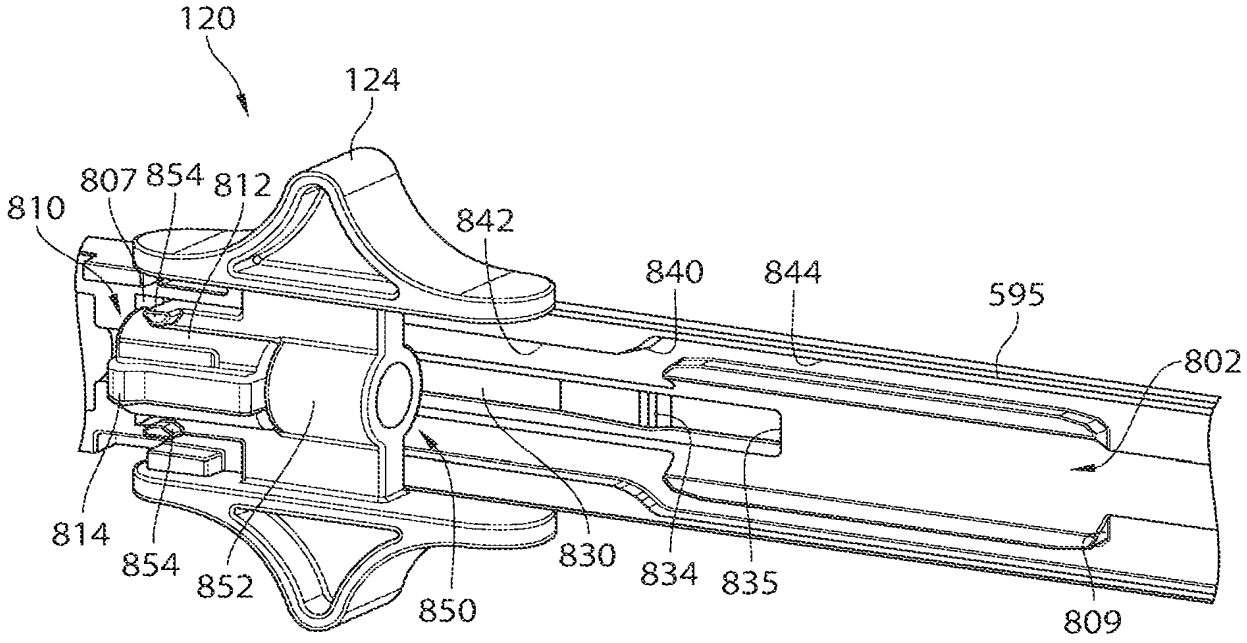

120
124
807
854
812
810
842
840
844
595
802
814
854
852
850
830
834
835
809

FIG. 8B

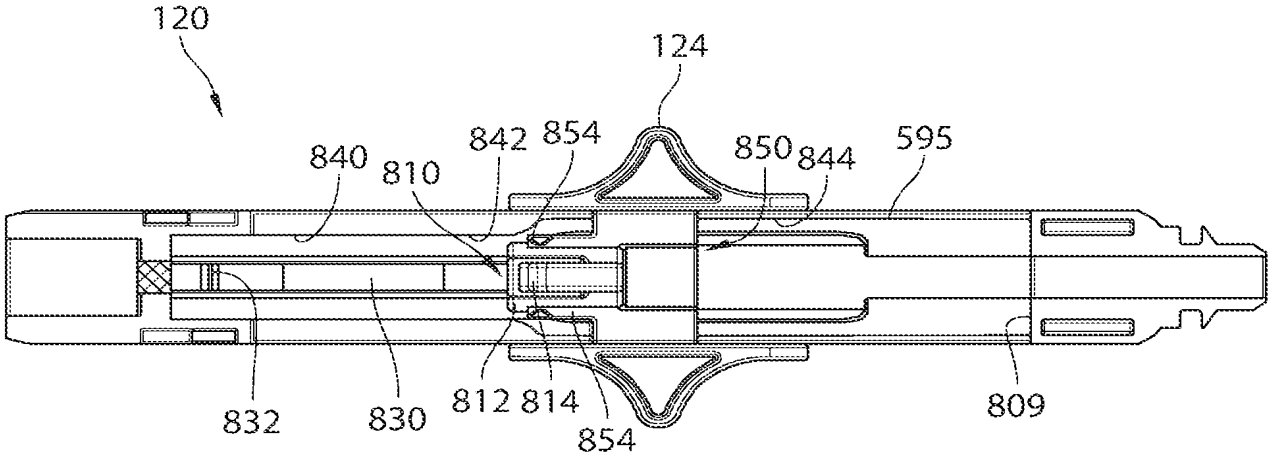

120
124
840
810
842
854
850
844
595
832
830
812
814
854
809

FIG. 8C

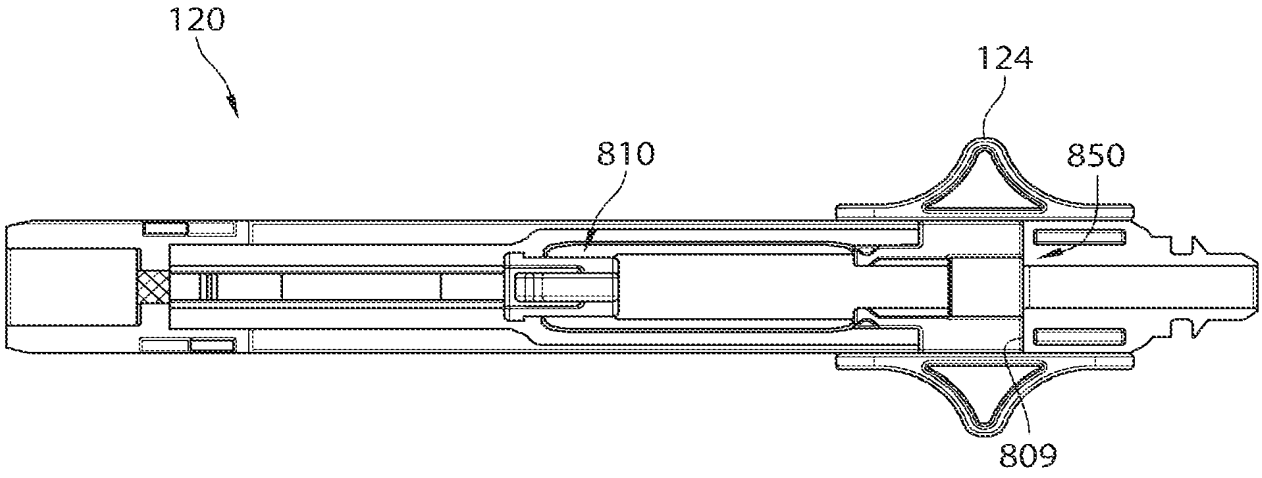

120
124
810
850
809

FIG. 8D

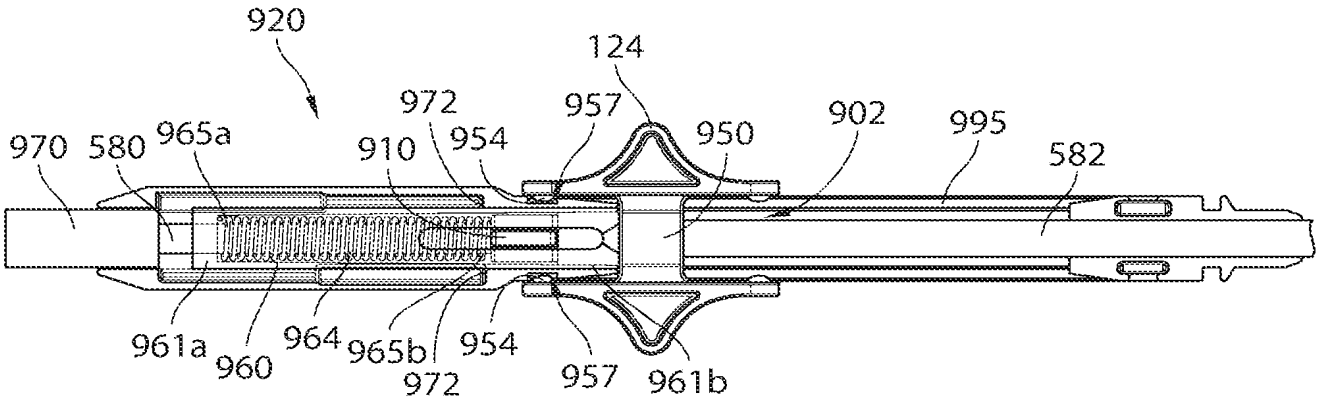


FIG. 9A

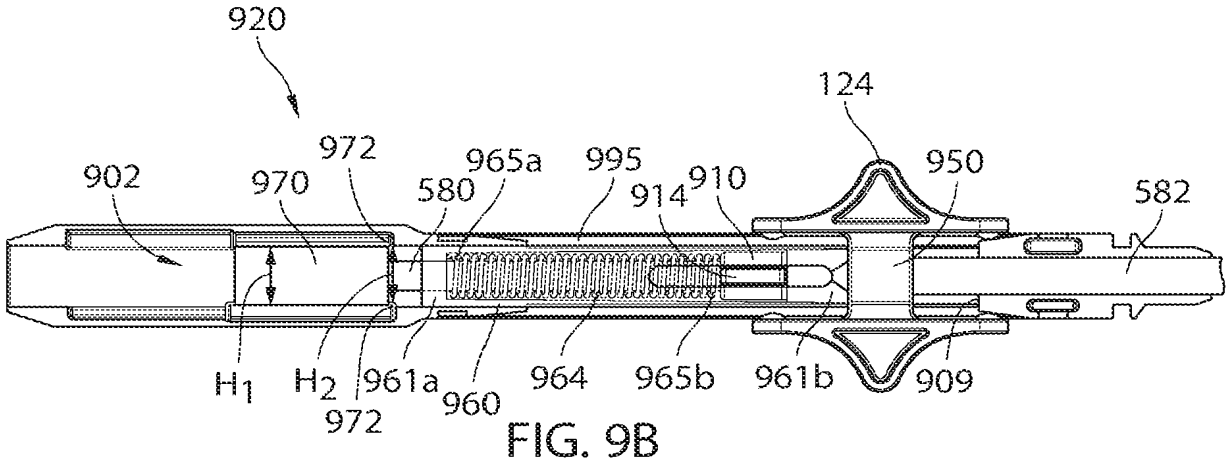


FIG. 9B

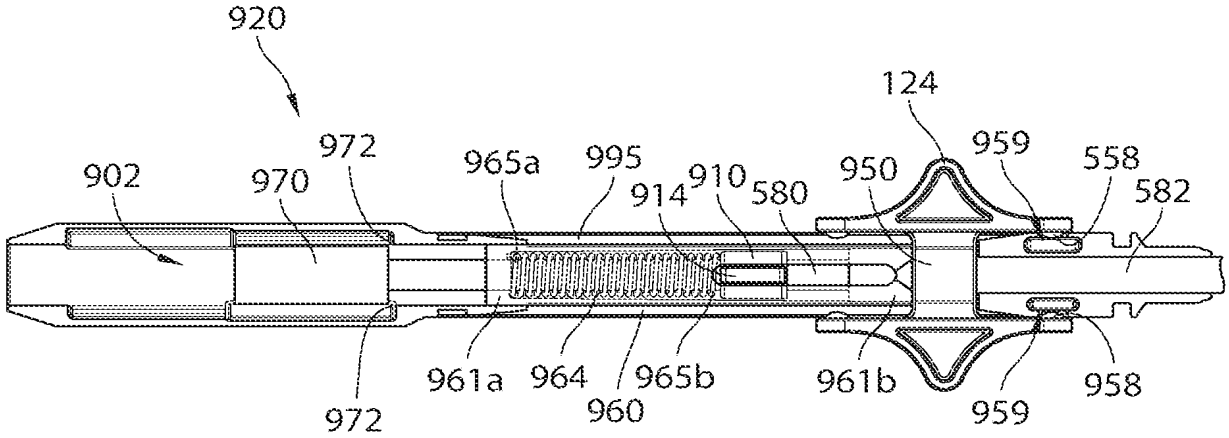


FIG. 9C

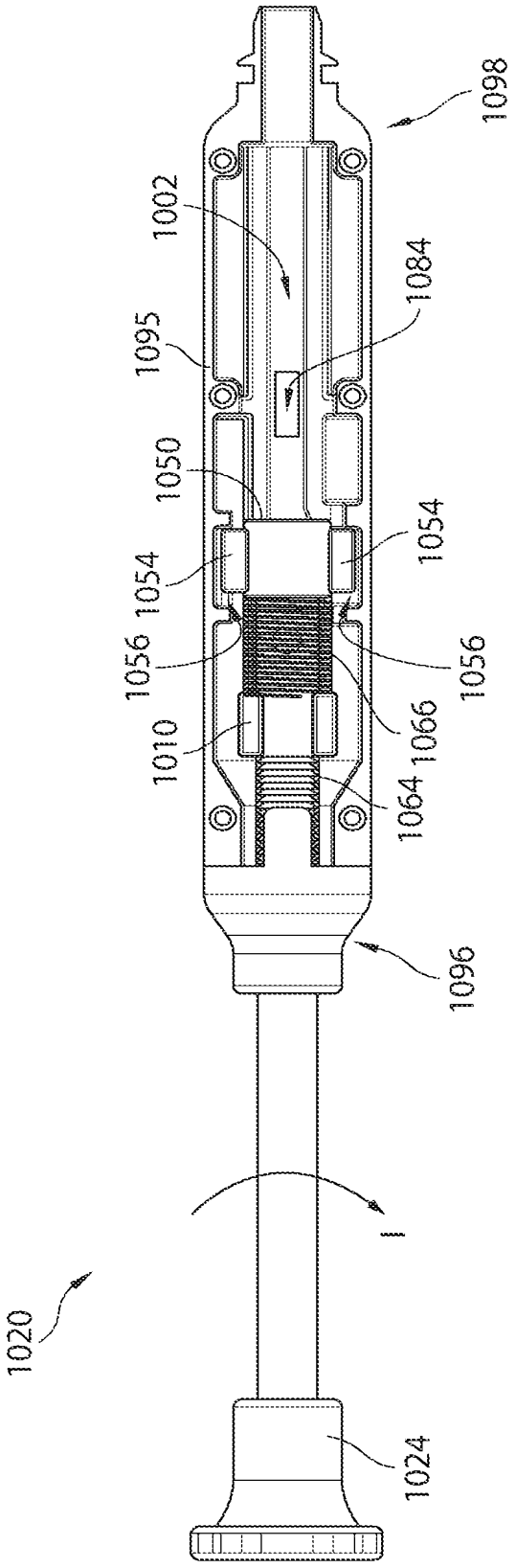


FIG. 10A

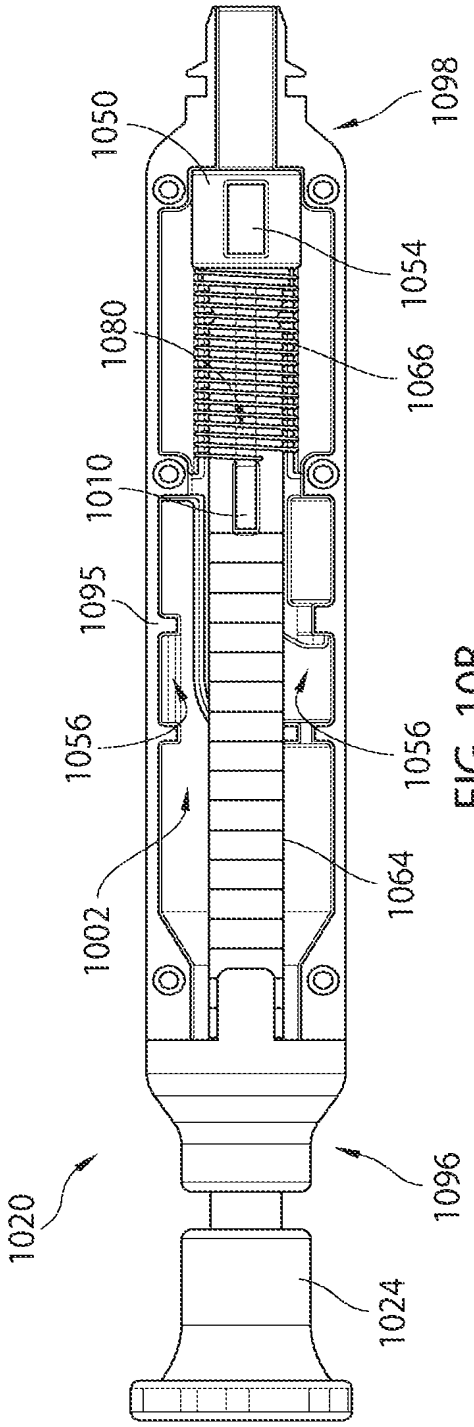


FIG. 10B

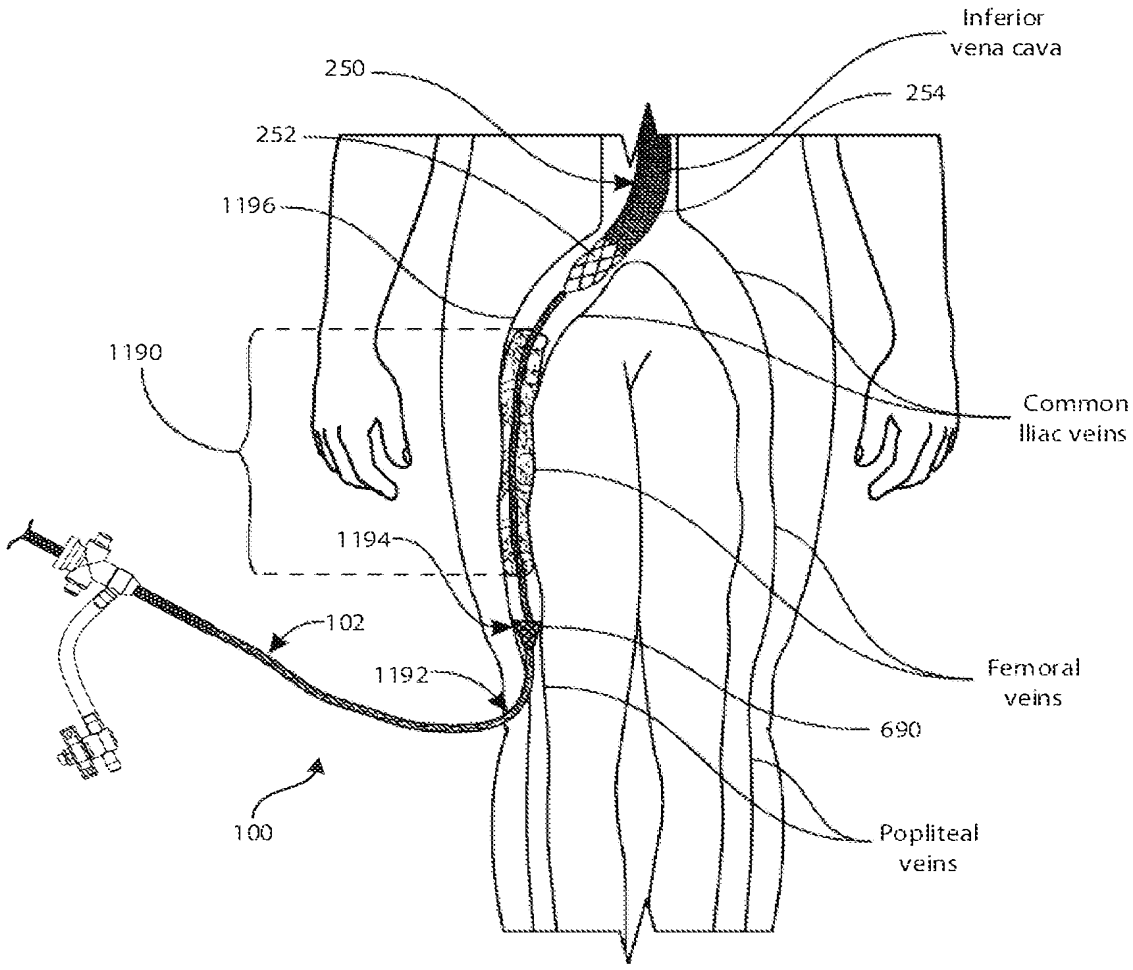

Inferior vena cava
250
254
252
1196
1190
Common Iliac veins
1194
102
1192
Femoral veins
690
100
Popliteal veins

FIG. 11

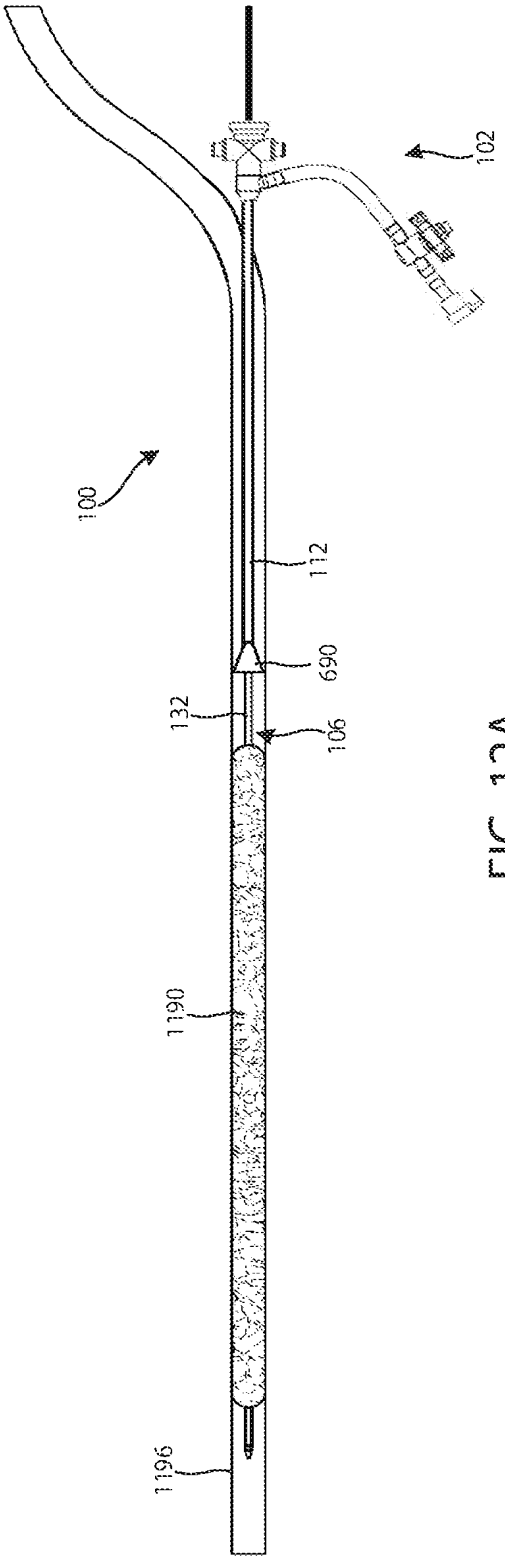


FIG. 12A

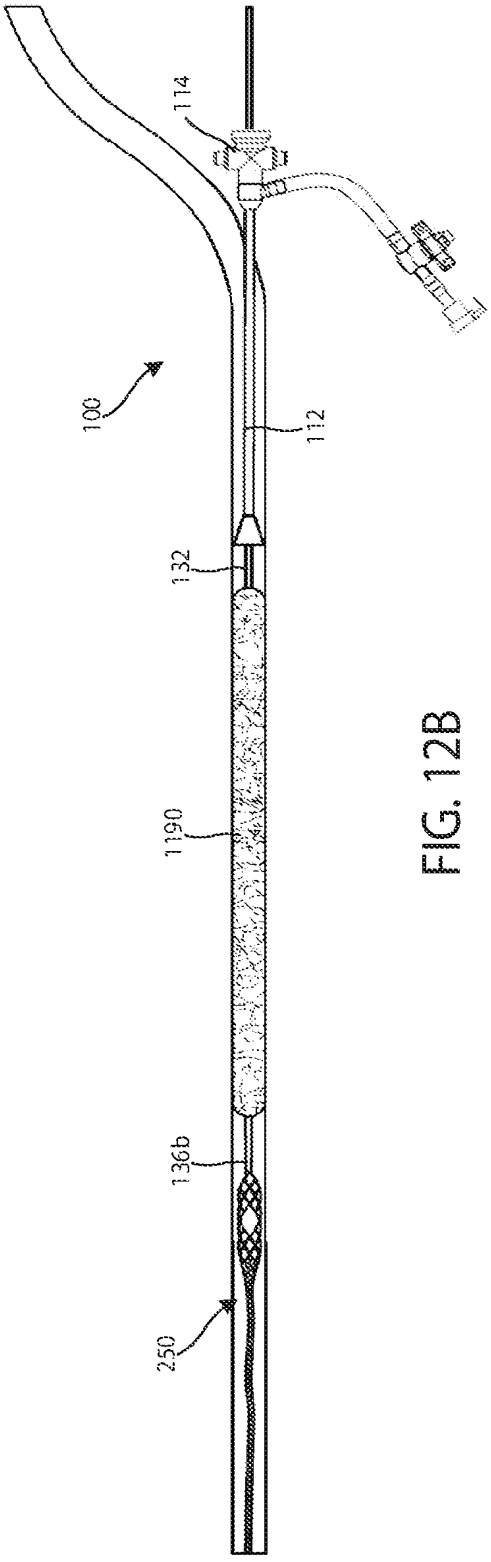


FIG. 12B

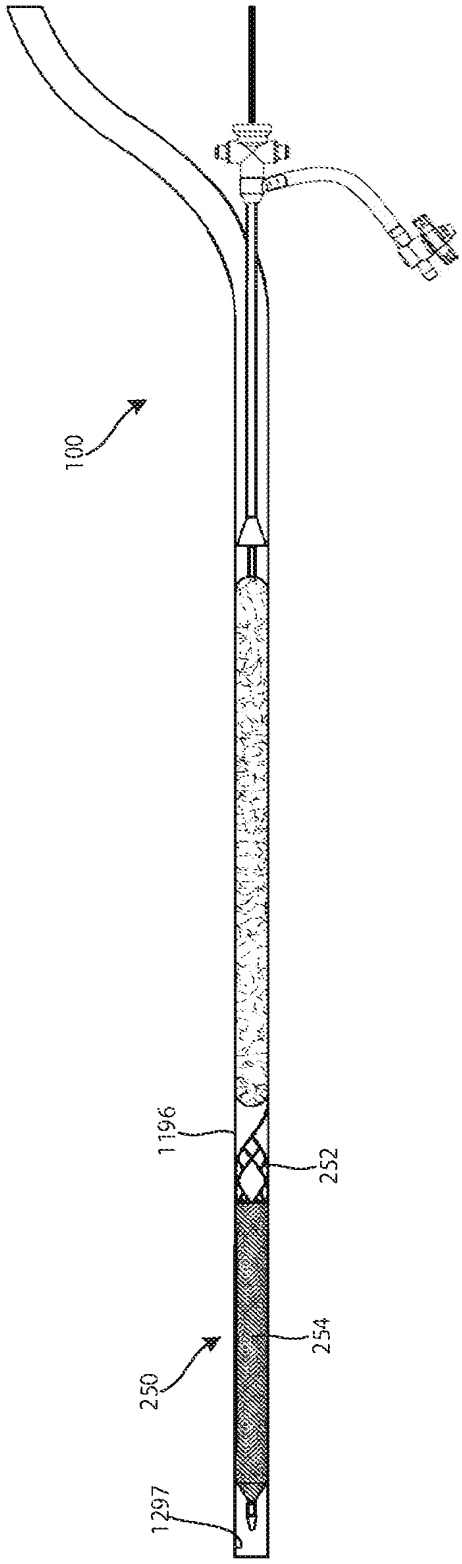


FIG. 12C

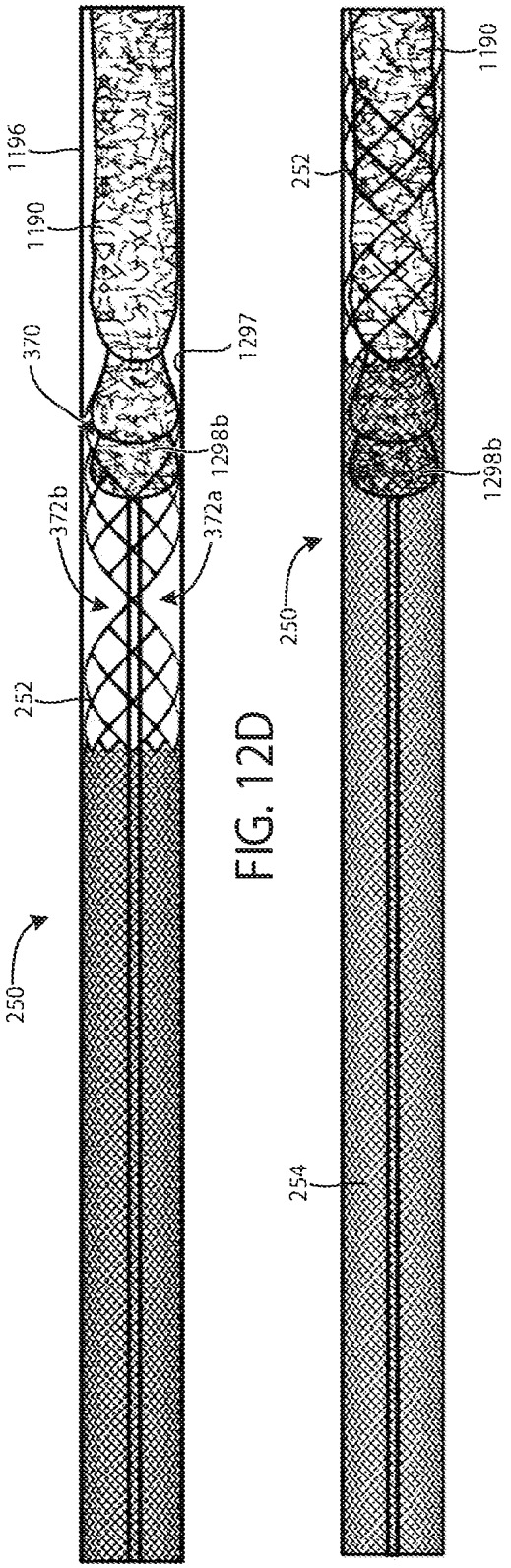


FIG. 12D

FIG. 12E

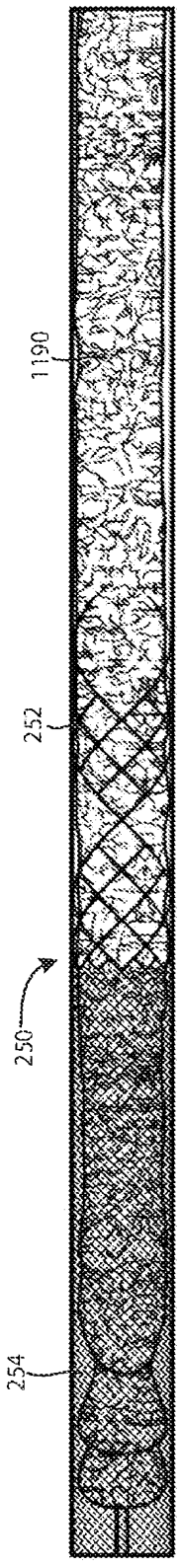


FIG. 12F

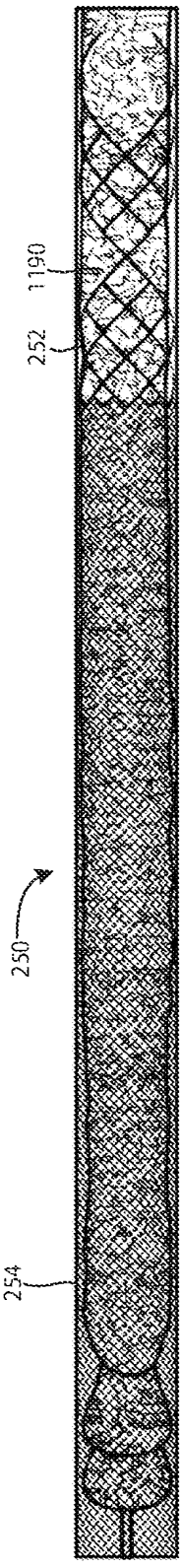


FIG. 12G

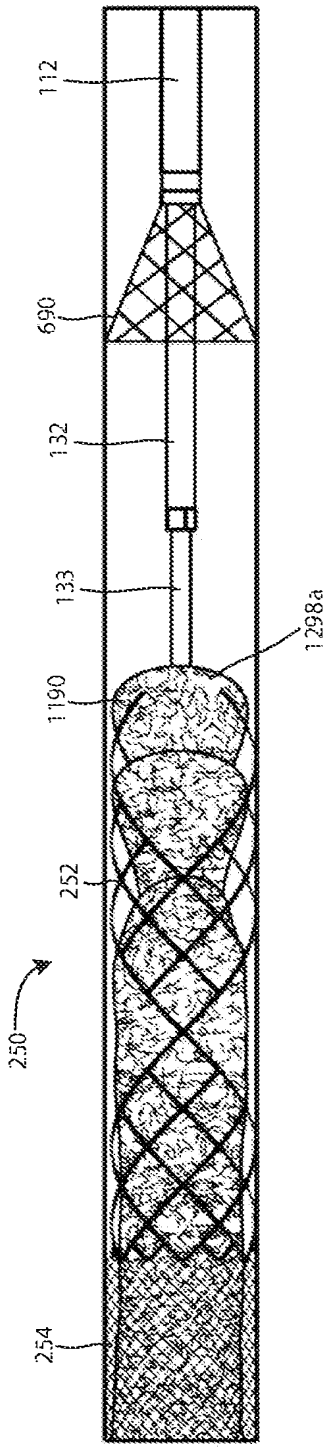


FIG. 12H

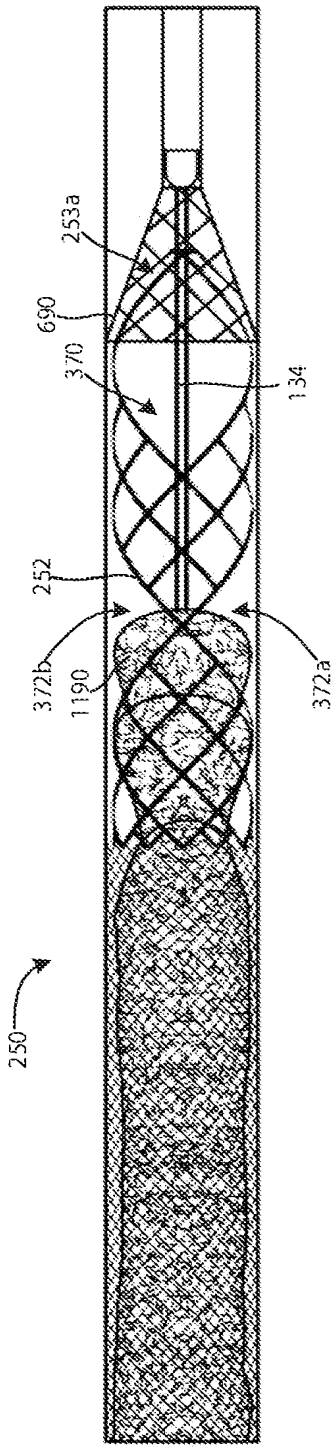


FIG. 12I

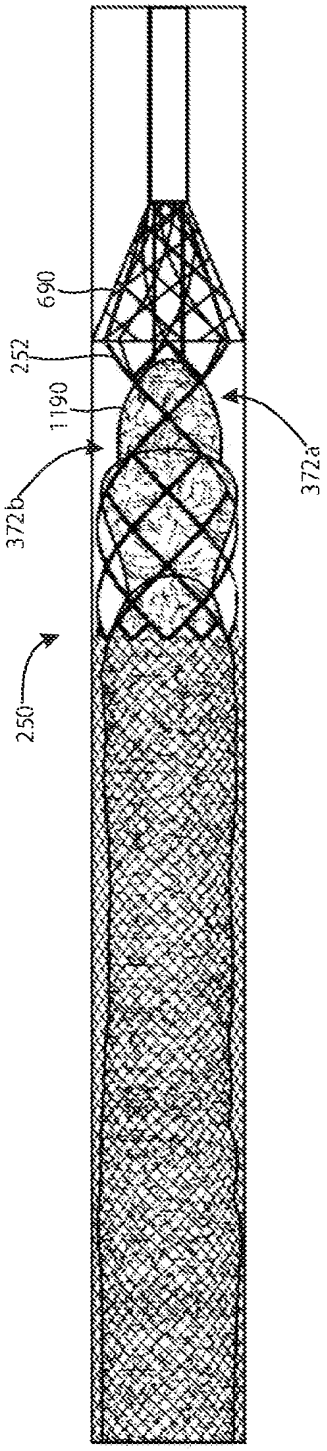


FIG. 12J

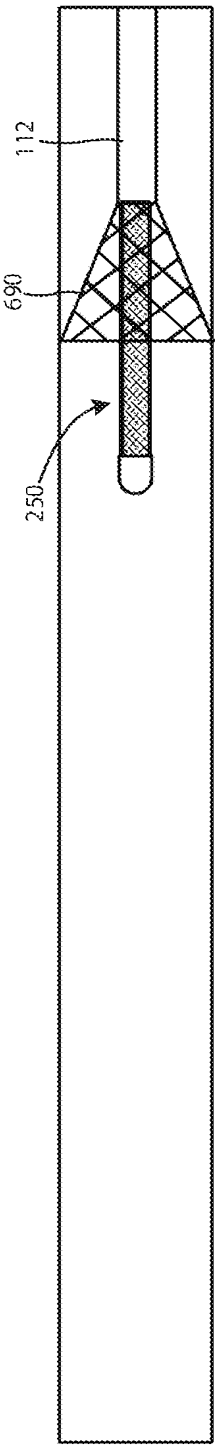


FIG. 12K

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/221; A61B 17/22; A61B 17/3207; A61B 17/34; A61F 2/01; A61F 2/86 (2021.01)

CPC - A61B 17/221; A61B 17/320725; A61B 17/3415; A61B 2017/22041; A61B 2017/22094; A61B 2017/2212; A61B 2017/2215; A61B 2017/320741; A61F 2/011; A61F 2/013; A61F 2002/016; A61F 2002/018; A61F 2230/0069 (2021.02)

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)

see Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

see Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0371779 A1 (NEURAVI LIMITED) 18 December 2014 (18.12.2014) entire document	1-10
A	US 2011/0160763 A1 (FERRERA et al) 30 June 2011 (30.06.2011) entire document	1-10
A	US 2017/0112513 A1 (INARI MEDICAL) 27 April 2017 (27.04.2017) entire document	1-10
A	US 2018/0092652 A1 (INARI MEDICAL, INC.) 05 April 2018 (05.04.2018) entire document	1-10

☐ 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

"D" document cited by the applicant in the international application

"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
25 March 2021	APR 14 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

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 extra sheet(s).

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.:

1-10

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)) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

Continued from Box No. III Observations where unity of invention is lacking

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-10, are drawn to a coring element for coring a vascular thrombus within a blood vessel of a patient.

Group II, claims 11-28, are drawn to a dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention: the coring element comprising: a unitary structure having a first region adjacent to a proximal portion of the unitary structure, wherein the first region includes a first mouth configured to core the vascular thrombus; a second region distal of the first region, wherein the second region is generally tubular and includes a first plurality of interconnected struts; a third region distal of the second region, wherein the third region includes a second mouth configured to core the vascular thrombus; and a fourth region distal of the third region, wherein the fourth region is generally tubular and includes a second plurality of interconnected struts as claimed therein is not present in the invention of Group II. The special technical feature of the Group II invention: a dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath, the dilator assembly comprising: a first shaft defining a lumen; a second shaft slidably positioned within the lumen of the first shaft; a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft as claimed therein is not present in the invention of Group I.

Groups I and II lack unity of invention because even though the inventions of these groups require the technical feature of capturing a vascular thrombus within a blood vessel of a patient, this technical feature is not a special technical feature as it does not make a contribution over the prior art.

Specifically, US 2018/0092652 A1 to Inari Medical, Inc. teaches capturing a vascular thrombus within a blood vessel of a patient (The method includes retracting the thrombus extraction device proximally so that the coring portion cores and separates a portion of the vascular thrombus from the venous vessel wall while the mesh structure captures the vascular thrombus portion. The method includes withdrawing the thrombus extraction device from the patient to remove the vascular thrombus portion from the venous vessel, para. 0008. One aspect of the present disclosure relates to a method for removal of thrombus from a blood vessel in a body of a patient, which blood vessel can be an artery or a vein, para. 0017).

Since none of the special technical features of the Group I or II inventions are found in more than one of the inventions, unity of invention is lacking.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 April 2017 (06.04.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/058280 A1

(51) International Patent Classification:
A61F 2/01 (2006.01)

(21) International Application Number:
PCT/US2016/017982

(22) International Filing Date:
15 February 2016 (15.02.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/284,300 28 September 2015 (28.09.2015) US
62/284,752 8 October 2015 (08.10.2015) US
62/245,560 23 October 2015 (23.10.2015) US

(71) Applicant: **GW MEDICAL LLC** [US/US]; 5849 Corte Margarita, Pleasanton, CA 94566 (US).

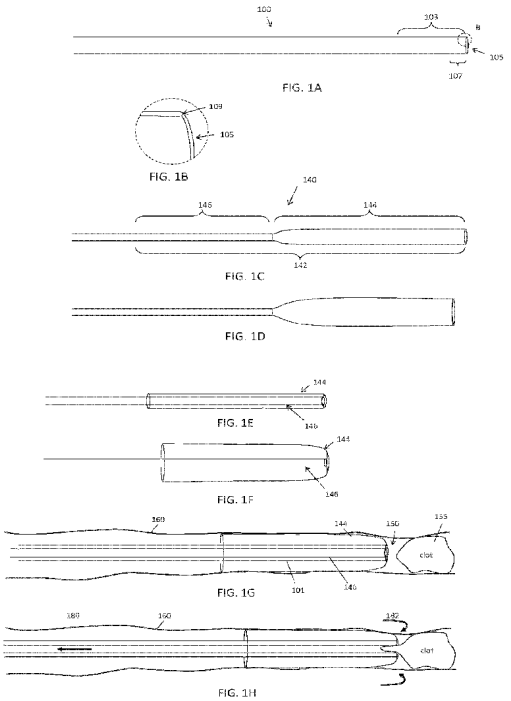
(72) Inventors: **GREENHALGH, E., Skott**; 5849 Corte Margarita, Pleasanton, CA 94566 (US). **WALLACE, Michael, P.**; 5849 Corte Margarita, Pleasanton, CA 94566 (US).

