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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 January 2012 (19.01.2012)

PCT

(10) International Publication Number
WO 2012/009675 A2

(51) International Patent Classification:
A61F 2/01 (2006.01)

(21) International Application Number:
PCT/US2011/044249

(22) International Filing Date:
15 July 2011 (15.07.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/364,718 15 July 2010 (15.07.2010) US

(71) Applicant *(for all designated States except US)*: **LAZARUS EFFECT, INC.** [US/US]; 767 El Solyo Heights Drive, Felton, California 95018 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MARTIN, Brian B.** [US/US]; 767 El Solyo Heights Drive, Felton, California 95018 (US).

(74) Agents: **BAGADE, Sanjay S.** et al.; Levine Bagade Han LLP, 2400 Geng Rd, Suite 120, Palo Alto, California 94303 (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, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

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

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) **Title**: RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

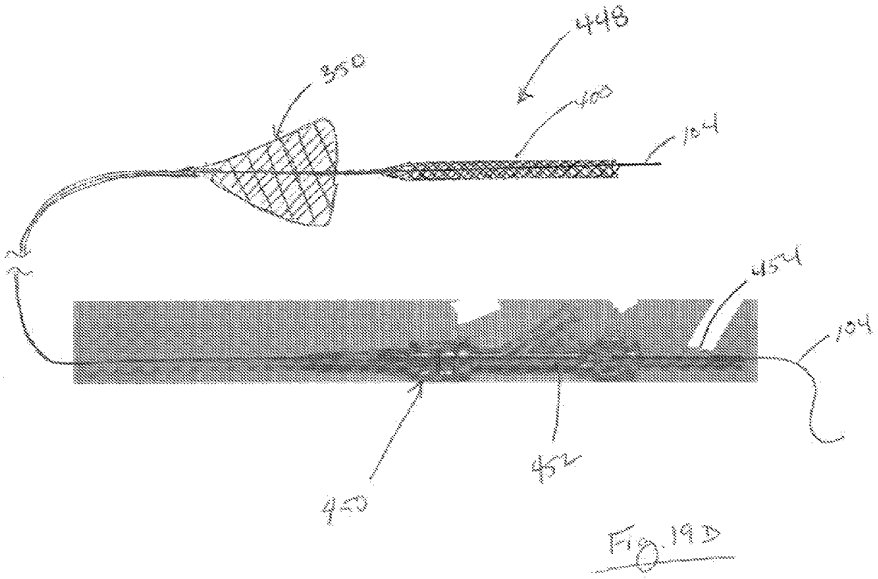


Fig. 19D

(57) **Abstract**: The devices and methods described herein relate to improved structures for removing obstructions from body lumens. Such devices have applicability in through-out the body, including clearing of blockages within the vasculature, by addressing the frictional resistance on the obstruction prior to attempting to translate and/or mobilize the obstruction within the body lumen.

WO 2012/009675 A2

RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

FIELD OF THE INVENTION

[0001] The devices described herein are intended to retrieve obstructions from the body. In a first variation, the devices are constructed in wire form where the wires diverge from a main bundle to form a variety of shapes that form a composite device. The benefit of such a diverging wire construction is that the composite complex device can be of a "joint-less" construction. Such devices have applicability through out the body, including clearing of blockages within body lumens, such as the vasculature, by providing a capturing portion that can envelop the obstruction to address the frictional resistance between the obstruction and body lumen prior to attempting to translate and/or mobilize the obstruction within the body lumen. In addition, the devices described below include features that prevent unwanted and premature mobilization of the obstruction when removing the obstruction through tortuous anatomy.

BACKGROUND OF THE INVENTION

[0002] Many medical device applications require advancement of device in a reduced profile to a remote site within the body, where on reaching a target site the device assumes or is deployed into a relatively larger profile. Applications in the cerebral vasculature are one such example of medical procedures where a catheter advances from a remote part of the body (typically a leg) through the vasculature and into the cerebral region of the vasculature to deploy a device. Accordingly, the deployed devices must be capable of achieving a larger profile while being able to fit within a small catheter or microcatheter. In addition, the degree to which a physician is limited in accessing remote regions of the cerebral vasculature is directly related to the limited ability of the device to constrain into a reduced profile for delivery.

[0003] Treatment of ischemic stroke is one such area where a need remains to deliver a device in a reduced profile and deploy the device to ultimately remove a blockage in an artery leading to the brain. Left untreated, the blockage causes a lack of supply of oxygen and nutrients to the brain tissue. The brain relies on its arteries to supply oxygenated blood from the heart and lungs. The blood returning from the brain carries

carbon dioxide and cellular waste. Blockages that interfere with this supply eventually cause the brain tissue to stop functioning. If the disruption in supply occurs for a sufficient amount of time, the continued lack of nutrients and oxygen causes irreversible cell death (infarction). Accordingly, immediate medical treatment of an ischemic stroke is critical for the recovery of a patient.

[0004] Naturally, areas outside of ischemic stroke applications can also benefit from improved devices. Such improved devices can assume a profile for ultimate delivery to remote regions of the body and can remove obstructions. There also remains a need for devices and systems that can safely remove the obstruction from the body once they are secured within the device at the target site. Furthermore, there remains a need for such devices that are able to safely removed once deployed distally to the obstructions in the even that the obstructions is unable to be retrieved.

[0005] Many physicians currently use stents to perform thrombectomy (i.e. clot removal). Typically, the physician deploys the stent in the clot, to attempt and push the clot to the side of the vessel and re-establish blood to flow. Tpa is often administered to dissolve the clot and is given in addition with the stent. Yet, if clot dissolution is ineffective or incomplete, the physician may attempt to remove the stent while it is expanded against the clot. In doing so, the physician drags the clot from the vessel and in a proximal direction into a guide catheter located in the patients neck (carotid artery). While this has shown to be effective in the clinic and easy for the physician to perform, there remain some distinct disadvantages using this approach:

[0006] First, the stent may not sufficient hold on the clot. In such a case, the clot might not move from the vessel. Second, the clot might mobilize from the original blockage site, but might not adhere to the stent during translation toward the guide catheter. This is a particular risk when translating through bifurcations, and the flow can migrate the clot (or pieces of the clot) into the branching vessel. Third, if the clot is successfully brought to the guide catheter in the carotid artery, the clot may be "stripped" from the stent as the stent enters the guide catheter. Fourth, dragging an open stent can be traumatic to the vessel. The stent is usually oversized compared to the vessel, and dragging this relatively fixed metallic structure can pull the arteries and/or strip the cellular lining from the

vessel, causing damage. Also, the stent can become lodged on plaque on the vessel walls resulting in further vascular damage.

[0007] Accordingly, a need remains a need for improved devices to remove occlusions from body lumens and/or vessels.

SUMMARY OF THE INVENTION

[0008] The examples discussed herein show the inventive device in a form that is suitable to retrieve obstructions or clots within the vasculature. The term obstructions may include blood clot, plaque, cholesterol, thrombus, naturally occurring foreign bodies (i.e., a part of the body that is lodged within the lumen), a non-naturally occurring foreign body (i.e., a portion of a medical device or other non-naturally occurring substance lodged within the lumen.) However, the devices are not limited to such applications and can apply to any number of medical applications where elimination or reduction of the number of connection points is desired.

[0009] One device according to the present disclosure includes a funnel device for securing debris and/or devices within a vessel. A variation of such a funnel device includes a shaft having a flexibility to navigate through tortuous anatomy and having a lumen extending therethrough; a funnel comprising a distal opening and a proximal portion connected to the shaft and a cavity therebetween such that when the funnel is expanded the funnel tapers in a proximal direction towards the shaft, the funnel comprising a mesh material secured to the shaft such that when expanded the mesh material forms a funnel configuration having at least an exterior mesh wall and an interior mesh wall that are shape set; and where at least a portion of the mesh material is porous to permit fluid flow therethrough. The walls of the funnel can be in contact or can be set to have a gap.

[0010] In some variation of the funnel the mesh material is compliant and where the interior mesh wall and exterior mesh wall are slidable relative to each other such that withdrawal of the device or debris proximally into the interior mesh wall of the funnel causes movement of the interior mesh wall while a portion of the exterior mesh wall remains stationary when positioned against the vessel.

[0011] The mesh material comprises a first and second end both located at the proximal end of the funnel, where at least either the first or second end can be affixed to the shaft and a

medial portion that forms a perimeter of the distal opening. In other variations, both the first and second end of the mesh material is affixed to the shaft.

[0012] One benefit of the funnel device is that the mesh material can be selected to be sufficiently flexible to permit flexible everting of the funnel over the shaft to permit insertion of the everted funnel and shaft into a secondary device.

[0013] Where necessary, the porosity of the funnel can be controlled or selected by altering braid density, a coating, and/or use of additional braid layers.

[0014] In some variations, the funnel device can include radiopaque markers. For example, at least one radiopaque marker can be placed on a distal end of the shaft.

[0015] The funnel can be fabricated from a single wire or a plurality of wires. The material can comprise a shape memory alloy, or a drawn filled tube material. Moreover, a portion of the mesh material can be fabricated from a radiopaque material.

[0016] Variations of funnels can also include any number of walls.

[0017] Another variation include a system for removing obstructions from a body lumen. For example, the system can include a retrieval device for securing the obstruction; a shaft having a flexibility to navigate through tortuous anatomy and having a lumen extending therethrough; where the retrieval device is axially advanceable through the lumen; a funnel comprising a distal opening and a proximal portion connected to the shaft and a cavity therebetween such that when the funnel is expanded the funnel tapers in a proximal direction towards the shaft, the funnel comprising a mesh material secured to the shaft such that when expanded the mesh material forms a funnel configuration having at least an exterior mesh wall and an interior mesh wall that are shape set; and where at least a portion of the mesh material is porous to permit fluid flow therethrough.

[0018] The present disclosure also includes methods of retrieving an obstruction from a vessel. In one example the method includes advancing an obstruction capture device into the blood vessel; engaging the obstruction capture device with the obstruction; deploying a multi-wall funnel having a plurality of walls, proximal to the obstruction capture device, where the multi-wall funnel comprises at least an exterior wall separated from an interior wall when the multi-wall funnel is expanded, the exterior and interior wall defining an opening and a cavity where the multi-wall funnel tapers in a proximal direction; withdrawing the obstruction capture device proximally into the opening and cavity of the

multi-wall wall funnel; securing at least a portion of the obstruction capture device within the multi-wall funnel by engaging the obstruction capture device with the interior wall of the multi-wall funnel, where continued proximal movement of the obstruction capture device causes the interior wall to move in an axially proximal direction.

[0019] In one variation, the obstruction capture device comprises an elongate stent; and where engaging the obstruction capture device comprises expanding the elongate stent within the obstruction. Alternatively, the obstruction capture device can comprise a distal basket and a proximal basket, and where engaging the obstruction capture device comprises placing the distal basket and proximal basket on either side of the obstruction.

[0020] In another variation the device includes a retrieval device where the retrieval device comprises an elongated stent and funnel in a single controllable unit. For example, the device can comprise an elongated stent extending from an inner connection wire or mandrel , where the inner connection wire or mandrel is coupled to a handle; a funnel extending from a outer shaft, where the elongated stent an inner connection wire or mandrel are moveable through the outer shaft, and where the outer shaft is coupled to the handle. Movement at the handle region of the inner connection wire or mandrel results in translation of the elongated stent into the funnel at the distal end of the device..