(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, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, 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).

[Continued on next page]

(54) Title: MECHANICAL THROMBECTOMY APPARATUSES AND METHODS



(57) Abstract: Methods and apparatuses for mechanically removing objects from a body. In particular, described herein are thrombectomy methods and mechanical thrombectomy apparatuses for removal of blood clots from within a lumen of a blood vessel.

WO 2017/058280 A1

Published:

— *with international search report (Art. 21(3))*

MECHANICAL THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to each of the following provisional patent applications, each of which is herein incorporated by reference in its entirety: 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.

INCORPORATION BY REFERENCE

[0002] 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

[0003] 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

[0004] 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 (e.g., blood clots) from the vasculature may improve patient conditions and quality of life.

[0005] 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.

[0006] 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.

[0007] 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.

[0008] Catheter directed thrombectomy and thrombolysis are commonly perceived to be less traumatic, less likely to decrease the morbidity and mortality associated with conventional surgical techniques. In recent years, direct administration of chemical lysing agents into the coronary arteries has shown to be of some benefit to patients who have thrombosed coronary arteries. In this procedure, a catheter is placed immediately in front of the blockage and a drip of streptokinase is positioned to be directed at the upstream side of the thrombus. Streptokinase is an enzyme which is able in time to dissolve the fibrin molecule. This procedure can take several hours and is not always successful in breaking up the thrombus. Furthermore, it can lead to downstream thrombus fragments (emboli) which can lead to blockage of small diameter branches. U.S. Pat. No. 4,646,736 discloses a thrombectomy device that permits rapid removal of an obstructive thrombus. However, the device is characterized by small catheter tip size and thus is unable to exert significant total force on clot masses. Also, a clot which is not in good position of purchase on a vessel wall in the "line of fire" of the rotating wire is not fibrinectomized. This is especially true of clots floating free in the blood stream, since it is virtually impossible to revolve within these clots in the absence of a constraint such as fingers.

[0009] Further disadvantages to this thrombectomy device include the difficulty of keeping the clot in the space above the wire during all degrees of rotation as the wire is moved sideways during rotation, which is sometimes necessary to sweep the arterial lumen. In fact, sweeping out an entire arterial lumen with a rotating wire is virtually impossible in all but the smallest, i.e., less than 1.5 mm diameter, arteries. An additional and serious possible disadvantage is that fragments of the clot may be embolized downstream.

[0010] Another approach for capturing emboli is described in U.S. patent application 2015/0005781. This application describes a catheter with a basket extending from the distal end. An actuator, such as a rod or cable, can be pulled proximally to retract the basket into the catheter. Unfortunately, the basket occludes the inside of the lumen, preventing the concurrent use with a positioning and/or supporting guidewire, and the basket must be held in or near the distal end of the catheter. Depending on the stiffness of the material (e.g., clot) being removed, retrieval of the basket often collapses the distal end of the catheter, preventing its use, and the basket can be difficult to pull into the catheter, particularly when holding a clot. This may result in sheering the clot. Finally the basket must be preloaded into the distal

end of the catheter prior to insertion into the vessel, and preloading may be both difficult and time consuming, and may risk disrupting the device prior to deployment.

[0011] Thus, 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

[0012] In general, described herein are medical apparatuses, including medical devices and systems including these medical devices, and methods of operating these medical devices, for collecting objects, including but not limited to blood clots (thrombi), tissue (biopsies, small tumors, polyps, calcifications, kidney stones, etc.). The apparatuses described herein typically include an elongate catheter having a lumen and a distal end and with a distal end opening into the lumen. The catheter may be low-profile neurovascular catheters (e.g., microcatheters, insertion catheters, etc.) having any appropriate diameter (e.g., <1 Fr, 1Fr-6Fr, 1Fr-9 Fr, etc.). A flexible tractor assembly or portion (e.g., which may be referred to herein as a flexible tractor tube or simply a flexible tube) is typically positioned and longitudinally slideable within the catheter, and arranged so that the distal end region ("distal tractor region") doubles back over the distal end of the catheter. The flexible tube ("tractor tube") is generally elongate and hollow and configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter. The distal end forming the distal tractor region may be tubular or not (e.g., it may be formed of strips of material, etc.). The combined catheter and flexible tractor assembly also forms a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire.

[0013] In use, a guidewire may be configured to slide through the apparatus (and may form part of the apparatus) to allow positioning and in some variations support, typically without interfering with the operation of the tractor tube drawing an object such as a blood clot into the body of the catheter.

[0014] In addition to the catheter having a flexible tractor tube that is arranged within the catheter and inverted or doubled over the distal end of the catheter, the apparatuses described herein may include one or more features or elements that permit these devices to operate within a vasculature without collapsing, particularly at their distal ends, despite applying a pulling moment over the distal edge/opening of the preferably quite soft distal end. Further, these apparatuses may be adapted to minimize the force required to withdraw the distal tractor region into the catheter and invert over the distal end opening of the catheter, without damaging or weakening the distal tractor region, preventing a failure mode in which the flexible tractor tube within the apparatus breaks, binds up, jams or tangles on its self or with the catheter. For example, as will be described in greater detail below, any of these apparatuses may include a selectively lubricious region at or near the distal end of the catheter. The catheter end may be shaped to allow inverting of the flexible tractor region of the distal end of the tube. In addition, the end profile of the catheter (e.g., the distal-most 5 mm, 4 mm, 3 mm, 2mm, 1mm, etc.)

may have an arrangement of stiffnesses (e.g., durometers) that prevent collapse/buckling of the catheter. Alternatively or additionally, the flexible tractor tube may be adapted for "sweeping" as much of the vessel around the catheter to collect objects from within the vessel while still allowing relatively low-force retraction into the catheter and inverting over the distal end of the catheter. The tractor portion of the flexible tube, which may refer to a distal portion of the tube within the catheter, may generally include a distal expandable (first) end region that is adjacent, either immediately adjacent or separated by a spacer region, to a second less-expandable (or non-expandable) end region. The second end region is proximal (when both the first end region and the second end regions are drawn into the catheter) to the first end region. The flexible tractor tube may extend all the way through the catheter to a proximal end and/or proximal handle, or it may end before the proximal end of the catheter and be connected to a puller. The puller may be another, possible less flexible tube, or a wire, rod, string, etc. The flexible tractor tube is generally configured to have a lumen through it (e.g., central lumen or radially offset lumen) through which a guidewire may be passed, passing through the apparatus, including the catheter and the flexible tractor tube. The flexible tractor tube may generally be operated (e.g., pulled proximally and in some variations pushed distally) while a guidewire is within this lumen.

[0015] The apparatus may be pre-loaded for deployment of the distal tractor region and capture of an object within a vessel, or in some variations it may be loaded *in vivo*, after or during positioning a guidewire and/or the catheter within a blood vessel. For example, in some variations, the apparatus may be adapted for use *in vivo* by holding the distal tractor region retracted into the catheter until the catheter is within the vessel, and preferably near the object to be removed. Once positioned, the distal tractor region of the flexible tube within the catheter may be distally extended from the catheter, expanded to form the capture shape that can be drawn and inverted over the distal end of the catheter either with or without advancing the catheter distally. Thus, the distal tractor portion may be safely and securely delivered to the necessary site within the lumen without risk to damage to the apparatus or the body.

[0016] For example, a method of performing a mechanical thrombectomy to remove a clot from a blood vessel may include: advancing a distal end of a catheter through the blood vessel towards the clot; exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable first end region; allowing the expandable first end region to expand within the blood vessel; positioning the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region while the expandable first end region is doubled over the less expandable second end region; and drawing the clot into the catheter by rolling the expandable first end region rolls over the distal end of the catheter so that the expandable first end region inverts as the expandable first end region is pulled into the catheter.

[0017] The step of advancing the distal end of the catheter through the blood vessel towards the clot may include advancing over a guidewire, as mentioned. The catheter may be slid distally over the guidewire or extended distally (or retracted proximally) with the guidewire. The inner (tractor) tube may

be held within the catheter (e.g., near the distal end, a middle region, or near the proximal end) or in some variations it may be inserted after positioning the catheter within the vessel. The distal end of the catheter may be positioned at, near or adjacent the object to be removed (e.g., the clot), or it may be separated by a predetermined distance, e.g., to allow space for the apparatus to set up by extending the distal tractor region out of the distal end of the catheter and expand in preparation for withdrawing the object into the catheter.

[0018] Thus, once positioned, the apparatus may be deployed by exposing the distal tractor region and positioning the distal end of the catheter and in some variations the guidewire, to allow the object to be captured and drawn into the catheter. The distal tractor region may be exposed by pulling the catheter proximally while either holding the flexible tube including the distal tractor region stationary (e.g., relative to the blood vessel) and/or by extending the flexible tube distally.

[0019] As mentioned, the flexible tube may include a distal tractor region that includes a first end region that is expandable. This end region is generally porous (e.g., formed of a mesh, knit, woven, or other material, including solid material having multiple openings therethrough) and adapted to grab the object (e.g. clot) to be removed. This first end region is generally expandable to between about 1.3x and about 10x the inner diameter of the catheter (e.g., between about 1.5 and about 7x, between about 1.5x and about 5x, between about 1.5 and about 4x, between about 1.5x and about 3x, etc.). This first distal end region forming the tractor portion is generally adjacent to the second end region that is less expandable (or not substantially expandable). The second region may extend proximally all the way down the catheter, or partially down the catheter. In general, the first end region of the tractor portion is exposed from out of the catheter and used to capture the clot or other object; the second end region may be exposed during positioning but may otherwise remain within the catheter during operation.

[0020] Thus, exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter may include extending or pushing the distal tractor region out of the distal end of the catheter. In some variations the distal tractor region is pre-formed so that the first expandable distal end region is doubled over the second distal end region; in other variations the first distal end region is in-line, distal to, the less expandable second distal end region. The catheter may then be moved distally so that a distal end region of the catheter (including the distal end) is extended in a gap radially between the expanded expandable first end region of the distal tractor region and the less-expandable second end region.

[0021] In any of the variations in which the distal tractor region is pushed out of the distal end of the catheter, e.g., during this initial *in vivo* set up phase, the flexible tube, and particularly the distal tractor region, may be configured or otherwise adapted to allow pushing out of catheter without binding up. Binding within the catheter of an expandable tube may occur if the expandable first end region in particular becomes caught on the inner walls of the catheter, preventing deployment. In some variations the expandable first end region is configured as a mesh tubular member having filaments (e.g. Nitinol, polymeric, etc.) having between about 24 to 144 stands, having a thickness of 0.0005 inches to 0.005 in diameter, wherein the mesh tubular member extends in a longitudinal axis, further wherein the mesh

tubular member has a length that is greater than 5 cm, forms a braid angle between crossing strands in a direction of the longitudinal axis of about 35 degrees or less when being pulled and inverted around the distal end of the catheter and expands to a diameter of greater than 1.5 times an inner diameter of the catheter outside of the catheter when unconstrained. Within this configuration, the tubular member has been found to be pushable.

[0022] In other variations, when the expandable first distal end region is pushed or extended out of the distal end of the catheter, it may be configured (e.g., pre-shaped, shape-set, etc.) to invert over the distal end of the catheter and expand. The catheter may be moved distally, aiding in pushing this expandable first end region of the distal tractor region proximally relative to the outside of the catheter.

[0023] In any of these methods, the distal tractor region may include the expandable first end region and a less expandable second end region proximal to the expandable first end region, and the expandable first end region is permitted to expand within the blood vessel.

[0024] Thus, towards the end of the deployment phase, the distal end of the catheter is typically positioned so that the distal end region of the catheter is radially between the less expandable second end region and the expandable first end region of the distal tractor region while the expandable first end region is doubled over the less expandable second end region.

[0025] Thereafter, an object (e.g., clot) may be drawn into the catheter by rolling the expandable first end region over the distal end of the catheter so that the expandable first end region inverts as the expandable first end region is pulled into the catheter.

[0026] As mentioned, positioning may include distally advancing the distal end of the catheter so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region.

[0027] A guidewire may be used with any of the methods described herein. For any of the methods described herein may include advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot. The guidewire may be inserted into or through the clot, or it may be positioned just before the clot. The guidewire may be left in during clot removal, or it may be partially or completely withdrawn first. For example, any of these methods may include advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot, further wherein drawing the clot into the catheter comprises advancing the catheter towards the clot over the guidewire while rolling the expandable first end region over the distal end of the catheter.

[0028] Drawing the clot into the catheter generally includes rolling the distal tractor region (e.g., the expandable first end region) over the distal end of the catheter. The apparatus may also be moved distally during actuation of the distal tractor region. For example, drawing the clot into the catheter may include withdrawing the tube proximally (to roll the distal tractor region over the distal end) and/or withdrawing the tube proximally while advancing the catheter distally.

[0029] In any of these methods, drawing the clot into the catheter may include withdrawing the tube proximally while advancing the catheter distally, wherein the tube is withdrawn at a different rate than the catheter is advanced. It may be beneficial in some configurations to advance the catheter distally more rapidly than the tube (distal tractor region) is drawn proximally. In some variations, the catheter may be advanced more slowly than the tube (distal tractor region) is withdrawn proximally. Alternatively in some variations, they are moved at the same rate. The rate of motion may be determined for the flexible tube by looking at the proximal motion (e.g., of the second end region) within the catheter.

[0030] In general the expandable first end region of the distal tractor region is expandable and may form a distal-facing mouth or lip that can engage with an object such as a clot. The mouth of lip of the expandable tractor region may form a tangent angle or roll angle (as described below in greater detail in reference to FIGS. 18 and 21D) with respect to the long axis of the catheter outer diameter (OD) in the range of 5-60 degrees and preferable at least 10 degrees (e.g., 10°-60°, 10°-50°, 10°-45°, etc.). As long as the roll angle is at least 10 degrees with the tube is retracted into the catheter, the tube should not bind or jam on the catheter tip. The mesh tube may be constructed by modifying is stiffness to ensure the roll angle in greater than 10 degrees. Alternatively or in combination to maintaining a minimum roll angle it may be desirable to maintain a physical space or gap between the tube material ID and the O.D of the catheter (as described in greater detail in FIG. 18, below) at the catheters most distal tip. The gap may need to be greater than, e.g., 0.1, mm 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 0.7 mm, 0.8 mm, 0.9 mm, 1.0 mm, etc. to ensure the tube rolls around the distal end of the catheter when the tube is retracted. The expanded material (e.g., a mesh, woven, braided, kitted, perforated, etc. material) may be allowed to expand within the blood vessel by itself. Thus the expandable first region may be self-expandable. The expandable first end region of the distal tractor region may be pre-biased to expand. In some variation a shape memory material (e.g., shape memory alloy) is used. In some variations a biasing element is included in or integral to the expandable first end region to expand so that the distal tractor region. The expandable first end region may expand to make contact with an intima of the blood vessel. In some variations the apparatus may be configured (e.g., sized, including sizing the expandable first end region) so that the distal-most end of the distal tractor region makes contact with the vessel lumen. Thus, any of the variations described herein may additionally or alternatively include a biasing element such as a loop, ring, scaffold, or the like to push the expandable distal end region open so that it can make contact with the vessel by applying an increased radial force to expand it open. In some variations this opening bias (loop, helix, ring, etc.) is located at or near the distal end of the expandable first end region of the distal tractor region.

[0031] Any of the variations described herein may include an expandable catheter tip. For example, in some variation the durometer of the catheter tip may be sufficiently soft to compress proximally when the distal tractor region is drawn proximally into the catheter; compressing the distal tip axially may expand it slightly (e.g., so that it may flare out) at the distal end.

[0032] As mentioned, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may comprise pushing the distal tractor region out of the distal end of the

catheter. Alternatively or additionally, exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter may comprise pulling the catheter proximally. For example, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may comprise pushing the distal tractor region out of the distal end of the catheter to expose the expandable first end region already inverted over the less expandable second end region.

[0033] In some variations, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended.

[0034] The expandable first end region of the distal tractor region may be any appropriate length, and any portion of this length (all of it, 90%, 80%, 70%, 60%, 50%, 40%, etc.) may be exposed during this set-up period. For example, in some variations, exposing the distal tractor region of the tube may comprise exposing at least 5 mm of the expandable first end. The expandable first end region may be, e.g. 5 mm or greater (e.g., 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 200, 300, 400, 500 mm, etc. between about 5 mm and 500 mm, between about any lower value of 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 200 mm and any larger value of 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 200, 300, 400, 500 mm, where the lower value is always lower than the larger value). In any of these variations, when exposing the distal tractor region, either just the expandable first distal end region may be exposed out of the catheter (e.g., when pushing the expandable distal end region out distally and allowing it to invert over the distal end of the catheter) or both the expandable first distal end region and the less expandable second distal end region may all or partially exposed. For example, exposing at least 1 cm of the expandable first end region and at least 1 cm of the less expandable second end region. The expandable first end region may be inverted (doubled back) over the less expandable second end region.

[0035] As mentioned, the expandable first end region may comprise any appropriate material that is both expandable and able to grip the object (e.g., clot). For example the expandable first end region of the distal tractor region may comprise a mesh that is coupled adjacent to the less expandable second end region. For example the expandable first end region may be one or more of: a woven material, a mesh braided material, a knitted material, or a film material with multiple openings therethrough. The less expandable second end region may be made of the same material or it may be made of a different material. The less expandable second end region may have the same structure (e.g., woven, etc.) or it may have a different structure, including a less-expandable variation of the structure of the expandable first end region. For example the less expandable second end region may be a non-porous (e.g. non-woven, non-knitted, etc. or solid material) or less porous (e.g., tightly woven, small pore size knitted holes, tight braid). In some variation the less expandable second end region may include a transition region between the expandable first end region (e.g., having an intermediate expandability) and a non-expandable portion

of the second end region. In general, the less expandable second end portion of the distal tractor region include non-expandable structures and materials.

[0036] A method of performing a mechanical thrombectomy to remove a clot from a blood vessel may include: advancing a distal end of a catheter through the blood vessel towards the clot; exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable fist end region and configured so that the expandable first end region is inverted over the less expandable second end region; allowing the expandable first end region to expand within the blood vessel so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region; and drawing the clot into the catheter by advancing the catheter distally and withdrawing the tube proximally within the catheter so that the expandable first end region rolls over the distal end of the catheter and inverts as the expandable first end region is pulled into the catheter.

[0037] As mentioned, the expandable first end region may be inverted over the less expandable second end region before exposing the distal tractor region. Alternatively, exposing the distal tractor region may include inverting the expandable distal end region over the less expandable second end region as the distal tractor region is exposed. In general, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may include pushing the distal tractor region out of the distal end of the catheter. Exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter may include pulling the catheter proximally.

[0038] A method of performing a mechanical thrombectomy to remove a clot from a blood vessel may include: advancing a distal end of a catheter through the blood vessel towards the clot; exposing a distal tractor region of a tube that is within the catheter out of the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region, wherein exposing comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended; allowing the expandable first end region to expand within the blood vessel as it is extended out of the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region; and drawing the clot into the catheter by withdrawing the tube proximally within the catheter so that the expandable distal end region rolls over the distal end of the catheter, collapses, and inverts as the expandable distal end region is pulled into the catheter. Exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may include pushing the distal tractor region out of the distal end of the catheter. Alternatively or additionally, exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter may include withdrawing the catheter proximally relative to the distal tractor region of the tube.

[0039] Also described herein are mechanical thrombectomy devices for removing a clot from a vessel, the device comprising: a catheter having a distal end and a distal end opening, wherein the catheter

has an inner diameter and an outer diameter; a distal tractor region of a tube within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region proximal to the expandable distal end region, the distal tractor region configured so that the expandable distal end region is inverted over the less expandable distal end region; a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter so that the catheter may be advanced between the expandable distal end region and the less expandable distal end region and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

[0040] For example, a mechanical thrombectomy device for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter; a tube having a distal tractor region within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region that is proximal to the expandable distal end region, further wherein the expandable distal end region is biased to invert over the less expandable distal end region as it is exposed from the distal end of the catheter; a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

[0041] Also generally described herein are mechanical thrombectomy apparatuses. For example, described herein are mechanical thrombectomy apparatus for removing a clot from a vessel, including: a catheter having a distal end and a distal end opening; a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire.

[0042] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile; a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and a guidewire

lumen through the catheter and the flexible tube configured to pass a guidewire. The catheter distal end durometer may be greater than 60A shore hardness or greater than 40D shore hardness.

[0043] A mechanical thrombectomy apparatus for removing a clot from a vessel that include: an inner catheter having a distal end and a distal end opening; a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter; an outer catheter extending over the inner catheter and flexible tube; a lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening of the inner catheter, wherein the majority of the flexible tube is not lubricious; and a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

[0044] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: an inner catheter having a distal end and a distal end opening; a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter; a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a predetermined force (e.g., that is greater than 0.01 N); and a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

[0045] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end, a distal end opening and an inner diameter; a flexible tube extending through the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter, the flexible tube having a low Poisson's ratio, such that the flexible tube has a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening; and a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire. The flexible tubes having a low Poisson's ratio may be less than 0.5 or in the range of 0.05 to 0.5 or 0.1 to 0.3.

[0046] As already mentioned above the flexible tube typically includes the distal tractor region having an expandable first end region and a less- (or non-) expandable second end region proximally adjacent to the first end region. Thus, the flexible tube may comprise a mesh tube.

[0047] In general, the catheters forming part of the apparatuses described herein are highly flexible, as would be appropriate for the tortious paths taken, e.g. by neurovascular catheters. In some variations, the aggregate stiffness of the assembled apparatus (having the flexible tube wrapped over the distal end and ready for operation) is within a predetermined percentage (e.g., within 10%, within 12%, within 15%, within 16%, within 17%, within 18%, within 19%, within 20%, within 25%, within 30%, etc.) of the original stiffness of the catheter without the flexible tube. For example, the flexible tube extending through the catheter and doubling back over the distal end of the catheter may increases the stiffness of a distal 5cm of the catheter by less than a predetermined percentage (e.g., 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.

[0048] In any of the variations described herein, the distal tractor region of the flexible tube is adapted to grab an object, e.g., clot. In particular, the flexible tube may be porous or have at least one porous section having a pore pattern having a longitudinal separation between pores of less than a predetermined distance (e.g., about 0.005 inches) in width. As used in this example "pores" includes windows, openings, gaps, etc. between strands of mesh (weave, etc.) as well as pores formed through a solid sheet of material. In general, for woven (and particularly braided) expandable first end region materials, smaller filaments may be better at grabbing, and therefore smaller pore sizes may be preferred. The optimal sizing may depend on the material, including filament size, pore percentage, size of the spacing of pores, pore diameters, etc. For example, in some variations it is beneficial to 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.) and a fiber diameter (for woven materials) that is <0.005. The effective pore size of the flexible tubular member required to make sure the clot or foreign body is grabbed may range from 50 to 1000 micrometers (μm), or in the range of 100-200μm, 100-300μm, 100-500μm or 500-1000 μm. The flexible tubular member may have a variety of pore sizes along its length.

[0049] In general, as used herein a woven material includes any material formed by weaving multiple strands of material in an interlacing pattern (e.g., interlacing strands, filaments, lengths of material, etc.). A mesh is one type of woven material. A woven material is typically more stretchable/expandable in certain directions (on the bias directions) depending on the elasticity of the material forming the weave. Woven materials are typically run in parallel or nearly parallel paths. A knitted material may be more flexible and generally refers to a single path or course that is meandering, forming loops that may be symmetrically arranged and interlocking. Woven material may be highly stretchable/flexible. Knitted constructs tend to be less stretchable but yet still highly flexible.

[0050] In any of the apparatuses described herein, and particularly the pre-loaded or pre-formed versions, the apparatus may include a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a force that is greater than a predetermined force threshold. For example, the releasable force threshold may be greater than about 0.001 N, greater than about 0.005 N, greater than about 0.01 N, greater than about 0.03 N, greater than about 0.05 N, greater than about 0.08 N, greater than about 0.1 N, greater than about 0.3 N, greater than about 0.5 N, etc.).

[0051] In any of the apparatuses described herein, the flexible tube may comprise a plurality of strips of flexible material, wherein the strips are arranged in parallel with the long axis of the flexible tube. Alternatively or additionally, in any of these variations, the distal end opening may comprise a plurality of notches or channels into which fibers or strips forming the flexible tube are drawn as the flexible tube inverts over the distal end opening.

[0052] In any of the apparatuses described herein, the flexible tube may comprise a polymeric tube having a plurality of holes therethrough. For example, the flexible tube may comprise a distal end, a

proximal end and a body region there between, wherein the body region transitions from a more flexible distal end to a stiffer proximal end.

[0053] As mentioned above, in any of the variations described herein, the distal end of the catheter (e.g., the distal opening region) may be adapted to prevent collapsing when inverting the distal tractor region over the catheter opening but still be soft enough to provide appropriate use for neurovascular applications. For example, any of the apparatuses described herein may have a durometer at the distal end (e.g., at the distal end opening/rim) that is greater than a durometer of a region immediately proximal to the distal end. Any of these distal end openings may have a rounded lip profile. In general, though the durometer of the distal end region may decrease (becoming 'softer') the durometer of the very distal end (the opening) may be high. This, along with a rounded end shape, may reduce the force needed to invert the distal tractor region (e.g., the expandable first end region) as it is drawn into the catheter, while preventing collapse of the distal end region of the catheter.

[0054] Any of the apparatuses described herein may also include a handle adapted to draw the flexible tube proximally relative to the catheter. The handle may be attached or attachable to the catheter and/or the flexible tube and may include separate controls for actuating each independently or, more preferably, in a coordinated manner (or toggle between these two modes). For example, any of these apparatuses may include a drive handle coupled to a proximal end region of the catheter, wherein the drive handle comprises a control configured to coordinate advancing of the catheter distally while retracting the flexible tube proximally when actuated.

[0055] Any of these apparatuses may also include an outer catheter extending over the catheter and flexible tube. The outer catheter may extend over the catheter and the flexible tube and may keep an external portion of the distal tractor region (outside of the catheter) collapsed until it has been delivered. Any of these apparatuses may include a lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening, wherein the majority of the flexible tube is not lubricious. This lubricious region may reduce the initial force required to start actuating the apparatus.

[0056] In any of the apparatuses described herein, the flexible tube may be configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter and the flexible tube may have a low Poisson's ratio such that the flexible tube (which may be a mesh tube) may have a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening.

[0057] Any of these apparatuses may include a puller (e.g., an elongate puller) within the catheter and coupled to a distal end of the flexible tube. The puller is typically configured to draw the flexible tube proximally, though in some variation it may also move it distally. For example, any of these apparatuses may also include an elongate puller within the catheter and coupled to a distal end of the flexible tube, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with the guidewire lumen though the flexible tube.

[0058] As mentioned, in some variations, the flexible tube comprises a soft outer mesh that is pushable. For example the distal tractor region (and particularly the expandable first end region) may be

formed from 24 to 144 stands, having a thickness of 0.0020 inches or less in diameter, wherein the mesh tubular member extends in a longitudinal axis, further wherein the mesh tubular member has a length that is greater than 5 cm, forms a braid angle between crossing strands in a direction of the longitudinal axis of about 35 degrees or less when being pulled and inverted around the distal end of the catheter and expands to a diameter of greater than 1.5 times an inner diameter of the catheter outside of the catheter when unconstrained.

[0059] When the flexible tube is formed of strands (e.g., woven, braided, etc.) the strands may be formed of any of the following; 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.

[0060] As mentioned, any of these apparatuses may be configured so that the flexible tube (e.g., expandable distal end region) are releasably held onto the catheter. For example any of these apparatuses may include a retaining ring around a distal end region of the flexible tube configured to releasably hold the flexible tube against the catheter.

[0061] In any of these variations, the flexible tube may be shape set to have different diameter when within the catheter after being pulled proximally into the catheter. In general, the flexible tube may include a plurality of woven or one (or more) knitted filaments. In some variations the entire (or majority of the) flexible tube is formed of a woven or knitted filament(s), and the proximal end of the flexible tube may form a tapered opening opposite from a filament or bundle of filaments forming a pull wire. Alternatively or additionally, the flexible tube may be formed from a sleeve of polymer having a thickness less than 0.020 inches, wherein the sleeve comprises a perforation pattern in which the perforations extend through the polymer. The perforation pattern may comprise perforations having a shaped consisting of one or more of: round holes, rectangular holes and zig-zag shapes.

[0062] Any of these apparatuses may include a pull wire coupled to one side of a proximal end of the flexible tube configured to be drawn proximally to pull the flexible tube within the catheter.

[0063] In general, the flexible tube may be any appropriate length. For example, the flexible tube may be between 3 to 200 cm (e.g., between 3 to 150 cm, 3 to 100 cm, 3 to 50 cm, etc.).

[0064] In any of the apparatuses described herein, the flexible tube of the apparatus may be configured so that the flexible tube may be retracted into the catheter by applying less than a predetermined amount of force (e.g., 500 grams of force, 450 grams of force, 400 grams of force, 350 grams of force, 300 grams of force, 250 grams of force, 200 grams of force, 150 grams of force, etc.) to a distal end of the flexible tube.

[0065] In any of these variations, the flexible tube may include a taper between the first end and a second end of the flexible tube. In some variations, the flexible tube may extend within the entire length of the catheter so that a proximal end of the flexible tube is configured to be pulled proximally away from the proximal end of the catheter to slide and invert the flexible tube over the distal end opening.

[0066] Any of the apparatuses described herein may also include a vacuum source. For example any of these apparatuses may include a guidewire vacuum pump coupled to a proximal end of the guidewire

lumen and configured to apply vacuum therethrough. For example, any of these apparatuses may include an outer catheter vacuum pump coupled to a space between the catheter and the flexible tube and configured to apply a vacuum within a lumen of the catheter between an inner wall of the catheter and the flexible tube.

[0067] As mentioned, the apparatus may include a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller. An outer catheter may be arranged over the catheter adjacent to a proximal end of the flexible tube. Any of these apparatuses may also include a handle having a control configured to coordinate advancing of the outer catheter to push the proximal end of the flexible tube distally and pulling the puller proximally to drawn the proximal end of the flexible tube into the catheter. For example, an apparatus as described herein may include: a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller; an outer catheter slideably arranged over the catheter coupled to a proximal end of the flexible tube; and a handle having a control configured to coordinate advancing of the outer catheter distally to push the proximal end of the flexible tube distally while pulling of the puller proximally to drawn the proximal end of the flexible tube into the catheter or pulling the outer catheter proximally to pull the proximal end of the flexible tube proximally while pushing of the puller distally to push the proximal end of the flexible tube out of the catheter.

[0068] Also described herein are methods of mechanically removing a thrombectomy including: advancing a guidewire at least to the proximal end of a clot in a blood vessel; advancing a thrombectomy (e.g. clot removal) apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0069] A method of mechanically removing a thrombectomy may include: advancing a guidewire adjacent a clot in a blood vessel; advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen over a rounded lip of the distal end opening of the catheter so that the flexible tube slides and inverts over the distal end opening, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0070] A method of mechanically removing a thrombectomy may include: advancing a guidewire adjacent a clot in a blood vessel; advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises an inner catheter having a distal end and a distal end

opening, a flexible tube extending along an outer diameter of the inner catheter and over the distal end of the catheter, and an outer catheter securing a distal end region of the flexible tube against the outer diameter of the inner catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that a lubricious proximal leader region of the flexible tube slides and inverts over the distal end opening, until a non-lubricious distal region of the flexible tube is drawn into the inner catheter; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0071] A method of mechanically removing a thrombectomy may include: advancing a guidewire adjacent a clot in a blood vessel; advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening; pulling or pushing the flexible tube distally out of the distal end of the catheter so that the flexible tube slides and inverts over the distal end opening and over the outer diameter of the catheter; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0072] In any of the methods described herein, the guidewire may be positioned at least partially within the clot in the blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0073] 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:

[0074] FIGS. 1A-1H illustrate one variation of an apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows a catheter portion of the apparatus; FIG. 1B shows an enlarged view of a distal end (opening) of the catheter; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube), showing the expandable first end region of the flexible tube in a collapsed (non-expended) configuration, while FIG. 1D shows the same distal tractor region with the expandable first end region expanded. FIG. 1E shows an assembled mechanical thrombectomy apparatus with the flexible tube extending through the catheter and doubling back over the distal end of the catheter so that the expandable first end region of the flexible tube (forming part of the distal tractor region) is at least partially outside of the catheter and in a non-expanded state. FIG. 1F shows the apparatus of FIG. 1E with the expandable first end region expanded. 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.

[0075] FIGS. 2A-2D show variations of flexible tubes (tractor tubes) that may be part of the apparatuses described herein. FIG. 2A shows the distal end of the flexible tube including the distal tractor region comprising the expandable first end region at the distal end, adjacent to a less-expandable second end region. In FIG. 2B the expandable first end region is formed of a plurality of woven fibers. In FIG. 2C the expandable first end region is formed of a sheet of material having a plurality of small pores throughout. In FIG. 2D the expandable first end region is doubled over the less-expandable second end region.

[0076] FIGS. 3A-3F illustrate the *in vivo* deployment and operation of one example of a mechanical thrombectomy apparatus. In this example, the distal tractor region is pushed through the catheter after positioning the catheter near a clot until the distal tractor region is exposed from the distal end of the clot (FIGS. 3A-3D) so that the expandable first end region expands to the intima of the vessel; the catheter is then advanced between the expandable first end region and the less-expandable second end region (FIGS. 3D-3E), and the expandable first end region is drawn into the catheter so that it inverts and pulls the clot into the catheter (FIGS. 3E-3F).

[0077] FIGS. 4A-4F illustrate *in vivo* deployment and operation of another example of a mechanical thrombectomy apparatus. In this example, the expandable first end region of the flexible (tractor) tube is deployed after positioning the catheter portion (FIGS. 4A-4B) by extending the expandable first end region out of the distal end of the catheter so that the expandable first end region double-back over the distal end region of the catheter (FIGS. 4C-4D). Once exposed and deployed, the expandable first end region may be drawn back into the catheter with or without advancing the catheter distally to pull the clot into the catheter (FIG. 4F).

[0078] FIGS. 5A-5E illustrate *in vivo* deployment and operation of another example of a mechanical thrombectomy apparatus in which the expandable first end region is extended distally out of the end of the catheter after it has been positioned within the vessel near the clot (FIGS. 5A-5C). Once the expandable first end region has been extended and allowed to expand within the vessel, the catheter and the rest of the flexible tube within the catheter may be advanced distally (FIG. 5D) so that the expandable first end region doubled over the distal end as shown. Thereafter the expandable first end region may be drawn back into the catheter with or without advancing the catheter distally to pull the clot into the catheter (FIG. 5E).

[0079] FIGS. 6A and 6B illustrate a mechanical thrombectomy apparatus including a catheter and flexible tube (tractor tube) extending through the catheter and doubling back over the distal end of the catheter (forming the distal tractor region) and an outer catheter or release protector catheter over the distal tractor region. FIG. 6A shows the apparatus positioned near a clot; FIG. 6B shows the apparatus used with a guidewire through the guidewire lumen of the apparatus for positioning and operating the apparatus.

[0080] FIGS. 7A-7D illustrate operation of a thrombectomy apparatus as shown in FIGS. 6A-6B, showing positioning the distal end/distal tractor region adjacent to the clot (FIG. 7A), then pulling the clot into the catheter (FIGS. 7B-7C) and finally removal of the clot and flexible tractor tube (FIG. 7D).

[0081] FIG. 8 shows a thrombectomy apparatus including an optional vacuum source.

[0082] FIGS. 9A-9D illustrate operation of a thrombectomy apparatus as described herein in combination with a guidewire. The guidewire may pass through the clot completely or partially and the apparatus may be actuated over the guidewire, providing enhanced stability and efficacy.

[0083] FIG. 10A shows one variation of a handle (proximal) handle for actuating an apparatus such as the thrombectomy apparatuses described herein. The handle may be coupled and may, separately or in a coordinated fashion, actuate movement of the catheter and flexible (tractor) tube, including the distal tractor region.

[0084] FIG. 10B shows another example of a proximal handle for an apparatus as described herein, which includes controllers for controlling (separately or together) actuation of the catheter and/or inner flexible tractor tube.

[0085] FIG. 11A shows another example of a proximal handle for an apparatus including a thrombectomy apparatus as described herein.

[0086] FIG. 11B is a mechanical schematic illustrating operation of a handle for an apparatus as described herein.

[0087] FIGS. 12A and 12B illustrate variations in which the expandable first end region of the flexible tractor tube of the apparatus is releasably secured to an outer surface of the catheter; prior to actuation of the apparatus, so that the distal tractor region can be drawn into the distal end of the catheter, the releasable attachment may be detached. In FIG. 12A an outer tubing (e.g., an outer catheter or release protector catheter over the distal tractor region) covers at least the end of the expandable distal end region. In FIG. 12B the expandable first end region of the distal tractor region may include a band, adhesive, weld (e.g., frangible adhesive or other attachment), clap, grasper, or the like, releasably securing the expandable first end region to the outer diameter of the catheter.

[0088] FIGS. 13A and 13B illustrate examples of the proximal end region (puller region) of the flexible (e.g., tractor) tube of the apparatuses described herein. FIG. 13A shows an example in which the proximal end of the tractor tube forms a pull wire that is radially offset from the lumen of the tube; a guidewire may still pass through the lumen of the tube (and catheter) for operation of the device, as shown. FIG. 13B shows an example in which the pull wire (or rod, member, etc.) is formed of a separate material than the rest of the flexible tractor tube.

[0089] FIG. 14 illustrates a distal tractor region including a limited lubricious region near a proximal end region of the expandable first end region of the distal tractor region; other portions of the expandable first end region may not be lubricious, nor may other portions of the rest of the distal tractor region.

[0090] FIGS. 15A-15D illustrate flexible (tractor) tubes having shaped expandable first end regions. In particular, these different expandable first end regions may be pre-set to different diameters which may help draw in and/or break the clot up within the catheter. FIG. 15A shows a first example in which the expandable first end regions is coupled to a puller portion by a plurality of pull wires. The expandable first end regions is shown not inverted over the more proximal portion of the flexible tubular member (tractor tube) in these examples. FIG. 15B shows a plurality of expandable end regions connected by a

plurality of pull wires that may not be radially expandable. FIG. 15C shows an expandable first end region having a plurality of pre-set diameters. FIG. 15D shows an expandable first end region coupled to a more proximal puller portion of the tractor tube by two or more bundles of the filaments forming the expandable first end region.

[0091] FIG. 16 illustrates another example of an expandable first end region that includes a plurality of releasable attachments to the outer diameter of the catheter; these releasable attachments (which may be frangible, elastic, etc.) can be released by applying sufficient force to allow the distal tractor region to be pulled into the catheter for actuating the apparatus.

[0092] FIG. 17 illustrates an example in which the expandable first end region is loaded (e.g., spring loaded, compressed, etc.) over the outer diameter of the distal end region of the catheter and releasably locked or otherwise held in place, e.g. by a reliable attachment; this releasable attachment may prevent deployment of the apparatus until actuation, and the loading of the expandable first end region may make it easier for the distal tractor region to invert over the distal end of the catheter to draw a clot into the apparatus.

[0093] FIGS. 18A-18C illustrate examples of expandable first end regions having different stiffnesses.

[0094] FIGS. 19A and 18B illustrate assembly methods for assembling an apparatus as descried herein.

[0095] FIGS. 20A and 20B illustrate exemplary profiles of expandable first end regions that may be used as part of a distal tractor region of an apparatus as described herein.

[0096] FIGS. 21A-21D show examples of apparatuses used to remove clots. FIG. 21A shows an example of an expandable first end region prior to coupling to a catheter. FIG. 21B illustrates the expandable first end region within a vessel (glass tube) being drawn into a catheter by pulling the proximal end of the flexible (tractor) tube. FIG. 21C shows the distal end region of the apparatus including the expandable first end regions doubled over the distal end region of the catheter. FIG. 21D illustrates the apparatus of FIG. 21C drawing a clot into the catheter.

[0097] FIG. 22 shows the expandable first end region of FIG. 21D with the captured clot after drawing it proximally out of the catheter.

[0098] FIGS. 23A-23D illustrate a mechanical thrombectomy apparatus as described herein capturing a blood clot and drawing it into the apparatus.

[0099] FIG. 23E illustrates the clot held within the flexible tractor tube after the flexible tractor tube has been removed from the catheter (e.g., proximally).

[0100] FIG. 24 is another example of an apparatus including a flexible tractor member in which the distal tractor region is formed of a plurality of filaments that are arranged as strips of material (longitudinally parallel) that are not woven or braided. These strips may be filaments, or tubes, etc.

[0101] FIGS. 25A-25F illustrate another variation of a distal tractor region of a flexible tractor assembly in which the expandable first end region (e.g., the distal end region of the distal tractor region) is formed of a plurality of filaments or strips, similar to that shown in FIG. 24; the distal end of the

catheter includes channels, as shown in FIGS. 25A-24B; the strips may fit within these channels, as shown in FIGS. 25C-25D. FIGS. 25E and 25F show sectional views through FIGS. 25C and 25D.

[0102] FIGS. 26A and 26B show a variation of the apparatus of FIGS. 25A-25F with an outer sleeve (e.g., an outer catheter or release protector catheter or other outer sleeve/protector)

[0103] FIGS. 27A and 27B show a sectional view through the apparatus of FIGS. 26A-26B.

[0104] FIG. 28 is an apparatus including a distal tractor region of a flexible tractor assembly having a plurality of longitudinally-parallel (non-woven/braided) filaments or strips in which the distal ends of the filaments or strips are connected to each other by a distal connector.

[0105] FIG. 29 shows a distal tractor region of a flexible tractor assembly in an apparatus in which the longitudinally-parallel (non-woven/braided) filaments or strips include grabbing elements.

[0106] FIGS. 30A-30C illustrate example of filaments/strips with grabbing elements. Grabbing elements (and/or filaments including them) may be used as part of any of the variations described herein, including woven or braided distal tractor regions.

[0107] FIG. 31 illustrates a variation in which the distal tractor region is adapted to be reciprocated (e.g., pushed and pulled) so that the expandable first end region may be draw into and reversed out of the catheter.

[0108] FIG. 32 illustrates another example of an apparatus as described herein in which the distal-most end of the expandable first end region is fixed to a portion of the distal end of the catheter; the rest of the expandable first end region is sufficiently elastic/flexible to be drawn into the catheter (pulling a clot with it). The flexible tractor assembly may then be left retracted and the entire apparatus withdrawn. This example may include an optional vacuum.