[0021] In one variation of the devices described herein, the device comprises a main bundle or group of wires that diverge to form a device having various shapes but few or no connections points or joints (where fabrication of such a construction is referred to as "jointless"). Clearly, the inventive devices described herein are not limited to such a jointless construction. Additional variation includes one or more leading wires that are attached to a capturing portion as described below.

[0022] Devices of the present invention can incorporate any number of wires of different characteristics including, but not limited to, materials, shapes, sizes and/or diameters. Clearly, the number of permutations of device configurations is significant. Providing devices with such a composite construction allows for the manipulation of the device's properties to suite the intended application.

[0023] As noted herein, the joint-less construction improves the flexibility and strength of the device by eliminating joints, connection points, or other attachment points. In addition, the joint-less construction improves the ability of the device to be delivered

through a small microcatheter. As a result, the device and microcatheter are able to access remote regions of the vasculature.

[0024] The devices may be fabricated to be self-expanding upon deployment from a catheter. Alternatively, the devices can be constructed from shape-memory alloys such that they automatically deploy upon reaching a pre-determined transition temperature.

[0025] It should be noted that in some variations of the invention, all or some of the device can be designed to increase their ability to adhere to the obstruction. For example, the wires may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to "weld" to the obstruction. Application of energy to the device can allow the surrounding portion to deform into the obstruction and "embed" within the obstruction. Alternatively, the device can impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. In another variation, a negative charge could be applied to further build thrombus and nest the device for better pulling force. The wires can be made stickier by use of a hydrophilic substance(s), or by chemicals that would generate a chemical bond to the surface of the obstruction. Alternatively, the filaments may reduce the temperature of the obstruction to congeal or adhere to the obstruction.

[0026] Additional devices and methods for treating ischemic stroke are discussed in commonly assigned U.S. Patent application nos.: 11/671,450 filed February 5, 2007; 11/684,521 filed March 9, 2007; 11/684,535 filed March 9, 2007; 11/684,541 filed March 9, 2007; 11/684,546 filed March 9, 2007; 11/684,982 filed March 12, 2007, 11/736,526 filed April 17, 2007, 11/736,537 filed April 17, 2007, and 11/825,975 filed September 10, 2007; the entirety of each of which is incorporated by reference. The principles of the invention as discussed herein may be applied to the above referenced cases to produce devices useful in treating ischemic stroke. In other words, the wire-shaped construction of devices according to present invention may assume the shapes disclosed in the above-referenced cases when such a combination is not inconsistent with the features described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.

[0028] Fig. 1A illustrates an example of a device according to the present invention when used in a system for removing obstructions from body lumens.

[0029] Fig. 1B illustrates a first example of an obstruction removal medical device.

[0030] Fig. 1C illustrates the obstruction removal device articulating relative to leading wires (or a main bundle) without deforming an open end of the capturing portion.

[0031] Figs. 2A to 2E show a capturing portion for use with systems described herein where the capturing portion has sections of varying axial strengths. Such features can optionally be designed to provide a spring force when a section of the capturing portion is compressed and/or staged inversion of the capturing portion so that it can be removed through an immovable obstruction.

[0032] Fig. 3A illustrates a first variation of the device having a joint-less construction of a capturing portion that articulates about a main bundle of wires.

[0033] Figs. 3B to 3H illustrate various constructions of capturing portions for use in the present invention.

[0034] Fig. 4A illustrates a variation of a capturing portion having a main bundle that extends beyond a certain distance to provide a device having an extremely flexible distal region and a relatively stiff proximal region with a strong joint region that will be sufficiently spaced from tortuous anatomy during use of the device.

[0035] Fig. 4B illustrates a main bundle having a curved or shaped portion.

[0036] Figs. 4C to 4E illustrate wires of different constructions within a main bundle.

[0037] Fig. 5A illustrates an example of a proximal foot located on a catheter of the present system.

[0038] Fig. 5B illustrates a distal and a proximal capturing portion located on a system under the present invention.

[0039] Figs. 5C to 5E illustrate an overview of a variation of a delivery system employing a proximal and distal capturing portion.

[0040] Figs. 5F illustrates compression or collapsing of a proximal capturing portion about an obstruction prior to translation of the obstruction in the vessel.

[0041] Figs. 6A to 6B illustrate an example of traversing an obstruction with a sheath to deploy a distal capturing portion.

[0042] Figs. 7A to 7C illustrates a condition where a section of the capturing portion deflects to provide a spring force that gradually drives a traversing section along the obstruction.

[0043] Figs. 7D to 7G illustrate staged inversion of the distal capturing portion to allow removal of the device from an immovable clot.

[0044] Fig. 8A illustrates closure of the proximal opening of a capturing portion without the benefit of articulation of the capturing portion about a leading wire.

[0045] Fig. 8B illustrates, conceptually, one benefit of articulation of a capturing portion about a leading wire or main bundle of wires.

[0046] Figs. 8C to 8D illustrate a proximal capturing portion and a distal capturing portion approaching an obstruction.

[0047] Fig. 8E illustrates the system as the two capturing portions are drawn together.

[0048] Fig. 8F illustrates a device after securing an obstruction between proximal and distal capturing sections.

[0049] Fig. 9 illustrates a main bundle as including an increased surface area or medial foot that is used to dislodge or loosen the obstruction from a wall of the body passage.

[0050] Fig. 10 illustrates a variation of a proximal and distal end of a retrieval device.

[0051] Figs. 11A to 11C illustrate a variation of a funnel catheter useful for retrieving objects from vessels or body lumens.

[0052] Fig. 12A shows an example of a retrieval device getting caught on a guide sheath.

[0053] Figs. 12B to 12D provide illustrative examples of funnel catheter used for removal of an obstruction.

[0054] Fig. 13A to 13G illustrates another variation of a funnel catheter using a mesh or layer of material to form a funnel.

[0055] Figs. 14A to 14D illustrate additional concepts to prevent or minimize flaring of the distal capture portion so that it may be withdrawn into a guide sheath.

[0056] Figs. 15A illustrates another variation of a distal basket and a proximal basket.

[0057] Figs. 15B to 15D illustrate a distal basket having features to minimize or prevent radial expansion during inversion or staged inversion.

[0058] Figs. 16A to 16F illustrate a variation of an infusion stent structure located at an end of a shaft.

[0059] Figs. 17A to 17E illustrate use of an infusion stent structure to open flow in a vessel having a clot.

[0060] Figs. 18A to 18C show a variation of system for retrieving obstructions from a lumen including a longitudinal stent along with a distal capture portion.

[0061] Fig. 19A to 19C illustrate additional variations of systems having a temporary stent coupled to a proximal structure that assists in removal of the obstruction when trapped between the temporary stent and the proximal structure.

[0062] Fig. 19D shows a variation of a combination device having a funnel and stent coupled to a single handle that allows relative movement between the stent and funnel.

[0063] Figs. 20A to 20F show variations of systems for removing an obstruction from a body lumen.

[0064] Figs. 21A to 21C show a variation of a multi-wall funnel.

[0065] Figs. 21D to 21L show additional variations of the construction of multi-wall funnels.

[0066] Fig. 22A illustrates a multi-walled funnel having a wall with a varying thickness.

[0067] Fig. 22B illustrates a funnel having multiple zones with varying porosity.

[0068] Fig. 22C shows a funnel with a polymer coating over or in the mesh of the funnel.

DETAILED DESCRIPTION

[0069] It is understood that the examples below discuss uses in the cerebral vasculature (namely the arteries). However, unless specifically noted, variations of the device and method are not limited to use in the cerebral vasculature. Instead, the invention may have applicability in various parts of the body. Moreover, the invention may be used in various procedures where the benefits of the method and/or device are desired.

[0070] Fig. 1A illustrates a system **10** for removing obstructions from body lumens as described herein. In the illustrated example, this variation of the system **10** is suited for removal of an obstruction in the cerebral vasculature. Typically, the system **10** includes a catheter **12** microcatheter, sheath, guide-catheter, or simple tube/sheath configuration for

delivery of the obstruction removal device to the target anatomy. The catheter should be sufficient to deliver the device as discussed below. The catheter **12** may optionally include an inflatable balloon **18** for temporarily blocking blood flow or for expanding the vessel to release the obstruction.

[0071] It is noted that any number of catheters or microcatheters maybe used to locate the catheter/microcatheter **12** carrying the obstruction removal device **200** at the desired target site. Such techniques are well understood standard interventional catheterization techniques. Furthermore, the catheter **12** may be coupled to auxiliary or support components **14**, **16** (e.g., energy controllers, power supplies, actuators for movement of the device(s), vacuum sources, inflation sources, sources for therapeutic substances, pressure monitoring, flow monitoring, various bio-chemical sensors, bio-chemical substance, etc.) Again, such components are within the scope of the system **10** described herein.

[0072] In addition, devices of the present invention may be packaged in kits including the components discussed above along with guiding catheters, various devices that assist in the stabilization or removal of the obstruction (e.g., proximal-assist devices that holds the proximal end of the obstruction in place preventing it from straying during removal or assisting in the removal of the obstruction), balloon-tipped guide catheters, dilators, etc.

[0073] Fig. 1B illustrates a first example of an obstruction removal medical device according to the features described herein. As shown, the device **200** generally includes capturing portion **226** comprising a translating section/surface **222** and a capturing section/surface **224**. In the illustrated variation, the translating section **222** shown comprises a wire framework. However, any number of configurations is within the scope of this disclosure. In many variations of the device, the translating section **222** provides a low friction surface so that it translates over the obstruction without significantly moving the obstruction. This permits the capturing portion **226** to envelop or surround the obstruction prior to attempting to move the obstruction within the body lumen. As noted herein, the translating section **222** attempts to reduce the outward radial force applied by the obstruction against the wall of the lumen during movement of the obstruction within the lumen.

[0074] Fig. 1B illustrates a distal section of the capturing portion **226** that serves as a capturing section/surface **232**. The capturing section **232** has an increased frictional surface (in this variation illustrated by the crossing **204** wires) so that it can capture and ultimately remove the obstruction. The frictional surface of the capturing section **232** can also be described as an increased coverage density. In essence, as the frictional surface of capturing section **232** coverage density increases, there is a greater "device" surface area to interact with the obstruction. In some variations the capturing section **232** increases in frictional surface between the translating section **234** and the end of the device **200**.

[0075] As shown, the device **200** includes a main bundle **202** comprising a group of individual leading wires **204**. In this variation, the bundle of leading wires **204** is surrounded by a coil or coiled wire **205**. The coiled wire **205** can comprise a single leading wire that joins the device **202**. Alternatively, the coiled wire **205** can extend terminate or wrap back prior to forming the capture portion **226**. Moreover, the coiled wire **205** can extend throughout a length the main bundle **202**, or along one or more segments of the main bundle **202**.

[0076] While the example shows the group consisting of four individual leading wires **204**, the bundle **202** can have any number of leading wires. In various examples 2, 4, or 8 wires were used to construct the device. In certain variations, the number of wires in the main bundle loop around from the capturing portion. For example, if 2 leading wires are used to construct the device, then when constructing the main bundle **202** 2 wires are set to extend distally towards the capturing portion, where the 2 wires are then shaped to form the capturing portion. Eventually, the wires then loop back to extend proximally away from the capturing portion. Therefore, the 2 wires are doubled in the main bundle to create 4 separate wires in the main bundle.