[0109] FIG. 33 is another example of an apparatus in which the puller portion of the flexible tractor assembly is formed of the same material as the distal tractor region but may be laminated or otherwise reinforced to have less flexibility/stretchability than the distal tractor region.

[0110] FIG. 34 illustrates another example in which the distal tractor region is adapted to compress the clot when draw into the catheter.

[0111] FIGS. 35A-35C illustrate operation of an apparatus as shown in FIG. 34 in which the clot is drawn into the catheter by withdrawing the expandable first end region of the distal tractor region into the catheter (e.g., pulling on the puller region of the tractor assembly) which compresses the clot (FIGS. 35A-35B); releasing the tractor assembly and/or pushing it distally may further break up the clot and release it from the distal tractor region so that it may be suctioned up proximally with a manual or powered vacuum source (FIG. 35C).

[0112] FIG. 36 illustrates an example of an apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally through the body (e.g., vessel) over a guidewire, which may be treated to engage the distal tractor region.

[0113] FIGS. 37A-37C illustrate an apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally.

[0114] FIGS. 38A and 38B illustrate another variation of an apparatus and method of using the apparatus to remove material from within a vessel, wherein the apparatus is an "infinite" tractor mechanism, in which a large amount of tractor material (e.g., mesh) is stored in an external holding region, wound-up but dispensable over an extended use.

DETAILED DESCRIPTION

[0115] In general, described herein are methods and apparatuses for mechanically removing objects from a body. Although these methods and apparatuses may be adapted for use to remove a variety of objects from a variety of regions of the body, they may be particularly well suited for removal of blood clots from within a lumen of a blood vessel. Thus described herein are mechanical thrombectomy apparatuses (e.g., device and systems).

[0116] The apparatuses described herein (e.g., mechanical thrombectomy apparatus for removing a clot from a vessel) may be assemblies including an elongate catheter having a distal end and a distal end opening, and a flexible tractor assembly at least partially within the catheter, where the distal end region of the tractor assembly is configured as a distal tractor region that at least partially extends within the catheter and doubles back over the distal end of the catheter. The tractor assembly may include a proximate pusher region which is connected to the distal tractor region. The flexible tractor assembly includes an elongate lumen that is configured to allow passage of a guidewire. The flexible tractor assembly is also 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 assembly may be referred to herein as a flexible tractor assembly, flexible tractor portion, flexible tractor tube, or simply a flexible tube, and is typically positioned and longitudinally slideable within the catheter, and arranged so that the distal end region ("distal tractor region") doubles back over the distal end of the catheter.

[0117] For example, FIG. 1A shows one variation of a catheter that may form part of the apparatuses described herein. In this example, the catheter 100 includes a distal end region 103 that includes a distal end 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal tip (distal end 105) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region (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.

[0118] The catheter 100 may also be referred to as the inner catheter or the tractor catheter. Any appropriate type of catheter may be used, including microcatheters appropriate for neurovascular use.

[0119] In some variations the distal end 105 of the catheter is adapted so that the distal tractor region may slide and invert over the distal end of the catheter without being caught (binding) 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). In some variations the distal tip includes one or more channels, as shown and described in FIGS. 25A-28, including channels around the distal-facing edge, to guide the sliding of the distal tractor region.

[0120] FIG. 1C shows an example of a flexible tractor tube 140. In FIG. 1C, the tube is flexible and elongate (having a generally greater length than the catheter 101), and includes a distal tractor region 142 that includes a distal-most expandable first end region 144 that is configured to fold over the immediately proximal region 146, which may be a less-expandable second end region. In general the expandable distal end region is configured to expand to a radial diameter that is between 1.3 and 10 times the diameter of the inner diameter of the catheter when unconstrained. FIG. 1D shows the expandable distal end region of FIG. 1C in an expanded configuration. Thus the expandable distal end region may be biased to expand open. The expandable distal end region may be formed as a mesh, woven or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[0121] The flexible tractor tube shown generically in FIG. 1C is shown with the expandable distal end region doubled back over itself (e.g. over the more proximal less-expandable second end region) in FIG. 1E. In FIG. 1E, the expandable distal end region is collapsed, while in FIG. 1F the expandable distal end region is expanded. In general, the expandable distal end region may be distinguished from the proximal less-expandable second end region, however in some variations the entire flexible tractor tube may comprise and expandable material (e.g., mesh, weave, etc.) that is pushed and/or pulled within the catheter and does not include a proximal less-expandable distal end region.

[0122] 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 101 and a flexible tractor tube that includes an expandable distal end region 144 that extends over the distal end region of the catheter and doubles-over the distal end of the catheter so that the expandable distal end region is continuous with an inner proximal less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The proximal end of the flexible tractor tube (not shown) may include a pusher/puller member that may be a rod or other member that is continuous with the distal end region (distal tractor region140). In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near the clot 155. The clot may be drawn into the catheter by withdrawing the distal tractor region 140 into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor tube (e.g., using a handle, not shown) resulting in pulling the expandable distal end region 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 distal end of

the expandable distal end region may be "loose" relative to the outer wall of the catheter, or it may removal attached or in some variations permanently attached.

[0123] In general, positioning these apparatuses and actuating them may be challenging because they must be highly flexible, both before actuating and during operation. For example, in general, the flexible tractor tube must not increase the stiffness/flexibility of the catheter, and particularly the distal end region of the catheter too much, or it may be too difficult and/or dangerous to maneuver, 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 5cm 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.

[0124] For example, FIG. 2A shows a flexible tractor tube 201. In this example, the flexible tractor tube includes a distal tractor region 242 with an expandable first end region 244 and a less-expandable second end region 246 that is distal to a proximal pusher region 201. The entire flexible tractor tube is hollow and may pass a guidewire (not shown). The various regions of the flexible tractor tube may be made of the same material (e.g., a woven, braided, etc. filament or filaments) or they may be made of different materials.

[0125] FIG. 2B shows a flexible tractor tube having a distal tractor region, or at least the expandable first end region 244' formed of a plurality of woven fibers. Alternatively the expandable first end region may be formed of one (or more) knitted fibers, or a combination of woven and knitted fibers. The expandable first end region may be biased open (as shown) by a shape-setting property of the fibers or woven/knitted pattern or by the inclusion of one or more biasing members (e.g., rings, springs, bands, filaments, etc.) that tend to bias at least the distal end region of the expandable first end region open.

[0126] FIG. 2C illustrates another variation of an expandable first end region formed of a sheet of material that includes a plurality of openings (e.g., pores, perforations, passages, windows, etc.). These openings may be any sizes, including non-uniform sizes (e.g. a range of sizes) or uniform sizes. The sizing of these opening through the sheet may depend on the material used, e.g., polymeric material (PTFE), silicone materials, polyurethanes, shape memory alloys, etc. In some variations it is beneficial to 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.) of the sheet.

[0127] In any of these variations, the distal tractor region is configured so that it may be inverted (e.g., doubled over) itself, as shown in FIG. 2D. In some variations the apparatus may be performed so that the expandable first end region is inverted over the itself and/or over the distal end region of the catheter, or it may be configured so that it can be deployed and inverted over the distal end of the catheter *in vivo* (e.g., within the blood vessel). In general, before the apparatus can be actuated the catheter may be inserted between the expandable first end region and the region proximal to the expandable first end

region on the flexible tractor tube, which may, in some variations, be the less-expandable second distal end region. This space 289 may be held open by a biasing member at or near the distal end of the expandable first end region. As mentioned, this expandable first end region opening biasing member may be a ring, band, spring, coil, or the like, and may be made of a biasing element (e.g., shape-set material, such as a shape memory alloy), rubber or other polymeric material, or the like.

[0128] In vivo deployment of the apparatuses described herein may provide a number of advantages for users operating the apparatus, despite associated challenges. FIGS. 3A-3F illustrates one example of a thrombectomy apparatus that is configured for in vivo deployment. In this example, the apparatus includes a catheter 301 that may be positioned (as with any of the variations described herein) using a guidewire 313. The guidewire may be extend to or into (or through) the object to be removed, shown as clot 355 in FIG. 3A within a blood vessel 360. The catheter of the apparatus may be inserted with or after the guidewire, and the catheter may be positioned near (e.g., adjacent to or immediately adjacent to) the clot with or without the flexible tractor tube at or near the distal end of the catheter. In FIG. 3A the catheter is positioned after the guidewire has been positioned, and, as shown in FIG. 3B, is removed from the vessel. The guidewire may be a wire, smaller catheter or combination of devices that may be positioned (e.g., steered) to and/or through the clot. Following positioning of the catheter, the inner flexible tractor tube 340 including the distal tractor region 342 is pushed through the catheter to the distal end region of the catheter, as shown in FIG. 3C. In this example the distal end of the flexible tractor tube forming the distal tractor region includes an expandable first end region shown as a mesh 344 that is connected to a proximal less-expandable second end region that is continuous with the rest of the flexible tractor tube, at the proximal end (pusher region 305). The braided mesh 344 of the expandable first end region is pre-inverted over the outside of the tubular second end region/pusher region in a collapsed (non-expanded) configuration, and can be slide through the inner lumen of the catheter, and (when the guidewire is left in position or used adjust the position) over the guidewire (not shown). As shown in FIG. 3D, the distal tractor region of the flexible tractor tube may then be exposed to the outside of the catheter by extending (in this example either pushing the flexible tractor tube distally and/or pulling the catheter proximally, allowing the expandable first end region of the distal tractor region (shown as mesh) 344 to expand along the length of the first end region. In FIG. 3D this is shown as a stent-like structure that may expand fully to the intima of the vessel forming a separation between the expandable first end region and the less-expandable (in this case non-expandable) second end region 346. In particular the expansion of the first end region may be greater than 1.3 times the diameter of the inner lumen of the catheter (e.g., greater than 1.5x, greater than 2x, greater than 2.2x, greater than 2.5x, greater than 3x, greater than 3.5x, greater than 4x, greater than 5x, greater than 6x, greater than 7x, greater than 8x, greater than 9x, greater than 10x, etc.).

[0129] In FIG. 3D, the catheter is slid distally between the first and second end regions of the distal tractor region. The clot may then be removed by withdrawing the expandable first end region proximally into the catheter either or both by pulling the flexible tractor tube (e.g., proximal puller region) proximally and/or advancing the catheter distally. In some variations it may be beneficial to both advance the

apparatus and particularly the catheter, while withdrawing the expanded first end region and inverting it into the catheter. The catheter may be advanced more quickly than the flexible tractor tube is withdrawn.

[0130] As shown in FIG. 3F, the clot 355 may be drawn in to the catheter with the expandable first end region.

[0131] Another variation of an *in vivo* deployment method and apparatus is shown in FIGS. 4A-4F. In this example, the self-expanding first end region of the flexible tractor tube is configured to self-expand over end of the catheter as it is pushed out of the catheter so that it will slide over the distal end of the catheter. As described above for FIGS. 3A-3B, the apparatus may be positioned using a guidewire 413 or the like. In FIG. 4A, the catheter 401 is positioned over the guidewire 413 adjacent to the clot 455 to be removed. In FIG. 4B the guidewire may be (optionally) removed, or (preferably) left in place. The flexible tractor tube 434 including the distal tractor region may then be moved distally within the catheter and extended with the expandable first end region 444 out of the distal end so that it inverts 466 over the distal end and slide proximally over the distal end region, as shown in FIG. 4C. This process may be aided by pushing the apparatus distally within the lumen of the vessel, as the expansion of the first end region 444 may help secure it against the wall of the vessel, as shown in FIGS. 4D-4E. Once exposed, the expandable first end region may be withdrawn into the apparatus by pulling the flexible tractor tube 434 proximally and/or advancing the assembly (or at least the catheter) distally, as shown in FIG. 4F. The clot 455 may then be drawn into the apparatus.

[0132] FIGS. 5A-5E illustrate another variation of an *in vivo* deployment and thrombectomy (clot removal) method using a mechanical thrombectomy apparatus. In FIG. 5A, the apparatus 500 including a catheter 501 and an inner flexible tractor tube 534 is advanced (e.g., over a guidewire, not shown) to be near a clot 555. In this example (which may be relevant to any of the methods described herein) the apparatus is positioned with the flexible tractor member having the un-deployed distal tractor region already positioned distally near the distal end region of the apparatus. As shown in FIG. 5B, the expandable first end region 544, which is in a collapsed configuration within the catheter 501 in FIG. 5A, is pushed out of the distal end of the catheter and expands to the walls of the lumen as shown in FIGS. 5B-5C. Once pushed out and expanded, the catheter and the portion of the flexible tractor tube within the catheter may be advanced distally, as shown in FIG. 5D, causing the expandable first end region 544 to invert, doubling over the distal end region of the catheter 501. By FIG. 5E, the apparatus has been deployed near the clot 555 and may be actuated as already described to remove the clot, but pulling the expandable first end region of the distal tractor region into the catheter, so that it inverts and draws the clot into the catheter. The catheter may optionally be simultaneously advanced. Note that the method of in vivo deployment described above may also be used to load an apparatus for insertion into a body in order to position the catheter radially between the expandable first end region and the more proximal portion of the flexible tractor tube.

[0133] FIG. 6A illustrates an example of another variation of a thrombectomy apparatus having a flexible tractor tube 634 with a flexible first (distal) end region 644 formed in this example of a braided (e.g., woven) or knitted material, where the flexible first end region (tractor region) is inverted over the

distal end of a catheter 601 and attached to the proximal end region of the flexible tractor tube 634. As in any of the apparatuses described herein this proximal end region of the flexible tractor tube may be a hypotube, catheter, or laminated weave/mesh or woven material that is pushable/pullable within the catheter and is attached at its distal end to the flexible tractor region (e.g., distal tractor region), including in some variations an expandable first end region. Note that in some variations the distal tractor region (the first end region) may not be expandable but may be just flexible.

[0134] In FIG. 6A, the first end region of the distal tractor region attached to the flexible tractor tube is covered by an outer catheter or sleeve (protector) 677. In this example, the apparatus also includes a mid-catheter 679 between the inner catheter 601 and the protector catheter or sleeve 677. In some variations the flexible first end region 644 may be attached to this mid catheter, including removably attached so that pulling the flexible tractor tube 634 proximally will disengage it and allow the mesh (the flexible first end region 644) to deploy in the vessel. In the variation shown in FIG. 6A the flexible first end region 644 is not attached to the middle catheter 679.

[0135] Any of the apparatuses described herein, including the apparatus shown in FIG. 6A may be used with (and may include) a guidewire 633 as shown in FIG. 6B. FIGS. 7A-7D illustrate the operation of the apparatus shown in FIGS. 6A-6B to remove a clot 755. In this apparatus the proximal end of the flexible tractor tube 734 may be coupled to a vacuum source (not shown) which may be actuated when withdrawing the tractor tube 734 proximally to invert the distal tractor region over the end of the catheter. In FIG. 7A the apparatus is positioned near the clot 755. In FIG. 7B, the distal tractor region is inverted and pulled into the catheter by pulling the flexible tractor tube 734 as shown by the arrow. In this example the distal tractor region is not expanded because it remains covered by the outer sleeve 777, as shown in FIGS. 7B and 7C. The apparatus may be advanced distally toward/over the clot either or both by pushing or by the action of pulling the distal tractor end region (shown in this example as a mesh 744) proximally to invert it over the distal end of the catheter. Once the clot is removed, the apparatus may be withdrawn and pulled out of the vessel, as shown in FIG. 7D.

[0136] As mentioned above, any of these variations may include one or more vacuum sources. FIG. 8 illustrates one example including a vacuum source showing a first optional vacuum source at the proximal end coupled to the lumen of the flexible tractor tube 834. For example, the coupling with the vacuum and the tractor tube 834 may be a rotating hemostatic value (RHV) as shown. In FIG. 8 a second (optional) vacuum connection is made between the (optional) outer catheter 877 and the inner catheter 801 or an (optional) middle catheter 878. Vacuum may be applied at any appropriate portion of the method, including during retraction of the flexible tractor rube 834 to remove the clot.

[0137] As mentioned, any of the apparatuses described herein may include a guidewire and may leave the guidewire in position during the procedure. FIGS. 9A-9D illustrate a method of removing an object (e.g., clot) when leaving a guidewire 913 in position. In this example, the apparatus is similar to the apparatus shown in FIGS. 6A-6B, and may include an optional vacuum source. In FIG. 9A the distal end of the catheter including the inverting portion of the flexible first end region 944 of the distal tractor region 944 is placed adjacent to the clot and actuated by pulling proximally to draw the clot into the

catheter as shown in FIG. 9B. In this example the clot has been penetrated by the guidewire 913, thus the catheter tip with the inverting tractor region may be advanced forward over the guidewire by pushing on the catheter 927 and/or by pulling the tractor tube proximally 919. This may be continued until the entire clot is within the catheter, as shown in FIG. 9C.

[0138] In any of the variations described herein, the apparatus may include one or more markers or may be configured for use with one or more contrast agent to assist in visualizing the methods described. Further any of these methods may include visualization. Visualization may be indirect (e.g., using fluoroscopy or equivalent techniques) or direct, e.g., using one optical fibers for direct visualization down the apparatus (e.g., thought the lumen of the apparatus).

[0139] In FIG. 9D, the tractor tube with the captured object (e.g. clot) may be removed proximally from the apparatus and the removed material may be examined (e.g., via histological/cytological examination). The catheter may be subsequently or simultaneously removed. As mentioned above, when removing the object (e.g., clot) it may be desirable to pull back (proximally) the guidewire at the same time that the flexible tractor tube is pulled back proximally (not shown). In some variations, the distal tractor region (e.g., braided/woven or knitted region) may grab onto the guidewire within the catheter and which may also help propel the apparatus distally over/toward the clot, as described in more detail in FIGS. 36 and 37A-37C, below.

[0140] In general, the rolling effect of the grabber (the distal tractor region) is activated by the motion of the catheter relative to the distal tractor region. If the distal tractor region is fixed proximally and the catheter is advanced, the distal tractor region may have a 1:1 grab ratio. If the distal tractor region is pulled though the catheter, the grabbing effect may be amplified. For example when the distal tractor region is pulled back (by pulling the tractor tube) and inverted into the inner catheter 1 unit to proximally within the catheter as the inner catheter is pushed 1 unit to distally, the grabbing effect is approximately 2x. If the distal tractor region is withdrawn into the inner catheter proximally two units as the inner catheter is advanced distally one unit, the grabbing effect may be approximately 3x. The concurrent motion of the distal tractor region and the catheter may be coordinated by a handle.

[0141] In general, any of the apparatuses described herein may include a handle. The handle may couple with the flexible tractor tube and/or the catheter (e.g., inner catheter) and/or any outer catheter (e.g., protector, sleeve, etc.). The handle may be configured to allow selective, separate actuation of the flexible tractor tube and/or the catheter and/or coordinate motion of these components. FIGS. 10A and 10B illustrate examples of handles that may be used. In FIG. 10A, the handle includes a drive mechanism to pull back the tractor tube, and therefore invert the distal tractor region over the distal end of the catheter and/or advance the catheter relative to the distal tractor region. In FIG. 10A, the handle include rotatable handle 1001couled to a catheter drive 1003. The handle connects to both the catheter 1005 and the inner flexible tractor tube 1009 having a distal tractor region 1011. The handle may be configured so that the ratio of the advancing (distally) of the catheter versus the pull (proximally) of the tractor tube may be selected and/or may depend on a thread pitch of the catheter drive thread or other mechanical mechanism.

[0142] Another variation of a handle is shown in FIG. 10B. In this example the handle may be attached to the tractor tube to pull (or push) 1017 the tractor tube and therefore invert the distal tractor region over the distal end of the catheter, and another portion of the handle may be coupled to the catheter to push/pull the catheter 1015.

[0143] FIG. 11A shows another variation of a handle mechanism 1107 configured to pull the grabber (distal tractor region) of any of the apparatuses described herein by coupling to the proximal end of the tractor tube at an attachment site 1105, and/or advance the catheter by coupling to the proximal end of the catheter. Another example of a handle mechanism is shown schematically in FIG. 11B, showing a levering mechanism 1109 and a coupling to the inner tractor tube that may be fixed or adjustable.

[0144] In any of the apparatuses (e.g., mechanical thrombectomy apparatuses) described herein, the distal tractor region may be preloaded in/on the catheter so that it can be actuated by pulling the tractor rube coupled to the distal tractor region proximally and/or advancing the catheter distally. In pre-loaded variations in which the distal tractor region includes a flexible and/or expandable first end region (e.g., formed of a mesh and/or weave of material) that is doubled over the distal end of the catheter, the apparatus may be adapted to prevent inadvertent dislodging and/or expansion of the first end region before it has been positioned at or near the clot.

[0145] FIGS. 12A and 12B illustrate examples of releasable attachments for the distal tractor regions attached to the outside of the catheter. Any of these attachments may be released by the application of an appropriate amount of force (e.g. pulling force) applied to the proximal end of the flexible tractor tube. For example in FIG. 12A, the outer distal end of the distal tractor region (shown as mesh 1204) is covered by a shoulder or sock extending from an outer catheter or tubing 1203). Similarly in FIG. 12B, the outer distal end of the distal tractor region (shown as mesh 1204) is covered by a separate band, ring, or sock 1209. The distal tractor region may be prevented from collapsing or reducing in diameter when tension (e.g. pulling proximally on the tractor tube) by adding filaments (e.g., in braided or woven variations, additional braid filaments), by adding a coating, by heat setting to a larger diameter, and/or by adding an axial inter-braiding pull wire.

[0146] Any of the variations described herein may include a proximal pull rod or pull wire as part of the flexible tractor tube. Further, the proximal end region of tractor tube may be less flexible than the distal end (distal tractor region). FIGS. 13A and 13B illustrate examples of flexible tractor tubes. In FIG. 13A, the tube includes a proximal taper region in which the distal tractor region 1305 is formed of a material (e.g., mesh/woven material) that tapers proximally 1307 into a pull wire, leaving room for a guidewire 1309 and permitting the distal tractor region to invert over a catheter. The proximal pull-wire portion may be formed of the filaments forming the distal tractor region, e.g., in variations in which the distal tractor region is woven or braided. These filaments may be reinforced, e.g., by other materials such as polymers that help make it stiffer or more compliant. FIG. 13B shows another example in which the proximal end of the flexible tractor tube is formed of a pull wire 1315 that may be a separate material or an extension of the braid wire bundle attached to the distal end of the pull wire and forming the distal tractor region 1317.

[0147] Any of the apparatuses described herein may be treated or adapted to reduce the force required to invert the distal tractor region over the end of the catheter. For example in some variations either the distal end may be treated to be lubricious, or all or a portion of the distal tractor region may be treated to enhance laboriousness. For example, in some variations only a portion of the distal tractor region, e.g., the portion that initially interacts/inverts over the distal end of the catheter is treated; the rest of the distal tractor region is not treated. FIG. 14 shows an example of such an apparatus. In FIG. 14, the proximal-most end 1405 of the expandable and/or flexible first end region (that is positioned outside of the catheter) is treated with a lubricous coating or formed of a lubricious material. The remaining portion (not shown to scale) of the first end region is not as lubricous 1403. Since the more proximal region 1405 is exposed to the vessel and the distal end of the catheter, it may more effectively track the target or allow the apparatus to track the target as well as start inverting over the distal end more effectively. This region may be made lubricious in any appropriate manner, including but not limited to coatings such as hydrophobic/hydrophilic coatings, and forming or including a more lubricious polymeric material (e.g. PTFE).

[0148] In general, any of the distal tractor regions described herein may be adapted to include different profiles, including pre-set to have (e.g., shape-set) profiles that may more readily slide/move over the distal end and/or grab a clot or other target object for removal. For example, FIGS. 15A-15D illustrate tractor tubes having different distal end profiles forming different distal tractor regions. In FIG. 15A for example, the distal tractor region includes a distal-most expandable and/or flexible first end region 1505 that is formed of a braided/mesh or woven material that is connected to proximal end of the tractor tube by a plurality of pull wires. These pull wires 1517 may be formed by the same wires or filaments forming the braided/mesh or woven distal end region. FIG. 15B shows another variation in which a plurality of discrete braided/mesh or woven distal end regions are connected by pull wires 1515; these pull wire regions 1515 may be less-expandable and/or flexible than the braided/mesh or woven regions 1516. In FIG. 15C, the distal end regions are braided/mesh or woven but pre-set to have different diameters. Thus these regions may have different shapes along their length; these shapes may be heat set to better grab or break up clot as they are pulled into the catheter. FIG. 15D illustrates an example of a braid or stent-like first end region 1521 that is connected to hypotube or other more proximal end region of the tractor tube 1520 by the same filaments or bundles of the same filaments forming the braided/mesh or woven distal tractor region 1523.

[0149] Any of the apparatuses described herein may also or alternatively include a plurality of releasable attachments to the outer surface of the catheter securing the distal tractor region (and particularly the distal end portion) to the outer surface. In FIG. 16, three rings 1603, 16.3', 1603'' forming releasable attachment are shown securing the distal end of the distal tractor region 1644 to an outside of a catheter 1601. In this example, a polymer coating/film is attached or integrated with the braid forming the distal tractor region to help prevent it from sliding or slipping off of the catheter prematurely (e.g., until pulled by a user). The apparatus can include multiple attachments, as shown, radially positioned along the length of the catheter to help it stay secure to the outer diameter of the

catheter delivery system. In some variations these releasable attachments are elastic member (e.g., a urethane ring) but may be frangible, and allowed to break to free the distal tractor region.

[0150] FIG. 17 shows another variation in which the releasable attachment is positioned so that a portion of the distal tractor region is spring-loaded (biased) to drive it in rolling over the distal end of the catheter and into the catheter lumen. In FIG. 17, The distal end of the distal tractor region 1704 may be secured (fixed, attached or loose but constrained) and a more proximal end region near the distal end of the catheter may be releasably secured to the catheter 1707. For example, a polymeric coating or film may be attached to the distal tractor region (shown as a braid 1744 in FIG. 17) and coupled to hold a portion of the distal tractor region 1705 between the distal end 1704 and releasable attachment site 1707 in tension (e.g., compressed). Release of the releasable attachment 1707 may then apply a force driving the distal tractor region around the distal end of the catheter, helping pull the clot into the apparatus, and reducing the force necessary to invert the distal tractor region.

[0151] As mentioned above, the material forming the distal tractor region may, and in particular the distal-most flexible and/or expandable first end region may be formed of any appropriate material. For example, the material may comprise a fabric, a weave, a knit, a braided, a sewn, a tube, and/or a flat sheet. The material may have any appropriate thickness, e.g., between 0.0005 to 0.015" wall thickness, and may have pores of any appropriate spacing/dimension (porosity) from low to high porosity. All or a portion of the distal tractor region may be radiopaque or radio transparent. In woven, knitted, braided or sewn variations, the material may be formed of multi- or mono-filaments. Different size filaments can be mixed together (e.g., big and/or small) to change gripping effect by increasing or decreasing fabric surface texture. In some variations the material (including the filaments forming the material) may be polymer based (e.g., PET, Nylon, Polypropylene, PTFE, ePTFE), elastic and non-elastic (e.g., PU, Silicone, rubber, lycra), metal filaments (e.g., Niti, drawn filled Niti indcluding DFT, i.e., Niti with Pt inner core, steel, stainless steel, cobalt chrome, etc.), and mix of metallic and polymer filaments. The ends of the fabric can be laser cut/welded or free cut. In some variations all or part of the distal tractor region includes a film or sheet. The film may be between 0.0005 to 0.008" thick. The film may be formed by tube extrusion or sheet and rolled into a tube. In some variations the film is yarn reinforced. The film may be slotted (e.g., may include holes and/or slits cut to improve gripping or sliding into the catheter. In some variations the film has a textured surface (e.g., textured inner surface that is exposed when inverted). The film may form a tube having ridges and/or rings (radial rings) and/or lines down the length, and/or a saw tooth pattern. A textured inner surface my include a mix of big and small filaments, and/or may be formed of more porous, less dense fabrics.

[0152] In some variation, the visibility of the grabber element is desirable but not required throughout. For example, as mentioned above markers may be located on the device. In some variations it may be desirable to see the entire structure or proximal and distal end of structure. For example, the material could be Nitinol or Nitinol drawn over platinum material (DFT) to enhance visibility.

[0153] Any of the variations may include a rotational auger element in the inside of any of the braid constructs to assist in pulling the clot back to the hub. As mentioned, any of these apparatuses may

include a vacuum source. The addition of the vacuum to the system may aid the ability of the distal tractor region to pull clot/emboli into the catheter. The vacuum applied may be stead/constant, ramped or pulsatile.

[0154] In some variations the apparatus and methods for using them may include a flow stopping proximal balloon (e.g., to be positioned proximal to clot), that may reduce pressure on clot during the procedure.

[0155] The apparatuses and methods described herein may be used to capture biopsy samples (e.g., from breast or any other organs). For example, these apparatuses can be used to remove bigger tissue segments (e.g., cancer, gallbladders, etc.) when a laproscopic procedure is performed.

[0156] When the material forming the distal tractor region is a woven/braided material, the resulting mesh structure may have a braid length ranging from 1 to 100cm long to around the outer diameter (O.D.) of the catheter, with a preferred length of between about 3-30cm.

[0157] In any of these variations, the tractor tube and/or catheter (including the distal tractor region) may be constructed so the distal tractor region may be pulled so that the distal tractor region is drawn (inverted) around the outer diameter of the catheter distal end with a minimal force so the catheter tip does not buckle or significant deform (e.g., snake) in the blood vessel, wherein the pull forces are less than about: 50 grams, 100 grams, 300 grams, 500 grams, 800 gram, 1000 grams, 2 kg, 3 kg, 5 kg, 8 kg, 10 kg, 15 kg, 20 kg, etc.

[0158] In variations in which the grabber (distal tractor region) is constructed as a woven (e.g., braided) structure at least on a distal end (e.g., the expandable and/or flexible first end region), examples of the filaments forming the woven structure may include: NiTi, NiTi-PT DFT wire (NiTi tube over Pt inner), PET, PP, Nylon, Algiloy, SS, hybrid materials. When used, NiTi may be etched to make is very smooth. The number of filament ends may be about: 16, 24, 36, 48, 77, 96, 144 or any number between these integers. Any braid construction may be used. For example, an exemplary braid construction may include 1 over 1 (1x1), 1x2, 2x2, etc. In some variations the filaments forming the woven and/or knitted material comprises a monofilament, e.g., having an outer diameter (O.D.) size of about: 0.0005", 0.00075", 0.001", 0.0015", 0.002", 0.003" or an combination of sizes or diameter size which is between the integers list herein. As mentioned, these apparatuses may be adapted for neuro vasculature used, e.g., assuming 2-3mm vessel inner diameter (ID). For example, an apparatus appropriate for neurovascular applications as described herein may include between 36 to 72 ends of a 0.001"to 0.002" polymer braid annealed to 3-7mm OD. In some variations, the distal tractor region includes 24 braided wires having an OD of 0.0005" by 0.0015" or 0.002" of flat Niti wire, annealed on a 2 mm mandrel, braided at a 45 degree angle. Alternatively in one variation the distal tractor region comprises a braided material formed from 24 wires of a 0.002" thickness Niti wire, annealed on a 2 mm mandrel, braided at a 45 degree angle. In one example, the distal tractor region comprises a braided material including 24 wires 0.002" DFT Niti wire, annealed on a 2 mm mandrel, braided at a 45 degree angle. In one example, the distal tractor region comprises a braided material including 8 ends of 0.003" wire mixed with 8 additional ends of 0.002" Niti wire on a 2 mm mandrel. In one example, the distal tractor region comprises a braided material including

16 ends of 0.002" platinum iridium wire, annealed on a 2 mm mandrel. In one example, the distal tractor region comprises a braided material including 24 ends of PP monofilament, having an outer diameter of 0.002" diameter. In one example, the distal tractor region comprises a braided material including 12 ends of 0.003" PP monofilament. In one example, the distal tractor region comprises a braided material including 16 ends of 0.003" PP mono. In one example, the distal tractor region comprises a braided material including 72 ends, 0.001" PET or PP, 8 mm mandrel, 90 degree braid angle, 1x1. In one example, the distal tractor region comprises a braided material including 36 ends, 0.001" PET or PP, 6 mm mandrel, 75 deg braid angle, 1x1. In one example, the distal tractor region comprises a braided material including 48 ends, 0.002" PET or PP, 8 mm mandrel, 90 degree braid angle, 1x1. In one example, the distal tractor region comprises a braided material including 24 ends, 0.002" PET or PP, 6mm mandrel, 70 degree braid angle, 1x1.

[0159] In variations in which the distal tractor region comprises a mesh, the tubular mesh may be formed from a knit or alternative structure that is constructed so it's radially compression (change in tubular mesh inner diameter, ID) experiences a 5-20% reduction in diameter when the mesh tractor is pulled axially and around the outside of the catheter tip and into the catheter ID. This 5-20% mesh diameter reduction, may aid in grabbing the clot or foreign object when pulling the mesh into the catheter, without generating so much radially compression force that the tubular mesh binds on the catheter tip when pulled and does not easily roll around the catheter tip. In contrast a woven mesh may collapse between 20-60% within the catheter when drawn proximally, which may provide a substantial amount of compression of a clot of other removed material.

[0160] In variations in which the apparatus is configured for use in the peripheral vessels (e.g., having between a 4 to 8mm vessel ID), the distal tractor region may be configured for this application. For example, the distal tractor region may include a braided material having 24 ends of PP, 0.009" PP monofilament formed on a 4 mm mandrel and annealed. The distal tractor region may include a braided material having 48 ends of PP 0.008" mono, 4 mm mandrel annealed. The distal tractor region may include a braided material having 72 ends 0.006" PP mono 4 mm mandrel annealed. The distal tractor region may include a braided material having 36 ends of .004" Niti, 4 mm mandrel annealed. The distal tractor region may include a braided material having 48 ends of 0.004" DFT Niti mandrel annealed.

[0161] In variations in which the apparatus is configured as a biopsy device (e.g., having a 4-12 mm sample size), the apparatus may be a woven material including 72 ends of PP .007" mono formed on a 10 mm mandrel. In some variations, the apparatus (e.g., the distal tractor region) may include 48 ends of 0.004" Niti formed on a 1mm mandrel. In some variations, the apparatus (e.g., the distal tractor region) may include 48 ends of PP 0.008" mono on a 12 mm mandrel.

[0162] In any of the variations described herein the apparatus may be configured to have a relatively low friction. In particular the distal tractor region may have a low friction to allow it to be more easily and/or reliably pulled through the catheter when retracting a clot. As already mentioned above, any of these variations may include a lubricous material and/or coating including using or coating one or more of the following materials on the grabber (distal tractor region): PET, PP, PTFE, ePTFE. When the material

forming the apparatus is a small diameter filament metallic structures, the filaments may be between 0.0005 to 0.003" in diameter. The material may be Niti, Stainless, MP35n, Ti, Platinum, Platinum Iridum, cobalt chromium allowy etc.

[0163] In variations in which the distal tractor region is a mesh (e.g., woven and/or kitted material), the diameter of the distal tractor region relative to the catheter diameter may be depended on the woven/knitted structure. For example, when braided, the ratio may be between 2 to 1 or greater; when warp knit, the ratio is between: 1.5 to 1 or greater. When formed as a lasered tube, the ratio is between 1.1 to 1 or greater. Similarly for braided tube or tape structures, the braid angle inside of the catheter should be between 0 to 45 degrees of the braid angle inside catheter, and between about 20 to 90 degrees of the braid angle outside catheter. In variations in which the distal tractor region includes a knit braid (e.g., a warp knit) tube, the apparatus may include 12 to 16 ends per inch. For an apparatus having a 0.0035" ID catheter: 12 to 16 ends of 20-40D PET multifilament may be used, or 12 to 16 ends of 0.0007 to .003" PET or Polypro or PTFE monofilament, or 12 to 16 ends of .0007 to .002" NITI, stainless, MP35n, etc.

[0164] As mentioned above, in some variations the distal tractor region is formed of ePTFE as a sheet (e.g., formed into a tube or tape). This material may be thin walled (e.g., between 0.0005 to 0.003" thick), think walled (between 0.0005 to 0.002"), and may fold/role over catheter tip. The material may include a 0.001 to 0.004" with lasered pattern that is stent-like.

[0165] Other examples of designs for apparatuses including distal tractor region of different shapes may be a function of catheter ID. For example, in some variations the apparatus may select the catheter ID, number of filaments, diameter/length of filaments, stiffness of bending/rolling stiffness, Poisson's ratio, friction (and/or texture) of the inner surface of the grabber, etc. Smaller diameter catheters may require less mesh filaments or smaller ePTFE tube IDS's than larger diameter catheters. For example, in some variations in which the distal tractor region is braided, the apparatus may include a 0.072" ID catheter having a distal tractor region with 24 to 72 ends of 0.0008" to 0.002 Niti wire, braided on a 6 mm mandrel at a 90 degrees braid angle. In some variations the distal tractor region is formed of 24 to 72 ends of 0.0008" to 0.002 PP monofil, braided on a 6 mm mandrel at a 90 degrees braid angle. In some variations the distal tractor region is formed of a knit braid (assume .072" catheter) and may include 16 ends or 40D PET multifil free warp-knitted, annealed on a 3 mm mandrel. In some variations the distal tractor region is formed of 16 ends of 0.002" PP monofil warp-knitted, annealed on a 3 mm mandrel. In variations having a distal tractor region formed of ePTFe tubes (again, assuming a 0.072" catheter), the distal tractor region may be 0.002" thick, 3mm tube. Alternatively, the distal tractor region may be a 0.002" thick, 3mm tube laser slotted to collapse and grab clot.

[0166] As mentioned, in some variations the apparatus is configured to include a gripping inner mesh surface in the distal tractor region. For example the apparatus may include a laser slotted ePTFE tube having larger diameter braid filaments and/or mixed diameter filaments. In some variations a gripping inner mesh surface may be formed with a knit braid that is a warp knit formed tube. Such a structure may have a natural macro structure to allow mesh rolling and gripping of clot, since filaments

do not enter catheter ID parallel to catheter, but rather they are perpendicular or looped relative to catheter long axis. For examples in which the distal tractor region is formed of an ePTFE laser slotted (sheet of) material, the structure may include slots cut to allow Poisson ratio to effect tube diameter while creating grippy texture to grab clot.

[0167] In general, the effectiveness of the distal tractor region in grabbing a clot may be enhanced by using self-expanding and/or stiffer distal tractor region (e.g., self-expanding and/or flexible first end regions of the distal tractor region). When the first end region of the distal tractor region is formed of a braid, stiffer filaments (e.g., formed of bigger diameter filaments, stiffer materials, larger number of fibers, etc.) may result in more expanded first end regions of the distal tractor region, as illustrated in FIGS. 18A-18C. In FIG. 18A a softer distal tractor region does not expand out beyond the OD of the catheter any substantial distance. FIG. 18B shows a slightly stiffer/more expandable first end region of the distal tractor region. FIG. 18C shows the most expandable distal tractor region 1801, which may optimally expand to the intima of the vessel 1803.

[0168] As shown in FIGS. 18A-18C, the mouth of lip of the expandable tractor region may form a tangent angle or roll angle (ϕ) with respect to the long axis of the catheter OD. This angle may be in the range of approximately 5° to 60° degrees (e.g., 10°-60°, 10°-50°, 10°-45°, 10°-40°, etc., and preferable at least 10 degrees). The inventors have surprisingly found that, in some variations, having a roll angle of at least about 10 degrees (e.g., 10°-60°, 10°-50°, 10°-45°, 10°-40°) with the tube as the tractor region is retracted into the catheter may prevent binding or jamming on the catheter tip. The mesh tube may be modified (e.g., at the distal tip or end region), including by modifying the stiffness and/or shape of the distal tip, to ensure the roll angle in greater than 10 degrees. Alternatively or in combination to maintaining a minimum roll angle it may be desirable to maintain a physical space or gap between the tube material ID and the O.D of the catheter (see, e.g., FIGS. 18A-18C) at the catheters most distal tip. The gap may need to be greater than 0.1 mm, 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 0.7 mm, 0.8 mm, or 1.0mm to ensure the tube rolls around the distal end of the catheter when the tube is retracted.

[0169] In any of these variations, the distal tractor region may be lubricious (e.g., hydrophilic coating, silicone coating, thin urethane or other thin elastomeric coating) as mentioned above. One or more polymeric braid ends may be included to enhance lubricity (e.g., polypropylene, nylon, etc.). Further, the braid angle may be kept small (e.g., less than 70 degrees, 50 degrees, 45 degrees, etc.) to allow better pulling. This angle may be measured when the distal tractor region is rolling around/over the tip of the catheter. Increasing the number of ends of the weave may also prevent locking of the first end region within the catheter, so that gaps/spaces between the braid elements are smaller and less likely to snag on the catheter tip when rolling the distal tractor region over the end of the catheter. Any of these apparatuses may also include an axial element when formed as a braided element that is less likely to collapse or reduce in diameter when pulled, and therefore less likely to hang up on the catheter opening when rolling over the tip. It may also be advantageous to use slightly larger braid filaments when using Niti (e.g., >0.0001" diameter); the greater the diameter, the less likely the braid may deform to lock onto

the catheter tip. As mentioned above, in some variations the distal tractor region may be heat set to automatically roll over the distal end of the catheter when advanced distally.

[0170] FIGS. 19A and 19B illustrate alternative methods for forming the doubled-back configuration of the distal tractor region. In FIG. 19A, the tubular distal tractor region 1903 may be coupled to a puller/pusher 1901 and then inverted over the catheter tip as mentioned above. In FIG. 19B, the tubular braid 1905 is attached distally through the braid to a wire/puller 1901 and pulled to invert it over the distal end of the catheter.

[0171] In general, the first end region of the distal tractor region may have any appropriate shape (refer to FIGS. 15A-15D). FIGS. 20A and 20B illustrate examples of tapered woven braids that may form the distal tractor region. In. FIG. 20A, the braid has a tapered side profile that may be attached to a puller (proximal end of the flexible tractor tube) and inverted. Any of the braids described herein may include a marker wire (e.g., DFT, gold, Pt, Pt iridium, etc.) to help with visualization (e.g., fluoroscopically). In FIG. 20B, the mesh is tapered more abruptly than in FIG. 20A.

[0172] As described above, in general, any of the catheters described herein may be adapted for use with these apparatuses. For example an appropriate catheter may be highly flexible with a good column stiffness (e.g., will not shorten in length when advanced distally). The catheter can have a high angle braid reinforcing element. For example, the catheter may have a high angle braid through proximal to distal end (70-85 degrees, small wire Niti, Stainless, cobalt chrome, MP35N, flat or round wire), and a lower braid angle for the distal 1 to 5 cm of the catheter. This will allow the id of the catheter to expand when axial compression is applied, and/or under an internal expanding force (e.g., clot).

[0173] In general, any of these catheters may include a changing stiffness/compliance. For example, the proximal third (1/3) may be stiffer; the middle section may be less stiff, and the distal 20% (1/5) may be the least stiff. Further, the distal tip of the catheter may have an appropriate radius (curve) as described in FIGS. 1A and 1B. In general, the radius should be smooth and round, and not square. In addition, the distal tip of the catheter may be made of a hard enough material (~72D or harder) to allow braid to roll and not grab onto tip. For example, the catheter tip may have a hard metallic structure to reduce friction (e.g., stainless steel, Pt, etc.). The less the catheter tip compresses/buckles when pulling the distal tractor region, the better. In some variations the catheter includes an additional reinforcement such as a braid reinforcement rather than a coil reinforcement, to prevent braid buckling for the last 5-10 cm of the catheter. Thus, as described herein, in some variations, the tip of the catheter may be made of a lubricous and/or hard material to help reduce the braid to catheter tip friction when the braid is pulled or pushed around the catheter tip. Lubricous materials may include flour-polymers like PTFE, FEP and/or hydrophilic coatings. Hard materials like Nylons, or metallics like stainless steel, Platinum and PT iridium alloys could be used at the tip and fused/attached to softer materials proximally. If a hard tip is put on the distal end of the catheter tip it may be short in length (e.g., < 5mm and preferably < 3mm) so it does not adversely affect catheter tracking.

[0174] FIGS. 21A-21D show examples of apparatuses used to remove clots. In this example, the distal tractor region was formed of a fine Denier PET mesh of approximately 72 ends that is 10 mm

(expanded) diameter pulled down onto a 0.071" catheter, as shown in FIGS. 21A and 21B. FIG. 21A shows an example of an expandable first end region prior to coupling to a catheter. FIG. 21B illustrates the expandable first end region within a vessel (glass tube) being drawn into a catheter by pulling the proximal end of the flexible (tractor) tube. FIG. 21C shows the distal end region of the apparatus including the expandable first end regions doubled over the distal end region of the catheter. FIG. 21D illustrates the apparatus of FIG. 21C drawing a clot into the catheter.

[0175] Another example examined a distal tractor region formed from a 6 mm braid having 72 ends and 0.001" diameter filaments rolling into and doubled over a 0.071" ID catheter. A 'medium hard' 5 mm clot that was 20 cm long was successfully removed. FIG. 22 shows the expandable first end region of FIG. 21D with the captured clot after drawing it proximally out of the catheter.

[0176] FIGS. 23A-23D illustrate a mechanical thrombectomy apparatus as described herein capturing a blood clot and drawing it into the apparatus. FIG. 23E illustrates the clot held within the flexible tractor tube after the flexible tractor tube has been removed from the catheter (e.g., proximally).

[0177] In some variations described herein the distal tractor region is not formed of a woven or knitted material, but is instead composed of strip or bundles of longitudinally arranged (e.g., in parallel or near-parallel arrangement). For example, FIG. 24 is another example of an apparatus including a flexible tractor member in which the distal tractor region is formed of a plurality of filaments that are arranged as strips of material (longitudinally parallel) that are not woven or braided. These strips may be filaments, or tubes, etc.

[0178] FIGS. 25A-25F illustrate another variation of a distal tractor region of a flexible tractor assembly in which the expandable first end region (e.g., the distal end region of the distal tractor region) is formed of a plurality of filaments or strips, similar to that shown in FIG. 24; the distal end of the catheter includes channels, as shown in FIGS. 25A-24B; the strips may fit within these channels, as shown in FIGS. 25C-25D. FIGS. 25E and 25F show sectional views through FIGS. 25C and 25D. FIGS. 25A, 25C and 25E show side views and FIGS. 25B, 25D and 25F show axial views. In this example, the catheter tip includes channels 2502 into which the filaments/strips 2503 run. The strips forming the distal tractor region are attached to the more proximate puller region of the flexible tractor tube 2505, shown in FIG. 25E.

[0179] FIGS. 26A and 26B show a variation of the apparatus of FIGS. 25A-25F with an outer sleeve (e.g., an outer catheter or release protector catheter or other outer sleeve/protector)

[0180] FIGS. 27A-27B show a sectional view through the apparatus of FIGS. 26A-26B.

[0181] FIG. 28 is an apparatus including a distal tractor region of a flexible tractor assembly having a plurality of longitudinally-parallel (non-woven/braided) filaments or strips in which the distal ends of the filaments or strips are connected to each other by a distal connector.

[0182] FIG. 29 shows a distal tractor region of a flexible tractor assembly in an apparatus in which the longitudinally-parallel (non-woven/braided) filaments or strips include grabbing elements.

[0183] FIGS. 30A-30C illustrate example of filaments/strips with grabbing elements. Grabbing elements (and/or filaments including them) may be used as part of any of the variations described herein,

including woven or braided distal tractor regions. Other options for filaments/strips with grabbing elements may include braided strips, mesh/woven strips, and micro-coils.

[0184] In any of these configuration described herein, the apparatus may be adapted to allow reciprocation of the distal tractor region, cycling from outside to inside and back outside of the distal end of the catheter. For example, FIG. 31 illustrates a variation in which the distal tractor region is adapted to be reciprocated (e.g., pushed and pulled) so that the expandable first end region may be draw into and reversed out of the catheter. In this example, the tractor tube (puller) 3105 is attached to the distal tractor region 3144 that may be attached (and in some variations is not attached) to a second catheter 3109 over the inner catheter 3101. The mid-catheter 3109 can be coupled to the puller 3105 and the two reciprocated together so that the braid reciprocated back and forth inside of the catheter 3101. This may help break up a clot, which may be particularly when used with suction.

[0185] FIG. 32 illustrates another example of an apparatus as described herein in which the distal-most end 3205 of the flexible first end region of the distal tractor region is non-releasably fixed to the distal end of the outside of the catheter 3201; the rest of the expandable first end region 3209 is sufficiently elastic/flexible to be drawn into the catheter (pulling a clot 3255 with it). The flexible tractor assembly may then be left retracted and the entire apparatus withdrawn. This example may include an optional vacuum 3260.

[0186] FIG. 33 is another example of an apparatus in which the puller portion 3305 of the flexible tractor assembly is formed of the same material as the distal tractor region 3344 but may be laminated or otherwise reinforced to have less flexibility/stretchability than the distal tractor region.

[0187] FIG. 34 illustrates another example in which the distal tractor region 3444 is adapted to compress the clot 3455 when draw into the catheter 3401. FIGS. 35A-35C illustrate operation of an apparatus as shown in FIG. 34 in which the clot 3455 is drawn into the catheter by withdrawing the expandable first end region of the distal tractor region into the catheter (e.g., pulling on the puller region 3505 of the tractor assembly) which compresses the clot (FIGS. 35A-35B); releasing the tractor assembly and/or pushing it distally may further break up the clot and release it from the distal tractor region so that it may be sectioned up proximally (FIG. 35C).

[0188] FIG. 36 illustrates an example of an apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally through the body (e.g., vessel) over a guidewire, which may be treated to engage the distal tractor region. In this example, the apparatus may be configured to pull the inner tractor tube (catheter 3605) which has the mesh forming the distal tractor region 3644 attached to its distal end and inverting over the distal end of the catheter 3601. Pulling the flexible tractor tube 3605 makes the braid roll over the opening of the catheter 3601. The mesh/braid forming the distal tractor region (e.g., the first end region of the distal tractor region) is constructed to collapse in diameter when tensile loads are applied to this structure and lock/grab onto inner wire (guidewire 3677). This inner guidewire may have a tacky, rough or knobby surface aid mesh/braid grabbing onto wire. As the mesh/braid grabs onto the guidewire, the tractor tube, as a

reactionary force, will be driven forward in the vessel. Alternatively the user will be able to easily advance outer catheter 3601 forward through vessel while pulling back on the tractor tube.

[0189] FIGS. 37A-37C illustrate another apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally. In FIG. 37A, the distal tractor region 3744 is attached to a middle catheter 3703 (an optional outer catheter 3705 may be included) and the opposite end of the distal tractor region 3744 is bonded to the distal end of the inner catheter 3701 within the inner diameter of this catheter. In FIG. 37B the inner catheter is advanced distally, expanding the distal tractor region both laterally and forward. As shown in FIG. 37C, the outer and inner catheters may then be pushed distally to move the apparatus more distally.

[0190] In some variations the distal and flexible tractor region may be held pre-loaded outside of the catheter, e.g., in a roll or bundle, over the distal end region of the catheter, so that it can be gradually pulled out of the external storage region and rolled and inverted over the distal end of the catheter. An example of one such variation is shown in FIGS. 38A and 38B. this exemplary apparatus may be used to remove material from within a vessel as shown in FIG. 38B, and may be referred to as an "infinite" tractor mechanism because a large amount (e.g., greater than 50 cm, greater than 60 cm, greater than 70 cm, greater than 80 cm, greater than 90 cm, greater than 100 cm, greater than 150 cm, 200 cm, greater than 300 cm, greater than 400 cm, greater than 500 cm, etc.) of tractor material (e.g., mesh) may be stored in an external holding region, wound-up but dispensable over an extended use.

[0191] In FIG. 38A, the apparatus may include the catheter (inner catheter) 3811 and the distal tractor region 3806 is formed of a mesh that is rolled up 3803 in a housing region 3813 proximal to the distal end of the catheter. The clot 3805 may be drawn into the catheter by pulling the distal tractor region proximally within the catheter. Because a great deal of distal tractor region may be stored and withdrawn proximally, this variation may be useful for very long procedures or where there is a lot of material to be removed.

[0192] This variation may allow a user to unroll a long length of mesh, which may be advantageous for more rigid tools, such as, for example, a rigid hypotube during surgery, for example, removing fat in a liposuction procedure, removing clot in an intracerebral hemorrhage or a larger peripheral vascular clot.

[0193] As mentioned above, in any of the variations described herein, the distal tractor member may be a woven (e.g., knit) or braided mesh material. The mesh may be a knit material, including, for example a weft knit, circular knit, warp braid knit, and/or braid knit.

[0194] 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.

[0195] 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 "/".

[0196] 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.

[0197] 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.

[0198] 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.

[0199] 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.

[0200] 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.

[0201] 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 method of performing a mechanical thrombectomy to remove a clot from a blood vessel, the method comprising:

advancing a distal end of a catheter through the blood vessel towards the clot;

exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable first end region;

allowing the expandable first end region to expand within the blood vessel;

positioning the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region while the expandable first end region is doubled over the less expandable second end region; and

drawing the clot into the catheter by rolling the expandable first end region over the distal end of the catheter so that the expandable first end region inverts as the expandable first end region is pulled into the catheter.

2. The method of claim 1, wherein positioning comprises distally advancing the distal end of the catheter so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region.

3. The method of claim 1, further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot.

4. The method of claim 1, further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot, further wherein drawing the clot into the catheter comprises advancing the catheter towards the clot over the guidewire while rolling the expandable first end region over the distal end of the catheter.

5. The method of claim 1, wherein drawing the clot into the catheter comprises withdrawing the tube proximally.

6. The method of claim 1, wherein drawing the clot into the catheter comprises withdrawing the tube proximally while advancing the catheter distally.

7. The method of claim 1, wherein drawing the clot into the catheter comprises withdrawing the tube proximally while advancing the catheter distally, wherein the tube is withdrawn at a different rate than the catheter is advanced.

8. The method of claim 1, wherein allowing the expandable first end region to expand within the blood vessel comprises allowing a biasing element in the expandable first end region to expand so that the distal tractor region makes contact with an intima of the blood vessel.

9. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter.

10. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises pulling the catheter proximally.

11. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter to expose the expandable first end region already inverted over the less expandable second end region.

12. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended.

13. The method of claim 1, wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.

14. The method of claim 1, wherein exposing the distal tractor region comprises exposing at least 1 cm of the expandable first end region inverted over at least 1 cm of the less expandable second end region.

15. The method of claim 1, wherein the expandable first end region comprises a mesh that is coupled adjacent to the less expandable second end region.

16. The method of claim 1, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, a knitted material, or a film material with multiple openings therethrough.

17. The method of claim 1, wherein advancing comprises advancing the distal end of the catheter through the blood vessel to position the distal end adjacent to the clot.

18. A method of performing a mechanical thrombectomy to remove a clot from a blood vessel, the method comprising:

advancing a distal end of a catheter through the blood vessel towards the clot;

exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable fist end region and configured so that the expandable first end region is inverted over the less expandable second end region;

allowing the expandable first end region to expand within the blood vessel so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region; and

drawing the clot into the catheter by advancing the catheter distally and withdrawing the tube proximally within the catheter so that the expandable first end region rolls over the distal end of the catheter and inverts as the expandable first end region is pulled into the catheter.

19. The method of claim 18, wherein the expandable first end region is inverted over the less expandable second end region before exposing the distal tractor region.

20. The method of claim 18,wherein the exposing the distal tractor region comprises inverting the expandable distal end region over the less expandable second end region as the distal tractor region is exposed.

21. The method of claim 18, further comprising, before exposing the distal tractor region, advancing a guidewire within the blood vessel to the clot and advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot.

22. The method of claim 18, further comprising, before exposing the distal tractor region, advancing a guidewire within the blood vessel to the clot and advancing the catheter over the guidewire

through the blood vessel until a distal end of the catheter is proximate to the clot and leaving the guidewire in place while drawing the clot into the catheter.

23. The method of claim 18, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter.

24. The method of claim 18, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises pulling the catheter proximally.

25. The method of claim 18, wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.

26. The method of claim 18, wherein the expandable first end region of the distal tractor region comprises a mesh that is coupled adjacent to the less expandable second end region.

27. The method of claim 18, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, or a film material with multiple openings therethrough.

28. A method of performing a mechanical thrombectomy to remove a clot from a blood vessel, the method comprising:

advancing a distal end of a catheter through the blood vessel towards the clot;

exposing a distal tractor region of a tube that is within the catheter out of the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region, wherein exposing comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended;

allowing the expandable first end region to expand within the blood vessel as it is extended out of the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region; and

drawing the clot into the catheter by withdrawing the tube proximally within the catheter so that the expandable distal end region rolls over the distal end of the catheter, collapses, and inverts as the expandable distal end region is pulled into the catheter.

29. The method of claim 28, further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot.

30. The method of claim 28, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter.

31. The method of claim 28, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises withdrawing the catheter proximally relative to the distal tractor region of the tube.

32. The method of claim 28, wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.

33. The method of claim 28, wherein the expandable first end region comprises a mesh that is coupled adjacent to the less expandable second end region.

34. The method of claim 28, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, or a film material with multiple openings therethrough.

35. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

a catheter having a distal end and a distal end opening;

a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and

a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire.

36. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

a catheter having a distal end and a distal end opening, wherein the distal end opening has a **durometer that is greater than a durometer of a region immediately proximal to the distal end**, further wherein the distal end opening has a rounded lip profile;

a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

37. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an inner catheter having a distal end and a distal end opening;

a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter;

an outer catheter extending over the inner catheter and flexible tube;

a **lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening of the inner catheter**, wherein the majority of the flexible tube is not lubricious; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

38. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an inner catheter having a distal end and a distal end opening;

a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter;

a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a predetermined force that is greater than 0.01 N; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

39. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

a catheter having a distal end, a distal end opening and an inner diameter;

a flexible tube extending through the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening

when a first end of the flexible tube is pulled proximally within the catheter, the **flexible tube having a low Poisson's ratio**, such that the flexible tube has a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

40. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a mesh tube.

41. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube extending through the catheter and doubling back over the distal end of the catheter increases the stiffness of a distal 5cm 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.

42. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube 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.

43. The apparatus of claims 35, 36, 37 and 39, further comprising a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a force that is greater than a predetermined force threshold.

44. The apparatus of claim 43, wherein the releasable force threshold is 0.01 N.

45. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a plurality of strips of flexible material, wherein the strips are arranged in parallel.

46. The apparatus of claims 35, 36, 37, 38 and 39, wherein the distal end opening comprises a plurality of notches or channels into which fibers or strips forming the flexible tube are drawn as the flexible tube inverts over the distal end opening.

47. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a polymeric tube having a plurality of holes therethrough.

48. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a distal end, a proximal end and a body region there between, wherein the body region transitions from a more flexible distal end to a stiffer proximal end.

49. The apparatus of claims 35, 37, 38 and 39, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile

50. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a handle adapted to draw the flexible tube proximally relative to the catheter.

51. The apparatus of claims 35, 36, 38 and 39, further comprising an outer catheter extending over the catheter and flexible tube.

52. The apparatus of claims 35, 36, 38 and 39, further comprising an outer catheter extending over the catheter and flexible tube and a lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening, wherein the majority of the flexible tube is not lubricious.

53. The apparatus of claims 35, 36, 37 and 38, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter wherein the flexible tube has a low Poisson's ratio such that the flexible mesh tube has a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening.

54. The apparatus of claims 35, 36, 37, 38 and 39, further comprising an elongate puller within the catheter and coupled to a distal end of the flexible tube.

55. The apparatus of claims 35, 36, 37, 38 and 39, further comprising an elongate puller within the catheter and coupled to a distal end of the flexible tube, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with the guidewire lumen though the flexible tube.

56. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a soft outer mesh member formed from 48 to 144 stands, having a thickness of 0.0020 inches or less in diameter, wherein the mesh tubular member extends in a longitudinal axis, further wherein the mesh tubular member has a length that is greater than 5 cm, forms a braid angle between crossing strands in a direction of the longitudinal axis of about 35 degrees or less when being pulled and inverted around the distal end of the catheter and expands to a diameter of greater than 1.5 times an inner diameter of the catheter outside of the catheter when unconstrained.

57. The apparatus of claim 56, where the strand is formed of any of the following; monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene, .

58. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a drive handle coupled to a proximal end region of the catheter, wherein the drive handle comprises a control configured to coordinate advancing of the catheter distally while retracting the flexible tube proximally when actuated.

59. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a retaining ring around a distal end region of the flexible tube configured to hold the flexible tube against the catheter.

60. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube is shape set to have different diameter when within the catheter after being pulled proximally into the catheter.

61. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a plurality of woven or knitted filaments.

62. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a plurality of woven or knitted filaments, and further wherein the proximal end of the flexible tube forms a tapered opening opposite from a bundle of filaments forming a pull wire.

63. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube is formed from a sleeve of polymer having a thickness less than 0.020 inches, wherein the sleeve comprises a perforation pattern in which the perforations extend through the polymer.

64. The apparatus of claim 63, wherein the perforation pattern comprises perforations having a shaped consisting of one or more of: round holes, rectangular holes and zig-zag shapes.

65. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a pull wire coupled to one side of a proximal end of the flexible tube configured to be drawn proximally to pull the flexible tube within the catheter.

66. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube is 3 to 50 cm.

67. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube of the apparatus is configured so that the flexible tube may be retracted into the catheter by applying less than 300 grams of force to a distal end of the flexible tube.

68. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a taper between the first end and a second end of the flexible tube.

69. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube extends within the entire length of the catheter so that a proximal end of the flexible tube is configured to be pulled proximally away from the proximal end of the catheter to slide and invert the flexible tube over the distal end opening.

70. The apparatus of claim 35, 36, 37, 38 and 39, further comprising a guidewire vacuum pump coupled to a proximal end of the guidewire lumen and configured to apply vacuum therethrough.

71. The apparatus of claims 35, 36, 37, 38 and 39, further comprising an outer catheter vacuum pump coupled to a space between the catheter and the flexible tube and configured to apply a vacuum within a lumen of the catheter between an inner wall of the catheter and the flexible tube.

72. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller and an outer catheter arranged over the catheter adjacent to a proximal end of the flexible tube, further comprising a handle having a control configured to coordinate advancing of the outer catheter to push the proximal end of the flexible tube distally and pulling the puller proximally to drawn the proximal end of the flexible tube into the catheter.

73. The apparatus of claims 35, 36, 37, 38 and 39, further comprising:

a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller;

an outer catheter slideably arranged over the catheter coupled to a proximal end of the flexible tube; and

a handle having a control configured to coordinate advancing of the outer catheter distally to push the proximal end of the flexible tube distally while pulling of the puller proximally to drawn the proximal end of the flexible tube into the catheter or pulling the outer catheter proximally to pull the proximal end of the flexible tube proximally while pushing of the puller distally to push the proximal end of the flexible tube out of the catheter.

74. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire at least to the proximal end of a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the

catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

75. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire adjacent a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen over a rounded lip of the distal end opening of the catheter so that the flexible tube slides and inverts over the distal end opening, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

76. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire adjacent a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises an inner catheter having a distal end and a distal end opening, a flexible tube extending along an outer diameter of the inner catheter and over the distal end of the catheter, and an outer catheter securing a distal end region of the flexible tube against the outer diameter of the inner catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that a lubricious proximal leader region of the flexible tube slides and inverts over the distal end opening, until a non-lubricious distal region of the flexible tube is drawn into the inner catheter; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

77. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire adjacent a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible

tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening;

pulling or pushing the flexible tube distally out of the distal end of the catheter so that the flexible tube slides and inverts over the distal end opening and over the outer diameter of the catheter; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

78. The method of claims 74, 75, 76, and 77, wherein the guidewire is positioned at least partially within the clot in the blood vessel.

79. A mechanical thrombectomy device for removing a clot from a vessel, the device comprising:

a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter;

a distal tractor region of a tube within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region proximal to the expandable distal end region, the distal tractor region configured so that the expandable distal end region is inverted over the less expandable distal end region;

a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and

a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter so that the catheter may be advanced between the expandable distal end region and the less expandable distal end region and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

80. A mechanical thrombectomy device for removing a clot from a vessel, the device comprising:

a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter;

a tube having a distal tractor region within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region that is proximal to the expandable distal end region, further wherein the expandable distal

end region is biased to invert over the less expandable distal end region as it is exposed from the distal end of the catheter;