[0077] The individual wires **204** themselves may be comprised of a number of different "micro" filaments, wires, or a single type of wire. Variations of the wires **204** are discussed in detail below; however, the wires **204** can be strands, filaments, or any similar structure that is able to be joined to form the device. The bundle **202** may be braided, wrapped, twisted, or joined in any manner such that they do not separate or become unbundled except where desired. For example, wires in any section of the device

200 can be bonded together (e.g., with epoxy, a polymeric coating, weld, solder, and/or adhesive, etc.) to prevent the wires from separating during deformation of the device as it deploys or removes the obstruction. In addition, the main bundle **202** can incorporate any number of features to assist in orienting the device **200** within the body passage. For example, the main bundle **202** can include a pre-set bend that would bias the capturing portion **226** in a desired orientation upon deployment as discussed below.

[0078] As also discussed below, variations of the present device **200** include capturing portions **226** where the translating section **234** provides a greater axial strength than an axial strength of the capturing section **232**. The axial strength (e.g., column strength) determines whether the respective section of the capturing portion **226** compresses when the device **200** encounters resistance from an object and as a proximal or pulling force is applied through the main bundle or leading wire **202**. In use, the translating section **234** resists axial compression and deformation so that it can locate about the obstruction. While the nature of moving the translating section will place the structure in a state of compression, there will be no visible deformation or deflection that prevents the translating section from advancing across an obstruction.

[0079] There are a number of approaches to adjust the axial strength of a capturing section **232** as well as the entire structure. In a first example, the manner in which the leading wire is wound to form the respective surface **232**, **234** impact the respective axial strength. As shown, the traversing section **234** comprises a series of wrapped wires extending in an axial direction. This axial alignment causes the wires to oppose axial forces and thus increases the axial strength of the traversing section **234** relative to the capturing section **232**. In the latter section, the wires **232** extend in a helical direction about the section **232**. Thus there is less resistance to an axial load when compared to the traversing section **234**.

[0080] Alternatively, or in combination, additional techniques can produce a device **200** with a capturing portion **226** that has sections of varying axial strength. In one example, the wire diameter can be adjusted to produce the desired column strength. Generally, for a given construction, a larger diameter wire increases the column strength of the section. In addition, larger diameter leading wires can terminate at the translating section **234** to permit smaller diameter wires to form the capturing section **232**. In another example, the

leading wire **204** composition can be selected to produce the desired axial strength. For example, drawn filled tube (DFT) wire has 30% platinum 70% nitenol. Decreasing the amount of platinum and increasing the nitenol increases the wire strength and results in higher column strength. In yet another example, the respective section, or the entire capturing portion **226**, can be processed to produce the desired axial strength. For example, changing the annealing profile (e.g., temp, time) affects the wire strength, and therefore the axial strength.

[0081] Variations of devices **200** described herein can have capturing portions with alternate configurations than those shown in above. The capturing portion **226** can include constructional designs such as a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a film, a membrane, a polymer covering, , or a plurality of crossing wires. In variations of the device, the capturing portion **226** is sufficiently permeable to allow blood or other fluid flow therethrough. As noted above, capturing portion **226** may be any structure that covers, encapsulates, engulfs, and/or ensnares the obstruction either fully or partially. Accordingly, although the capturing portion **226** is illustrated as a filter/bag, the wires may diverge to form a coil, helical shape, other mesh structure, or any other structure that defines a space that can be translated over the obstruction to ultimately remove the obstruction **2**.

[0082] The capturing portion **226** can include an open proximal end **228**, a permeable distal end **230** and a capturing surface **232** located therebetween. The capturing surface **232** of the capturing portion **226** defines a volume, cavity, or space that is able to cover, encapsulate, envelop, engulf, ensnare and/or surround the obstruction. Generally, the term traversing wire or filament refers to the section of leading wire **204** that forms the traversing surface **238**. Generally, the traversing wires form the capturing surface **238** and then form the open proximal end **228**. As discussed herein and illustrated below, the open proximal end **228** expands within the lumen, typically to the lumen walls, so that the obstruction enters the open proximal end **228** as the bundle **202** (or leading wire) translates the device **200** proximally.

[0083] The permeable distal end **230** is typically sufficiently porous so that fluid or blood may flow through. However, the end **230** is sufficiently closed (or has an increased surface area) so that the obstruction should not escape through the distal end **230** of the

device **200**. This construction typically causes the obstruction to become ensnared within the capturing portion **226** and prevented from passing through by the permeable distal end **230**.

[0084] As shown in Fig. 1C, an important feature of the present devices **200** is that the main bundle **202** and capturing portion **226** can articulate relative to one another without interfering with the size or profile of the open proximal end **228**. This feature is described more fully below. As shown, the main bundle **202** extends through the open proximal end **228** and through at least a the traversing section **234**capturing portion **226**.

[0085] Fig. 1C illustrates a condition where the main bundle **202** and capturing portion **226** articulate relative to one-another. Because the main bundle **202** joins the capturing section **232** at a distance from the open proximal end **228** movement of the main bundle **202** relative to an axis **236** of the capturing portion **226** does not reduce a profile of the open proximal end **228**. If the main bundle **202** were affixed or connected to the open proximal end **228**, then any movement of the bundle **202** away from the capturing portion's axis **236** would exert a force on the open end. This force, in turn, would cause the open end to narrow or deform. By doing so, the open end would not be able to uniformly expand against the lumen wall to capture the obstruction.

[0086] Turning now to the construction of the device **200**, as shown above, the main bundle or a leading wire **202** extends beyond the open proximal end **228** and forms the capturing portion. In one variation, the construction of the device relies on converging/diverging wires to form continuous shapes so that the device is completely joint or connection free. However, as noted herein, the leading wire or main bundle **202** can be affixed to a structure that forms the capturing portion via an attachment point, joint, or junction. In addition, the structures forming the capturing portion can be fabricated from such processes as laser cutting of tubes, etching, metal injection molding, or any other such process.

[0087] The devices of the present invention can also include additional features to aid in removal of obstructions. For example, as shown in Figs. 1B to 1C, the open proximal end **228** can include one or more petals or flanges **238** extending radially outward. The flanges **238** allow device **200** to have a flared structure at the open proximal end **228**. In one example, the capturing portion **226** can be slightly oversized relative to the body

passage containing the obstruction or slightly larger than the capturing portion. The flanges **238** provide an additional force against the wall of the passage to ensure that the device **200** is able to surround or encapsulate the obstruction. In yet another feature, in variations of a system having a proximal and distal capturing portion, the flanges can serve to lock the proximal and distal capturing portions together once they encapsulate or surround an obstruction. This feature minimizes the chance that the obstruction escapes from the capturing portions as the device and obstruction are removed from the body lumen.

[0088] In additional variations, the main bundle can diverge to form the capturing portion in multiple locations so long as the capturing portion's ability to articulate is not sacrificed. For example, the main bundle can diverge in several locations along the capturing surface (not shown).

[0089] Figs. 1B to 1C also shows an integrally formed reinforcement ring **240** located along the length of the capturing surface **232** (i.e., on the traversing wires). The reinforcement ring **240** can be a separate or discrete ring located on or in the capturing surface **232**. Alternatively, or in combination, the reinforcement ring **240** can be a ring shape that is integrally formed through arrangement of the wires **204** (as show in Figs. 1B to 1C). The reinforcement ring **240** assists in expanding the device when deployed in the body lumen and/or prevents the device (e.g., the open proximal end) from collapsing as the device moves within the lumen to secure the obstruction. The reinforcement ring **240** can comprise a single wire, or a twisted pair of wires. Alternatively, the rings do not need to extend entirely circumferentially around the capturing surface. Instead, a reinforcement portion may extend between adjacent traversing wires but does not necessarily extend around the circumference of the capturing section. As noted herein, reinforcement portions may extend between adjacent traversing wires in multiple locations.

[0090] Figs. 2A to 2E show several benefits of varying axial strengths of the different sections of a capture portion **226**. As shown in Fig. 2A, when the physician retrieves the capturing portion **226** by pulling on the leading wire or main bundle **202** (as shown by arrow **120**), the entire capturing portion **226** translates as shown by arrow **122**. However, when the device **200** encounters resistance (as schematically shown by force arrows **124**)

the lesser axial strength of the capturing section **232** causes axial deformation or compression of the capturing section **232** (as shown by Fig. 2B). In certain variations, the capturing section **232** can be constructed to function as spring such that deformation of the capturing section **232** stores energy. Accordingly, the physician can pull the main bundle **202** to build energy in the capturing section **232**, then relax the force on the main bundle **202**. The stored energy in the capturing section **232** gradually drives the open proximal end of the translating section **234** over or along the obstruction. The physician can apply this "pull and relax" technique repeatedly until the obstruction is sufficiently captured by the capturing portion **226**.

[0091] Fig. 2C shows an additional safety benefit given the varying axial strengths of the different sections of a capture portion **226**. In the event the capturing portion **226** encounters an excessive degree or threshold of force (as denoted by arrows **124**), the reduced axial strength of the capturing section **232** can invert within the translating section **234**. As shown, the permeable distal end **230** of the capturing section **232** inverts and is pulled by the main bundle **202** within the translating section **234** and reduces in size. As shown in Fig. 2D, continued pulling on the main bundle **202** causes eventual inversion of the translating section **234** so that the capturing section **232** extends through the translating section **234** and the permeable distal end **230** is now proximal to the translating section **234**. Continuing to apply move the main bundle **202** in a proximal direction **120** inverts the capturing portion **226** as shown in Fig. 2E. As shown, the translating section **234** is now distal to the capturing section **232**. This causes a reduction in the size of the capturing portion through inversion of the capturing portion **226**. This feature permits withdrawal of the capturing portion **226** within a delivery sheath **106** or through an immobile obstruction (as discussed below). As shown below, the ability to sequentially invert the capturing portion **226** and reduce its diameter enables retrieval of the device if deployed distal to atherosclerotic plaque or an immobile object where continued pulling against the object could cause damage or tearing of the body passage or vessel wall. It was found that retrieval devices that are not constructed with regions of varying axial strength, spring function, or staged inversion can often flatten or expand in diameter when attempting to retrieve the device though an immobile or stubborn obstruction.

[0092] Fig. 3A illustrates an additional variation of a capturing portions **226** according to the present disclosure. In Fig. 3A, the main bundle **202** and the group of wires **204** branch or diverge at the permeable distal end **230** to form the capturing portion **226**. In additional variations, the main bundle **202** can branch or diverge within a mid-portion of the capturing surface **232** rather than at the permeable distal end **230**. In such a case, the wires **204** form the capturing surface **232** first and ultimately branch to form the remainder of the capturing portion. In any case, by extending through the open proximal end **228**, the main bundle **202** is able to articulate relative to the capturing portion **226** without significantly reducing a profile of the open distal end **228**. As discussed above, the capturing surface **232** of these variations is fabricated (either through processing or wire construction) to have an axial strength that is lower than that of the traversing section **234**.

[0093] Fig. 3B illustrates a variation having an integrated reinforcement ring **240**. Typically, the reinforcement ring **240** provides radial strength to the capturing portion **226** to prevent collapse or deformation that would otherwise interfere with enveloping the obstruction. A reinforcement ring **240** may allow for use of wires that would otherwise provide unacceptable radial strength. For example, the reinforcement ring **240** may permit use of smaller diameter wires thereby allowing the device **200** to compress to a smaller diameter during delivery via a catheter.

[0094] In addition to the reinforcement ring **240**, Fig. 3B includes an open proximal end **228** having a number of petals/flanges **238**. In this variation, although the flanges **238** intersect one another, they are independently moveable.