a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and

a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

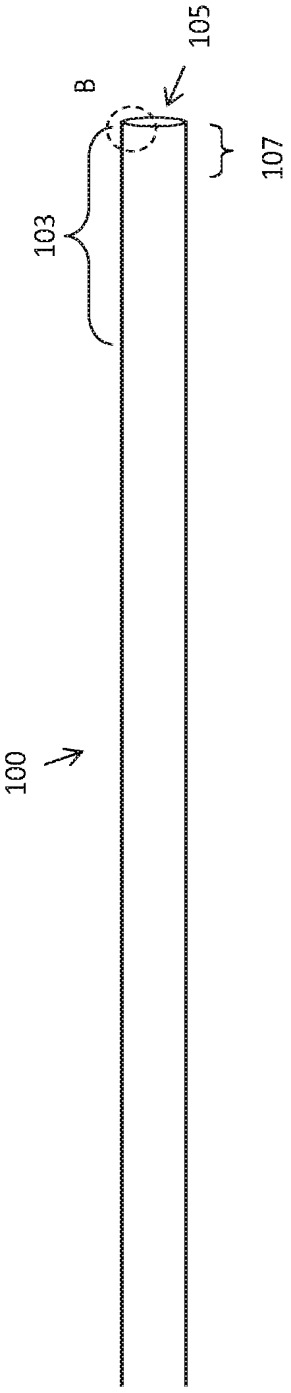


FIG. 1A

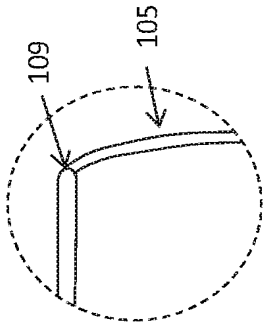


FIG. 1B

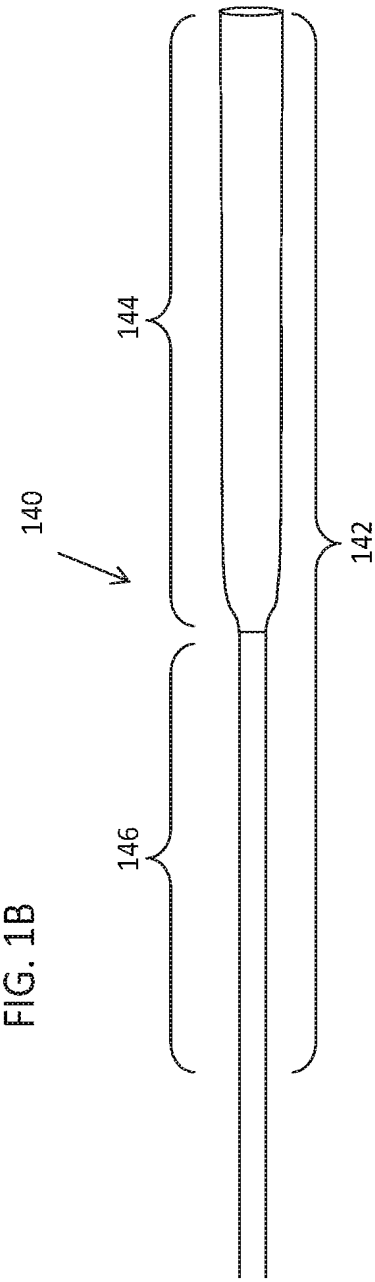


FIG. 1C

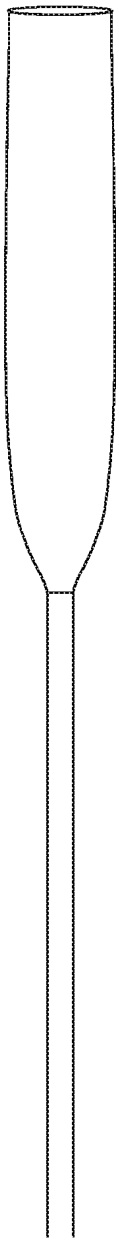


FIG. 1D

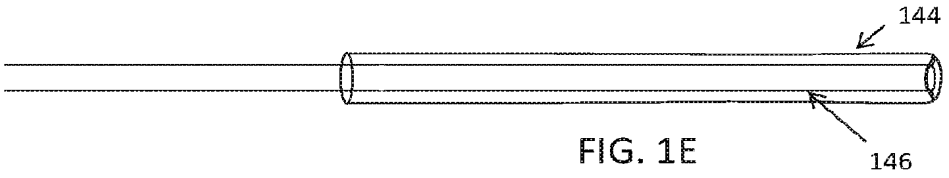


FIG. 1E

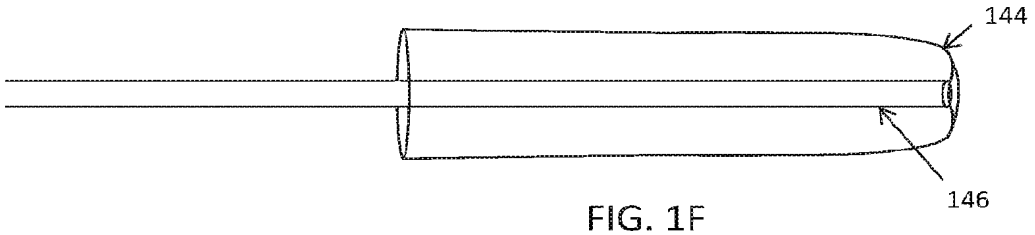


FIG. 1F

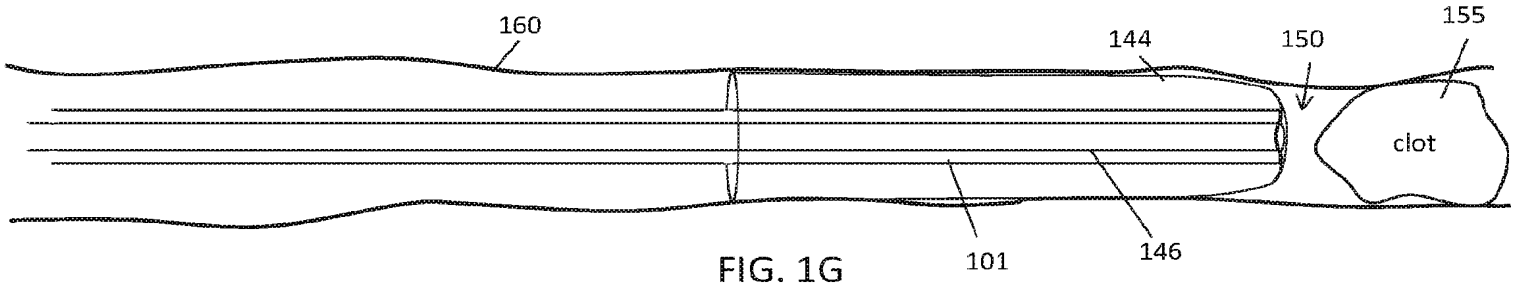


FIG. 1G

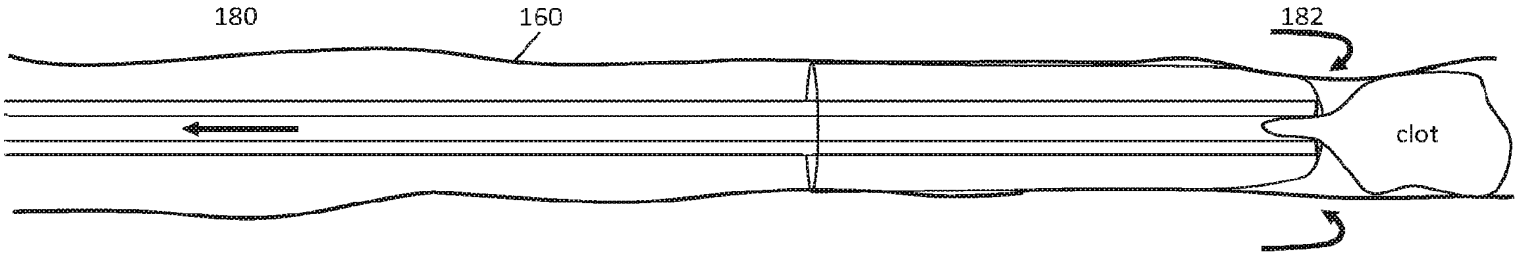


FIG. 1H

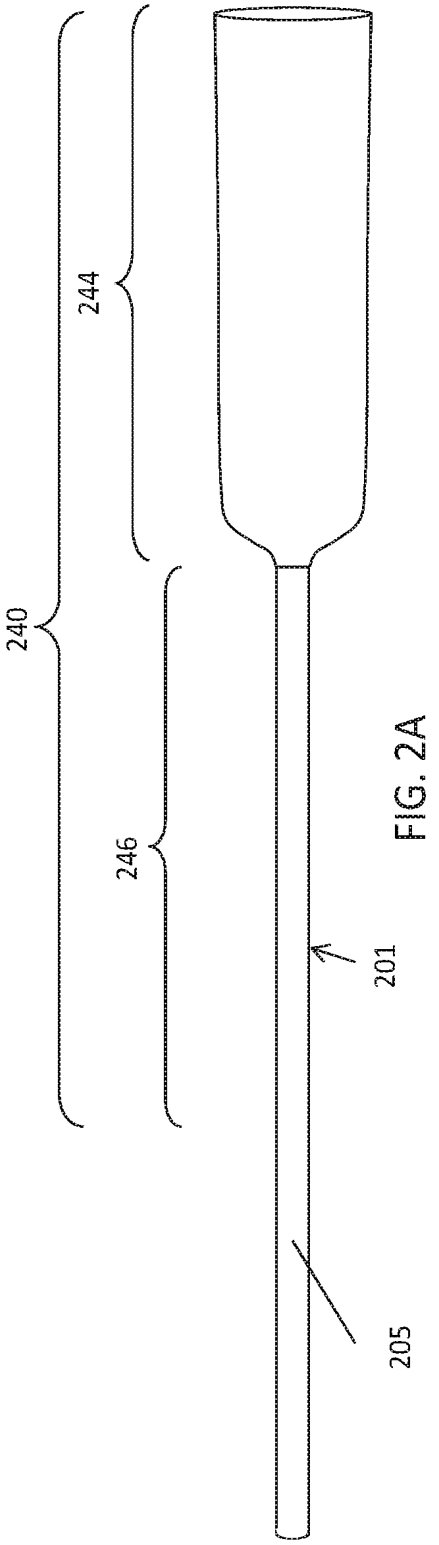


FIG. 2A

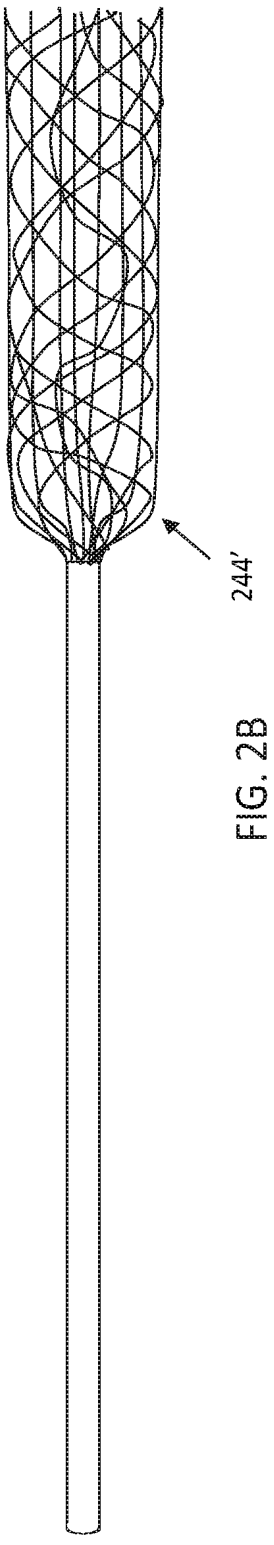


FIG. 2B

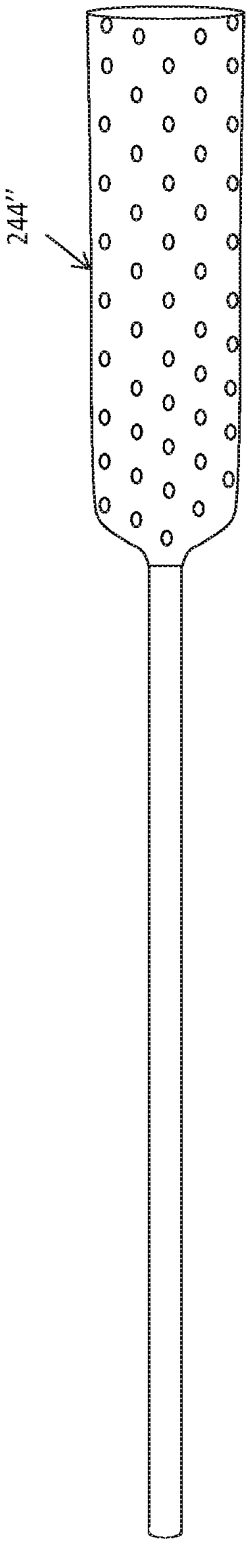


FIG. 2C

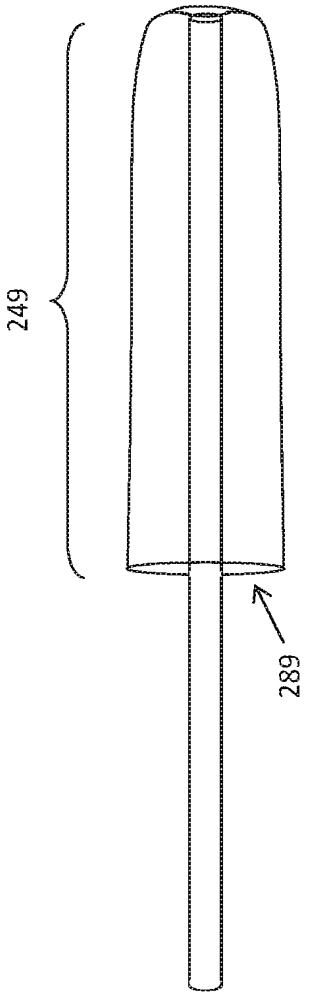


FIG. 2D

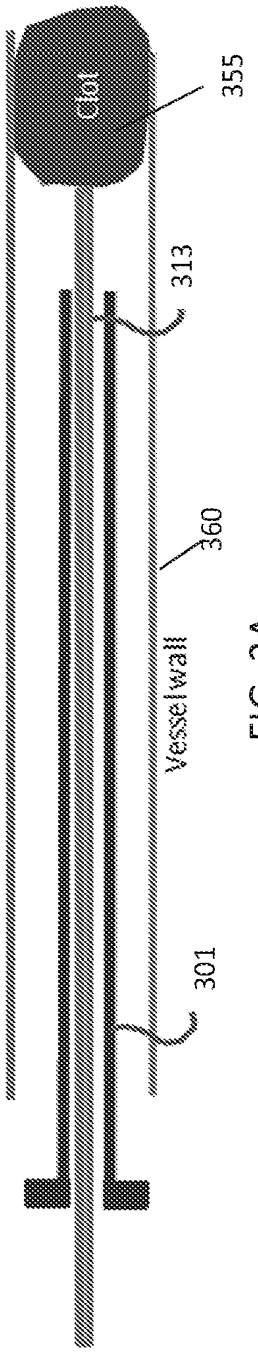


FIG. 3A

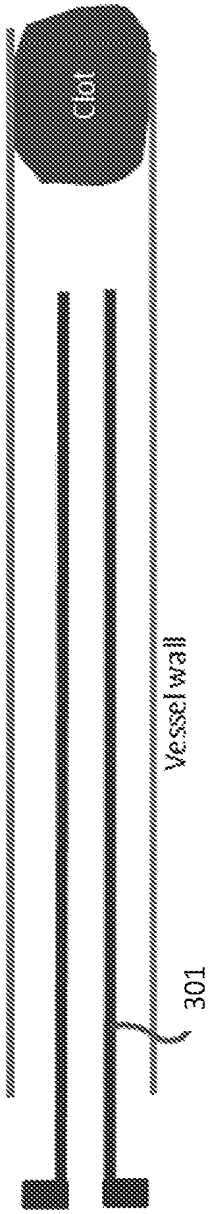


FIG. 3B

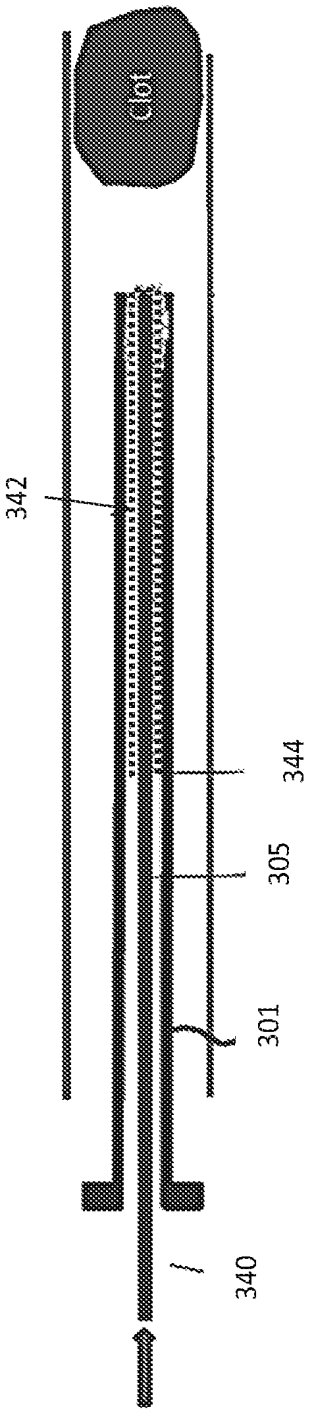


FIG. 3C

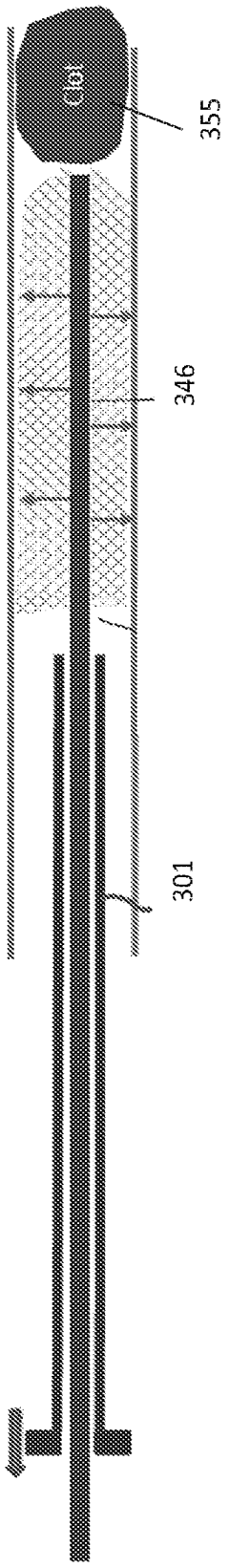


FIG. 3D

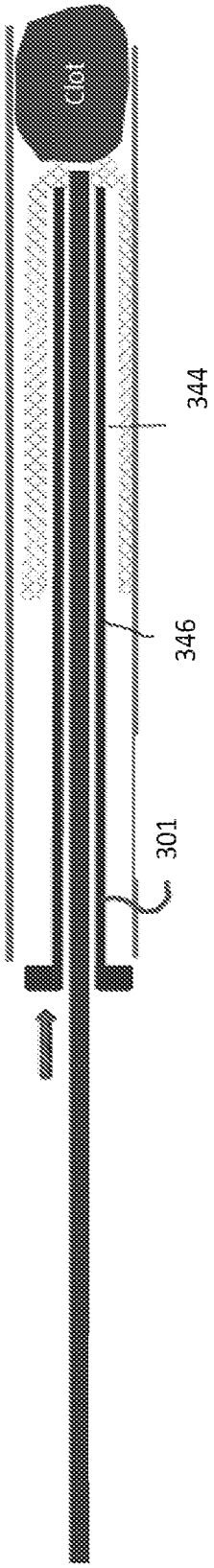


FIG. 3E

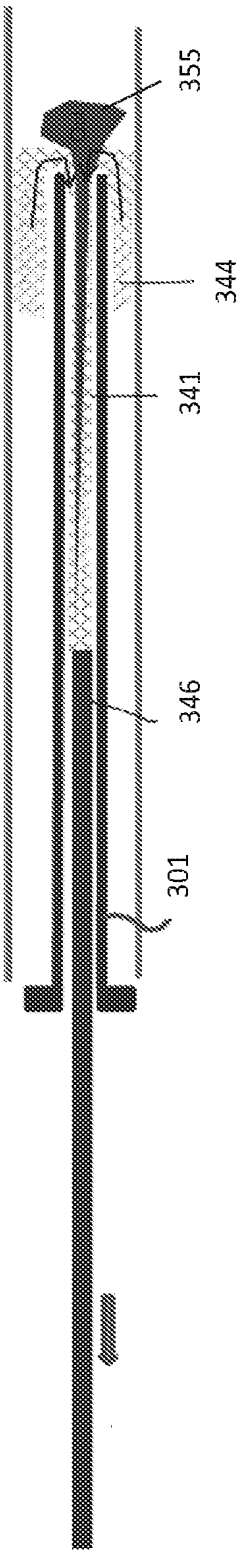


FIG. 3F

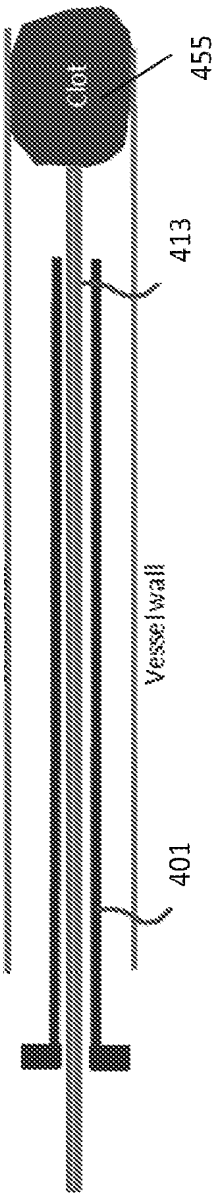


FIG. 4A

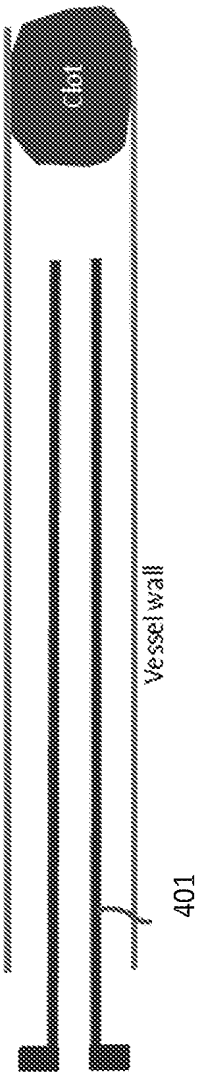


FIG. 4B

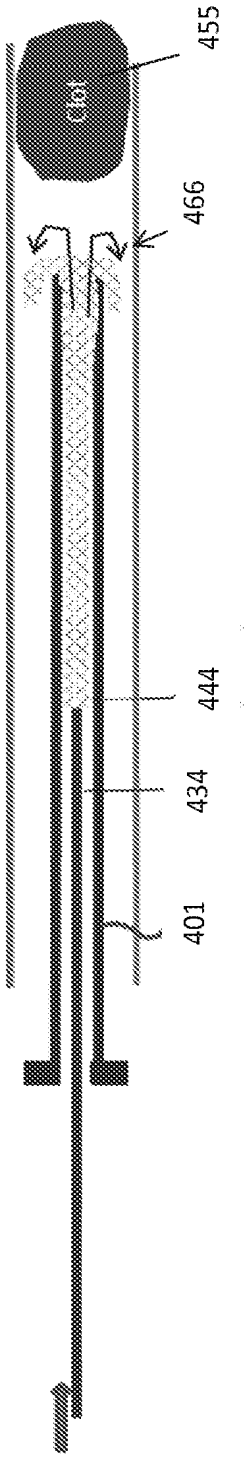


FIG. 4C

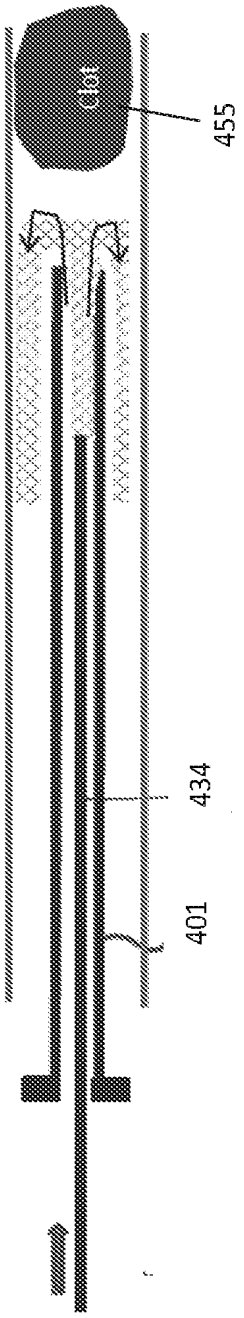


FIG. 4D

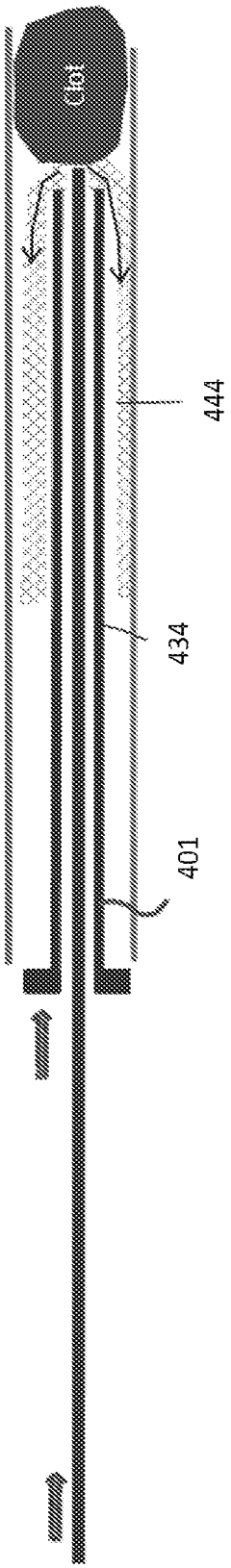


FIG. 4E

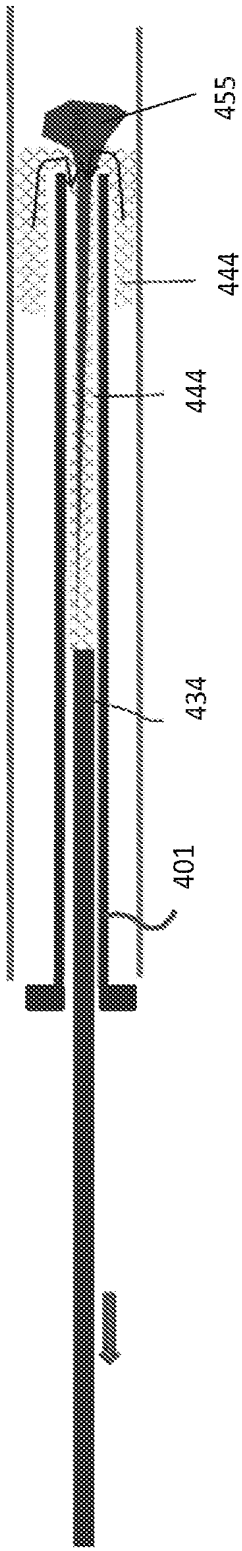
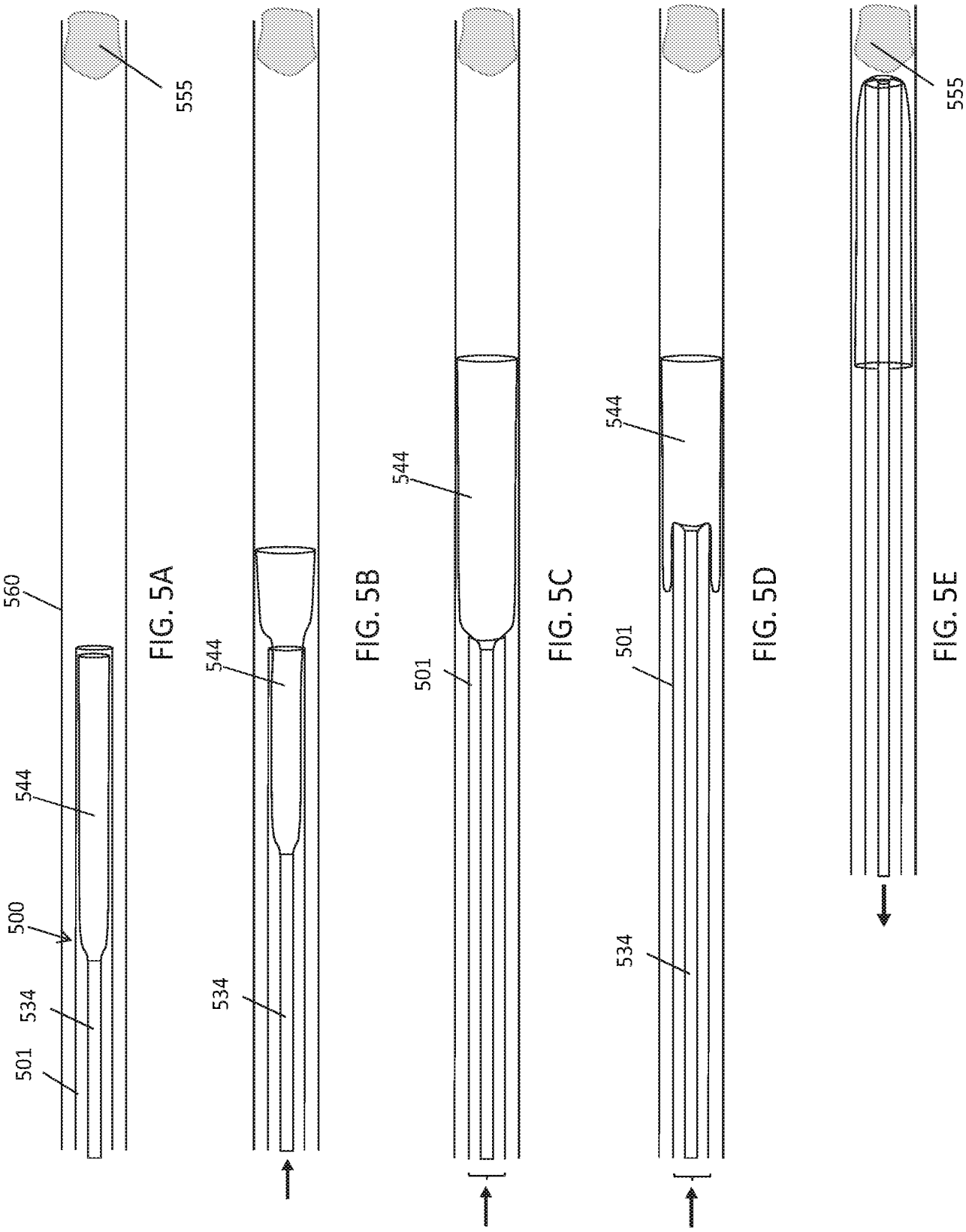


FIG. 4F


555
560
544
500
534
501
FIG. 5A
544
534
FIG. 5B
544
501
FIG. 5C
544
501
534
FIG. 5D
555
FIG. 5E

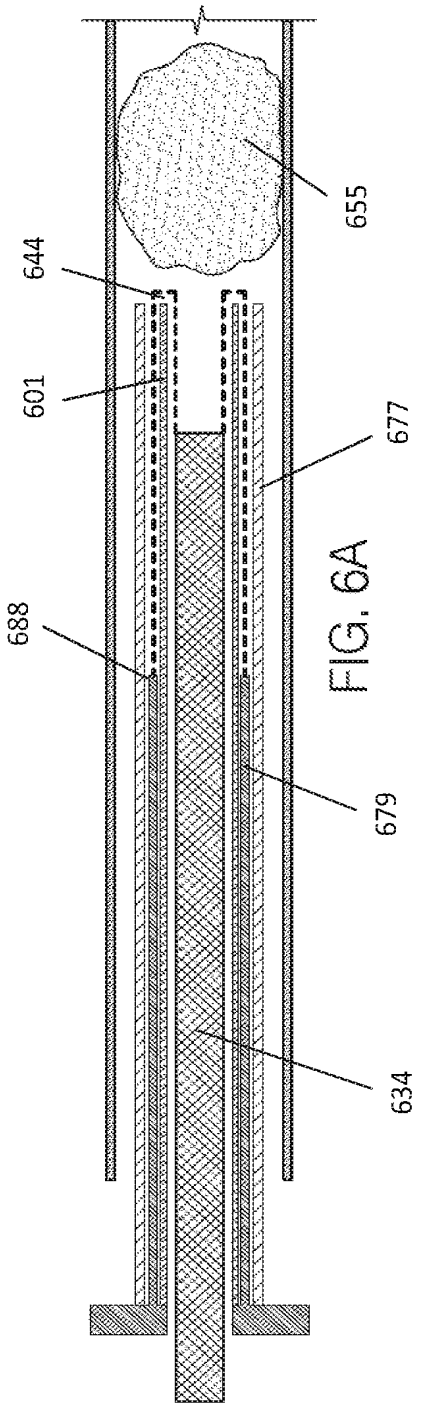


FIG. 6A

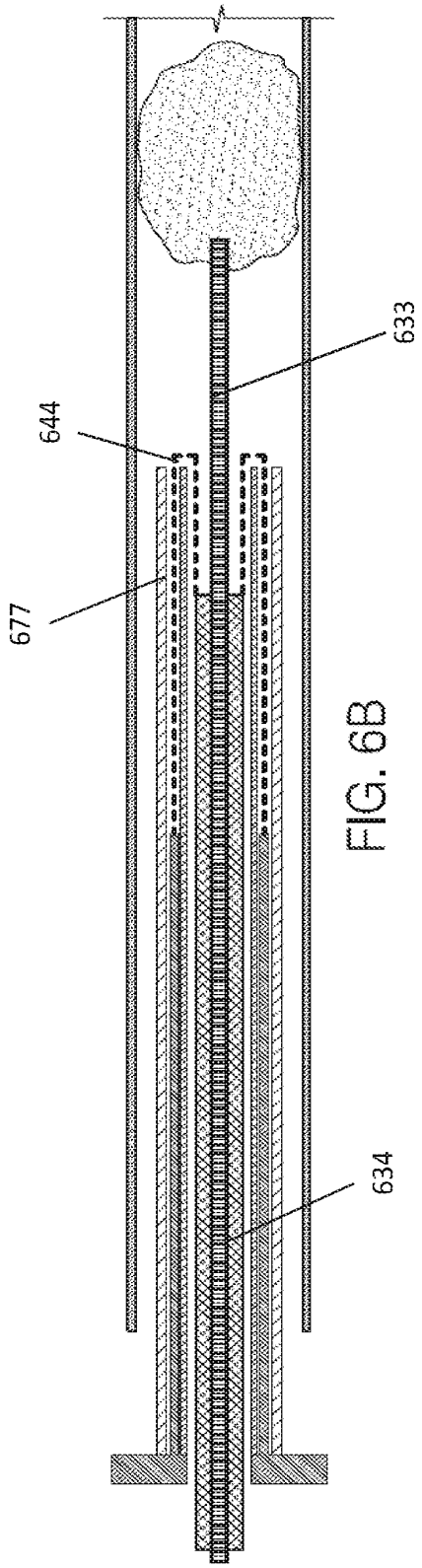


FIG. 6B

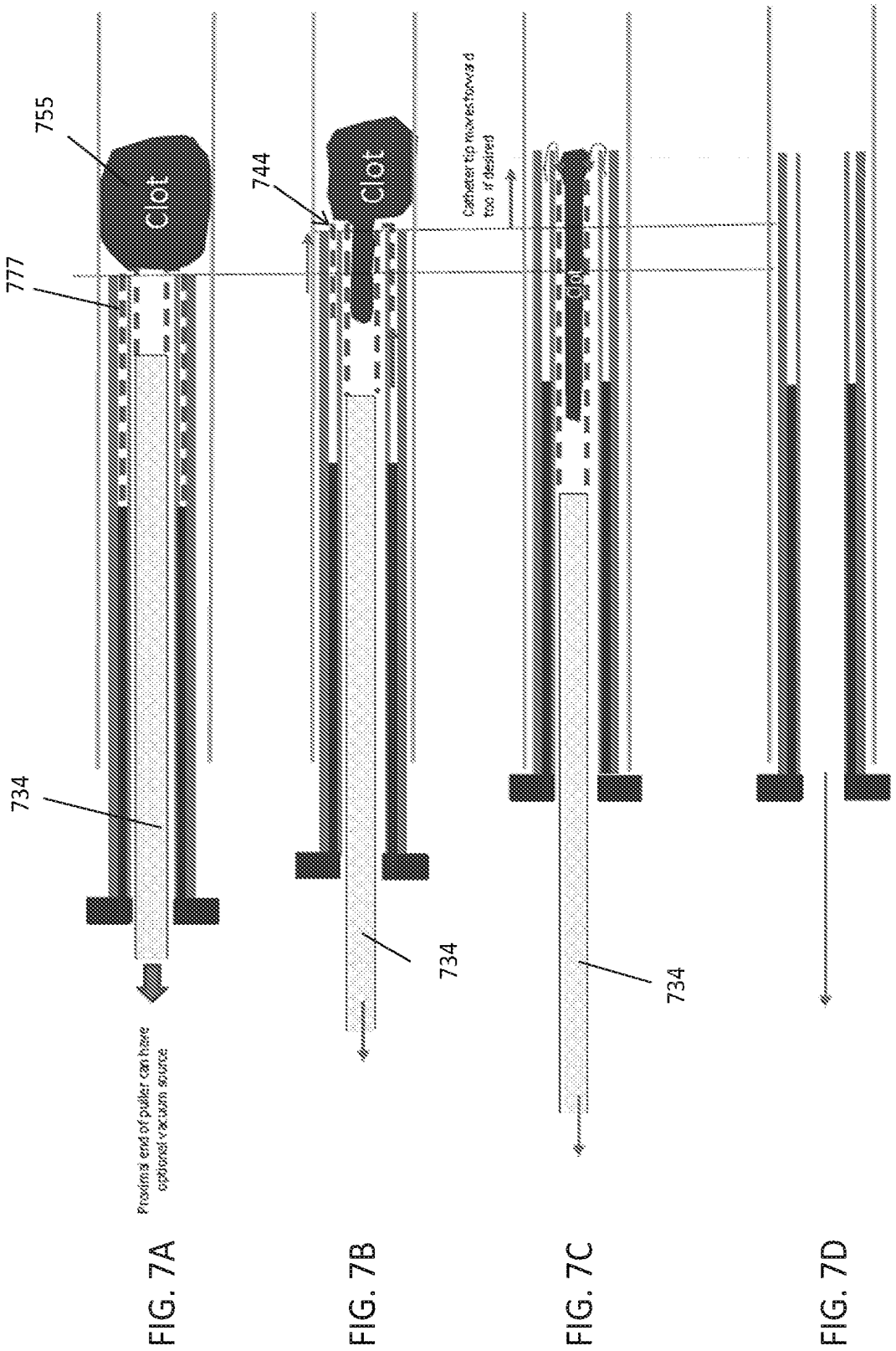


FIG. 7A FIG. 7B FIG. 7C FIG. 7D

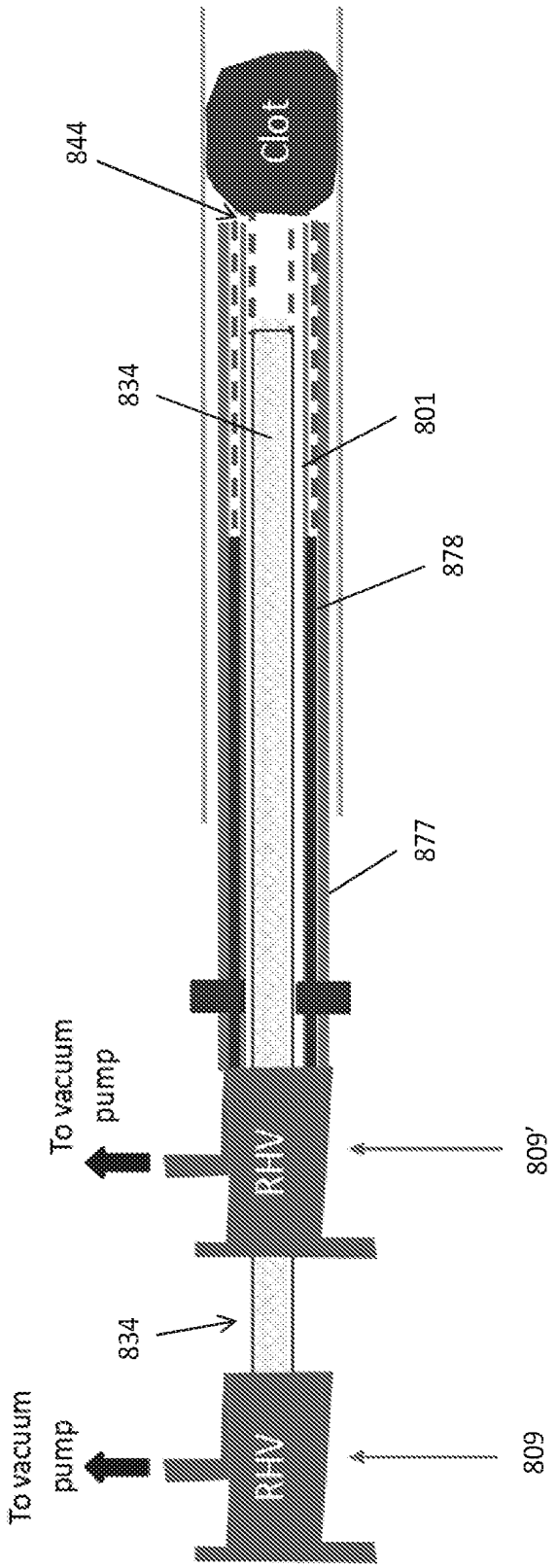
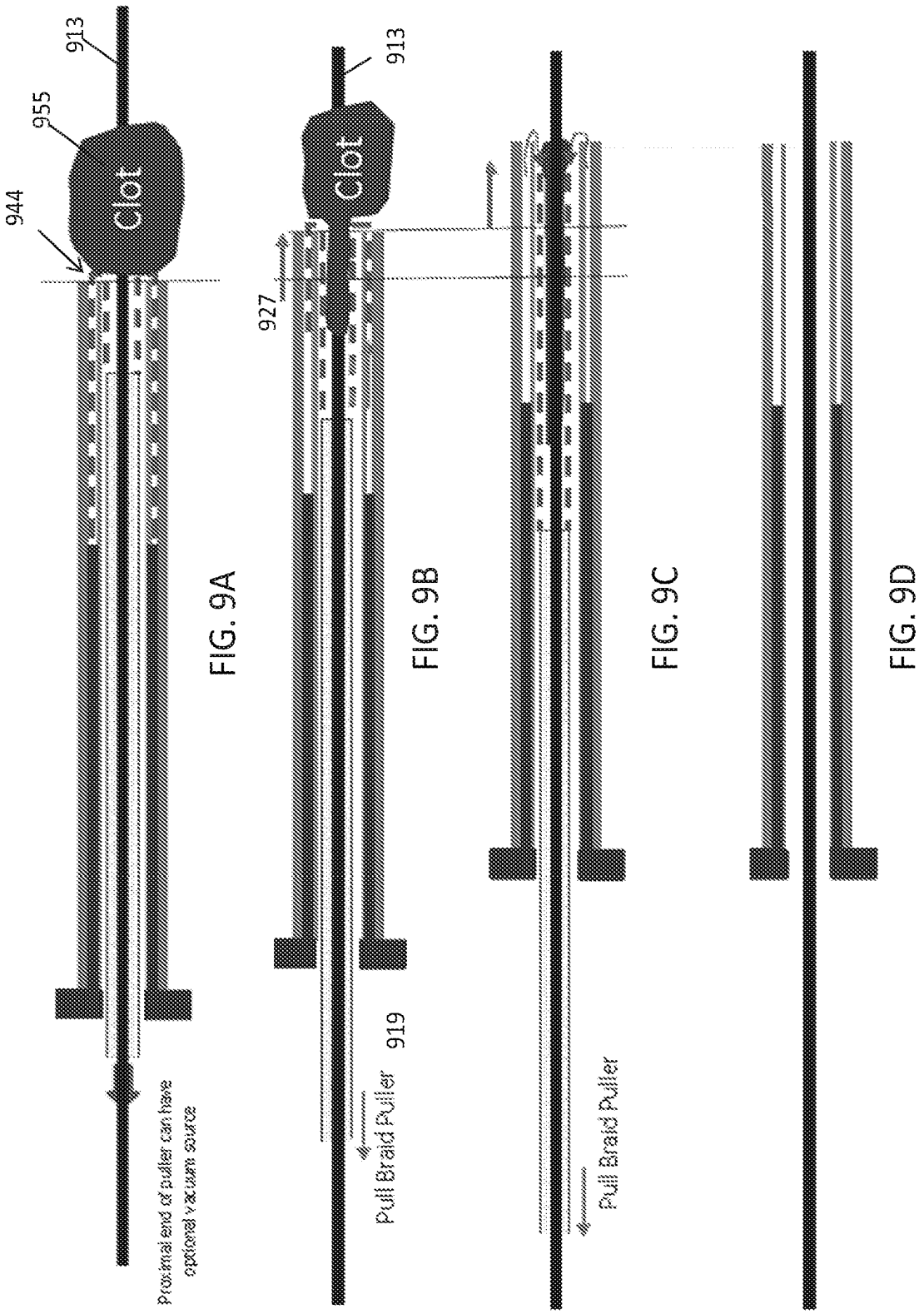

844
Clot
834
801
878
877
To vacuum pump
RHV
809'
834
To vacuum pump
RHV
809

FIG. 8


913
955
944
Clot
Proximal end of puller can have optional vacuum source
FIG. 9A
913
927
Clot
Pull Braid Puller
919
FIG. 9B
Pull Braid Puller
FIG. 9C
FIG. 9D