[0095] Fig. 3C shows a variation of a device **200** where the capturing portion **226** includes flanges **238** that are interwoven or connected with adjacent flanges **238**. (Variations include bonding or otherwise joining the adjacent flanges together.) This feature provides the flanges **238** with a higher radial strength that reduces the likelihood that the flanges **238** bend or distort when moving in the body lumen or removing the obstruction.

[0096] Figs. 3D to 3E illustrate additional variations of devices having capturing portions **226** that have a basket type configuration. As shown, the capturing portions **226** and surface **232** comprise a denser mesh of traversing wires that ultimately lead to the

traversing section **234** that terminates in flanges **238** at the open proximal end **228**. In such variations, a first portion of the traversing surface **232**that is adjacent to the open proximal end has a low coverage density relative to the remaining portion of the capturing surface having a higher coverage density that eventually forms the permeable distal end **230**. This construction lowers the lowering frictional resistance of the first portion of the capturing surface when moving over or against the obstruction but allows the remaining portion of the capturing surface to encapsulate and secure the obstruction.

[0097] As shown in Fig. 3E, the wires diverge from the main bundle towards the distal end of the capturing portion **226** to form the permeable distal end **230**. The permeable distal end **230** can actually have the same configuration as the capturing surface **232**. In other words, the permeable distal end can simply be an extension of the capturing surface that extends over the distal end of the capturing portion.

[0098] Naturally, the divergence of the wires can occur over a length of the capturing portion **226** rather than immediately at the distal end. For example, as show in Fig. 3D, the wires diverge towards a mid-section of the capturing portion and ultimately form the permeable distal end **230**.

[0099] Fig. 3F illustrates a variation of a device **200** having multiple reinforcement rings **240**. As noted above, the reinforcement rings provide additional radial strength to the capturing portion **226** as the device **200** moves within the body lumen and prevents distortion of the capturing portion **226**. However, as noted above, the device will be fabricated to provide varying regions of axial strength to allow for either the spring effect or the staged inversion discussed above. In any case, the rings **240** do not need to extend around an entire circumference of a device, variations include any number of supports that extend between adjacent traversing wires.

[0100] Fig. 3G illustrates another variation of a device **200** having a leading wire **202** extending to a distal end **230** of a capturing portion **226**. In this variation the capturing portion **226** is fabricated from a stent-type structure. As noted above, it is within the scope of this disclosure to use any type of similar structure such as a laser cut tube, a chemically etched or photo etched tube, a polymer or metal injection molded structure, a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a film, a membrane, a polymer covering, or a plurality of crossing wires as the capturing portion

226 so long as the device can be compressed to a small size for delivery and expand after traversing the obstruction. The illustrated variation also shows a covering **270** located on the distal end **230** of the capturing portion **226**. The length of the polymeric covering **270** can vary across the capturing portion **226** to prevent the obstruction from escaping as the device is translated over the obstruction. Furthermore, the covering **270** can be polymeric or a wire mesh. However, typically the covering has sufficient porosity to allow blood to flow through the device **200**. In this variation, the flanges **238** form the translating surface.

[0101] Fig. 3H illustrates another feature for use with system described herein. In this variation, the system includes a proximal capturing portion **260** located on an exterior of a delivery sheath **106**. The main bundle **202** extends through the sheath **106** to a distal capturing portion (not shown). As discussed below, the proximal capturing portion **260** can be similar to the distal capturing portions **226** described herein with the exception that the distal end **262** of the proximal capturing portion is open while the proximal end **264** of the proximal capturing portion is closed. Furthermore, the proximal capturing portion **260** articulates with respect to the sheath **106** much in the same manner as the distal capturing portion **226** articulates relative to the main bundle **202**. In this variation, the proximal end **264** of the proximal capturing portion **260** is tapered or has a smaller profile than the remaining proximal capturing portion **260**. Such a feature may be useful to improve the deliverability of the device to the intended site as well as to maneuver around any obstructions within the body passage. In addition, as noted below, the proximal capturing portion **260** can be compressed about the obstruction to improve the ability of the system to remove the obstruction. The construction of the proximal capturing portion **260** can optionally include variations having regions of differing axial strength, or sections capable of generating spring force. Typically, since the proximal capturing portion **260** is not advanced distal to the obstruction, the need for staged inversion is not necessary. Accordingly, any number of capturing designs can be incorporated for the proximal capturing portion.

[0102] In some variations, the leading wire can extend to the proximal end of the system for manipulation by the physician. However, it is often the case that the characteristics of the device must vary along its length. For example, when the device is intended for use

in remote tortuous anatomy, the proximal section of the device is desirably stiffer (to advance the distal portion of the device to the target anatomy). However, the distal section of the device must have properties that make it suitable for the tortuous anatomy. In the case where devices are used in the cerebral vasculature, the distal section must be extremely flexible, while the proximal section should be stiff. In many cases, different material properties are required. A problem then arises in attempting to join different materials especially in the joining region.

[0103] Conventional joining methods include soldering, welding, gluing, thermal junctions, etc. These joining methods produce an area having an increase in the stiffness of the device. For example, if two wires are to be laser welded together, then the section where they are joined has an overlap which yields greater stiffness than the rest of the wire. This increased area of stiffness is often balanced against the strength of the joined segment. If the joined region is too long, the strength will be sufficient but the increase in stiffness often prevents navigation through the tortuous anatomy. IF the joined region is too short, then the device can navigate through the anatomy but the bond is weaker and a risk of failure increases.

[0104] Fig. 4A illustrates another variation of an improvement for use with the devices described herein especially for use in tortuous anatomy such as the cerebral vasculature. In this example, the capturing portion **226** is show with a number of leading wires **204** extending proximally. To provide the desired characteristics, the leading wires **204** are joined in region **196** to wires **198** having a structure that is suitable for the proximal anatomy (e.g., the wires are larger in diameter or stiffer). To enable use of the device **200** in the cerebral anatomy without compromising bond strength characteristics or flexibility of the device **200**, the leading wires extend a pre-determined region so that the bond region **196** is placed out of the tortuous anatomy. Since the cerebral vasculature is approximately 30 centimeters in length, the leading wires **204** can extend for a length **195** of at least a predetermined length so that it remains very flexible when navigating the cerebral vasculature or other tortuous anatomy. In one example the length was 20 centimeters (but can be 30 or more centimeters). By deliberately extending the leading wires **204** by length **194**, the length of the bond region **196** can be chosen to accommodate the proximal anatomy (where a greater stiffness of the bond region **196** can

be accommodated). The length of the bond region **196** can vary depending on the application (e.g., from 2 to20 cm for a device intended for cerebral the cerebral vasculature). However, the bond can extend along the entire proximal section of leading wire.

[0105] Fig. 4B illustrates an addition aspect of for use with devices described herein where the main bundle **202** has a curved or bend portion **252**. This pre-set shape assists in orienting the capturing portion **226** within the body passage since the bend will cause the device to bias against a wall of the body passage.

[0106] Fig. 4C and 4D show cross sectional views taken along the line A-A in Fig. 4B. As shown, the wire form construction described herein allows for a number of configurations depending on the particular application. For example, the individual wires **204** (as discussed herein) may themselves comprise a bundle of smaller wires or filaments. In addition, the wires can be selected from materials such as stainless steel, titanium, platinum, gold, iridium, tantalum, Nitinol, alloys, and/or polymeric strands. In addition, the wires used in a device may comprise a heterogeneous structure by using combinations of wires of different materials to produce a device having the particular desired properties. For example, one or more wires in the device may comprise a shape memory or superelastic alloy to impart predetermined shapes or resiliency to the device. In some variations, the mechanical properties of select wires can be altered. In such a case, the select wires can be treated to alter properties including: brittleness, ductility, elasticity, hardness, malleability, plasticity, strength, and toughness.

[0107] The device may include a number of radiopaque wires, such as gold and platinum for improved visibility under fluoroscopic imaging. In other words, any combination of materials may be incorporated into the device. In addition to the materials, the size of the wires may vary as needed. For example, the diameters of the wires may be the same or may vary as needed.

[0108] In addition, the individual wires may have cross-sectional shapes ranging from circular, oval, d-shaped, rectangular shape, etc. Fig. 4C illustrates one possible variation in which a number of circular wires **204** are included with a d-shaped wire 205. Moreover, the device is not limited to having wires having the same cross-sectional shape or size. Instead, the device can have wires having different cross-sectional shapes. For

example, as shown in Fig. 4D, one or more wires **205** can have a different cross-sectional shape or size than a reminder of the wires **204**. Clearly, any number of variations is within the scope of this disclosure.

[0109] To illustrate one such example, a device can have 8-12 wires made of .003" round superelastic material (e.g., nitinol). The device may additionally have 2-4 wires made from .002" platinum for fluoroscopy. Of the 8-12 nitinol wires, 1-4 of these wires can be made of a larger diameter or different cross-section to increase the overall strength of the device. Finally, a couple of polymer fibers can be added where the fibers have a desired surface property for clot adherence, etc. Such a combination of wires provides a composite device with properties not conventionally possible in view of other formation means (such as laser cutting or etching the shape from a tube or joining materials with welds, etc.). Clearly, any number of permutations is possible given the principles of the invention.

[0110] In another example, the device may be fabricated from wires formed from a polymeric material or composite blend of polymeric materials. The polymeric composite can be selected such that it is very floppy until it is exposed to either the body fluids and or some other delivered activator that causes the polymer to further polymerize or stiffen for strength. Various coatings could protect the polymer from further polymerizing before the device is properly placed. The coatings could provide a specific duration for placement (e.g., 5 minutes) after which the covering degrades or is activated with an agent (that doesn't affect the surrounding tissues) allowing the device to increase in stiffness so that it doesn't stretch as the thrombus is pulled out. For example, shape memory polymers would allow the device to increase in stiffness.

[0111] In another variation, one or more of the wires used in the device may comprise a Drawn Filled Tube (DFT) such as those provided by Fort Wayne Metals, Fort Wayne, Indiana. As shown in Fig. 4E, such a DFT wire 252 comprises a first material or shell 208 over a second material 210 having properties different from the outer shell. While a variety of materials can be used, one variation under the present devices includes a DFT wire having a superelastic (e.g., Nitinol) outer tube with a radiopaque material within the super-elastic outer shell. For example, the radiopaque material can include any commercially used radiopaque material, including but not limited to platinum, iridium,

gold, tantalum, or similar alloy. One benefit of making a capturing portion from the DFT wire noted above, is that rather than having one or more markers over the capturing portion, the entire capturing portion can be fabricated from a super-elastic material while, at the same time, the super-elastic capturing portion is made radiopaque given the core of radiopaque material within the super-elastic shell. Clearly, any composite DFT wire 252 can be incorporated into the system and capturing portions described herein.

[0112] Fig. 5A shows a working end of a variation of a system **10** for removing an obstruction from a body lumen. In this variation, the system **10** includes a main bundle **202** and capturing portion **226** extending out of a micro-catheter or catheter **102**. The micro-catheter **102** can optionally include a proximal foot **256** that can slide axially over main bundle **202** and can be variably positioned in relation to the capturing portion **226**. The proximal foot **256** can include any number of configurations apart from the petal/flange **258** configuration (i.e., the foot can be a balloon, coil, shoulder, etc. where such structures simply replace the petals in Fig. 5A). In any case, the proximal foot **256** provides an increased surface area that provides an opposing force to the capturing portion **226**, where the opposing force aids the movement of the obstruction within the capturing portion **226**. Alternatively, the proximal foot stabilizes the obstruction and keeps the obstruction from moving with the capturing portion until the capturing portion envelops the obstruction.

[0113] The size of the proximal foot **256** can be adjusted depending on the target site anatomy. For example, a larger surface area can be employed if the target site is within a bifurcation of the body passage. The size of the proximal foot **256** can also be adjustable during the procedure. For example, in the case of a petal/flange **258** configuration, the petals **258** can assume a larger size to initially stabilize the obstruction and then reduce in size to allow the obstruction to be completely engulfed by capturing section **226**.

[0114] The proximal foot **256** can extend from an interior of the catheter **102**, such as from within the internal lumen of the catheter, or from an additional lumen within a wall of the catheter. Alternatively, the proximal foot **256** can be permanently affixed to the catheter **102**. In such a case, a separate catheter (without a proximal foot) can be employed to traverse the obstruction for deployment of the device distally to the obstruction. Once the device is deployed, the catheters can be exchanged to provide the

proximal foot. In an additional variation, the proximal foot **256** can be affixed to a delivery sheath (as described below) and be collapsed within the catheter, where advancement out of the catheter expands the proximal foot **256** so that it may function as described above.

[0115] In an additional variation, a proximal capturing portion (as shown in Fig. 3H) can be used with a foot **256** that is located about the main bundle **202**. Such a variation may or may not include a distal capturing portion. Accordingly, the construction of the proximal capturing portion (as described herein to include sections of varying axial strength) can be used to perform a push and relax technique (similar to that of the pull and relax technique described herein).

[0116] Fig. 5B illustrates another variation of the system **10** where the system includes a proximal capturing portion **260** located on an exterior of a delivery sheath **106**. Naturally, the proximal capturing portion **260** could also be affixed to an exterior of a micro-catheter. The proximal capturing portion **260** is similar to the capturing portions **226** described herein with the exception that the distal end **262** of the proximal capturing portion is open while the proximal end **264** of the proximal capturing portion is closed. The proximal capturing portion can also optionally be configured to have regions of varying axial strength, spring rate, and various other features associated with the distal capturing portion **226**. In the illustrated variation, the capturing portion **226** and main bundle **202** move relative to the proximal capturing portion **260** to capture an obstruction. Furthermore, the proximal capturing portion **260** articulates with respect to the sheath **106** much in the same manner as the distal capturing portion **226** articulates relative to the main bundle **202**. As shown, the petals **238** on the open ends **228** and **262** can interact to nest once the capturing portions **226** and **260** are moved sufficiently close to one another. The outward force caused by the retained obstruction provides a frictional interaction between adjacent petals/flanges **238** to maintain the nesting.

[0117] Variations of the device include additional structures, such as springs, hooks, barbs, etc, to cause the open ends 228 and 262 to interlock. As noted above, a separate catheter can be used to initially deploy the capturing portion **226** beyond the obstruction. Although the capturing portions shown have the same configuration, the capturing portions **226** and **260** used in any given system do not have to match in size, shape, and

configuration. For example, the proximal capturing portion can be impermeable to flow while the distal capturing portion allows flow. In another example, one basket may be undersized relative to the other to improve nesting.

[0118] In any case, the construction of the system **10** shown in Fig. 5B includes open ends **228** and **262** of capturing portions **226** and **260** that are unconnected. Accordingly, as the capturing portions **226** and **260** move towards one another as a result of the main bundle **202** translating relative to the delivery sheath **106** the open ends are free to articulate around the main bundle **202** and delivery sheath **106** respectively to remain expanded against the lumen wall.

[0119] Figs. 5C to 5E illustrate a variation of a system for delivery of the capturing portions **226** and **260**. Fig. 5C shows the proximal **260** capturing portion affixed to a delivery sheath **106**. In alternate variations, the proximal capturing portion **260** can be replaced with a proximal foot (not shown). As noted above, the main bundle or leading wires **202** extends through the delivery sheath **106** and connects to the distal capturing portion **226** beyond the opening **228** of the distal capturing portion **200**. The main bundle or leading wire **202** extends through the proximal capturing portion **260**. This allows the free ends of the capturing portions **228** and **262** to remain relatively unattached so that they can articulate and conform to the curvature of the vessels (as discussed below). The capturing portions **226** and **260**, main bundle **202** and delivery sheath **106** extend through a microcatheter **102**.

[0120] Fig. 5D illustrates a state of deployment after the microcatheter **102** traverses the obstruction (not shown). Once the microcatheter **102** is distal to the obstruction, the distal capturing portion **226** deploys from the end of the microcatheter **102**. As noted herein, the capturing portions can self-expand or can expand upon actuation by the physician. In any case, the distal capturing portion **226** should be sufficiently collapsible to remain within the microcatheter **102** for deployment distal to an obstruction. To deploy the distal capturing portion **200** from the catheter **102**, the main bundle **202** can translate to push the distal capturing portion **226** to eject it from the catheter **102**. Alternatively, the microcatheter **102** can be withdrawn from the distal capturing portion **226**.

[0121] Fig. 5E illustrates the deployment state after the catheter **102** is withdrawn proximal to the obstruction (not shown) and after the proximal capture portion **260** is delivered from the microcatheter **102**. As noted above, the proximal capture portion **260** can be affixed to an exterior of the catheter, in which case the catheter may be either de-sheathed or exchanged. Alternatively, and as shown, the proximal capturing portion **260** is affixed to a delivery sheath **106** and is fabricated to collapse within the microcatheter for ultimate deployment, whereby translating the sheath **106** delivers the proximal portion **260** from the microcatheter.

[0122] Fig. 5F shows another aspect of the system **10** where the proximal end **264** of the proximal capturing portion **260** is collapsed or compressed about an obstruction **2** prior to translation of the obstruction **2** within the vessel. In this illustration, the proximal capturing portion **260** is compressible by advancing the catheter **102** over the closed proximal end **264** of the capturing portion **260**. In such a case, the proximal capturing portion **260** is slidable within and relative to the catheter **102.** Naturally, variations may include compressing the proximal end **264** during translation of the obstruction **2**. In either case, the proximal capturing portion **260** can be compressed in a number of different ways. For instance, the proximal basket can be compressed using a catheter **102**(as shown), or the delivery sheath **106**, or any other number of mechanisms (not illustrated).

[0123] As shown, the proximal end **264** can be compressed using a sheath **106** and/or catheter **102** However, other means of compressing may be employed (e.g., a loop structure, a tube over the sheath, a draw-string configuration, etc.) In use, once the distal capturing portion **226** is deployed distally to the obstruction **2** and the catheter **102** is withdrawn proximal to the obstruction **2**, the proximal capturing portion **260** is deployed. As the proximal capturing portion **260** partially (or totally) engulfs the obstruction **2**, the physician can collapse or compress the proximal capturing portion **260** to better secure the obstruction within the system **10**.

[0124] It is noted that any number of shapes, configurations, as well as any number of joined wires may be contemplated to form devices under the present disclosure. However, variations of the invention include selecting a number of wires to produce specific structural properties to the device. For example, the devices can have any

number of wires where the limit is determined by the ability to produce a device of a sufficiently small size to access the area containing the obstruction. However, in some cases, it may be desired that wires are chosen to impart specified characteristics. For example, in the illustrated variation, the main bundle may comprise any number of wires that do not diverge to form subsequent shapes in the device. In other words, not all of the wires forming a section are required to diverge to form an adjacent section. Instead, these non-diverging wires may simply "loop" back away from the device. In an additional variation, one or more wires may diverge to form a particular portion of the capturing portion (e.g., the closed end, traversing wires, etc.). Then the wires can loop back to converge again with the main bundle.

[0125] Figs. 6A to 6E show one example of the deployment of a variation of a device according to the present invention about an obstruction in a vessel. The figures are intended to demonstrate the initial placement of the device immediately prior to removal of the obstruction.

[0126] Fig. 6A illustrates an obstruction **2** lodged within a body lumen or vessel **6**. In the case where the vessel is a cerebral artery, the obstruction may result in an ischemic stroke. Using standard interventional catheterization techniques, a microcatheter **102** and guidewire **104** traverse the obstruction. The microcatheter **102** may be advanced through the obstruction **2**. Alternatively, the microcatheter **102** may "push" aside the obstruction and is advanced around the obstruction. In any case, the microcatheter **102** travels from the near end **3** (or proximal side) of the obstruction **2** to the far end **4** (or distal side) of the obstruction **2**. It is noted that the catheter **102** may be centered or off-center with respect to the obstruction **2**. Furthermore, the device may or may not be used with a guidewire to navigate to the site and traverse the obstruction.

[0127] Some variations of the device may be placed without an accompanying guidewire. Moreover, the structures discussed herein may be directly incorporated into a guidewire assembly where deployment may require a sheath or other covering to release the components from constraint.

[0128] Fig. 6B illustrates deployment of a capturing portion **226** and main bundle **202** of the device **200** from within the microcatheter **102** distal to the obstruction **2**. Accordingly, in most variations, the capturing portion **226** is designed to fit within the

catheter **102** for delivery and expand upon deployment. Alternatively, the device may be actuated to assume the desired shape (e.g., upon reaching a transition temperature where one or more wires comprise a shape memory alloy). As shown, the capturing portion **226** includes a traversing section **234** and a capturing section **232**. In some procedures the traversing section **234** engulfs the obstruction **2** with little or no complication as the main bundle **202**, catheter **102**, or sheath **106** pulls the capturing portion **226** in a proximal direction.

[0129] However, as discussed above, there may be some procedures where the distal capturing portion **226** is deployed distal to an obstruction **2** that is deposited within the vessel or lumen such that a steady translation of the capturing portion **226** will not engulf the obstruction **2**. Figs. 7A to 7G illustrate some examples of such a situation. As shown in Fig. 7A, a sheath **106** might be able to traverse the obstruction **2** to deploy the distal capturing portion **226** in preparation for engulfing the obstruction **2**. Fig. 7B illustrates a condition where the traversing section **234** engages the obstruction **2** but is unable to easily or fully engulf the obstruction **2**. However, in those variations where the capturing portion **226** includes regions having different axial strength (as discussed above), continued pulling of the main bundle **202** in a proximal direction **120** causes the capturing section **234** to compress. When the capturing section **234** is constructed to function as spring, the deformation of the capturing section **232** stores energy from the proximal movement of the main bundle **202**. This storing of energy allows the physician to relax the pulling force **120** on the main bundle **202**. Fig. 7C shows a compressed capturing section **234**. The energy stored in the capturing section **232** gradually drives the open proximal end **228** of the translating section **234** over or along the obstruction **2**. The physician can apply this "pull and relax" technique repeatedly until the obstruction is sufficiently captured by the capturing portion **226**. In some variations, the capturing section **234** remains compressed as the obstruction **2** finally breaks loose and removed.

[0130] Fig. 7D represents the situation where a distal capturing portion distal to an object **2** that is significantly embedded within a vessel or body lumen. In such cases, the force required to remove the obstruction **2** may damage the vessel or lumen. Such obstructions include atherosclerotic plaque or other immobile objects. As shown, when the distal capturing portion **226** is pulled once the proximal force **120** reaches a threshold value (as

determined by the construction of the capturing portion **226**) the capturing portion **226** undergoes a staged inversion as the permeable end **230** enters the traversing section **232**. In this variation, the permeable end **230** actually enters the obstruction **2**. The construction of the capturing portion **226** prevents flattening or expanding in diameter, where such movements would prevent removal of the capturing portion. Again, if the force applied by the capturing portion **226** breaks the obstruction **2** free. The obstruction **2** can be removed even though a part of the capturing portion **226** is within the obstruction **2** as shown in Fig. 2D.