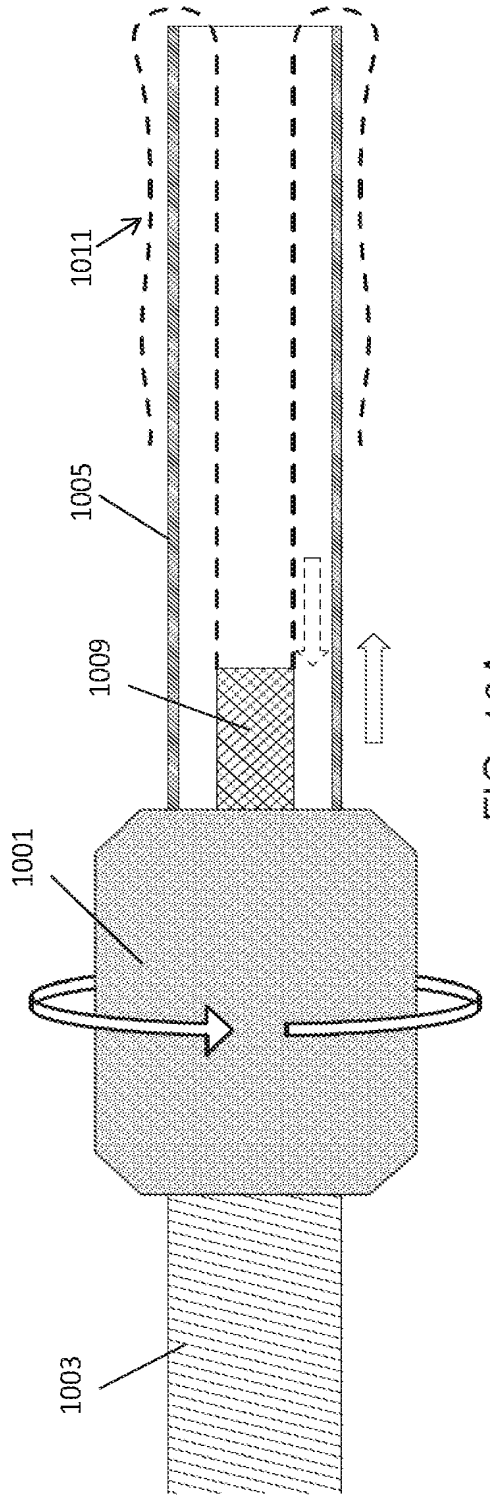


FIG. 10A

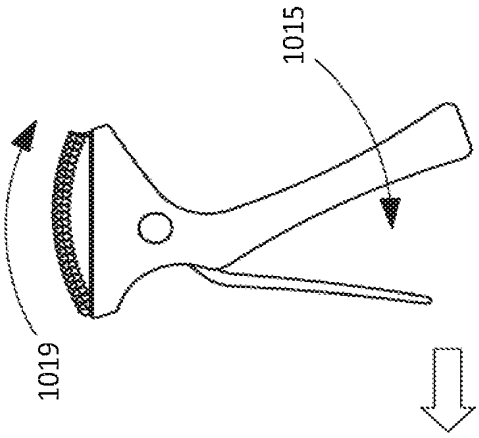


FIG. 10B

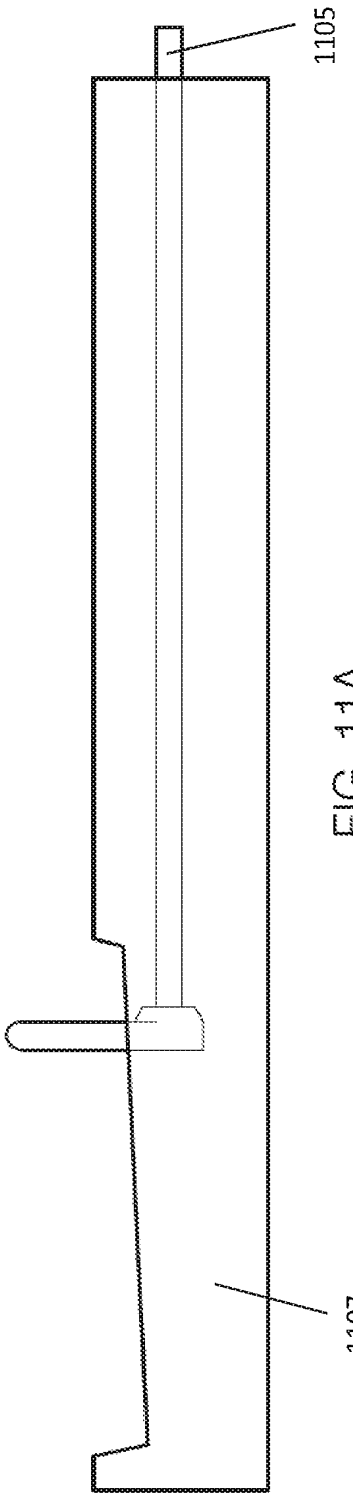


FIG. 11A

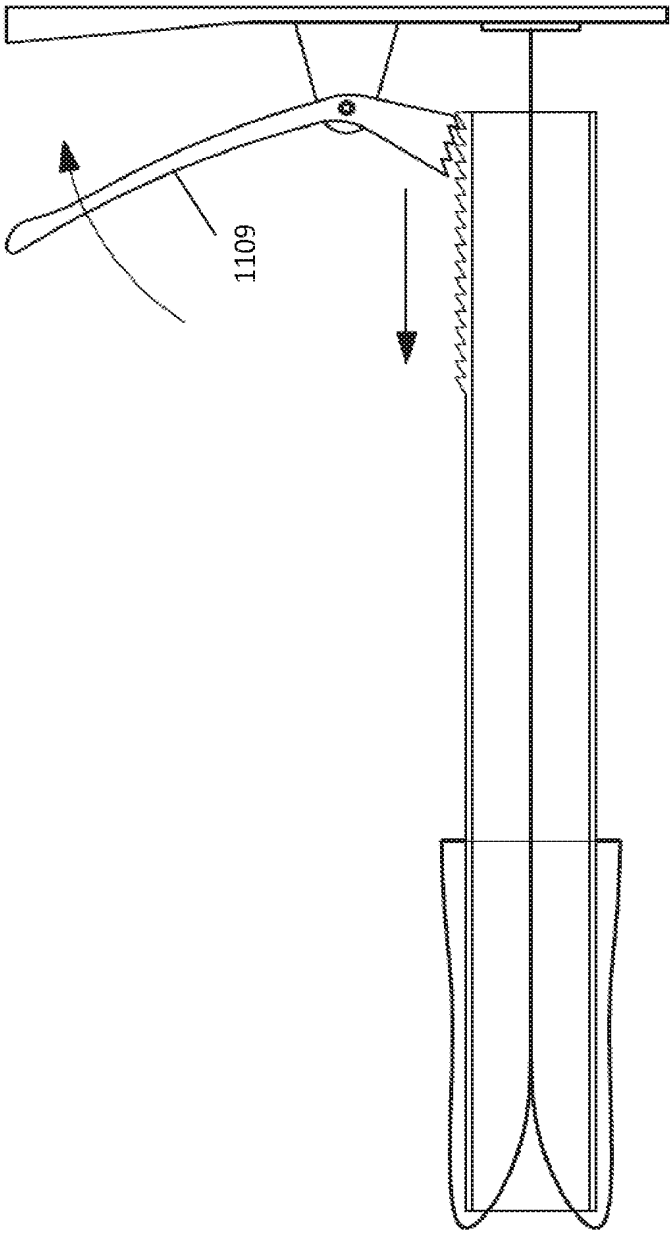


FIG. 11B

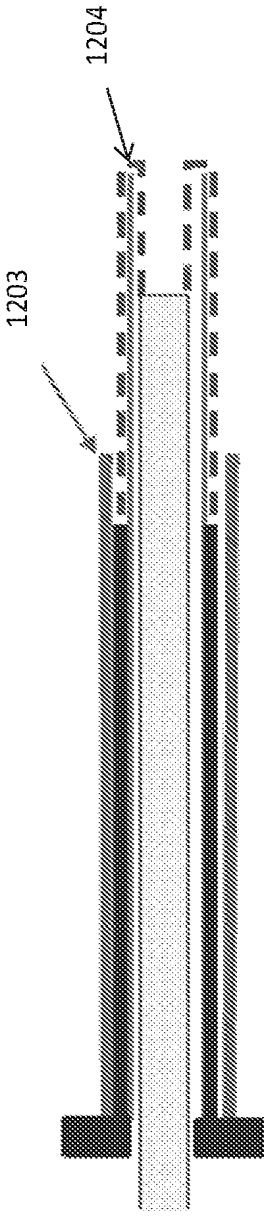


FIG. 12A

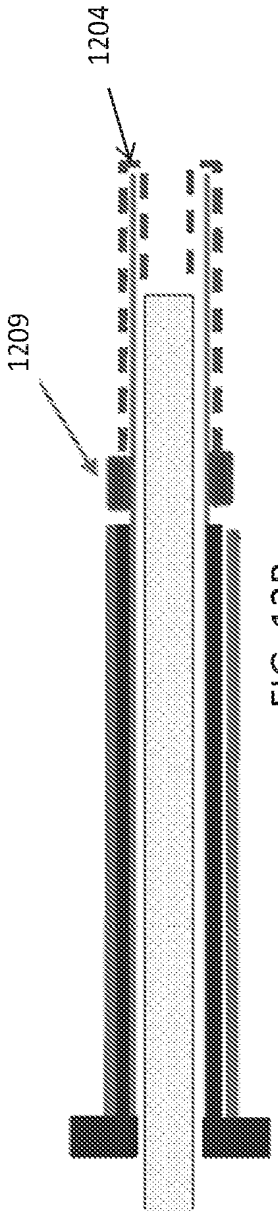


FIG. 12B

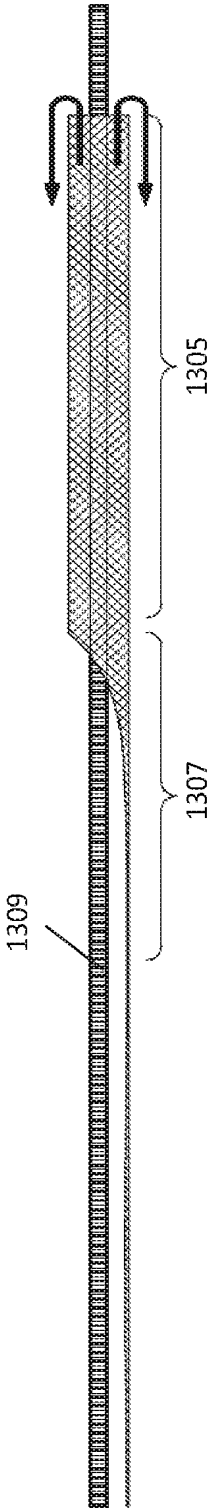


FIG. 13A

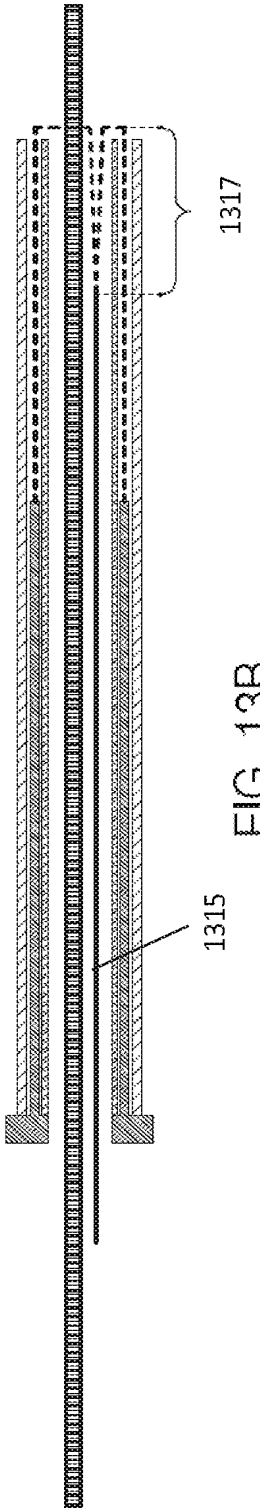


FIG. 13B

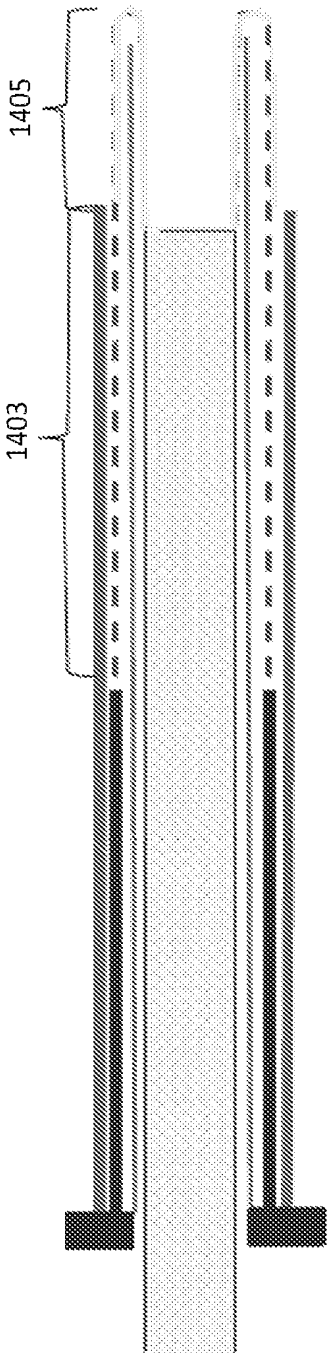


FIG. 14

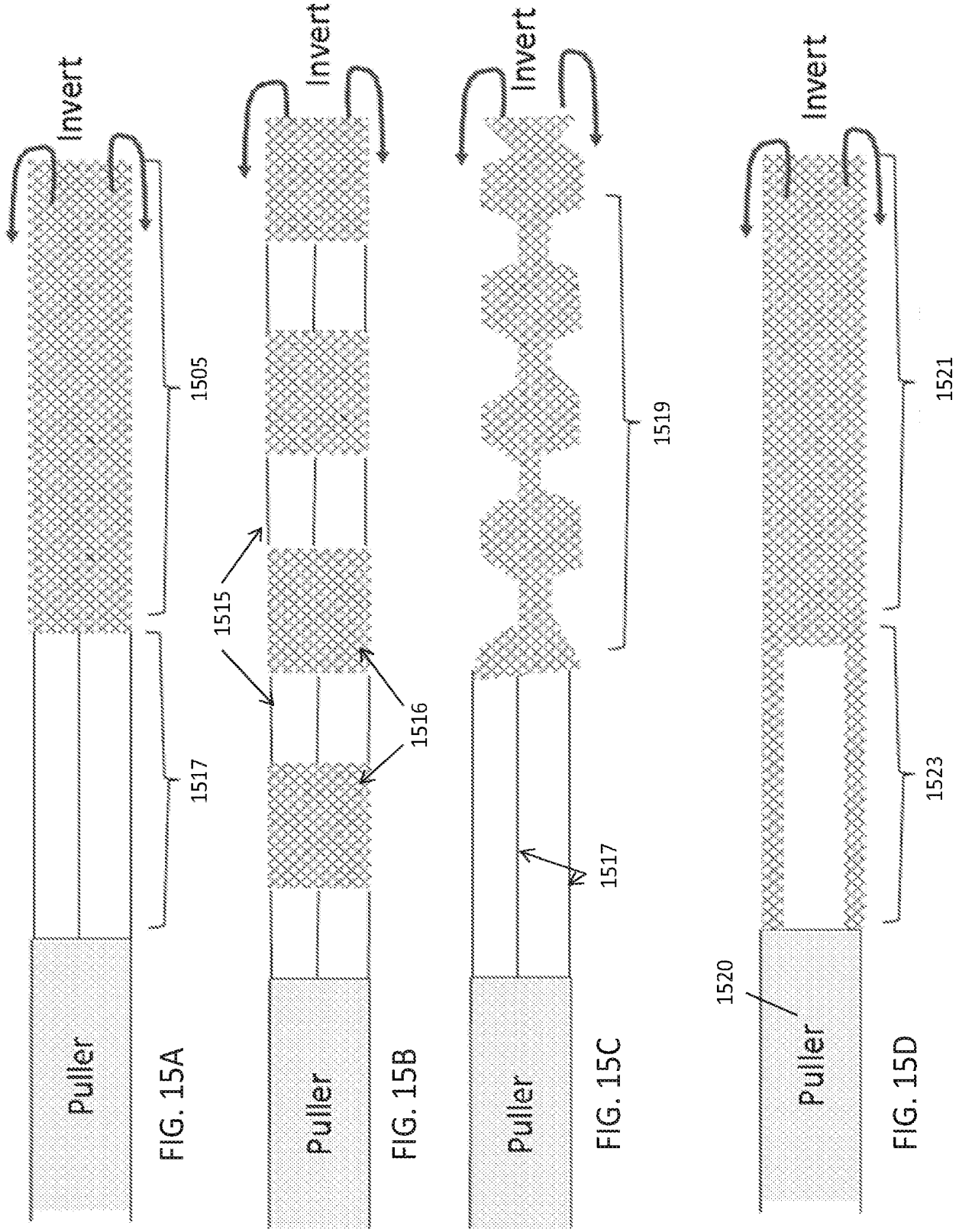


FIG. 15A FIG. 15B FIG. 15C FIG. 15D

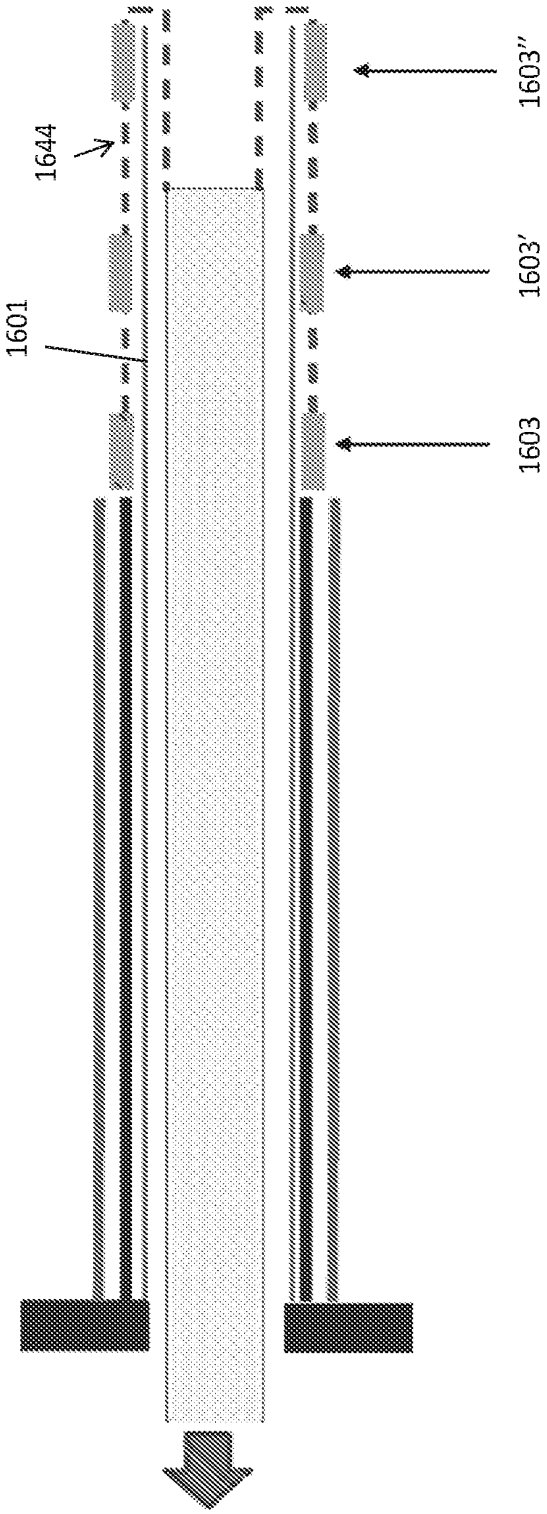

1644
1601
1603''
1603'
1603

FIG. 16

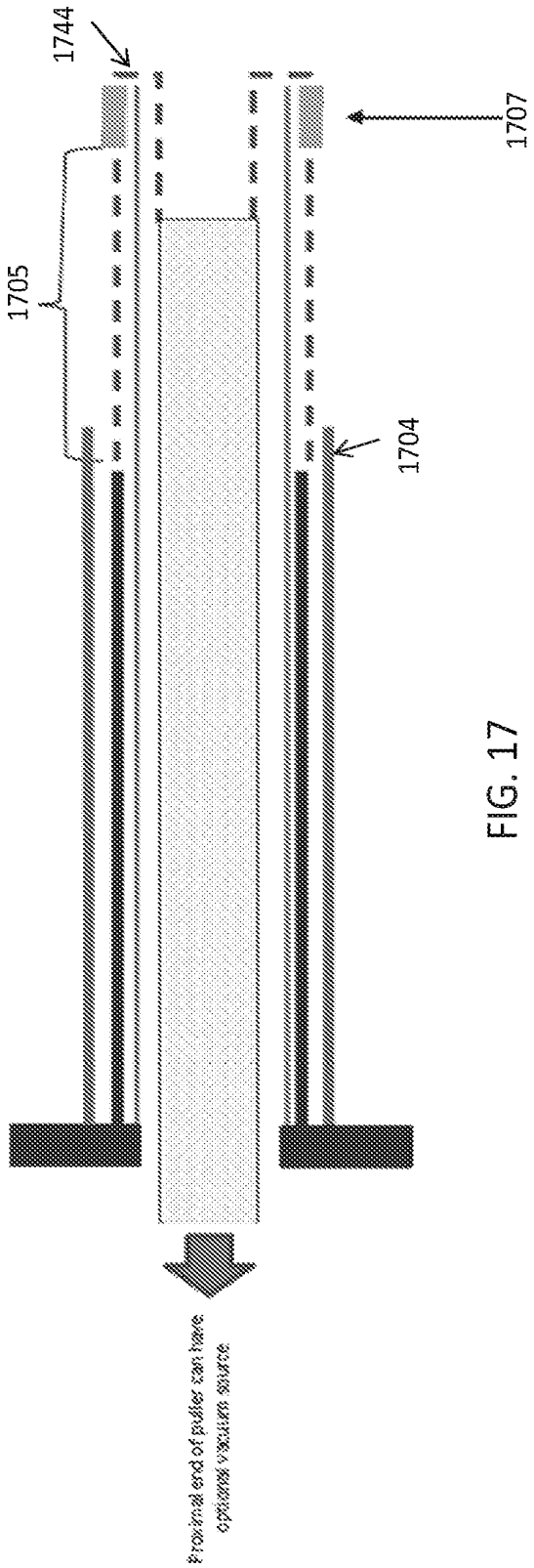

1744
1705
1707
1704
Proximal end of puller can have optional vacuum source

FIG. 17

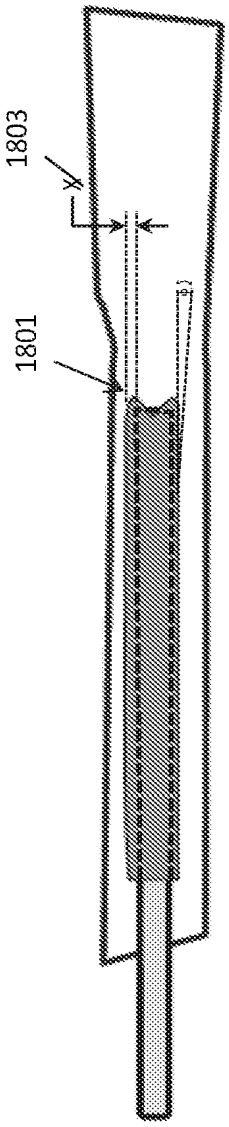


FIG. 18A

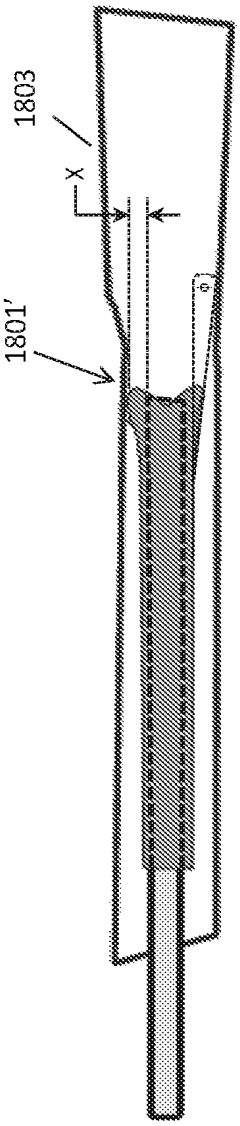


FIG. 18B

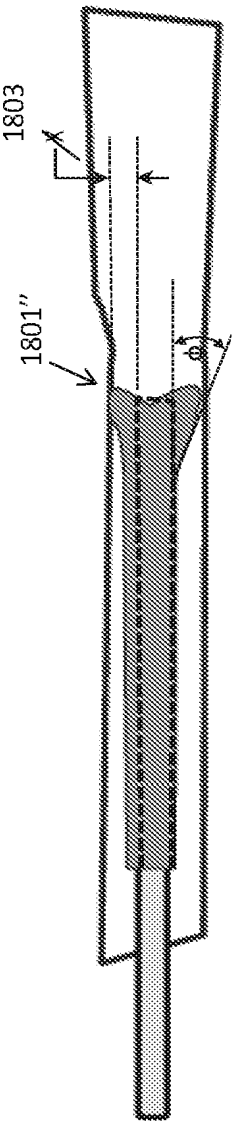


FIG. 18C

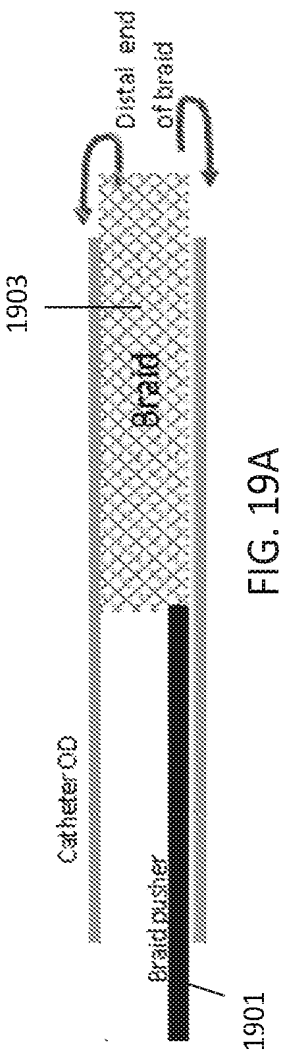


FIG. 19A

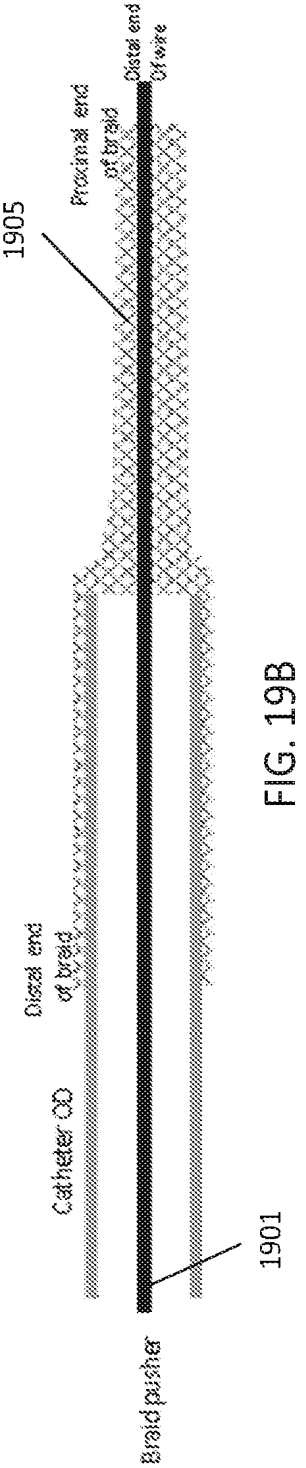


FIG. 19B

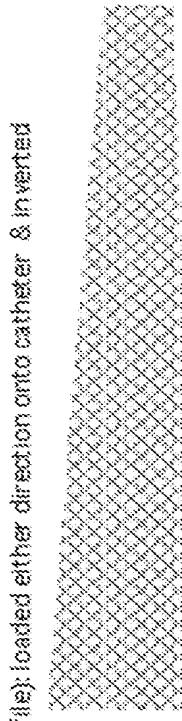


FIG. 20A

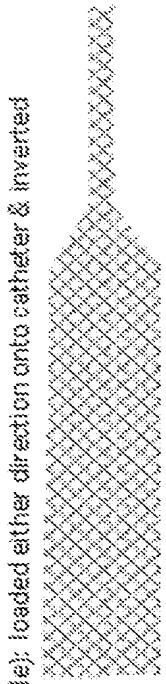


FIG. 20B

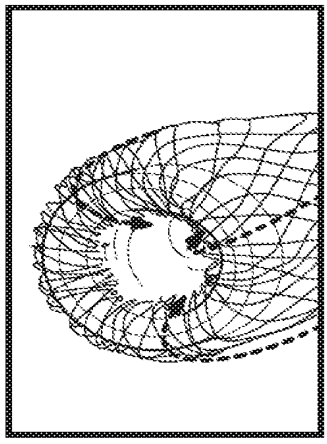


FIG. 21C

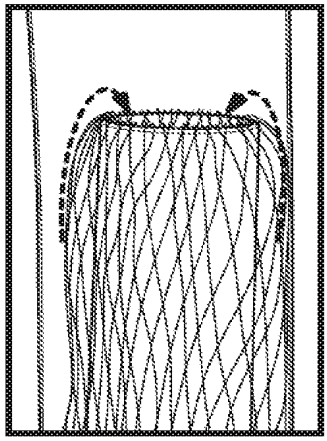


FIG. 21B

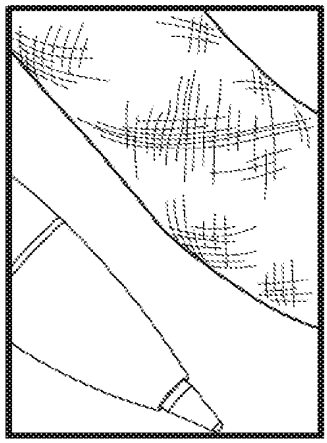


FIG. 21A

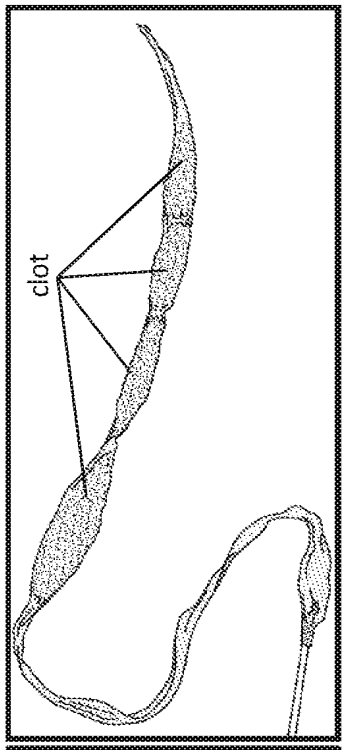


FIG. 22

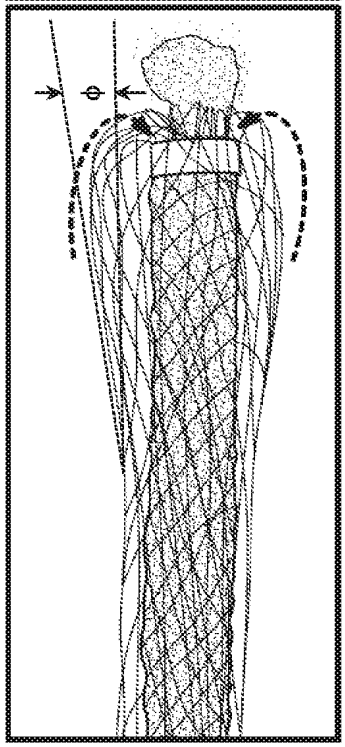


FIG. 21D

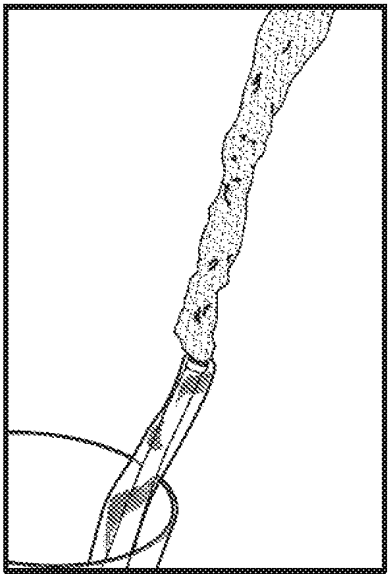


FIG.23B

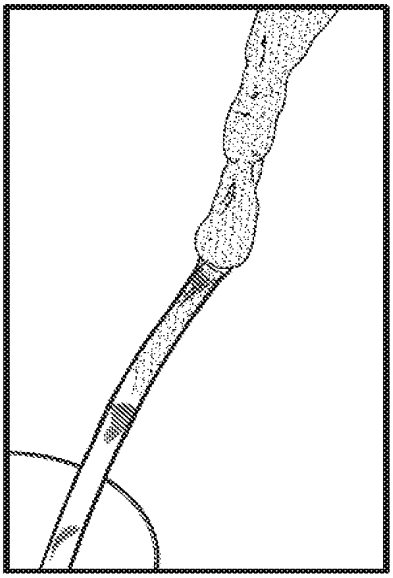


FIG. 23C

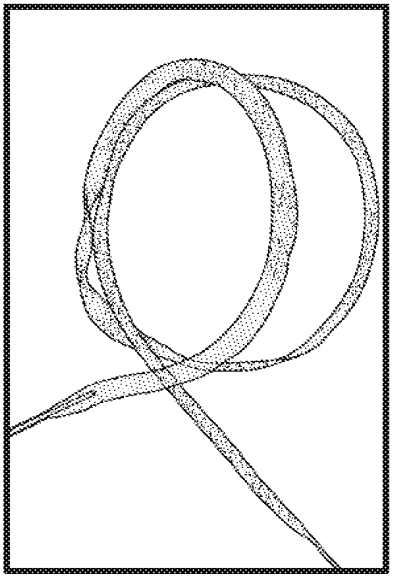


FIG.23E

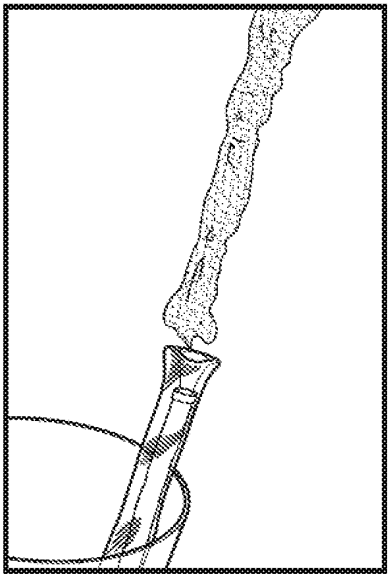


FIG.23A

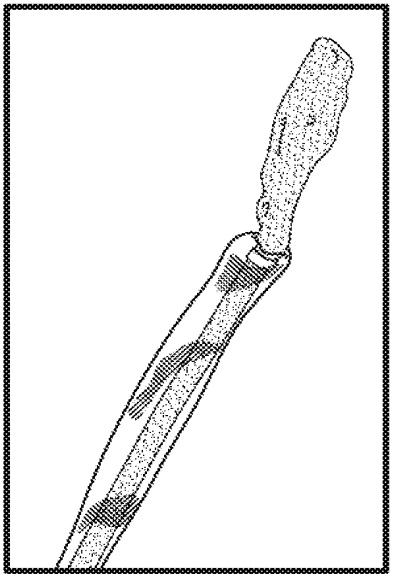


FIG.23D

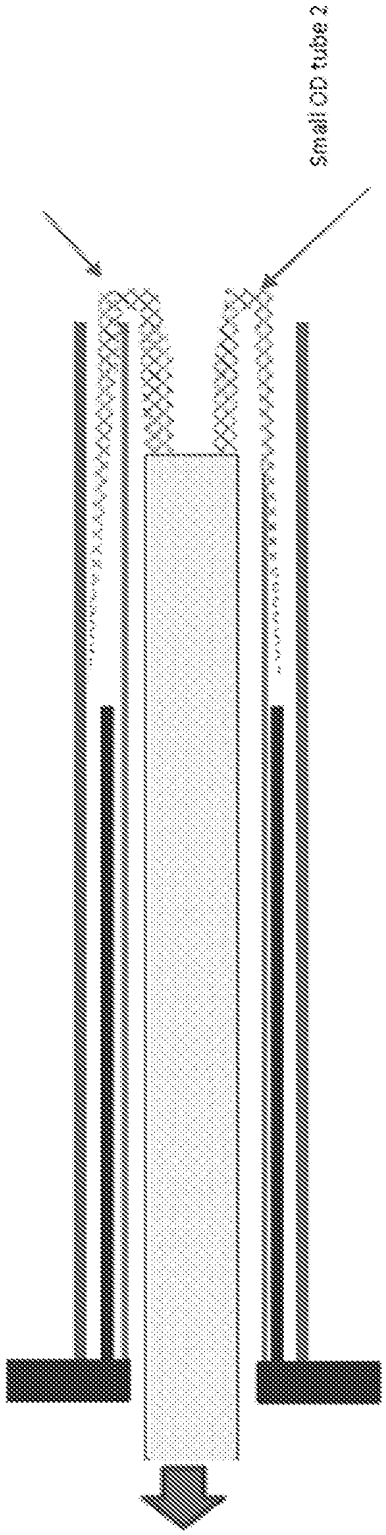


FIG. 24

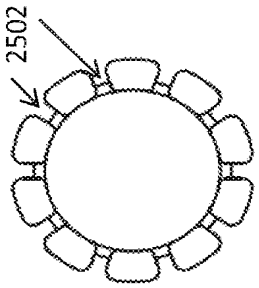


FIG. 25B

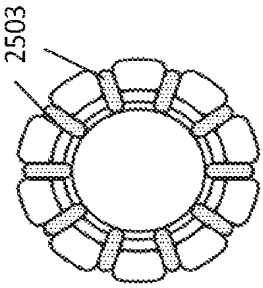


FIG. 25D

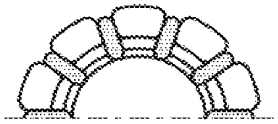


FIG. 25F

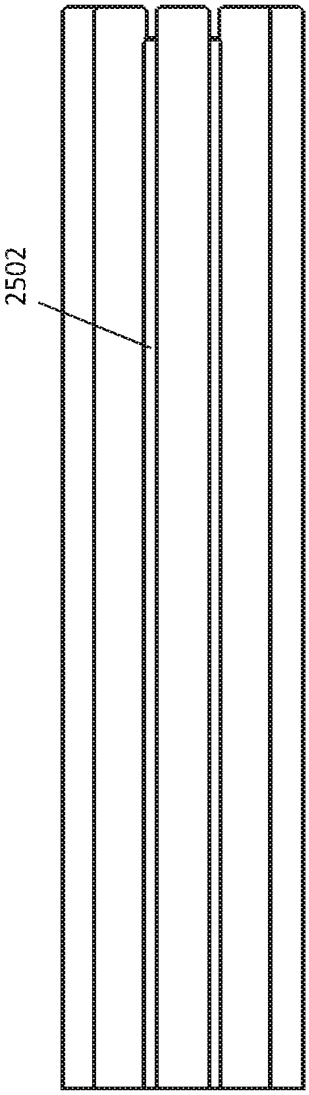


FIG. 25A

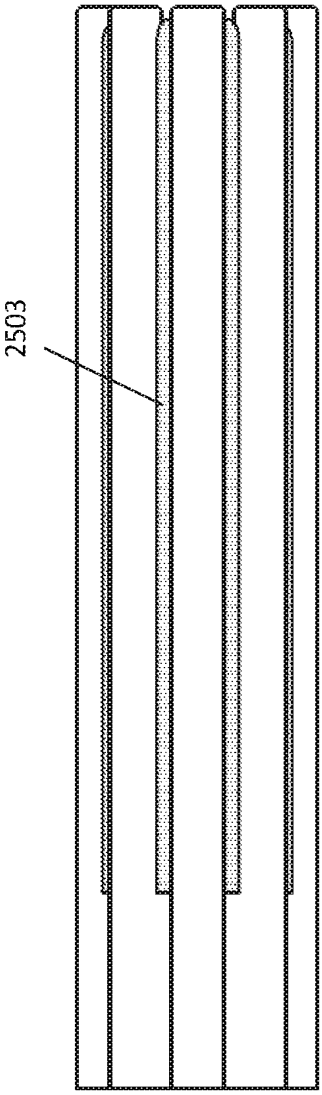


FIG. 25C

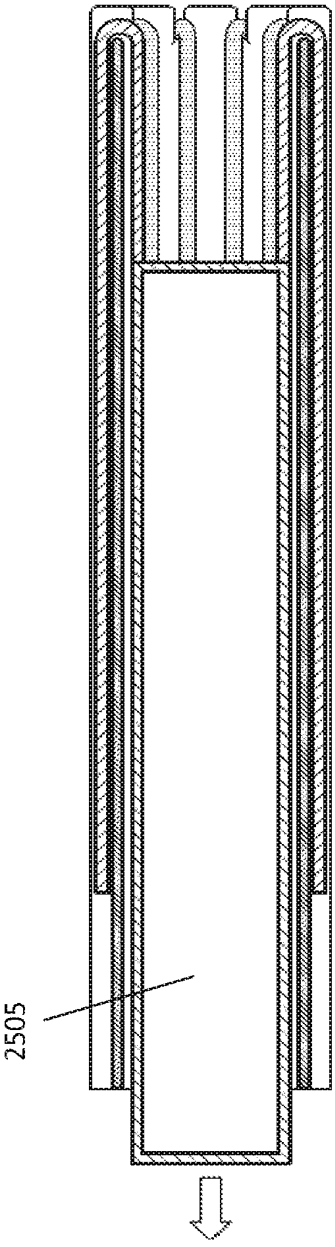


FIG. 25E

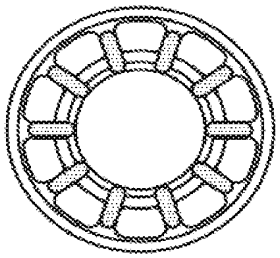


FIG. 26B

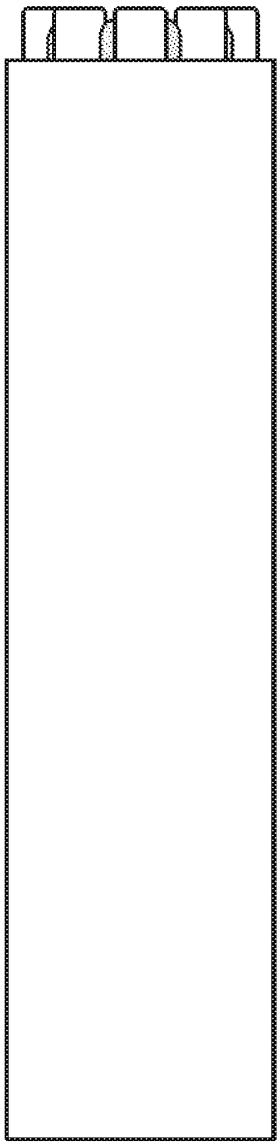


FIG. 26A

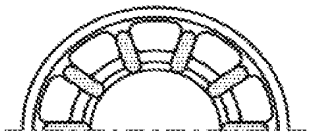


FIG. 27B

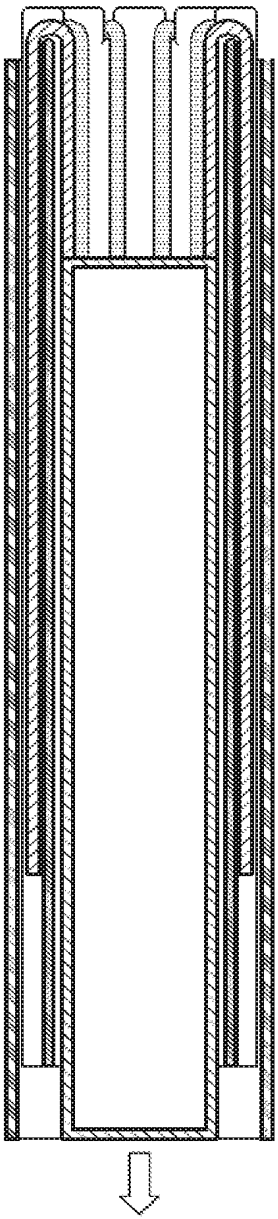


FIG. 27A

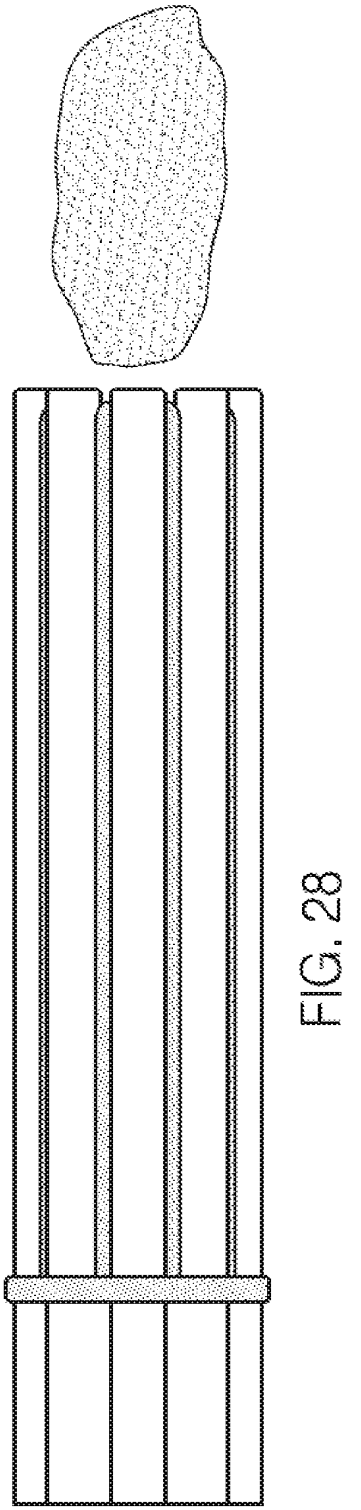


FIG. 28

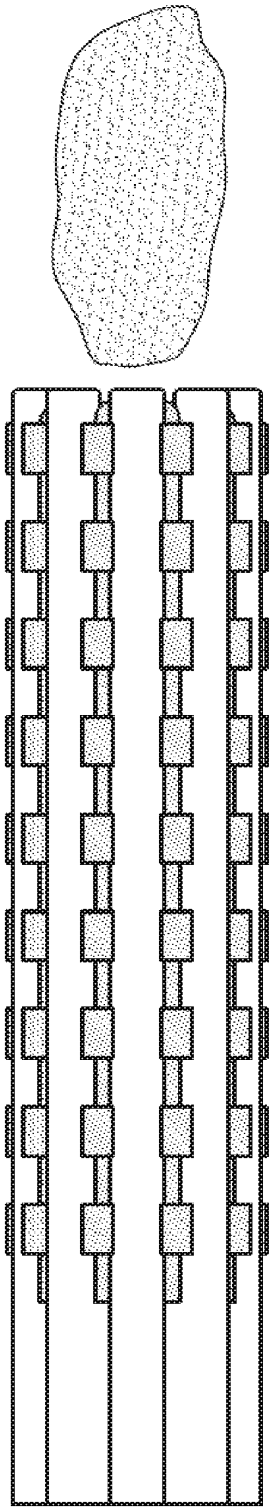


FIG. 29

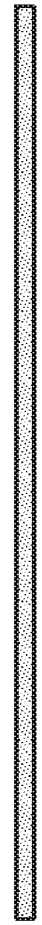


FIG. 30A

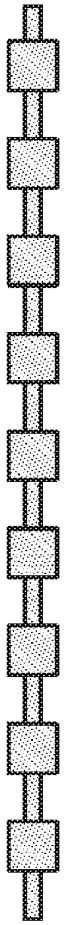


FIG. 30B

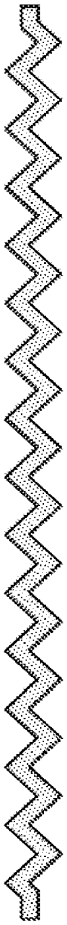


FIG. 30C

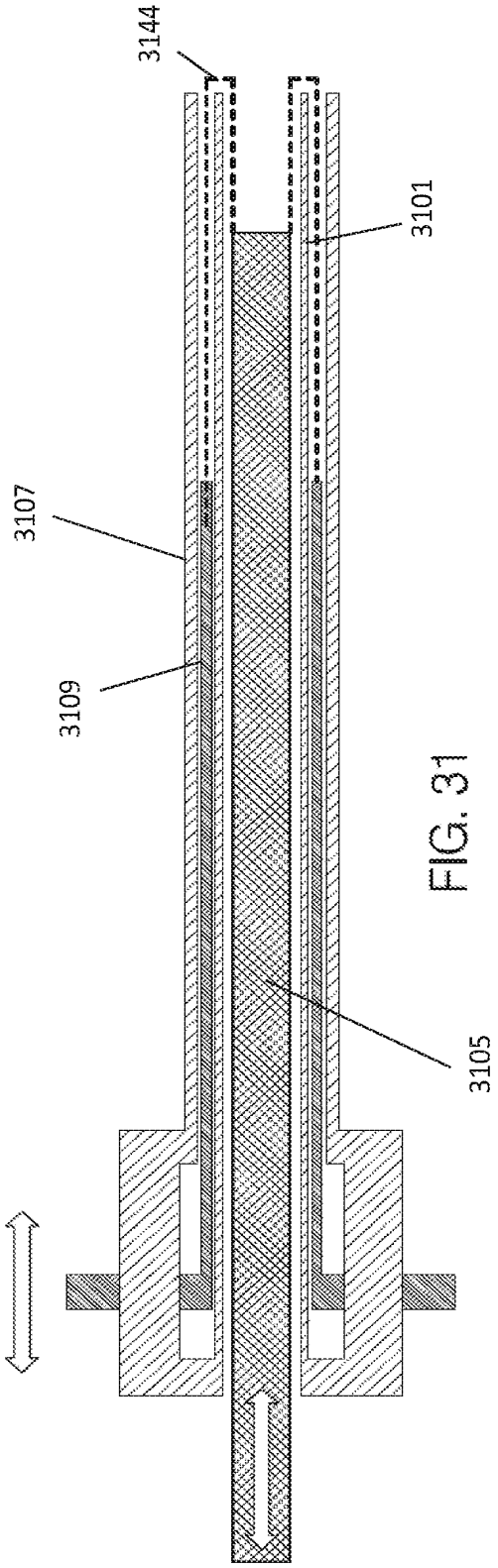


FIG. 31

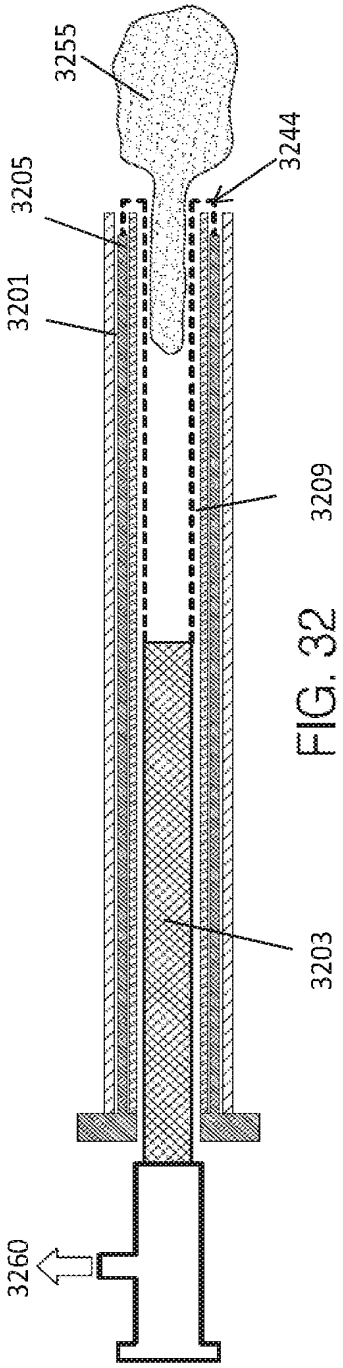


FIG. 32

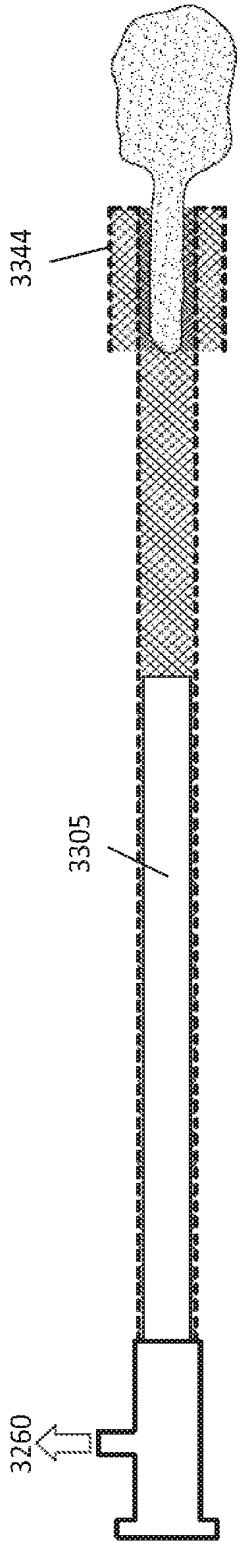


FIG. 33

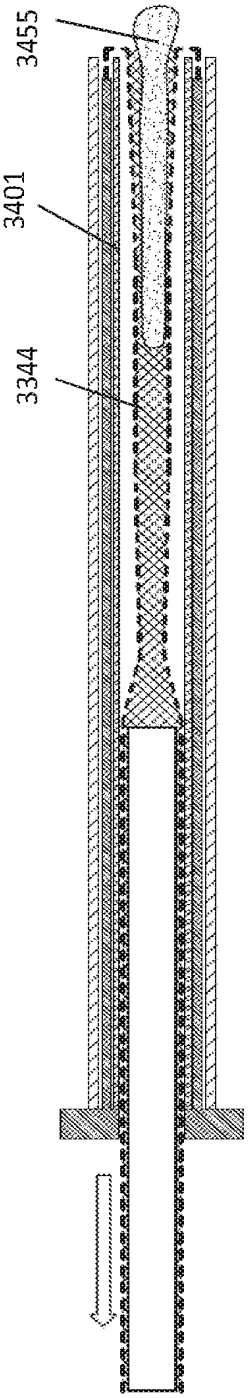


FIG. 34

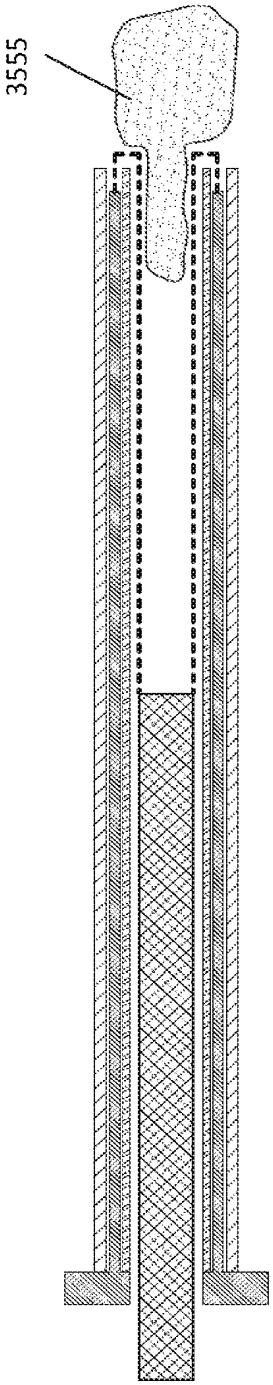


FIG. 35A

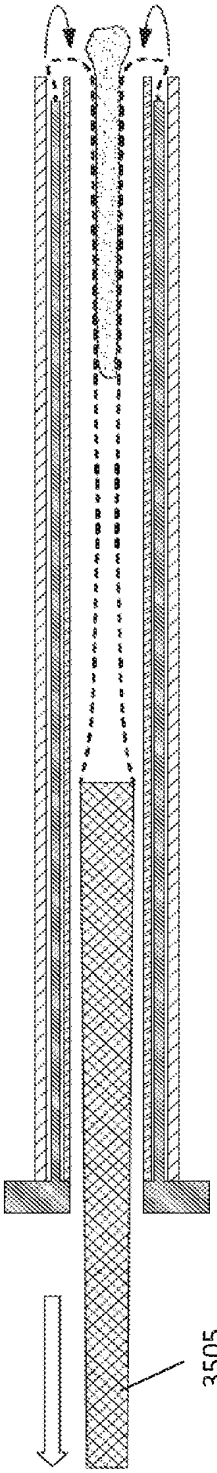


FIG. 35B

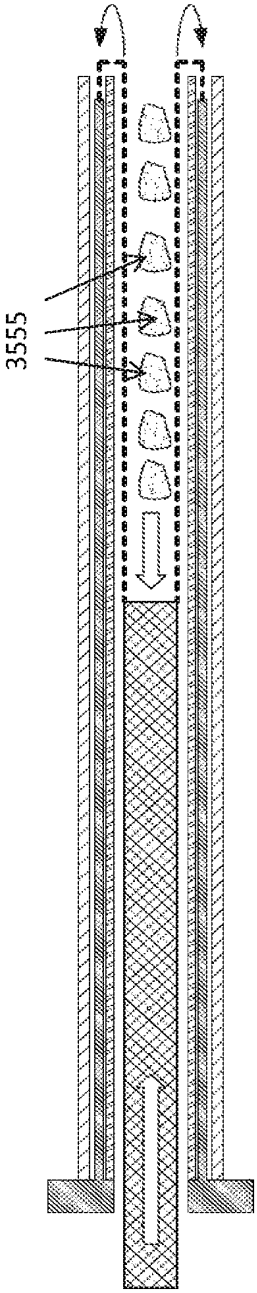


FIG. 35C

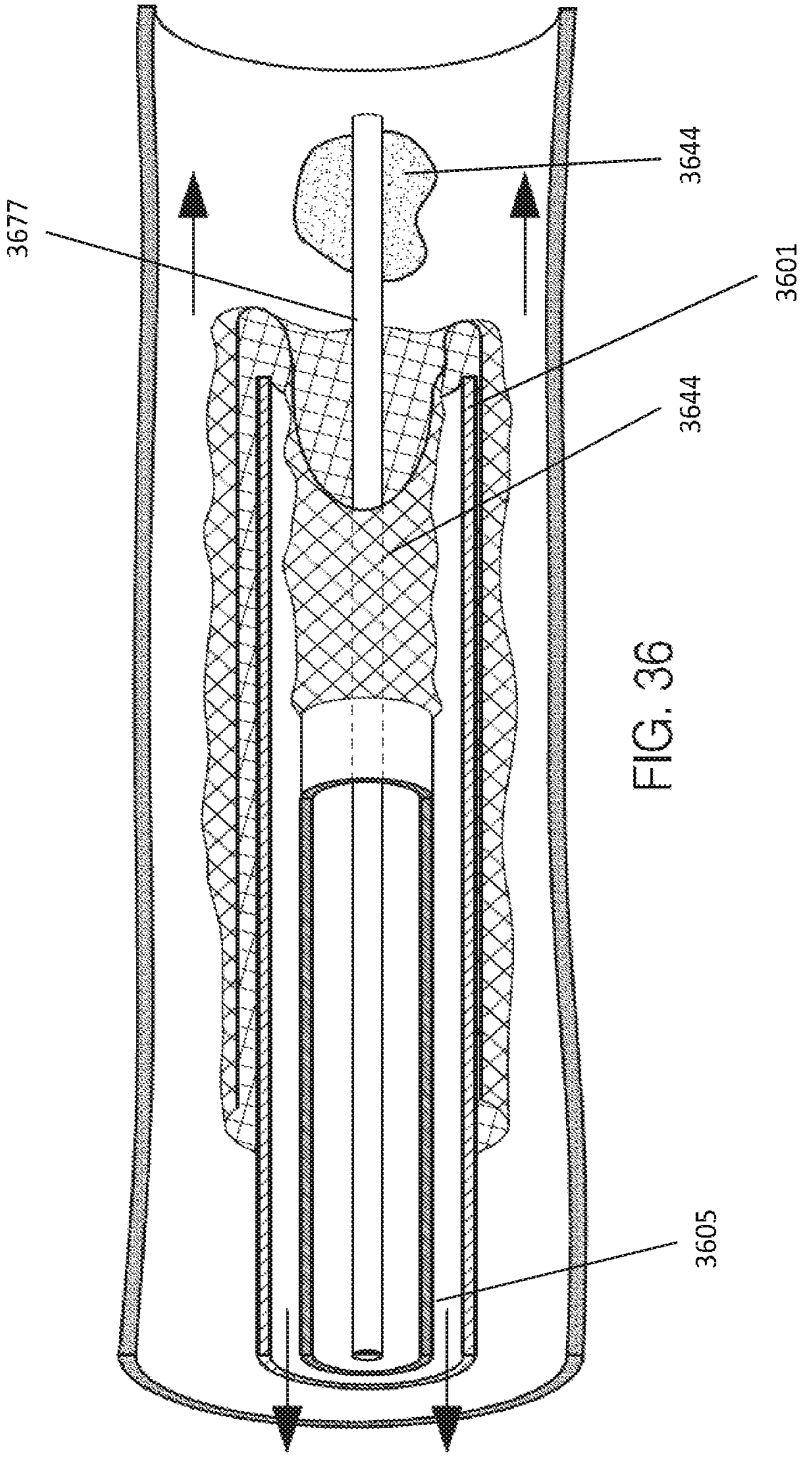


FIG. 36

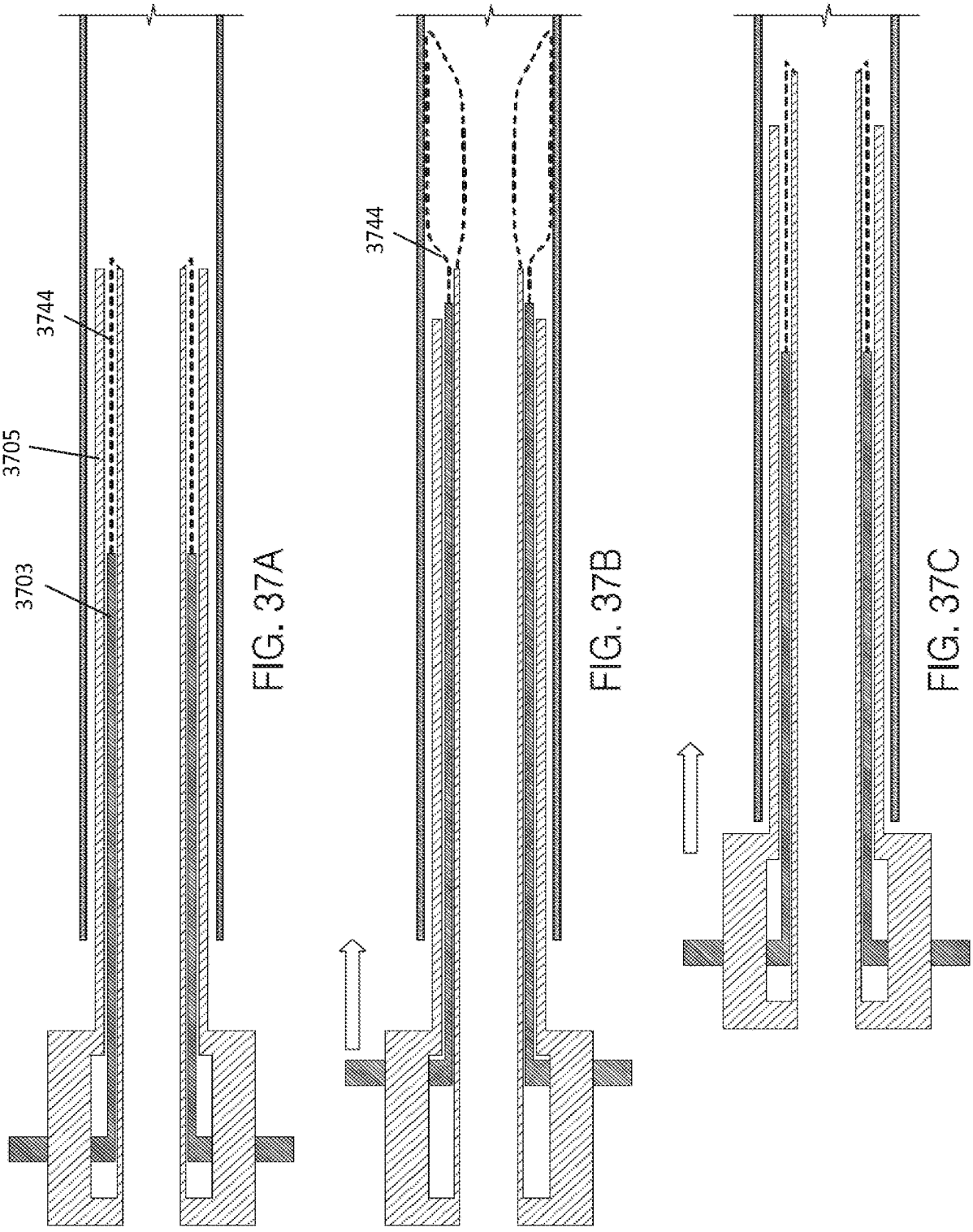


FIG. 37A

FIG. 37B

FIG. 37C

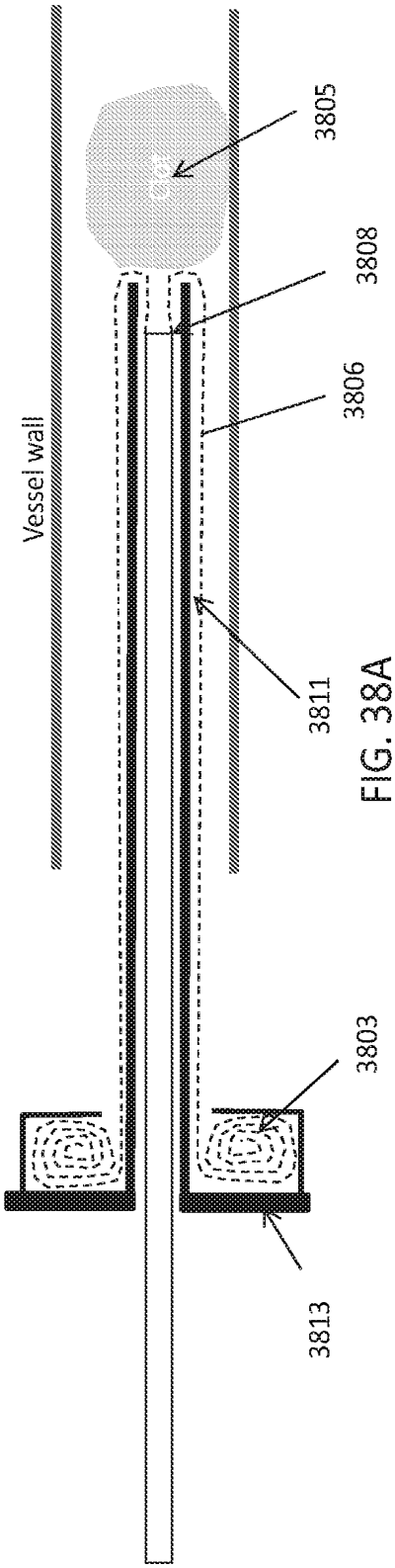


FIG. 38A

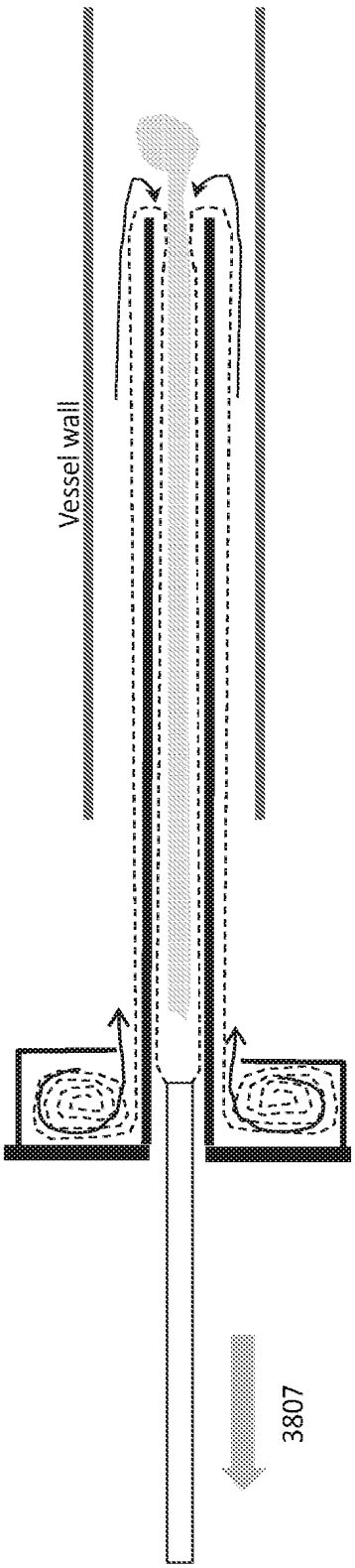


FIG. 38B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/17982

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/01 (2016.01)
CPC - A61B 17/221, A61F 2/01, A61B 2017/22038, A61B 2017/22079, A61B 2017/22081
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(8) - A61F 2/01 (2016.01)
CPC - A61B 17/221, A61F 2/01, A61B 2017/22038, A61B 2017/22079, A61B 2017/22081

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
(CPC) 606/200, 159, 127; (CPC) A61B 2017/221*; A61F 2/013, 2002/01*
(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);
Search Terms: thrombectomy, embolectomy, remov*, captur*, thromb*, clot*, emboli*, plaque*, invert*, inversion, evert*, intussuscept*, mesh, net, basket, smooth*, round*, edge, tip, end, stiff*, reinforc*, snag*, expand*,

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 2015/0005781 A1 (LUND-CLAUSEN et al.) 01 January 2015 (01.01.2015) Entire document, especially Abstract, para[0003], para[0036]- para0042] and FIGS. 1-3.	1-2 5-20, 23-28, 30-34 --- 3-4, 21-22, 29, 35-39, 74-76, 79-80 --- 77
Y -- A	US 2010/0249815 A1 (JANTZEN et al.) 30 September 2010 (30.09.2010) Entire document, especially Abstract, para[0029] and FIGS. 1-4.	3-4, 21-22, 29, 35-39, 74-76, 79-80 --- 77
Y	US 2006/0293696 A1 (FAHEY et al.) 28 December 2006 (28.12.2006) Entire document, especially Abstract, para[0018], para[0125]- para[0126].	36, 75
A	US 2013/0317589 A1 (MARTIN et al.) 28 November 2013 (28.11.2013) Entire document.	1-39, 74-77, 79-80
A	US 2010/0030256 A1 (DUBRUL et al.) 04 February 2010 (04.02.2010) Entire document.	1-39, 74-77, 79-80
A	US 2003/0083693 A1 (DANIEL et al.) 01 May 2003 (01.05.2003) Entire document.	1-39, 74-77, 79-80
A	US 2007/0149996 A1 (COUGHLIN) 28 June 2007 (28.06.2007) Entire document.	1-39, 74-77, 79-80
A	US 2007/0112374 A1 (PAUL et al.) 17 May 2007 (17.05.2007) Entire document.	1-39, 74-77, 79-80

☐ Further documents are listed in the continuation of Box C. ☐

* 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
26 April 2016	06 MAY 2016
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. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/17982

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.: 40-73, 78
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:

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.:

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.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
GWM-02-PCT2		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2017/029366	25 April 2017 (25-04-2017)	25 April 2016 (25-04-2016)
Applicant		
STRYKER CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

☒ the text is approved as submitted by the applicant

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

☒ the text is approved as submitted by the applicant

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 3a

☐ as suggested by the applicant

☐ as selected by this Authority, because the applicant failed to suggest a figure

☒ as selected by this Authority, because this figure better characterizes the invention

b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/029366

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.: 17-25
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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.:
1-16

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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/029366

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.
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 16	1,16
A	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1,16

☐ 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 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
29 June 2017	29/08/2017

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/US2017/029366

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

Form PCT/ISA/210 (patent family annex) (April 2005)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-16

A mechanical thrombectomy apparatus comprising: a catheter, a tractor, a puller and a tractor hold to secure an end of the tractor to an outside surface of the catheter until a force greater than a threshold force is applied by pulling the tractor proximally within the catheter.

---

2. claims: 26-31

A mechanical thrombectomy apparatus comprising: a catheter, a tractor, a puller and a guide wire lumen extending through the catheter, the puller and the tractor, and configured to pass a guide wire.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 17-25

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2017/029366	25.04.2017	25.04.2016

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/22 A61B17/221

Applicant
STRYKER CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Telephone No. +31 70 340-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☑ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 17-31

because:

☒ the said international application, or the said claims Nos. 17-31 relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 17-31

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☒ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-16

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-16
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-16
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The methods according to claims 17- 25 are methods of treatment of the living human or animal body by surgery.

The surgical methods claimed, at least implies the surgical step of positioning a distal end of the thrombectomy apparatus adjacent to the clot within the vessel.

Therefore, no preliminary international examination is required to the subject matter of these method claims (see Article 34(4) and Rule 67.1 PCT).

Re Item IV

Lack of unity of invention

This Authority considers that the application does not meet the requirements of unity of invention and that there are two inventions covered by the claims indicated as follows:

claims: 1-16

A mechanical thrombectomy apparatus comprising: a catheter, a tractor, a puller and a tractor hold to secure an end of the tractor to an outside surface of the catheter until a force greater than a threshold force is applied by pulling the tractor proximally within the catheter.

claims: 26-31

A mechanical thrombectomy apparatus comprising: a catheter, a tractor, a puller and a guide wire lumen extending through the catheter, the puller and the tractor, and configured to pass a guide wire.

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The common technical features of subject 1 and 2 is:

"A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

a catheter having a proximal end and a distal end and a distal end opening;

a tractor comprising 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, 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 puller coupled to the first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter".

These features are known from prior art document GB 2498349 A.

In particular, document GB 2498349 A (Figs.: 1- 3; page 8, line 12- page 11, line 5) discloses a mechanical thrombectomy apparatus for removing a clot from within a vessel, the apparatus comprising:

an elongate catheter (12) having a proximal end and a distal end and a distal end opening;

a tractor (14) comprising a flexible tube that extends within the catheter (12), inverts over the distal end opening of the catheter (12) and extends over the distal end of the catheter (12), wherein the tractor (14) is configured to invert by rolling over the distal end opening of the catheter (12) when a first end (16) of the tractor (14) is pulled proximally within the catheter (12); and

a puller (wire; 20) coupled to the first end (16) of the tractor (14), wherein the puller (20) extends within the catheter (12) to the proximal end of the catheter (12).

Therefore, the special technical features, in the sense of Rule 13.2 PCT, of the two subjects are:

for subject 1: that the mechanical thrombectomy apparatus further comprises comprises a tractor hold attached to an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor to an outside surface of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter, wherein the threshold force is between 50 g of force and 500 g of force; in order to provide a controlled positioning of the elongate catheter within the vessel.

for subject 2: that the mechanical thrombectomy apparatus further comprises comprises a guide wire lumen extending through the catheter, the puller and the tractor, and configured to pass a guide wire; in order to facilitate the navigation of the thrombectomy apparatus through the vessel.

It appears that between the different subjects mentioned, no same or corresponding special feature can be found apart from those already known from the prior art.

It is also submitted that the different subjects clearly intend to solve problems of different nature.

In conclusion, there is not technical relationship between the subjects identified, and thus, the above mentioned set of claims is not so linked by a general inventive concept.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC)

D2 WO 2012/009675 A2 (LAZARUS EFFECT, INC.)

2 Independent claim 1 and 16, positive opinion.

Document **D1** (Figs.: 1- 4; page 8, line 12- page 11, line 16) is regarded as being the prior art closest to the subject matter of claims 1 and 16, and discloses discloses a mechanical thrombectomy apparatus for removing a clot from within a vessel, the apparatus comprising:

an elongate catheter (12) having a proximal end and a distal end and a distal end opening;

a tractor (14) comprising a flexible tube that extends within the catheter (12), inverts over the distal end opening of the catheter (12) and extends over the distal end of the catheter (12), wherein the tractor (14) is configured to invert by rolling over the distal end opening of the catheter (12) when a first end (16) of the tractor (14) is pulled proximally within the catheter (12);

a puller (wire; 20) coupled to the first end (16) of the tractor (14), wherein the puller (20) extends within the catheter (12) to the proximal end of the catheter (12); and

tractor holding ties (30; Fig.: 4; page 11, lines 11- 16) attached on an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor holding ties (30) hold secures a second end of the tractor to an outside surface of the catheter until the are released by the surgeon by a couple of trigger wires.

The subject matter of claims 1 and 16 therefore differs from this known mechanical thrombectomy apparatus in that the tractor hold means is released by a pulling force applied to the tractor, of for example a value greater than between 50 g and 500g of force.

The problem to be solved by the present invention may be regarded as the need for a simpler and improved system of releasing the attachment between the tractor and the catheter.

The solution to the problem proposed in claims 1 and 16 of the present application is considered as involving an inventive step (Article 33(3) PCT) because the subject matter of claims 1 or 16 is neither taught nor suggested in the relevant prior art; nor detailed hints towards the specific combination of features can be seen to exist in the prior art.

3 Claim 2- 15 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII

Certain defects in the international application

4 Independent claims 1 and 16 are not in the two part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art **D1** being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

5 The features of claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

6 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in **D1** and **D2** is not mentioned in the description, nor are these documents identified therein.

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	**09/07/2022 01:36:11 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	Christina Flores
PATENT CENTER #	60942681	FILING DATE	07/14/2022
CUSTOMER #	25096	FIRST NAMED INVENTOR	Benjamin E. Merritt
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Matthew Williams

Documents

TOTAL DOCUMENTS: 100

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
JP2004097807.PDF	14	Foreign Reference	1635 KB
JP2005230132.PDF	16	Foreign Reference	1385 KB
JP2005323702.PDF	13	Foreign Reference	1049 KB
JP2006094876.PDF	15	Foreign Reference	1239 KB
JPH06190049.PDF	7	Foreign Reference	502 KB
WO1997017889.PDF	32	Foreign Reference	1215 KB
WO2000053120A1.PDF	54	Foreign Reference	7589 KB

WO2005046736A2.PDF	87	Foreign Reference	1215 KB
WO2006110186A2.PDF	88	Foreign Reference	1311 KB
WO2007092820A2.PDF	76	Foreign Reference	1656 KB
WO2009155571A1.PDF	33	Foreign Reference	712 KB
WO2010010545A1.PDF	193	Foreign Reference	7068 KB
WO2010023671A2.PDF	96	Foreign Reference	4358 KB
WO2010049121A2.PDF	36	Foreign Reference	1209 KB
WO2010102307A1.PDF	103	Foreign Reference	4276 KB
WO2011054531A2.PDF	42	Foreign Reference	1011 KB
WO2012065748A1.PDF	23	Foreign Reference	712 KB
WO2012009675.PDF	108	Foreign Reference	9044 KB
WO2014047650A1.PDF	41	Foreign Reference	1127 KB
WO2014081892A1.PDF	63	Foreign Reference	1819 KB
WO2015061365A1.PDF	39	Foreign Reference	1084 KB
WO2015006782A1.PDF	69	Foreign Reference	1770 KB
JP2011526820_WO2010003135-pto.PDF	79	Foreign Reference	9108 KB
JP2001522631_WO9923958.PDF	79	Foreign Reference	10274 KB
WO2010002549A2.PDF	40	Foreign Reference	954 KB
WO2004018916A1.PDF	30	Foreign Reference	943 KB

WO2020036809A1.PDF	95	Foreign Reference	1959 KB
WO2021127202A1.PDF	66	Foreign Reference	2118 KB
CN1083483198.PDF	117	Foreign Reference	2099 KB
CN111281482A.PDF	117	Foreign Reference	2627 KB
CN103764049A.PDF	92	Foreign Reference	13655 KB
CN104068910A.PDF	11	Foreign Reference	1440 KB
CN102186427B.PDF	29	Foreign Reference	5208 KB
WO2015189354A1.PDF	76	Foreign Reference	2491 KB
WO0202162A2.PDF	75	Foreign Reference	1288 KB
EP1254634B1.PDF	10	Foreign Reference	292 KB
WO2019222117A1.PDF	61	Foreign Reference	2167 KB
GB2498349.PDF	17	Foreign Reference	1660 KB
WO0032118A1.PDF	46	Foreign Reference	973 KB
WO2017058280A1.PDF	91	Foreign Reference	3454 KB
WO2012049652A1.PDF	38	Foreign Reference	860 KB
WO2017189535A2.PDF	104	Foreign Reference	2722 KB
WO2017189550A1.PDF	61	Foreign Reference	1119 KB
WO2017189591A1.PDF	46	Foreign Reference	862 KB
WO2017189615A1.PDF	54	Foreign Reference	1021 KB
WO2017210487A1.PDF	50	Foreign Reference	1192 KB

GB1588072.PDF	14	Foreign Reference	2292 KB
AU2015210338B2.PDF	43	Foreign Reference	1398 KB
WO2018049317A1.PDF	78	Foreign Reference	2847 KB
WO2019010318A1.PDF	83	Foreign Reference	3172 KB
WO2019094456A1.PDF	122	Foreign Reference	4368 KB
WO2012162437A1.PDF	64	Foreign Reference	2873 KB
WO2009086482A1.PDF	91	Foreign Reference	5354 KB
WO9839053A1.PDF	69	Foreign Reference	2562 KB
WO9833443A1.PDF	35	Foreign Reference	1291 KB
WO9851237A1.PDF	35	Foreign Reference	1336 KB
WO2009082513.PDF	51	Foreign Reference	2325 KB
WO2018148174.PDF	239	Foreign Reference	12620 KB
WO2021248042.PDF	42	Foreign Reference	1792 KB
WO2021076954.PDF	39	Foreign Reference	1699 KB
WO2011073176.PDF	23	Foreign Reference	879 KB
WO2021067134.PDF	36	Foreign Reference	1557 KB
WO2022032173.PDF	75	Foreign Reference	2829 KB
CN110652645.PDF	26	Foreign Reference	11919 KB
WO2019246240A1.PDF	49	Foreign Reference	2678 KB
JP07323090.PDF	36	Foreign Reference	189 KB

WO2022103848.PDF	46	Foreign Reference	1904 KB
WO2022109021.PDF	38	Foreign Reference	1605 KB
WO2022109034.PDF	44	Foreign Reference	2231 KB
NPL_EESR_201915816_Mar_31_2021_11pages.PDF	11	Non Patent Literature	9908 KB
NPL_ISR_WO_PCTUS2055645_April_14_2021_12pages_uspto.PDF	12	Non Patent Literature	933 KB
NPL_EESR_188534655_May-7-2021-7-pages.PDF	7	Non Patent Literature	4761 KB
NPL_Vorwerk_Temporary_Caval.PDF	4	Non Patent Literature	2561 KB
NPL_ISR_WO_PCTUS2014854_Oct_5_2020.PDF	11	Non Patent Literature	1094 KB
NPL_ISR_WO_PCTUS2018655_Dec_16_2020.PDF	20	Non Patent Literature	1996 KB
NPL_ISR_WO_PCTUS2017684_Nov_30_2020.PDF	17	Non Patent Literature	1601 KB
NPL_EESR_201850922_Sep_11_2020.PDF	6	Non Patent Literature	495 KB
NPL_EER_187457940_July_20_2020.PDF	4	Non Patent Literature	272 KB
NPL_Wikipedia_Embolectomy.PDF	4	Non Patent Literature	253 KB
NPL_OSullivan_Thombolysis.PDF	8	Non Patent Literature	675 KB

NPL_Capture_Vascular_Systems.PDF	1	Non Patent Literature	77 KB
NPL_Edwards_Fogarty.PDF	1	Non Patent Literature	58 KB
NPL_Boston-Scientific_Fetch2.PDF	2	Non Patent Literature	2174 KB
NPL_Penumbra_Indigo_System.PDF	7	Non Patent Literature	389 KB
NPL_YouTube_Merci.PDF	1	Non Patent Literature	822 KB
NPL_Covidien_Solitaire.PDF	6	Non Patent Literature	939 KB
NPL_ISR_WO_PCTUS1950467_Dec_18_2019.PDF	16	Non Patent Literature	1625 KB
NPL_ISR_WO_PCTUS1729440_July_7_2017.PDF	14	Non Patent Literature	1261 KB
NPL_ISR_WO_PCTUS1729472_July_7_2017.PDF	15	Non Patent Literature	1391 KB
NPL_ISR_WO_PCTUS1735543_Aug_14_2017.PDF	11	Non Patent Literature	1042 KB
NPL_ISR_WO_PCTUS1729366_Aug_29_2017.PDF	16	Non Patent Literature	1415 KB
NPL_ISR_WO_PCTUS1750933.PDF	13	Non Patent Literature	1219 KB
NPL_ISR_WO_PCTUS1729345_2-28-2018.PDF	23	Non Patent Literature	2255 KB
NPL_EESR_168522126_Aug_22_2018.PDF	6	Non Patent Literature	467 KB
NPL_EESR_181748914_Oct	6	Non Patent Literature	521 KB

_5_2018.PDF			
NPL_ISR_WO_PCTUS18409 37_Nov_14_2018.PDF	15	Non Patent Literature	1412 KB
NPL_ISR_WO_PCTUS18596 07_Mar_28_2019.PDF	23	Non Patent Literature	2687 KB
NPL_ISR_WO_PCTUS16179 82_May_6_2016.PDF	14	Non Patent Literature	2558 KB
NPL_ISR_WO_PCTUS19326 01_July_23_2019.PDF	14	Non Patent Literature	1474 KB
IDS SB08 - 111552-8016US4.pdf	30	Information Disclosure Statement (IDS) Form (SB08)	364 KB

Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
JP2004097807.PDF	7747540CA12BCDF1AC92800C9735D6688106F1D13C768D171 DD5B1A62902ABC24119A68BE288758353836E823E865BB4E70 E3A805782A581F444344ADB4597FC
JP2005230132.PDF	C7AC8CE5106B77C8D04CC7494A3701C7D53493317B573F470 8F690C1E8BD1FD36D802E5C0B254DED74A484DA29B4EC3E4 B84E5B9443C8BF8EC070510881B79AC
JP2005323702.PDF	AF201BE1056B119A5DA8E97C989E9E6AB48F14F3ED96551CE A34AEE252BBC5E9C480189A00DE6A47E8A54ECE4E4B046DD 45E9CCD1A606244E7016E4F1F242067
JP2006094876.PDF	C811BB9102BBAF1456D3321FCBA1E093664538AD36DA7C121 790745BD1E625AC8A3083B115E5FFFA446F0E57B565C7F11B5

	CFE44EC587BAF5886DE95292C34BF
JPH06190049.PDF	C9DEFF6FB632C1B1C29468A474A0CA48D9460424ED7E02CB542E000843D7F6EE0ED558F8E0486212EC4DC9DF402B31603DDE83746BAA81EFC086B4141E1D7975
WO1997017889.PDF	4C3E0AC6276C4B5E1976557EE0EE567B2AD044AF2A665764AE563842C9AC92DC5902B5FB03EE8DCCC1009677FC51F4D2F76590B8EF4BDEE3AF8E83AC0971C88D
WO2000053120A1.PDF	AF8B62F32E4D70FA684515293ED3B439ADEF2A993470C1D983691B248D363D516B97DC5EB467F713AD15FC50E62CF429CBD8E796981CA71926F506AAAC872FDA
WO2005046736A2.PDF	F60EF1F61D22BD14502ECCCB30A9032C72F8111629CE9CE13D54C731F8A8D84FEABFF1982AE7F03BDC946A1ED1B27797FB61D54021E0D21B5160A779F1FA072A
WO2006110186A2.PDF	BFF386025DF219AD9DC0ABC33B9D68B4A701D951207B7E0072EBC7E9E56D07E08E2A6ED692F3E73C4F46DA2866AF80A48BA703FB7D28FE53AC9214986E49978C
WO2007092820A2.PDF	4022087F50AAB157D5E5BFD766EF3DC4A919DADB69A9C1B2FC423E2BA952C5A274D960897651889A7BE2AB9A02462399C94212849C298FCCA1BB398B55962783
WO2009155571A1.PDF	C7A5E759315553F4A7D453734DF6E3EA56DCE73FCB9C1A2D07D143A0EF3A42AE7D1980653F3EE738F6D09A8BC4E01E44D37E1541278B79587AEFF3281B434382
WO2010010545A1.PDF	557D76F8586BCA5CB7B169DDAFFF7118DBFB8305EEAECD6D1BAB3B0ACC8C37B61561C6CFA57287728EC230A906ECBD6D665A6B507DCD2FD186E0D209678A2E95
WO2010023671A2.PDF	E028392A66370F23D7A90D158A0B3BAD9DE214EB31AD721F1F29DC93671570C9556CC0EFD98D3CACB4888F06E671AA866B958630900690 4B66C0AD933E2BADE5
WO2010049121A2.PDF	D53C10B13BB5D9083B084B44A11B794D481B61F631E6A19DF9BD14B5CD35460B05B25819CE58F278FB09B3BE8261EBFD7C

	DF42E61E963D387EC5586BCBC60576
WO2010102307A1.PDF	82CCD6DD2A4DF7FBC84707A826B778D90C6F604F46C15EBC79486DE730121F0BFDB07065DC68A94F1A08B526E3385CB0E777FC24498B1E6A1FA9884B5002F3EE
WO2011054531A2.PDF	6ED9E7B1643644F584DCC373A9F777D4433DC935FDBD5D66500CE41DEC0DE0211640A1F55295E6712AD8E97DA5BD1B7F42117F37CD064D41941F8C94B940711D
WO2012065748A1.PDF	FBFCC6018B1C8A00F9D73D641829D814385C9B9942E01A7FCAFB40B86018C76215A793968798FB8F3D83955422F401AA031F4A54F111EA3AE3B4F099E6786040
WO2012009675.PDF	94E662779927E29CC83B0CAF2A1C47396C9061DADDDB7AE4D0704FE54F22B5B9FCB50A66CB8F65E25EDF55B62FF196AE215B144B84773A41FCEA69EF99F1648C
WO2014047650A1.PDF	E37B47E87912AD0B8A29E8FAF817E70B87570906E4B5D52079173A0AF9F3262B83B25F22D88F38B5B4A7D037EED01A9CCAF832039CD67190D4817E7C465A0D05
WO2014081892A1.PDF	8E3796041E264B439CF5A295CBAC75031354FF84F0402B939DBBF86E5D2F7A1DA0F807EB0CE9957FE6EF0025D5F1D6B937E18BDA6ADB1E4967CC9D6739B46B15
WO2015061365A1.PDF	371DAA188F6E95C2987DCC1A4F123EC44986A504A805BFA5AFE5834686BD51E8AF54D4886097DAB25E156F46D25E34D2FBF0D58F1CDD4F932E176590D64B3288
WO2015006782A1.PDF	DD6F4A3B757F4ED6A2D88D0AF3C3DB6EE1D8A1E71D82ABB472F7BB4D65CC8331871F1F3DF5494CEDE9A6619087DDB93A4FF220984B0994706EDFB75E9A4E75E0
JP2011526820_WO2010003135-pto.PDF	E976B15AEC16031CDAE6FAB5FC9D4737E8C6A626D2482C3CDE9C0186D65FB5B5382A65E29F3834836F38B706EA1B2C3475C08ED8ABDF1E36955E194B5D59029F
JP2001522631_WO9923958.PDF	E92251F4009D5CC9C7C79BA0BBAAF89C0E2E72AF30056D92DF4189CB8E6A50DA9C1B7AFC3819371DD208BAF8CD91E37E

	940E341F68E4E7AF514AEC67D68D77BE
WO2010002549A2.PDF	8E4E350AE7B59B20500EFA3C55DEF0515B059924D368D86DC2E3C0763B80A66EA88E1D926A0ACD4425C483CC2CB69E8231FFFDBFD19ACA6333842CC53106778A
WO2004018916A1.PDF	16BCAC80EFD5B4726C6583B88EFB36730045E5A82FB14028F9128ABB54D198A00E85BA2C04B0BF59132C36575EF7A7C0524650AC40FAA67726A1CAF5C8EF1029
WO2020036809A1.PDF	FCA87D5381CBCA12ED734078597E59D524DAA3FD9565BEEE4A9EF63233D33C498B3D24A402E370CCF9907B45377E3223528F965DACCF6DA44B01363DC2EB7B5F
WO2021127202A1.PDF	E2BEF569935400DE57872753D210B6AE04C1C6BA1CCD25EFD57F12A80D6791EBDC12CE8D30F346861FDA10FE6642C3ECF895B5DBF4742BBD96A25188D02A3E23
CN108348319B.PDF	5EA62D756056C0EF5ECCFDBDB6273E84F49E8BC7EE6C1C4A744C7483518C232141795C4EBDC740299491C1208F3084A1E2FFE13A10DD2FBF7E444B05CA95888B
CN111281482A.PDF	3C036DDB6AB434A3CB94D08D085C73E19FD1A3C15D3BC4ADB816C844E4BAA187114336F6BC42366211A8F3060596DC7C46F6D10C33765724EAA06246D584DDC6
CN103764049A.PDF	6DB37A6A3AA932782F27EB4437281D7AE5D83449D56B7E973A2BEFC682B800AC76BE53112F97508049F0588D86C8B8AD4E778238F14BC3C1D32D97EC583D1EB0
CN104068910A.PDF	567572F0EEFC8CB41CC1DA81C088D01ED5519DF4D114A61C71ED56BC048D0080BE2105A75E4090D746FA8B0476EF26A356D4EC51A801248CE9BE02D1266144A1
CN102186427B.PDF	9052DAAED6C26A4751CC92299ABF7C1FCF787C17154CE3B9EC8B830A76E47E930A9090CF032469FBC0B80D3BE894709FAC7DF00D0646B8347E58E103D0543711
WO2015189354A1.PDF	FF818A1B46A03AF741D2C45B918FCD9F6E8F39044AB546EA5357E4DAE4D71AADAF78C003AD727D7D4C2ABADEFC6CDD88

	EC647941E7A84E932543A32C6508D9A2
WO0202162A2.PDF	318D622CF3F2461D1D0A6AEABB1EC94C2FFEF764C76A0F57E6F29EA95906C75A567C6E2437C557BAAEE9E464E82C3A3BA53FB8E5A68E945CD066D62C368C2A6B
EP1254634B1.PDF	8FDAD2D4FF0EB09DBC2B87BAB7F7DDEFD5988A7D354942E61A24B66F682FBFE8FE6D8CFD1A407617A0544FA7E47393A7277E63E255EC4A6BE888B78855476A8F
WO2019222117A1.PDF	E26BA471D85DEECC3D2A71B689D50568EC53380960B3DC99EBACB2DE433484D86B3B0CF330F11C569F5F60BF883234F187CC9DDEB2ECC67E33D6D42594F28E09
GB2498349.PDF	8F331CE61776A9C9169F0A27D86DB7D3D09396CCA0735242D8EC9DFE6517A8E9F54B1BD18C9F95ABB5566B17DF381BDA34AF3A808050B16DC28EDACD4BF6B477
WO0032118A1.PDF	D8CF88213BB2616FDD805FC7AF7C65FF28DC8CF65474BF95E8A8A5774026072A202F343F9F498F6A53BC007D96B9C957EAFB4032CC85F69C42767872E2276EEA
WO2017058280A1.PDF	0260318884C1D3DDB924BA1D615D9FD812EB02AC087CDA96B186F72C40642200DDB965ADA32AD3C59AC1D749A54D0B4D96756FC2A3B7909F30F3CD58176976F5
WO2012049652A1.PDF	A72932834FC9C8BACE12B3AC157CD3BC4A4E848D184D3638F1F475EC55AADABABA8FCA99D73773EA4C7A99FCCD385D63276A643DA46C6E49BC95BB24EB0C46E2
WO2017189535A2.PDF	BAA543D4AEBB1AE1DF7D93C5C5CB5A75D73947BD47919EB09E394C12EDE6CB9149FFFBCF92DD8BE1DEC7E5CE09BF27FD2EDB6B2BFB6450B2A5118862B98D32EE
WO2017189550A1.PDF	2DD8661E857902AE98570B8152A1752B92206E0B082D95E7AB6B123BF8B7A07154051769498 6D55B292ED56C8DA7C62885606435870C86172175C101D349D8E1
WO2017189591A1.PDF	E68F4CE645DBBCA82BAFBDD1952551277109F44EF910542A91BBA0513BA2A6D84566AC385BF5DB98BF06F945DD935A3BA2

	7E30ACF2CFFEDBF66946DFD4C6729A
WO2017189615A1.PDF	5A46658C7BC1CCDC458B400475CF1844F65E5C917644A557D A9F2319354EC2973B9B1D9FE86F71EE51F722DBB444D7F7C5 0189655F1FA54AA392D9FD8632ADB0
WO2017210487A1.PDF	90B2BE83A13EF6F9909D54B9EC3176B43DBD09B06AFCBE1D E56741252E48DC00D87618FA0838928AC71E76752DC2D04637 EFE1755A7D7C33D87BB02D8A4A0B85
GB1588072.PDF	68831D240FACBF8AA44EB0B7A60FF3A3C618932E772CA2F38 5832E0027F72A074734C1D71BF080C632CF09CE522E1B1489C E950AE3CBE4FB4C3C8504B7ABBD1E
AU2015210338B2.PDF	7BFEFA454A2CA6AFF7DDB44A5D3DE63303F4DEAC607A5E50 67197D39B6E887AD9F4968558D4213A530E723E228B52FA392 AAE84FB443EBA24049F55228110A1B
WO2018049317A1.PDF	1FF1FF2E272481FB7CB00EF45C643A0A660F227CBFE2080B4 1E3B3BDF64E8425A19EEB1CCE269E0BC46778BDCD1147054 ED116BDA78DEDA53854437094D71D19
WO2019010318A1.PDF	E7701FE5281F380382AB9E7FC0F47B3326C6B8B5B2A4B0BA8 8B48049D52350BEC825A3B16C8985862C515EFF73F74E16354 F0C0AA9400FD60EFE4BDB5F113B60
WO2019094456A1.PDF	2E3EA267F54DEE0A32C8363C91C2DCE2F403BDA042C3B7E1 1068946415B46CFC19B524F6DE9FB1E1A283FB3B9E71343D8 C8B2F2042D9B4AE44164C1994D7B371
WO2012162437A1.PDF	B6EBFB6EFFA7D42B5B328FB0A6160D0CCB53C81CA17598B1 24DF9CD9291112BA6421BF92B6288C22F2D5CBF990858292B7 C87582EDD9C750D3DF4F6288063FEA
WO2009086482A1.PDF	740E56A9CDD39BC0599B4C9B92E46875F15C8C4A3F6C1702D 07A05AE77B7C79E53989044D0E19F28B197668F67C1D8EDA0 3A35209416C3201E82125F19114D50
WO9839053A1.PDF	661CBCA2A9B10D392B3F70F403CBE00FAC00BABEFCF0F12E D6EF1220D143755FCBDD70FE47957F8F3A0C142E154627A3D

	6F928FBFBB2F9FA3B6528DBD5314582
WO9833443A1.PDF	1695C6018B646359D3DC1039A66E678283A7B77432F293F794D0DB24DA0403B86549910B1F11F56170C64EDEA2968A9207D0BC228F82E0B536ADDF753BF90477
WO9851237A1.PDF	875492DF7197902A71A2AC45452E988CF46D3A9296427292923FD94AE480D6ED60B7666F258223E641FAD7BC8214A5785301E78CF6AE16B610644E734A701AE8
WO2009082513.PDF	2B5EC03CE13CEB2F65C7A52D6B6C76AA51C74321A7128716694865126928C1C43B97EF1615448422DF6DAD893714DD98EE38C085DEB78F6A3E335C733CDFFAB3
WO2018148174.PDF	B7F22DA0406791DCDEFBAE9C63A2B547F933184D5A64286F625A7A41E24C06233C01025E6385352719A44434E0A9E191D2DE2F94274C70F101272B8807257C11
WO2021248042.PDF	1F61234EF5E47029DFFE611F0AFC468F297AFF03B837F835EECF0F31B87BE6CDFDA6AC3D44CD7EB760460CEE7F8A8D56A021BB014AEDBF20434EF40D41DE8E8C
WO2021076954.PDF	13AFE4003B49570137032EE374C7C5BA8866368540F9774515A846CBAB2EF21F8B676924178A86AE439221E39B17594E225BE8BFB594A076E4CDE8FB9D13CF76
WO2011073176.PDF	A31D95FA259A89C1E8431F308183DFFE32593E5F572ADF5F2D20F31311F1800A9E78A24559B567E2B4A2F8B6DDA7B83855E56ECDB5F710823D0AACBD3E70050D
WO2021067134.PDF	555B9C7FDDD8071F94F7F4275FBDE85D3CBBC8E595BF606AEC58178CD1B5B1585F5BBB5FF37E1869A3AC239D4183474247B48AAB9755B84D83C0DDA7BB14B5EF
WO2022032173.PDF	A8F699D4BE9D924579002A2C0C77BE10FE9182638AA95251070A5575658B04CD4D7FF7C439C5AA37664FB5A6AC0EB92370FBF2E3AACEC0E4AAB6B8CB75A62436
CN110652645.PDF	5553DE5352E13CE4E1BC190CF5C8A4158BF5FE1519E5658D7660DF3E9B5C79FF5E10280726810E873833276A5C58A166F24