[0131] Fig. 7E shows advanced inversion of the capturing portion **226** as the capturing section **234** is now proximal to the traversing section **232**. The traversing section **232** may be deformed upon inversion but will taper towards the capturing section **234** as the capturing section **234** passes through the obstruction **2** (typically via an opening that was previously created by advancement of a sheath **106** through or around the obstruction **2**).

[0132] Fig. 7F shows the capturing portion **226** nearly passing through the obstruction **2** so that it may be removed from the body. As shown in Fig. 7G, the capturing portion **226** is now fully inverted and is in a state where it can re-enter a catheter for removal from the patient.

[0133] The construction described herein that allows for staged inversion of the capturing portion **2** provides a significant safety feature. A physician must undertake additional surgical intervention to remove any retrieval device that has become lodged distally to an immobile obstruction. The ability of staged inversion allows the physician to invert and remove the capturing portion **226** if application of a predetermined or threshold force is exceeded by proximal displacement of the device. This feature reduces the need for additional surgical intervention to remove a retrieval device that would otherwise become lodged or separated as a result of excessive forces being applied.

[0134] Figs. 8A to 8B illustrate an additional benefit of affixing a leading wire or bundle of wires **202** beyond a proximal opening **228** of a capturing portion **226**. Fig. 5A illustrates a basket type structure **90** where a wire **202** is affixed to a proximal end **92**. As shown, as the leading wire **202** pulls the basket **90** through tortuous anatomy **6**, the force component pulling away from an axis of the device **90** causes the proximal open end **92** to constrict or reduce in size. As shown, as the proximal end **92** approaches the

obstruction **2** the perimeter of the end is not placed against the walls of the body passage **6**. As a result, the constricted opening **92** places an increased axial force on the obstruction **2** as the basket **90** translates over the obstruction **2** (because the proximal end **92** pushes against the obstruction rather than sliding around it), making encapsulation of the obstruction more difficult and possible leading to vascular damage.

[0135] Fig. 8B shows a device **200** according to the principles disclosed herein. The leading wire **202** is affixed to the distal end **230** of the capturing portion **226**. As the main bundle 202 is pulled through the curved vascular path, the capturing portion **226** pivots or articulates about the bundle 202 and remains aligned with the axis of the vessel. As a result any misalignment between the leading wire **202** and an axis of the capturing portion **226** does not affect the open proximal end **228**. As noted above, some closing of the open proximal end may occur, though it will not be sufficient to interfere with the obstruction as the capturing portion moves over the obstruction. Such a configuration allows the perimeter of the open proximal end **228** to remain against the wall of the passage **6**. As shown, because the open proximal end **228** is not constricted, the open proximal end **228** is better suited to slide around the obstruction for eventual removal.

[0136] Fig. 8C shows withdrawal of the microcatheter **102** to the proximal side **3** of the obstruction **2** and deployment of a proximal capturing portion **260** (in alternate variations, a proximal foot can be used or the capturing portion **226** alone can be used). Again, the catheter **102** can be exchanged for a catheter **102** having a proximal capturing portion **260**. Alternatively, and as shown in the accompanying figures, the proximal capturing portion **260** can be affixed to a delivery sheath **106** that is fed through the microcatheter **102**.

[0137] As also shown in the figure, the main bundle **202** and capturing portions become misaligned due to the tortuousity of the anatomy. However, because the capturing portions **226** and **260** are able to pivot or articulate relative to the main bundle **202** and catheter **102** or sheath **106**, the open ends are able to remain against the lumen wall. In conventional devices where the open end is attached to either a wire or catheter, when the wire or catheter bends in the anatomy, the forces exerted on the open ends deform or distort the end to assume a reduced profile. Accordingly, the physician may have difficulty in removing an obstruction if the profile of the open end becomes reduced in

size. Closing of the open end can also result in vascular damage if the physician applies too much force in translating the device.

[0138] Fig. 8D shows movement of the capturing portions **226** and **260** adjacent to the obstruction **2**. The proximal capturing portion **260** can remain stationary or may be advanced relative to the distal capturing portion **226**. Regardless, the physician is able to ensnare the obstruction **2** within the cavities defined by the capturing portions **226** and **260**. Fig. 8E illustrates the system as the two capturing portions are drawn together. For purposes of clarity, the obstruction is not shown. Upon sufficient advancement of the capturing portion **226** and proximal capturing portion **260** relative to one-another, flanges **238** on the respective open ends can interlock. This feature provides added safety in removing the device as the obstruction is encapsulated between the two nested portions.

[0139] Fig. 8F illustrates a device **200** after securing an obstruction between a proximal **260** and distal **226** capturing sections. As shown, the captured obstruction **2** is held between capturing portions **226** and **260** where the flanges **238** nest within one-another to "lock" the capturing portions together. In some variations of the device, one of the capturing portions can be undersized relative to the other. This configuration allows for the undersized capturing portion to become further compressed as the devices are pulled together. The compression of the capturing surface then serves to further compress the obstruction **2** captured within the device.

[0140] The capturing portions described herein can include coverings or wrappings so long as the other features of the device are not impaired. Such coverings can be located on both capturing portions **226** and **260**, only one or more capturing portions. The covering can include a strand or fiber wrapped or woven about the section, a polymer film, or a dipped polymer coating such as silicone, urethane, etc. The coating on either capturing portion can be solid or porous. In the latter case, blood can continue to flow through the coating. In one variation, the proximal capturing portion **260** could employ a solid covering while the distal capturing portion **200** could include a porous covering. In such a case, blood or other fluid flow could be temporarily halted by the presence of the solid covering to assist in removal of the obstruction.

[0141] Fig. 9 illustrates a variation of the system where the main bundle **202** includes a medial foot **274**. The construction of the medial foot **274** can be similar to that of the

proximal foot discussed above (e.g., wires looped into a petal configuration.) However, the medial foot includes a surface area or diameter larger than a diameter of the main bundle. In any case, the increased surface area of the medial foot **274** provides an increased resistance to the obstruction **2** as the distal capturing portion **200** and main bundle **202** are pulled in a proximal direction towards an obstruction **2**. The medial foot **274** engages the obstruction **2** to partially displace or loosen the obstruction from the walls of the body passage. The medial foot **274** can be slidably located on the main bundle such that after a threshold force, the medial foot moves within the distal capturing portion **200**. The main bundle **202** can include any number of medial feet **274**.

[0142] Although the illustrated variation shown above comprise open-ended, circular, looped or partial loop shape cross sectional areas, variations of the capturing portions can include any number of shapes. For example, such a shape can include a circle, an arcuate shape, a partial circular shape, a loop, an oval, a square, a rectangle, a polygon, an overlapping loop, a pair of semi-circles, etc.) The various shapes may be heat set to be either self-expanding (i.e., superelastic) or the use of shape memory alloys can allow for the device to assume the particular shape upon reaching a desired transition temperature.

[0143] The exemplary shapes discussed above permit the shaped section to adjust in diameter in response to placement in varying diameters of body lumens. It is noted that a device may have different shaped sections on different ends of the device.

[0144] While many different shapes are contemplated to be within the scope of this disclosure, the shapes will depend upon the ultimate application of the device. As noted herein, the illustrated examples have particular applicability in retrieving obstructions from the vasculature. Accordingly, for these applications the shaped sections should form a shape so that they can expand against a vessel wall without causing trauma to the vessel. For example, upon release from the catheter, the shaped section can assume their resting shape and expand within the vessel. The resting shape can be constructed to have a size slightly greater than that of the vessel. Sizing the device relative to the target vessel may assist in placing the parts of the device against a vessel.

[0145] In an additional aspect, the shaped sections may be designed to have an unconstrained shape that is larger than the intended target vessel or simply different than a cross sectional profile of the intended vessel (i.e., not circular or tubular, but e.g., linear

or other different shape). In such an example, as the shaped section is released from the delivery catheter, the shape section attempts to return to the unconstrained shape. In those variations where the unconstrained shape is different from the circular profile of the vessel, the leading wire assumes a shape that accommodates the vessel but is more rigid and stable since its unconstrained shape is entirely different from that of the vessel. In other words, the shaped section continually exerts an outward force on the vessel.

[0146] In yet another aspect, the shaped sections shown herein may not necessarily lie in the same plane. Instead, they can be axially spaced by an offset. One benefit of constructing the device to have non-planar shaped section is that the configuration might allow for delivery of the device through a smaller microcatheter because the shaped sections do not interfere with one another when collapsed to fit within the microcatheter.

[0147] Another aspect applicable to all variations of the devices is to configure the devices (whether the traversing filament or the surrounding portion) for better adherence to the obstruction. One such mode includes the use of coatings that bond to certain clots (or other materials causing the obstruction.) For example, the wires may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the device secures about a clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction. Coatings may also be combined with the capturing portions or catheter to improve the ability of the device to encapsulate and remove the obstruction (e.g., a hydrophilic coating).

[0148] Such improvements may also be mechanical or structural. Any portion of the capturing portion can have hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. The hooks, fibers, or barbs **154** can be incorporated into any portion of the device. However, it will be important that such features do not hinder the ability of the practitioner to remove the device from the body.

[0149] In addition to additives, the device can be coupled to an RF or other power source (such as **14** or **16** in Fig. 1A), to allow current, ultrasound or RF energy to transmit through the device and induce clotting or cause additional coagulation of a clot or other the obstruction.

[0150] The methods described herein may also include treating the obstruction prior to attempting to remove the obstruction. Such a treatment can include applying a chemical

or pharmaceutical agent with the goal of making the occlusion shrink or to make it more rigid for easier removal. Such agents include, but are not limited to chemotherapy drugs, or solutions, a mild formalin, or aldehyde solution.

[0151] As for other details of the present invention, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts that are commonly or logically employed. In addition, though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention.

[0152] Fig. 10 illustrates one variation of a retrieval device **200** including a distal capture portion **226** coupled to one or more leading wires in the form of a main bundle **202**. The main bundle extends through a sheath **106** that includes a proximal capture portion **260**. The configuration of the retrieval device **200** can incorporate the proximal and distal capture portions discussed herein as well as various other configurations discussed in the commonly assigned patent applications noted above. In addition, the relative sizes of the various components shown in Fig. 10 and discussed below are for illustrative purposes only.

[0153] An end **264** of the proximal capture portion **260** is affixed to a distal end of the sheath **106**. However, as noted above, other variations are within the scope of the disclosure. The main bundle **202** can optionally terminate at a handle **242**. As noted above, in certain variations, the main bundle is joined to a stiffer wire or stiffer bundle of wires. This allows the device **200** to have a very flexible distal section with a relatively stiffer proximal section. Fig. 4A above, discusses placement of a joint at a location spaced from the distal section of the device so as to increase a bond strength but not impair the distal section's flexibility. In any case, the device **200** can have a proximal bundle **203** that comprises either the exposed wires or a covering/tube over the wires. In certain variations, the bundle or wire **202**, **203** can be encapsulated with a coating.

[0154] The proximal end of the sheath **106** includes a sheath handle **244**. As discussed herein, axial movement of the bundle **202** or proximal bundle **203** (typically at the handle **242**) results in movement **126**, or translation of the bundle within the sheath **106**. This

action moves the distal capture portion **226** (as shown by arrows **126**). In certain variations, the device **200** is loaded into a microcatheter (not shown but discussed above) that is delivered to the site of the obstruction and crosses the obstruction.