	332E318A350F97451C32228ABA25F
WO2019246240A1.PDF	AC9E188A6FA5E446E41856952F6073DD3CC4D3213795B8B168CD8A359B6B5023D860D42EEE016F3AC9D183FD760B6F585457298FFE5DCDF01B78D52003E79266
JP07323090.PDF	E292370C2400C6206EAC34013B790067ACCAFCF72B649381F21F0B140B914FACD8BC5334FF7EF9A1E9482BBC2B7CC3816EB9B24A3FCD3EB9DC12F92A952BCA4D
WO2022103848.PDF	8158AA870EF4E2C6EC76F13BDE8BB480FB238FEAC5367E7305EF08F4595113C9B2C61F64B07CF1CF7D4970CD162C24C6DE935AB842B618CDA0375AFFCD11C644
WO2022109021.PDF	CF71CB99C6422F630E54AF3838F47B8260810E5132258D14E66F390323A10AA5489C9BE2E2F377699F2BFEA39661D41F2C9A812D1ADAC87FCE8484CCD1ACC0E6
WO2022109034.PDF	987B71D46F2C34DAD73A486CB07682F5228915368B4AC9D175A5C4212C63B5FB4CFCC090917D2ACC3444E8793E78FB548D25C8B7BB3947203AE367D581A6D2B9
NPL_EESR_201915816_Mar_31_2021_11pages.PDF	BA10DE789588BF68AE1314865EF4233C8243A679AD4E14672C676D3CEED20D74A28B88FBF983AE6CF5FEF671997D2EDE0FF0017D202EBC8C27CE0E3F0A609BE6
NPL_ISR_WO_PCTUS2055645_April_14_2021_12pages_usptо.PDF	D0252D5CFA87D956D48B131A43004AC751E6BA39460B846AC9AD70D071408DDFA059B5CA920332415F1CA72BBD4CD64D03C6547CD79E74153987E85F70537DA7
NPL_EESR_188534655_May-7-2021-7-pages.PDF	5C08D110BD4812E07F251F6384E80518DD684524D0486899EF3D86AF18CCEB44285DA0DFB5A50646763C4B9470EFD8A8D1850131779FAC69166625427A9A1D68
NPL_Vorwerk_Temporary_Caval.PDF	2791D9AD5029ECFB48E07917D62689D87D413B3196501FCEA13885C3906A72758A465AA1B615AD70B52D122FD0B5E21517EBA87D9503EF0F3E9D7ECDDE8DED56
NPL_ISR_WO_PCTUS2014854_Oct_5_2020.PDF	9F097E6239E251199E9E8E6203EAD7227A293FB8D0E6ED9D3BEA655869C12261B7C259DAD811F67A3B30E50E0B21DCE611

	7A5C4483C7A4FD7F4D2C337323047E
NPL_ISR_WO_PCTUS2018655_Dec_16_2020.PDF	4B2DB90273833F88033FA806A742BF5C09F9FA0EB59BCBACFDA121C752FC1D7DBE6CAB336060AF595CBF7191AB7935C0C62D9EAE812CC4BA82D5F09089C6776C
NPL_ISR_WO_PCTUS2017684_Nov_30_2020.PDF	9BDEA8634E9C3D65FBC2DA3689CED016876C6246A9A7688C64541A6DD960064A08C359F4B52093BD0BEA8C21C89845490E69DC66671A5E332C4D8A5E4B1A63CF
NPL_EESR_201850922_Sep_11_2020.PDF	281D83D8F15F5BD21C83FF3D49FD62DCCDD4F241DF422E50A106EF9023359A6DC7B1BB1EA7A5775F3AEEB07719FC88FCBE2767E114D62D67116F67E11E613FA1
NPL_EER_187457940_July_20_2020.PDF	2026E5DAF64E5B98DCD9ACF839558C3B1C9A90E9B599D1B0AEA83F5B81A6706E048C9E909B92A5DFFC7326EE8AE6ED64738465D747D6963A547920B1B8640B5B
NPL_Wikipedia_Embolectomy.PDF	18FF0EABCC5B0A172CF2113D91E815F117811DBAB9D9DA2A27F009EAFF0ACBC9C1D82065AF74F5C62DB7DA90F11C793B851A7DBA19CDB15CFD744C434DF963C7
NPL_OSullivan_Thombolysis.PDF	8212E3735CF9F7A01D66C9D294E7A92326D7D1068C919A836A642F3CAFC1BCB42BF2ECAB265B0FA066DB1250E362655D5662C89C0644BFE9FC6BAC68AEF888C7
NPL_Capture_Vascular_Systems.PDF	9ACD0664B139B8CE1C32D56E817AF8776E0A883B0ECB684270B4E4B791135CB89CF282AB41EFD255D56D9E7646CCA969C514143B91B95F85307F8F69456CDF6C
NPL_Edwards_Fogarty.PDF	822A5D1A8C20327FF183878067CB3D2289815D64385CF42664B9F565D167EE7F31F67C77CA6828C94C35CC60866939945DBEEFC8AE360B75DE9E2D029596881A
NPL_Boston-Scientific_Fetch2.PDF	1C294C8388BEBD1E9B4BAF2173A39C9BDF6D4A608AFFE5AA6DE372907D9B49488FBA4D3CB9075AA0319C64512EF7AC333843F5C8A78DCC16F3F92FE5FA8095D9
NPL_Penumbra_Indigo_System.PDF	75EF1F16B01007C7F421FF0B13ED52213A4498134B7E6D13D943F3A1F042DD2307F237615350C9D1B49635E4EE1D9EA2E882

	BD114FA51CD20AAA3771C04E55E7
NPL_YouTube_Merci.PDF	1161585176C27B77ADF4B2B6AFD615C0C000E2A118B4A308EA66C65446B21870CCFFB897956AEF01C25DB5A81B9BB362C76C03C21B068F130B226B8A6B082B04
NPL_Covidien_Solitaire.PDF	BD0B2D401B55396BF1CD4CF10DE8361100B6DCA7D7773DA1F28A6E09193F925552336C597CC162253325A6AC404EEA1BF3A765EF7A94C542EC993A4D43631BE9
NPL_ISR_WO_PCTUS1950467_Dec_18_2019.PDF	D10D882F672CB338B60E63404774D9ECC1A8F905B187E3A69E80ECD7271B864A5B82C427AD4E30C6606E96D6BFD35B835D1C58DB1BB664D503590D77ECF72524
NPL_ISR_WO_PCTUS1729440_July_7_2017.PDF	75169C207E3436C498C3CA51786343B157AAC28C3E8AB5CC4A3F5B8C5EAD704CCD3BE4E8D82FC6BF9861377DA68C6198F75E2A7DF46FA7FF020236B968DDDE59
NPL_ISR_WO_PCTUS1729472_July_7_2017.PDF	D0083465862CA1B152EC20ACC5AC9E5BD5A6B745E700CC2F44269DC34BFF99FF9186A762B1A25D24C557BFE9196AE18D86C11BD65C65B42F0063C6EA31BCF8F5
NPL_ISR_WO_PCTUS1735543_Aug_14_2017.PDF	C50726C87E46D984D11C9A5A2A25D0A9BC0B911B4E38A30F1368C9B34BA943BCAEED4E22523FF7B2192119C5F96F58489F769D0BE25D7AC019E52D170A083BFE
NPL_ISR_WO_PCTUS1729366_Aug_29_2017.PDF	85DBDAA3CBAB11045F54B6F628E8D03B10FE6D6039A6E6B24D692F2AE1F4A98428F6C50BBC58442BDF688783E72B9B26AF69E4BD9C1B33E9E3925C5820B5BCD3
NPL_ISR_WO_PCTUS1750933.PDF	1754579101147623F315966CA8EF206B94B17B997AC58B82B896D5B2C53EE047515861BEDC0A0234C2DC9FE0990E2DD153E79917CFDF2A5773C6BB8681F590DD
NPL_ISR_WO_PCTUS1729345_2-28-2018.PDF	51AB5B7009AAB23BA66FE3A4CD8B928198C1BEC469F9FBD53448ED75ADCDF04A1B20ED0D3C5916AC55F21A12E1181138BA130875B2279F693DFD7393FEC696F6
NPL_EESR_168522126_Aug_22_2018.PDF	F4357A36D4DD6FD630CBC5F4290ABD0FBAFBCEF6AB9647C3D5864ED49468B0FD5DB884995CC32BA60A05AD0552E3A5019

	F42EA9CA7FC6F91C18024E6EE7726B8
NPL_EESR_181748914_Oct_5_2018.PDF	4AA22CF1FB9F11B6E93AFAD9C5AEAFA9C08C30706766EB6EF3156F58D1E87682E5EC778F7929B7C171D4CD8011E54412C4063109231C8AF5CAEDECEBC05F4923
NPL_ISR_WO_PCTUS1840937_Nov_14_2018.PDF	B169C616750A5643B3C903BDE3392E7B2310BD036A1FC3F653FEF32C12D86C186AB7A23E31A85D9978D144DC36DE8E68DB20D49518E353D3EE16766623349793
NPL_ISR_WO_PCTUS1859607_Mar_28_2019.PDF	30CD2A9C0C5B87FF675C97B3F167FB77F9A2B1A9443ACB3107E691CB5507981E79E67BE5367B0A3E9796C0045997D3810FD2D8685CEC32D874165AEE5F6BAB91
NPL_ISR_WO_PCTUS1617982_May_6_2016.PDF	4213D9FDB013A2C6F9F8F66CEAF03C3612DACAFBE7EECC8EFEDCA9B6E4DB57EF103838F426F22FA2E72D83350CF37E511AD301C1347A1F6946C098C99A3104E8
NPL_ISR_WO_PCTUS1932601_July_23_2019.PDF	86B0B936CF05D04DCD0BEC4269D592DC181B7602C17F37E13C5BFB98C319DFC4E84AD44B112098E2A19BF0B64CC0ECB4845E6DF742E15BF2BAD1751E9BAB31B1
IDS SB08 - 111552-8016US4.pdf	E6E9F781E2EFC040F09A57F576E37CAB4BF958606FD3FE326F633A0A2B697121E61AC2C049B6E82DD4B4BAF230F6211D038275C51753A9B5E3B9DE1AF4B95D98

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.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 April 2021 (22.04.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/076954 A1

(51) International Patent Classification:
A61B 17/14 (2006.01) *A61F 2/01* (2006.01)
A61B 17/22 (2006.01) *A61M 25/01* (2006.01)
A61B 17/32 (2006.01) *A61M 25/08* (2006.01)

(21) International Application Number:
PCT/US2020/056067

(22) International Filing Date:
16 October 2020 (16.10.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/916,044 16 October 2019 (16.10.2019) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventor: **DINH, James Quang**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(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, IT, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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,

(54) Title: SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS

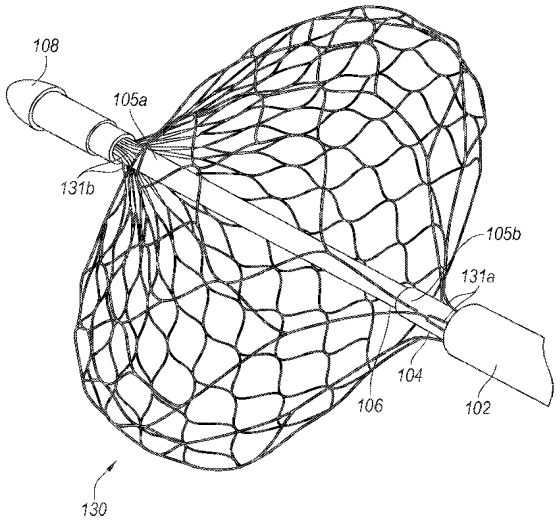


Fig. 1C

(57) Abstract: Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. A device in accordance with embodiments of the present technology can include, for example, a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion. The struts can form a plurality of first cells in the proximal portion and a plurality of second cells, smaller than the first cells, in the distal portion. The device can be pulled against clot material within a blood vessel to engage, disrupt, and/or capture the clot material.

WO 2021/076954 A1

[Continued on next page]

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).

Published:

— *with international search report (Art. 21(3))*

SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/916,044, filed October 16, 2019, and titled "SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology relates generally to systems, devices, and methods for the intravascular treatment of colt material (e.g., emboli and/or thrombi) within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to expandable devices for engaging and removing clot material.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT can obstruct drainage of venous blood from the legs leading to swelling, ulcers, pain and infection. DVT can also create a reservoir in which blood

clots can collect and then travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body. This can result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. Embolectomies, for example, are a surgical technique involving incising a blood vessel and placing a balloon-tipped device (such as the Fogarty catheter) at the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to withdraw the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and restenosis regularly occurs after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage, and in many patients the thrombolytic agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack the ability to be appropriately fixed against

the vessel. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all of the clot material.

[0010] Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0012] Figures 1A and 1B are side views of a clot treatment system in a pre-deployed configuration and a deployed configuration, respectively, configured in accordance with embodiments of the present technology.

[0013] Figure 1C is an enlarged perspective view of a distal portion of the clot treatment system shown in Figure 1B configured in accordance with an embodiment of the present technology.

[0014] Figures 2A–2C are a side view, a proximally-facing perspective view, and a distally-facing perspective view, respectively, of a clot treatment device of the clot treatment system of Figures 1A–1C configured in accordance with embodiments of the present technology.

[0015] Figure 3 is a flow diagram of a process or method for operating the clot treatment system to remove clot material from within a blood vessel of a human patient in accordance with an embodiment of the present technology.

[0016] Figures 4A–4F are schematic illustrations of a distal portion of the clot treatment system during a procedure to remove clot material from a blood vessel of a human patient in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0017] The present technology is generally directed to systems, devices, and methods for removing clot material from a blood vessel of a human patient. In some embodiments, a clot removal system can include a delivery catheter and a clot treatment device. The clot treatment device can include a plurality of interconnected struts forming a unitary structure that is movable

between a compressed configuration and an expanded configuration. In the expanded configuration, the unitary structure can include (i) a proximal connection region, (ii) a proximal conical region extending from the proximal connection region, (iii) a cylindrical region extending from the proximal conical region, (iv) a distal conical region extending from the cylindrical region, and (v) a distal connection region extending from the distal conical region. In some embodiments, a first portion of the struts form first cells in the proximal conical region, and a second portion of the struts form second cells in the distal conical region that are smaller than the first cells.

[0018] In some embodiments, the system further includes a handle configured to be gripped by an operator, and a first shaft coupled between the handle and the proximal connection region of the clot treatment device. The clot treatment device can be maintained in the compressed configuration within a lumen of the delivery catheter and near a distal terminus of the delivery catheter. To move the clot treatment device to the expanded configuration, the operator can move the handle to advance the first shaft to thereby advance the clot treatment device past the distal terminus and out of the lumen of the delivery catheter. When the clot treatment device is no longer constrained by the delivery catheter, the clot treatment device can expand (e.g., self-expand) to the expanded configuration. In some embodiments, the system further includes a second shaft extending at least partially through the first shaft and coupled to the distal connection region of the clot treatment device. Relative movement between the first and second shafts can allow the clot treatment device to lengthen/shorten and to correspondingly radially expand/compress.

[0019] During a procedure to remove clot material from a blood vessel of a human patient, the clot treatment device can be expanded distal of the clot material within the blood vessel, and then retracted proximally into the clot material to capture/disrupt the clot material. In one aspect of the present technology, the larger first cells of the clot treatment device are configured to receive the clot material therethrough as the clot treatment device is pulled against the clot material, and the smaller second cells of the clot treatment device are configured to retain the clot material within the clot treatment device. In another aspect of the present technology, the clot treatment device has sufficient radial stiffness (e.g., at the cylindrical region) to inhibit the clot treatment device from slipping (e.g., not engaging) the clot material when the clot treatment device is pulled against the clot material. Accordingly, the clot treatment device can be used to capture/disrupt adhered, organized, and/or chronic clots that would otherwise be difficult to remove.

[0020] Although many of the embodiments are described below with respect to systems, devices, and methods for treating a pulmonary embolism, other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating deep vein thrombosis (DVT), etc.). Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–4F can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–4F can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–4F.

[0021] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems and devices of the present technology can be used in any orientation suitable to the user.

[0022] Figures 1A and 1B are side views of a clot treatment or clot removal system 100 ("system 100") configured in accordance with embodiments of the present technology. The system 100 is in a constrained/pre-deployment configuration in Figure 1A, and the system 100 is in an expanded/deployed configuration in Figure 1B. Referring to Figures 1A and 1B together, in the illustrated embodiment the system 100 includes a delivery catheter 102 (e.g., a tube, a shaft, etc.; which can also be referred to herein as an outer shaft) defining a lumen and having a proximal end portion 103a and a distal end portion 103b. The proximal end portion 103a of the delivery catheter 102 is coupled to a hub 110, such as a sealable hub, valve, etc. The lumen of the delivery catheter 102 can be fluidly coupled to a port assembly 112 via the hub 110.

[0023] In the illustrated embodiment, the port assembly 112 includes a fluid control device 114 fluidly coupled between (i) a port connector 116 (e.g., a Luer connector/fitting) and (ii) a tubing section 118 coupled to the hub 110 (e.g., to a branch or side port of the hub 110). The fluid control device 114 is actuatable to fluidly connect the lumen of the delivery catheter 102 to the port connector 116. In the illustrated embodiment, the fluid control device 114 is a stopcock while, in other embodiments, the fluid control device 114 can be a clamp, valve, and/or other suitable fluid control device. During a clot removal procedure using the system 100, various components (e.g., syringes, vacuum sources, etc.) can be coupled to the port connector 116 to remove fluid from and/or inject fluid into the lumen of the delivery catheter 102. For example, in some embodiments a syringe or other pressure source can be coupled to the port connector 116 and used to draw a vacuum while the fluid control device 114 is closed, and the fluid control device 114 can then be opened to instantaneously or nearly instantaneously apply the vacuum to the lumen of the delivery catheter 102 (e.g., to generate suction at the distal portion 103b for removing clot material). In other embodiments, a constant vacuum source (e.g., a pump) can be coupled to the port assembly 112 to provide constant aspiration of the lumen of the delivery catheter 102. In some embodiments, flushing fluid (e.g., saline) can be injected through the port assembly 112 to flush the lumen of the delivery catheter 102.

[0024] In the illustrated embodiment, the system 100 further includes an intermediate shaft 104 (e.g., a catheter, tube, etc.) extending at least partially through the lumen of the delivery catheter 102 and defining a lumen, and an inner shaft 106 (e.g., a catheter, tube, etc.) extending at least partially through the lumen of the intermediate shaft 104. Accordingly, in some embodiments the delivery catheter 102, the intermediate shaft 104, and the inner shaft 106 are coaxially aligned/arranged. The system 100 further includes a clot treatment device 130 coupled to the intermediate shaft 104 and the inner shaft 106. The delivery catheter 102, the intermediate shaft 104, the inner shaft 106, and the clot treatment device 130 can collectively be referred to as a treatment portion 111 (e.g., an insertion portion) of the system 100. As described in greater detail below with reference to Figures 3–4F, the treatment portion 111 is configured to be inserted through a guide catheter to position the clot treatment device 130 at a treatment site during a clot removal procedure.

[0025] As described in greater detail below with reference to Figures 2A–2C, the clot treatment device 130 can be a self-expanding unitary structure comprising a plurality of interconnected struts. In the pre-deployment configuration shown in Figure 1A, the clot treatment device 130 is constrained within the delivery catheter 102 and thus obscured. In the

deployed configuration shown in Figure 1B, the clot treatment device 130 extends past the distal end portion 103b of the delivery catheter 102 (e.g., a distal terminus of the delivery catheter 102) and is radially expanded.

[0026] Figure 1C is an enlarged perspective view of a distal portion of the system 100 shown in Figure 1B configured in accordance with an embodiment of the present technology. In the illustrated embodiment, the intermediate shaft 104 includes a distal end portion 105b coupled to a proximal portion 131a of the clot treatment device 130. In some embodiments, the proximal portion 131a of the clot treatment device 130 includes a plurality of struts that are gathered together and secured to the distal end portion 105b of the intermediate shaft 104. For example, the struts at the proximal portion 131a of the clot treatment device 130 can be secured to the outer surface of the intermediate shaft 104 via adhesives, fasteners, a hub or other device, etc. The inner shaft 106 includes a distal end portion 107 coupled to a distal portion 131b of the clot treatment device 130. In some embodiments, the distal portion 131b of the clot treatment device 130 includes a plurality of struts that are gathered together and secured to the distal end portion 107 of the inner shaft 106 via a friction fit, pressure fit, etc., between the inner shaft 106 and a distal tip 108 (e.g., an atraumatic tip). In other embodiments, the struts at the distal portion 131b of the clot treatment device 130 can be secured to the outer surface of the inner shaft 106 via adhesives, fasteners, a hub or other device, etc.

[0027] Referring again to Figures 1A and 1B together, the intermediate shaft 104 includes a proximal end portion 105a coupled to the handle 120 (e.g., to a distal portion of the handle 120) to operably couple the handle 120 to the clot treatment device 130. Accordingly, the intermediate shaft 104 extends between and operably couples the handle 120 and the clot treatment device 130. In some embodiments, a proximal end portion of the inner shaft 106 (obscured in Figures 1A and 1B) is not coupled to any portion of the system 100 and floats within the lumen of the intermediate shaft 104. In one aspect of the present technology, this arrangement allows the inner shaft 106 to move relative to the intermediate shaft 104 in response to external forces on the clot treatment device 130, thereby allowing the clot treatment device 130 to elongate/shorten longitudinally and to correspondingly radially compress/expand. In other embodiments, the proximal end portion of the inner shaft 106 can be coupled to an actuation mechanism 122 (shown in dashed lines in Figures 1A and 1B) of the handle 120. The actuation mechanism 122 can be configured to drive the inner shaft 106 proximally and/or distally to shorten and/or elongate, respectively, the clot treatment device 130. More specifically, in some embodiments distal movement of the actuation mechanism 122 relative to

the handle 120 can move the inner shaft 106 distally relative to the intermediate shaft 104 to lengthen and radially compress the clot treatment device 130, while proximal movement of the actuation mechanism 122 relative to the handle 120 can move the inner shaft 106 proximally relative to the intermediate shaft 104 to shorten and radially expand the clot treatment device 130.

[0028] In the illustrated embodiment, the handle 120 further includes a proximal hub 124, such as a Luer hub, configured to receive a guidewire (not shown) therethrough. The handle 120, the inner shaft 106, and the tip 108 can together define a lumen for receiving the guidewire therethrough. In some embodiments, the guidewire can have a diameter of about 0.035 inch, about 0.018 inch, less than about 0.1 inch, less than about 0.05 inch, etc. In some embodiments, the handle 120 further includes a lock feature 126 such as, for example, a spinlock or a push-in-and-turn lock. The lock feature 126 is configured to selectively engage (e.g., lockingly engage) with a mating feature 115 of the hub 110. Locking the handle 120 to the hub 110 via the lock feature 126 and the mating feature 115 secures the position of the intermediate shaft 104 relative to the delivery catheter 102. In the illustrated embodiment, the intermediate shaft 104 is longer than the delivery catheter 102 such that a portion of the intermediate shaft 104 and the clot treatment device 130 extend distally from the distal end portion 103b of the delivery catheter 102 when the handle 120 is lockingly engaged with the hub 110.

[0029] To deploy the clot treatment device 130 from the pre-deployment configuration (Figure 1A) to the deployed configuration (Figure 1B), an operator can move the handle 120 distally toward the hub 110 and/or can move the hub 110 toward the handle 120. This movement advances the intermediate shaft 104 distally through the delivery catheter 102 and pushes the clot treatment device 130 distally out of the delivery catheter 102. The clot treatment device 130 can self-expand as it is released from the lumen of the delivery catheter 102. When the handle 120 abuts the hub 110, the operator can actuate the lock feature 126 to secure the position of the intermediate shaft 104 relative to the delivery catheter 102 to, for example, maintain the clot treatment device 130 in the deployed configuration.

[0030] In some embodiments, proximal movement of the handle 120 and/or distal movement of the hub 110 (e.g., from the position shown in Figure 1B to the position shown in Figure 1A) can retract the clot treatment device 130 back into the delivery catheter 102. That is, in some embodiments the clot treatment device 130 can be resheathed within the delivery catheter 102. In such embodiments, the clot treatment device 130 can be repeatedly expanded

and then retracted and compressed into the delivery catheter 102. In some embodiments, the tip 108 is configured (e.g., sized and shaped) to abut the distal end portion 103b of the delivery catheter 102 in the pre-deployment configuration (Figure 1A). This can inhibit or even prevent the clot treatment device 130 from being pulled fully through the delivery catheter 102 and, in some embodiments, can substantially seal the lumen of the delivery catheter 102. In other embodiments, the tip 108 is sized and shaped to allow the tip 108—and thus the entire clot treatment device 130—to be retracted through the delivery catheter 102.

[0031] Figures 2A–2C are a side view, a proximally-facing perspective view, and a distally-facing perspective view, respectively, of the clot treatment device 130 in the expanded configuration in accordance with embodiments of the present technology. Referring to Figures 2A–2C together, the clot treatment device 130 comprises a plurality of struts 240 that together define a plurality of first cells 250 (e.g., interstices, pores, openings, etc.) and a plurality of second cells 252. The struts 240 can have a variety of shapes and sizes and, in some embodiments, the struts 240 can have a thickness and/or diameter between about 0.0125–0.150 inch, between about 0.075–0.125 inch, between about 0.090–0.150 inch, and/or other dimensions. In general, the struts 240 together form a unitary structure that is configured to engage, capture, disrupt, and/or separate a portion of a thrombus (e.g., a vascular thrombus) from a blood vessel containing the thrombus.

[0032] In the illustrated embodiment, (i) the first cells 250 generally face proximally while the second cells 252 generally face distally, and (ii) the first cells 250 are larger than the second cells 252. As best seen in Figure 2A, the clot treatment device 130 includes (i) a first region 242 including the proximal portion 131a, (ii) a second region 243 distal of the first region 242, (iii) a third (e.g., central) region 244 distal of the second region 243, (iv) a fourth region 245 distal of the third region 244, and (v) a fifth region 246 distal of the fourth region 245 and including the distal portion 131b. In the illustrated embodiment, the struts 240 are gathered together (e.g. positioned proximate one another) at the first and fifth regions 242, 246 to facilitate their connection to the intermediate and inner shafts 104, 106, respectively, as shown in Figure 1C. The second region 243 can have a generally conical shape that tapers (e.g., radially narrows) in the proximal direction. Similarly, the fourth region 245 can have a generally conical shape that tapers in the distal direction. The third region 244 can have a generally tubular/cylindrical shape including, for example a generally flat outer strut surface/boundary 248. Moreover, in the illustrated embodiment the first and second regions 242, 243 have fewer of the struts 240 than the fourth and fifth regions 245, 246 to thereby define the larger first cells 250. Conversely, the

fourth and fifth regions 245, 246 have more of the struts 240 than the first and second regions 242, 243 to thereby define the smaller second cells 252. The third region 244 can be a transition region in which the number of the struts 240 increases in the proximal direction (e.g., toward the fourth region 245) such that some of the first cells 250 abut some of the second cells 252 in the third region 244. In other embodiments, the first cells 250 can be formed only in the second region 243, can occupy the entire third region 244, can extend into the fourth region 245, etc.

[0033] In some embodiments, the clot treatment device 130 is made from a shape memory material such as a shape memory alloy and/or a shape memory polymer. For example, the clot treatment device 130 can comprise nitinol and/or a nitinol alloy. Similarly, the clot treatment device 130 can be made using a variety of techniques including welding, laser welding, cutting, laser cutting, expanding, etc. For example, in some embodiments the clot treatment device 130 can first be laser cut from a piece of nitinol (e.g., a nitinol tube), and then further shaped using a heat setting process such that the clot treatment device 130 has the illustrated shape in the expanded configuration. For example, as is known in the art of heat setting nitinol structures, a fixture, mandrel, or mold may be used to hold the clot treatment device 130 in its desired configuration, and then the clot treatment device 130 can be subjected to an appropriate heat treatment such that the struts 240 of the clot treatment device 130 assume or are otherwise shape-set to the outer contour of the mandrel or mold. The heat setting process may be performed in an oven or fluidized bed, as is well-known. Therefore, the heat setting process can impart a desired shape, geometry, bend, curve, serration, scallop, void, hole, etc., in the super-elastic and/or shape memory material or materials used to form the clot treatment device 130. Accordingly, the clot treatment device 130 may be radially constrained without plastic deformation and will self-expand on release of the radial constraint.

[0034] In general, the size of the clot treatment device 130 can be selected based on the size (e.g., diameter) of the blood vessel from which thrombus is to be extracted. In some embodiments, in a fully-expanded configuration unconstrained within a vessel, the clot treatment device 130 can have a length L (Figure 2A) of between about 0.025–1.50 inches, between about 0.70–1.15 inches, etc. In some embodiments, in the fully-expanded position unconstrained within a vessel, the clot treatment device 130 can have a maximum diameter D (Figure 2A; e.g., at the third region 244) of between about 0.025–1.5 inches, between about 0.71–1.34 inches, etc.

[0035] The clot treatment device 130 is configured (e.g., shaped, sized, angled, formed, etc.) to engage, disrupt, and/or capture clot material from within a blood vessel when the clot

treatment device 130 is retracted through/against the clot material in the expanded configuration. For example, as described in greater detail below with reference to Figures 3–4F, the clot treatment device 130 can be withdrawn proximally through/against the clot material. In one aspect of the present technology, the larger first cells 250 are configured to receive the clot material therethrough as the clot treatment device 130 is pulled against the clot material, and the smaller second cells 252 (and associated struts 240) are configured to retain the clot material within the clot treatment device 130. In another aspect of the present technology, the clot treatment device 130 has sufficient radial stiffness (e.g., at the third region 244) to inhibit the clot treatment device 130 from slipping (e.g., not engaging) the clot material when the clot treatment device 130 is pulled against the clot material. Accordingly, the clot treatment device 130 can be used to capture/disrupt adhered, organized, and/or chronic clots. In some embodiments, portions of the struts 240 (e.g., at the second region 243) can be sharpened and/or can include a cutting element (e.g., a knife or knife edge) attached thereto or otherwise integrated with to further facilitate disruption/cutting of the clot material.

[0036] Figure 3 is a flow diagram of a process or method 360 for operating the system 100 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a patient (e.g., a human patient) in accordance with an embodiment the present technology. Figures 4A–4F are schematic illustrations of a distal portion of the system 100 inserted through a guide catheter 470 during a procedure to remove clot material PE from a blood vessel BV of a patient in accordance with embodiments of the present technology. Although some features of the method 360 are described in the context of the embodiments shown in Figures 4A–4F for the sake of illustration, one skilled in the art will readily understand that the method 360 can be carried out using other suitable systems and/or devices described herein.

[0037] With reference to Figures 3 and 4A, at block 361, the method 360 can include positioning a distal portion 471 of the guide catheter 470 proximate to the clot material PE within the blood vessel BV (e.g., at a treatment site). In the illustrated embodiment, a distal terminus of the guide catheter 470 is positioned proximate to a proximal portion of the clot material PE. However, in other embodiments the distal terminus of the guide catheter 470 can be positioned at least partially within the clot material PE, or the distal terminus of the guide catheter 470 can be positioned distal of the clot material PE. Access to the blood vessel BV can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, such as when the blood vessel BV is a pulmonary blood vessel, an introducer (e.g., a Y-connector with a hemostasis valve; not shown) is connected to the guide catheter 470 and can be partially

inserted into the femoral vein. A guidewire 472 can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the clot material PE, the guidewire 472 can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire 472 can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire 472 can be extended to a location just proximal of the clot material PE. After positioning the guidewire 472, the guide catheter 470 can be placed over the guidewire 472 and advanced to the position proximate to the clot material PE as illustrated in Figure 4A.

[0038] In some embodiments, a pressure source can be coupled to the guide catheter 470 and used to aspirate the lumen of the guide catheter 470 to, for example, generate suction (e.g., as indicated by arrows A) to suck/draw all or a portion of the clot material PE into the guide catheter 470. For example, in some embodiments a vacuum can be pre-charged (e.g., in a syringe fluidly coupled to the lumen of the guide catheter 470) and the vacuum can be applied to the lumen of the guide catheter 470 to instantaneously or nearly instantaneously generate suction at the distal portion 471 of the guide catheter 470 (e.g., to generate a suction pulse at the distal portion 471 of the guide catheter 470). Specific details of such methods and associated devices are disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0039] However, even where suction is applied to remove/dislodge the clot material PE from the blood vessel BV, the suction may not be enough to dislodge/disrupt all the clot material PE. For example, many chronic (e.g., organized) clots can strongly adhere to the walls of the blood vessel BV—making it difficult to remove them. In one aspect of the present technology, the system 100 can be inserted through the guide catheter 470 before, during, and/or after suction is applied via the guide catheter 470 to engage, disrupt, and/or capture the clot material PE—even where the clot material PE is strongly adhered within the blood vessel BV.

[0040] For example, with reference to Figures 3 and 4B, at block 362, the method 360 can include advancing the clot treatment device 130 (compressed within the delivery catheter 102 and thus obscured in Figure 4B) through the guide catheter 470 to proximate the clot material PE. More specifically, the treatment portion 111 of the system 100 can be advanced through the guide catheter 470 in the compressed pre-deployment configuration until the tip 108 is positioned

(i) distal of the distal portion 471 of the guide catheter 470 and (ii) distal of the clot material PE within the blood vessel BV. In other embodiments, the tip 108 can be positioned within the clot material PE. In some embodiments, the treatment portion 111 can be advanced over the guidewire 472 while, in other embodiments, the guidewire 472 can be omitted.

[0041] With reference to Figures 3 and 4C, at block 363, the method 360 can include moving the clot treatment device 130 from the compressed pre-deployment configuration to the expanded deployed configuration such that the clot treatment device 130 is expanded distal and/or partially within the clot material PE. For example, as described in detail above with reference to Figures 1A and 1B, an operator of the system 100 can advance the handle 120 distally toward the hub 110 and/or retract the hub 110 toward the handle 120 to move the intermediate shaft 104 relative to the delivery catheter 102 to advance the clot treatment device 130 out of the delivery catheter 102, thereby allowing the clot treatment device 130 to expand (e.g., self-expand) within the blood vessel BV. In the illustrated embodiment, the clot treatment device 130 (e.g., the outer strut surface 248 of the third region 244) contacts (e.g., engages, apposes, etc.) the wall of the blood vessel BV. In some embodiments, the clot treatment device 130 is oversized relative to the blood vessel BV such that the clot treatment device 130 exerts a radially outward force on the wall of the blood vessel BV. In other embodiments, the clot treatment device 130 can be sized such that it does not contact the walls of the blood vessel BV.

[0042] With reference to Figures 3 and 4D, at block 364, the method 360 can include retracting the clot treatment device 130 proximally (e.g., in the direction of arrow B) into/toward the clot material PE. More specifically, with reference to Figures 1A and 1B, the operator can pull the entire system 100 proximally (e.g., by gripping the hub 110) to retract the treatment portion 111 through the lumen of the guide catheter 470. As the clot treatment device 130 is retracted, the clot treatment device 130 engages the clot material PE to capture/disrupt the clot material PE. For example, the clot material PE can enter through the first cells 250 (Figures 2A–2C) and be retained within the clot treatment device 130 by the smaller second cells 252 (Figures 2A–2C). In one aspect of the present technology, the clot treatment device 130 can shear the clot material PE from the wall of the blood vessel BV even where the clot material PE is strongly adhered to the wall of the blood vessel BV.

[0043] In some embodiments, where the inner shaft 106 floats within the lumen of the intermediate shaft 104, the length L (Figure 2A) of the clot treatment device 130 can increase as the clot treatment device 130 is pulled into/against the clot material PE and the intermediate shaft

104 moves proximally relative to the inner shaft 106. In other embodiments, where the system 100 includes the actuation mechanism 122, the operator can actuate the actuation mechanism 122 to increase the longitudinal and/or radial stiffness of the clot treatment device 130 by locking or substantially locking the relative position of the intermediate and inner shafts 104, 106.

[0044] With reference to Figures 3 and 4E, at block 365, the method 360 can include retracting the clot treatment device 130 and the captured clot material PE into the lumen of the guide catheter 470. In some embodiments, the clot treatment device 130 can be fully removed from the guide catheter 470. In some embodiments, if any of the clot material PE remains in the blood vessel BV, the clot treatment device 130 can be cleaned and blocks 362–365 can be repeated to capture the remaining clot material PE. Alternatively, a new clot treatment device 130 can be reinserted through the guide catheter 470 to capture the remaining clot material PE. In some embodiments, the clot treatment device 130 can break apart the clot material PE without necessarily capturing the clot material PE and, after or during retraction of the clot treatment device 130, aspiration can be applied to the guide catheter 470 to suck the remaining clot material PE into the guide catheter 470. Finally, with reference to Figures 3 and 4F, at block 366, the method 360 can include removing the guide catheter 470 from the blood vessel BV and from the patient after a sufficient portion of the clot material is removed from the patient.

[0045] Several aspects of the present technology are set forth in the following additional examples:

1. A clot treatment system, comprising:

an outer catheter defining a lumen;

an inner catheter positioned at least partially in the lumen of the outer catheter; and

a clot treatment device including a plurality of interconnected struts forming a unitary structure movable between a compressed configuration and an expanded configuration, wherein in the expanded configuration the unitary structure includes—

a proximal connection region coupled to the outer catheter;

a proximal conical region extending from the proximal connection region, wherein a first portion of the struts form first cells in the proximal conical region;

a cylindrical region extending from the proximal conical region;

a distal conical region extending from the cylindrical region, wherein a second portion of the struts from second cells in the distal conical region, and wherein the second cells are smaller than the first cells; and

a distal connection region extending from the distal conical region and coupled to the inner catheter.

2. The clot treatment system of example 1 wherein the inner catheter has (a) a distal end portion coupled to the distal connection region of the clot treatment device and (b) a proximal end portion configured to float within the lumen of the outer catheter.

3. The clot treatment system of example 1 or example 2 wherein the inner and outer catheters are configured to receive a guidewire therethrough.

4. The clot treatment system of any one of examples 1–3, further comprising a handle coupled to a proximal end portion of the outer catheter, wherein the handle includes an actuation mechanism coupled to a proximal end portion of the inner catheter, and wherein actuation of the actuation mechanism is configured to translate the inner catheter relative to the outer catheter to longitudinally compress or longitudinally elongate the clot treatment device.

5. The clot treatment system of any one of examples 1–4, further comprising:

a delivery catheter defining a lumen; and

a handle coupled to a proximal end portion of the outer catheter and movable between a first position and a second position relative to the delivery catheter, wherein—

in the first position, the clot treatment device is constrained within the lumen of the delivery catheter in the compressed configuration, and

in the second position, the clot treatment device is positioned distal of the lumen in the expanded configuration.

6. The clot treatment system of example 5, further comprising a hub coupled to a proximal end portion of the delivery catheter, wherein the handle includes a lock feature configured to secure the handle to the hub in the second position.

7. The clot treatment system of example 5 or example 6 wherein the handle, the delivery catheter, the outer catheter, and the inner catheter are configured to receive a guidewire therethrough.

8. The clot treatment system of any one of examples 1–7 wherein, in the expanded configuration, the cylindrical region has a diameter of between about 0.71 inch to about 1.34 inches.

9. The clot treatment system of any one of examples 1–8 wherein the struts of the clot treatment device are configured to self-expand from the compressed configuration to the expanded configuration when unconstrained.

10. The clot treatment system of any one of examples 1–9 wherein the struts of the clot treatment device include a shape memory material.

11. The clot treatment system of any one of examples 1–10 wherein the unitary structure includes (a) a first number of the struts in the proximal conical region and (b) a second number of the struts in the distal conical region that is greater than the first number of struts.

12. A method of clot removal, the method comprising:

positioning a distal portion of a guide catheter proximate to clot material within a blood vessel of a human patient;

advancing a clot treatment device through the guide catheter to proximate the clot material;

expanding the clot treatment within the blood vessel distal of the clot material, wherein the clot treatment device includes a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells;

generating suction at the distal portion of the guide catheter; and

proximally retracting the clot treatment device through the clot material.

13. The method of example 12 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire.

14. The method of example 12 or example 13 wherein the proximal portion of the unitary structure is coupled to an outer catheter extending at least partially through the guide catheter, and wherein the distal portion of the unitary structure is coupled to an inner catheter extending at least partially through the outer catheter.

15. The method of example 14 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire extending through the guide, outer, and inner catheters.

16. The method of any one of examples 12–15 wherein generating suction at the distal portion of the guide catheter includes generating suction, before proximally retracting the clot treatment device, to aspirate a first portion of the clot material into the guide catheter.

17. The method of example 16 wherein proximally retracting the clot treatment device includes proximally retracting the clot treatment device through a second portion of the clot material remaining in the blood vessel to capture the second portion of the clot material.

18. The method of any one of examples 12–17 wherein proximally retracting the clot treatment device through the clot material includes capturing at least a portion of the clot material, and wherein the method further comprises retracting the clot treatment device and the captured clot material into the guide catheter.

19. A clot treatment system, comprising:

an outer shaft defining a lumen;

an inner shaft positioned at least partially in the lumen of the outer shaft; and

a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the proximal portion is coupled to the outer shaft, wherein the distal portion is coupled to the inner shaft, and wherein the struts form a plurality of first cells in the proximal portion and a plurality of second

cells in the distal portion, and wherein the first cells are larger than the second cells.

20. The clot treatment system of example 12 wherein the outer shaft and the inner shaft are configured to receive a guidewire therethrough.

21. A clot treatment device, comprising:

a plurality of interconnected struts forming a unitary structure movable between a compressed configuration and an expanded configuration, wherein in the expanded configuration the unitary structure includes—

a proximal connection region;

a proximal conical region extending from the proximal connection region, wherein a first portion of the struts form first cells in the proximal conical region;

a cylindrical region extending from the proximal conical region;

a distal conical region extending from the cylindrical region, wherein a second portion of the struts from second cells in the distal conical region, and wherein the second cells are smaller than the first cells; and

a distal connection region extending from the distal conical region.

22. The clot treatment device of example 21, further comprising:

a first shaft coupled to the proximal connection region and defining a lumen; and

a second shaft coupled to the distal connection region and extending at least partially through the lumen of the first shaft.

23. The clot treatment device of example 21 or example 22 wherein the second shaft has (a) a distal end portion coupled to the distal connection region and (b) a proximal end portion configured to float within the lumen of the first shaft.

24. The clot treatment device of any one of examples 21–23 wherein the struts are configured to self-expand from the compressed configuration to the expanded configuration when unconstrained.

25. The clot treatment device of any one of examples 21–24 wherein the struts are made from a shape memory material.

26. A clot treatment device, comprising:

a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells.

[0046] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0047] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0048] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the

technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.