[0155] In some variations, the sheath hub **244** includes one or more locking hubs **246**. Where actuation (either axial or rotational) of the locking hub **246** locks the main bundle **202** relative to the sheath handle **244** and sheath **106**. It follows that such locking action also locks the distal capture portion **226** relative to the proximal capture portion **260**. A variety of methods can be employed to increase a frictional interference between the locking hub **246** and the proximal bundle **203**. As a result, when a physician determines a length of an obstruction, the physician can set a spacing between the capturing portions **226 260** by locking the proximal bundle **203** relative to the sheath hub **244**. Accordingly, the proximal bundle **203** can include any type of incremental markings to allow the physician to readily determine a spacing of the capturing portions. As illustrated, the sheath hub **244** can include additional injection ports to deliver fluid or other substances through the sheath **106**.

[0156] As noted above, the device **200** can be used with micro-catheter. In those variations it is important that the device **200** is loaded without damaging the distal bundle **202**, capture portions **226 260**, and/or sheath **106**. As a result, the device **200** can include an optional funnel **286** that reduces the proximal capture portion **260** (and /or the distal capture portion **226**) for loading within the microcatheter and/or sheath **106**.

[0157] Another variation of the device **200** includes an insertion tool **280** slidably affixed to the sheath **280**. Because variations of the device **200** can be extremely flexible, the insertion tool **280** can be used to provide column strength to the sheath **106**, bundle **202** or other components as the device **200** is pushed into the microcatheter. The insertion tool comprises a rigid section **282** and a frictional coupler **284**. The rigid section **282** has a column strength that supports the device **200** to prevent buckling. The frictional coupler **284** can be a flexible material that allows an operator to squeeze or grip the coupler **284** to create a temporary frictional interface between the loading tool **280** and the device **200** (typically the sheath **106**). Such an action allows axial advancement of the device **200** as the loading tool **280** is advanced into the microcatheter. Once the rigid section **282** is fully inserted into the microcatheter, the operator releases the frictional

coupler **284** and can withdraw the loading tool **280** from the catheter without withdrawing the device **200**. The insertion tool **280** can also include an optional loading tube **286** slidably coupled to the rigid section **282**. When used, the funnel **286** can withdraw the proximal and distal capturing portion **226 260** within the loading tube **286**. The loading tube **286** then couples to a microcatheter allowing the capturing portions to advance therein as the rigid section **282** and frictional coupler **284** advance the device **200** relative to the loading tube **286**.

[0158] Fig. 11A illustrates a funnel catheter **300** useful for retrieving objects from vessels or body lumens. Typically, when a physician captures an obstruction in various retrieval devices, the device and the obstruction are easily removed from the body by withdrawing the device and obstruction into a sheath, guide catheter or introducer ("guide catheter"). However, in some circumstances, a physician has difficulty withdrawing the obstruction loaded device within a sheath, guide catheter or introducer. Specifically, one or more components of the retrieval device might become caught on an edge of the guide catheter. The concern may still remain even when using a guide catheter having an increased diameter (such as when the retrieval device catches on one edge of the guide catheter tip). Moreover, large guide catheters are difficult to advance within various parts of the anatomy. As a result, the obstruction loaded device must travel further. Movement of the obstruction loaded device within the body creates the risk that the obstruction will detach or break apart and cause additional adverse consequences.

[0159] The funnel catheter **300** includes a first and second slotted funnels **330**, **340** located at the distal end of an inner shaft **302.** Each funnel **330 340** comprises a number of extensions or tines **332 342**. The inner shaft **302** can be cut to produce the first tines **332**. Alternatively, the first tines **332** can be affixed to a portion of the inner shaft **302**. The second slotted funnel **340** is offset in both a proximal and rotational position relative to the first slotted funnel **330**. The purpose of this dual offset is discussed in detail below. As shown, the second funnel **340** can be a slotted tube that is affixed over the inner shaft **302**. In an alternate variation, a plurality of second tines **342** can be located about the inner shaft **302** to form a second slotted funnel **340**. As shown in Fig. 11B, the tines **332 342** can be configured to expand outward (if not restrained) via use of a coil or other spring-type means. Alternatively, they can be actuated to expand outward.

However, in most cases, the tines **332** **342** can expand passively upon entry of the retrieval device **200**. The expansion of one or both funnels assists in receiving the retrieval device. In additional configurations, one or more funnels can be designed so that they remain in a cylindrical shape rather than expand outwards (as shown in Fig. 11C). Variations of the funnel catheter **300** can include configurations having one or more funnels, or configurations where the tines spaced or adjacent (or a combination thereof).

[0160] Fig. 11C also illustrates the dual offset nature of the dual funnel catheter **300**. The first offset is a linear offset **316** such that the distal ends of the first tines **332** or funnel **330** extends beyond a distal end of the second tines **342** or second funnel **340**. The second offset comprises a rotational offset (denoted by rotational angle **A**). For example, the illustrated rotational offset **A** is 45 degrees. However, the rotational offset can vary depending on the particular application. In most variations, the rotational offset **A** will place the second tines **342** over the gaps or spaces between the first tines **332**. The number of tines can vary depending on the application. Variations of the funnel catheter can include discontinuous funnels with two or more tines.

[0161] Turning back to Fig. 11A, the funnel catheter **300** can optionally include any number of medical fittings or components. As shown, the catheter **300** includes a hemostasis valve or hub **306** at the proximal end. The hemostasis valve **306** can include a fluid side port **308** for delivery of fluid through the catheter **300**. The catheter **300** can also include one or more radiopaque markers **310** so that the location of the funnel or funnels **330** **340** can be identified via non-invasive imaging (e.g., under fluoroscopy). The funnel catheter **300** can also optionally include one or more markers **312**. Such markers are useful to inform a physician (who is only able to view the proximal end of the device **300**) of the distance to the first or second funnel. As a result, the physician will be able to determine whether the funnels are advanced out of the guide catheter. Fig. 11A also shows the funnel catheter **300** as including a loading tool **314**. The loading tool **314** can be advanced over the funnels **330** **340** to compress the funnel when loading into a guide catheter or other sheath.

[0162] Figs. 12A to 12C provide an illustrative example where use of a funnel catheter **300** aids in removal of an obstruction **2** loaded within a retrieval device **200**.

[0163] As shown in Fig. 12A, attempting to remove the obstruction **2** when engulfed in the retrieval device **200** creates a risk that one or more portions of the device **200** become caught on the guide sheath or access catheter **108**. In some cases, the physician can simply engage the device **200** against the distal end of the guide sheath **108** and withdraw until the obstruction **6** and device **200** are located in an acceptable area of the body or withdrawn entirely from the body. For example, in certain situations, the obstruction **6** and device **200** can be withdrawn with the guide sheath **108** until all components reach a high flow, non-critical locations (e.g., the groin area). In the case of a clot, a clot dissolving substance (TPA) can then be applied to dissolve and remove the clot. Alternatively, the physician can attempt to aspirate through the guide sheath **108** in an attempt to draw the entire retrieval device **200** and obstruction **2** within the guide sheath **108**. In yet another variation, the physician can advance fibers or guide wires out through the guide sheath **108**, then withdraw the obstruction **2**/retrieval device **200** and attempt to use the fibers or guide wires as a moveable surface to capture the device **200**. Furthermore, the physician can attempt to use a variety of existing devices (e.g., the FastCath provided by Genesis Medical Inc., the Merci Retriever provided by Concentric Medical Inc., or any commercially available snare or distal protection device) to remove the engulfed obstruction **2** from the body.

[0164] In some variations, the capturing portions discussed above can be constructed to improve their ability to be withdrawn into a guide sheath. For example, increasing the number of petals or flanges on the traversing sections increases the probability that the distal flanges nest within the proximal capturing portion. Alternatively, or in combination, the petals **238** on the distal capturing portion can be staggered in length or position to ease insertion into the proximal capturing portion. In another variation, the petals **238** shape or curvature can be adjusted so that they do not flare outward.

[0165] Fig. 12B shows a distal end of a funnel catheter **300** as it receives an obstruction **2** loaded retrieval device **200**. As shown, the tines **332** of the first funnel **330** receive the device **200**. The tines **332** minimize the likelihood that the device **200** becomes caught. The limited surface area of the tine **332** (combined with the rounded tines **332 342**) produces a tendency for the device **200** to deflect away from the tines as it is withdrawn into the funnels. The second funnel **340**(being rotationally offset from the first funnel

330 provides coverage over the spaces between the first tines **332** thereby assisting in nesting of the device **200** within the funnels. Ultimately, the device **200** and obstruction **2** are withdrawn into a guide sheath **108** and removed from the body.

[0166] Figs. 12 C to 12D show additional variations of funnel catheter **300**. Fig. 12C shows a single funnel **330** having a plurality of tines **332**. Fig. 12D illustrates a dual funnel catheter **300** having a discontinuous first funnel **230** and a second funnel **346**. The second funnel **346** can be a continuous funnel so long as it is able to retract within the guide sheath **108**. As shown, the second funnel **346** can include a single slit **348** that allows the funnel to compress within the guide sheath **108**. In addition, the variation of Fig. 12D can be used without the first discontinuous funnel **330**. Accordingly, as the retrieval device **200** and clot **2** approach the funnel **346** and enters the funnel, further withdrawing the retrieval device **200** causes squeezing of the retrieval device **200** and obstruction **2**. In yet another variation, the funnel **346** can incorporate a drawstring to compress the funnel **346** once the retrieval device **200** and obstruction are located therein.

[0167] Fig. 13A to 13B illustrates another variation of a funnel catheter **350** suited to remove a retrieval device **200** from the body. As shown in Fig. 13A, the funnel catheter **350** includes a first shaft **352** and a second shaft **354** slidably located therein. A mesh **370** is fused to each shaft **352 354** at a distal location **362 364**. Accordingly, relative movement of the shafts **352 354** (either the first shaft **352** can be pushed or the second shaft **354** can be pulled) creates a funnel shape **372** as the mesh portion affixed to the second shaft **354** is inverted within the remainder of the mesh **370**. It is noted that in some variations of the system, the mesh funnel funnels are combined with the tine based funnels described above. Such that one funnel comprises the tines while the other comprises the mesh structure described herein.

[0168] In another variation, a third distally located capture portion (similar to a distal capture portion) can be used to draw the retrieval device within a guide sheath. In such a variation, the third capture portion can be a larger distal capture portion and when the retrieval device engulfs an obstruction, the third basket portion can be proximally withdrawn to capture the retrieval device and obstruction.

[0169] As illustrated in Fig. 13B, as the retrieval device **200** and obstruction **2** approach the funnel catheter **350**, the distal attachment points **362 364** of the shafts **352 354** are

moved together to invert the mesh **370** and form a funnel **372**. The retrieval device **200** can then be withdrawn into the funnel. This design allows for the retrieval device **200** to be fully withdrawn into the catheter **350** while the funnel **372** is expanded. Alternatively, the funnel **372** can be used to compress the retrieval device **200** and obstruction **2** prior to withdrawal into the catheter **350**.

[0170] The mesh **370** can include any medically acceptable material such as a nitenol braid. Furthermore, the mesh allows for flow through the vessel or lumen while expanded. However, additional variations of the device can include a solid layer of material substituted for the mesh.

[0171] Figs. 13C to 13E illustrate another variation of a funnel catheter **350** suited to remove a retrieval device **200** from the body. As shown in Fig. 13C, the funnel catheter **350** includes a first shaft **352** and a second shaft **354** slidably located therein. A mesh **370** is joined only the rear shaft **354** at a distal location **362**. The end of the mesh **370** is free at the distal end of the device **350**. The mesh **370** is sized at a distal end **371** to neck down. Accordingly, as the distal shaft moves rearward, the mesh **370** is unsupported. The necked section **371** of the mesh allows for distal advancement of the device **200** through the neck portion **371**. However, as shown by Fig. 13D, rearward movement of the device **200** causes engagement with the neck portion **371**. Further rearward movement of the device **200** causes the unsupported mesh **370** to form a funnel shape **372** as shown in Fig. 13E. The funnel shape allows for the retrieval device **200** to be fully withdrawn into the catheter **350** while the funnel **372** is expanded. Alternatively, the funnel **372** can be used to compress the retrieval device **200** and obstruction **2** prior to withdrawal into the catheter **350**. To compress the funnel, the device **200** can be advanced out of the funnel and away from the mesh **370**. Next, the distal shaft **352** can be advanced through the neck portion **371** of the mesh **370** to receive the device **200**. In another variation, the device **350** can include a single shaft **354** where the mesh **370** can extend beyond the shaft **354**. The mesh can be heat set to assume a funnel shape upon the application of a current or as it reaches body temperature. In another variation, the mesh **370** can comprise a super-elastic material that assumes the shape shown in Fig. 13E when released from a constraining member.

[0172] Figs. 13F to 13G illustrate yet another variation a funnel catheter **350** suited to remove a retrieval device **200** from the body. In this variation, the funnel catheter **350** includes a single shaft **354** having a mesh **370** is fused to a distal location **364**. The mesh **370** is free at a proximal side. The mesh is also pre-formed to assume a funnel shape as shown in Fig. 13G. Accordingly, upon delivery the mesh **370** can be constrained (e.g., via a sheath, or other removable restraint). Once the restraint is removed, the mesh **370** expands to form a funnel **372**.

[0173] Figs. 14A to 14D illustrate additional concepts for use with various retrieval devices **200**. Fig. 14A illustrates a distal capturing portion **226** and a proximal capturing portion **260** where the proximal capturing portion includes a covering **212** (e.g., a polymeric covering or a wire or fiber wound about the flanges **238**). The covering **212** prevents the flanges **238** of the distal capturing portion **226** from flaring outside of the proximal capturing portion **260**.

[0174] Fig. 14B illustrates a variation of a reentry sleeve where tines **332** of the reentry sleeve **302** include protrusions **214** on an inner surface. The protrusions **214** cause the tines **332** to splay out as the retrieval device **200** is withdrawn within the tines **332**. As the reentry sleeve **302** is withdrawn in a guide catheter (as discussed above) the protrusions serve to compress the retrieval device **200** even further.

[0175] Fig. 14C and 14D illustrate variations of a wire or fiber **218** affixed to the flanges **238** of a distal capturing portion **226** to assist in compressing the flanges **238** prior to entry within a guide sheath. As shown in Fig. 14C the fiber **218** can be affixed to a suture ring **216**. As the fiber **218** is pulled, the suture ring **216** compresses the flanges **238** to prevent outward flaring. In Fig. 14D, one or more fibers **218** are affixed to one or more flanges **238**. Once the obstruction is captured, the fibers can be pulled to draw the flanges **238** closed.

[0176] Fig. 15A illustrates another variation of a retrieval device **200** having the features described herein. In this additional variation, retriever device **200** is provided sterile (EtO), and is covered by a sleeve to protect the device prior to use. The variation can be used with a commercially available .027" ID microcatheter and 8F guiding catheter. As discussed above, retriever device **200** includes a distal basket **226** and a proximal basket **260** that are mounted coaxially relative to each other where the distal basket is smaller

than the proximal basket, as shown in Fig. 15A. In a variation of the device, the two baskets can be delivered into the target vessel as an integrated system through a microcatheter. In one example, the proximal basket measures 8 mm in length and 3.5 mm in diameter; and the distal basket measures 6.5 mm in length and 2.7 mm in diameter. In this variation, the proximal and distal baskets are designed to nest together in situ, and have features (tulips) at their extremities which permit an inter-nesting geometry. This example allows for a nested basket structure of 13mm in length. The distal basket is delivered on the distal side of the thrombo-embolus, and the proximal basket proximal is delivered on the proximal side of the thrombo-embolus or clot. The two baskets are then brought together, and the entire system (including the captured thrombo-embolus) is pulled back to the guide catheter (in the carotid or subclavian artery) where it is removed (optionally with the aid of the Exit Funnel.)

[0177] As described above, the baskets are delivered on either side of a clot. In one variation of the system described herein, each basket of the retriever device **200** is radiopaque enabling a physician to visualize and position the baskets, and encage the clot or obstruction under fluoroscopy. Once the baskets are positioned together, they can be locked together in position using a Rotating Hemostatic Valve (RHV) or similar device at the proximal handle region, and the entire system is removed.

[0178] In certain variations, the baskets of the retriever device **200** are designed to be very soft and flexible. In such cases, each basket is made from a continuous wire structure, and is free from welds, solders, adhesives, or other mechanical junctions. The continuous wire structure is comprised of a thin nitinol tube with a platinum core. This material is radiopaque and allows for direct and continuous fluoroscopic visualization during embolectomy procedures. The absence of external marker bands reduces the stiffness of the device resulting in improved device performance and deliverability, as well as reduces the frictional forces to enhance the ease and ability to fully surround the clot in vivo.

[0179] The nitinol wires comprising the distal basket are integrated directly into the full length core wire at the proximal region of the device. Similarly, the nitinol wires comprising the proximal basket terminate into a long flexible coil, which is then integrated directly into the wall structure of the proximal shaft. The design of both

baskets is free from joints, welds, adhesives or other junctions which promotes enhanced flexibility, deliverability and strength.

[0180] The baskets of the retriever device **200** are designed to reduce the frictional forces between the embolus and the vessel wall prior to mobilizing the embolus. In the design of conventional devices, the embolus is "grabbed and pulled" in one motion, thereby exerting a considerable translation force on the both the embolus and on the vessel. In contrast, and as shown in Fig. 15B, the design of the retriever device **200** first reduces the frictional forces using section **234** before the embolus is mobilized by capturing section **232**. As each basket surrounds the embolus, low friction wires break the contact between the vessel and the embolus, reducing the friction and allowing for easier subsequent mobilization of the embolus.

[0181] Fig. 15B also illustrates another feature for a variation of the system described herein. In this variation, a distal basket **226** is constructed to have a crossing mesh pattern as shown by crossing wires in sections **235**. This crossing wire mesh **235** permits the distal basket **226** to limit radial expansion when encountering a significant resistance force prior to the staged inversion described above. Therefore, radial expansion is limited by the crossing sections **235** during pulling of the distal basket **226** and to prevent or reduce the chance of premature inversion. The crossings pattern of the capturing section **232** transmits the longitudinal force more axially, limiting the radial expansion. Fig. 15C illustrates the distal basket encounters a resistance when moved proximally. Fig. 15D illustrates the crossing or twist **235** pattern of the capturing section to selectively interfere at one or more interference points **237**. This selective interference limits further radial expansion to limit the capturing portion **232** from expanding in radial size and improves the removal of the device without causing the device to expand and become more fixated distally to an obstruction.

[0182] Fig. 16A illustrates another variation of a device according to the present system. In this variation the system includes an infusion stent structure **400** for deploying into a thrombus or clot and immediately re-establishing flow. This stent structure **400** can also deliver t-PA for improved results. The infusion stent structure **400** is provided sterile (EtO), and can be covered by a sleeve to protect the device prior to use. It can be used with a commercially available .027" ID microcatheter and a commercially available

.010" guidewire (or .010"distal/.012"proximal guidewire). However, the infusion stent structure **400** can also be used with other catheters and guidewires as needed.

[0183] In one variation, the infusion stent structure **400** is a self-expandable braided stent measuring 25mm in length and 2.5mm in diameter. As shown in Fig. 16B, the structure **400** can have a proximal shaft **402** with a central lumen opening **406** at a distal end of the shaft **402.** This lumen and opening allows the optional passage of a guide-wire or the delivery of lytics or other substances. The guidewire ensures that distal access is maintained until optimal placement is achieved and provides the ability to mechanically agitate or disrupt the thrombus with the wire, which freely passes through the lumen of the proximal shaft into the lumen of the stent, even in a deployed state. Additionally, as shown in Fig. 16C this central lumen of the proximal shaft allows for the removal of the guide-wire and for direct intra-arterial infusion of t-PA **2** through the proximal shaft and opening **406**- directly into the thrombus. The stent's braided construction also facilitates recapture into the microcatheter, a known problem with current temporary stent designs.

[0184] Fig. 16D illustrates a partial cross sectional view of the stent structure **400** where the central lumen extends through a section of the stent **400** and further optionally includes a number of ports **408** in addition to the lumen opening **406**. This permits delivery of s substance along a length of the stent rather than at the lumen opening.

[0185] As discussed above, the infusion stent **400** can be formed from a continuous wire structure where the wires overlap to form a braided stent structure. The result is a continuous wire structure that is free from any welds, solders, adhesives, or other mechanical junctions. Variations include the continuous wire structure being comprised of a thin nitinol tube with a platinum or other radiopaque core. The wire material is radiopaque and allows for direct and continuous fluoroscopic visualization during recanalization procedures. The absence of external marker bands reduces the stiffness of the device resulting in improved device performance and deliverability, and results in a reduction of frictional forces that enhances the ease and ability to recapture the device with the microcatheter.

[0186] The nitinol wires of the stent continue to form a long flexible coil, which is integrated directly into the wall structure of the proximal shaft. This means that the structure is a continuous integration of the stent and delivery shaft resulting in a design

that is free from joints, welds, adhesives or other junctions that promotes enhanced flexibility, deliverability and strength.

[0187] As shown in Fig. 16E and 16F, a beneficial design feature of the braided wires is that the wires slide easily and independently over one another. This facilitates resheathing of the stent back into the microcatheter. The sliding wires allow the stent to change the mesh pattern during resheathing into the microcatheter, allowing for facilitated removal of the stent from within a clot as compared to other temporary stents on the market. Fig. 16F shows the wires sliding into a more axial orientation (i.e., parallel to an axis of the stent) at the proximal region as they enter the microcatheter, resulting in easier re-entry. This prevents the stent from expanding in diameter upon withdrawal. The stent can be permanently affixed to the shaft **402** or it can be releasbly detachable from the shaft (e.g., through a mechanical release, electrolytic detachment joint, etc.)

[0188] Figs. 17A to 17E illustrate one example of use of an infusion stent device **400**. As shown, a microcatheter **12** is positioned and traverses a clot or obstruction **2.** Optionally, one variation of the system can include a .014" guidewire (not shown) and a .027" microcatheter **12** to traverse the clot. The guidewire can be used to agitate or maneuver through the clot and the guidewire can be optionally removed as shown in Figs. 17A and 17B.

[0189] Next, infusion stent **400** is then delivered to the site of the clot **2** through the microcatheter **12** in a constrained state. The microcatheter can optionally be pulled proximally back through the clot **2** to expose the stent **400** as shown in Fig. 17C. Next, when the microcatheter **2** is moved proximal to the clot **2** the stent **400** self-expands (or can be acutated via a spring release or other mechanism). As shown in Fig. 17D, the expanded stent **400** pushes the occlusion **2** aside, providing immediate recanalization to the vessel **6** and flow to the distal territories. In addition, the stent structure **400** includes a lumen **406** for delivery of the guidewire, fluids, or other devices as necessary. For example, as shown in Fig. 17E, the stent structure can further include a flush tube or lumen extending therethrough. The tube can either be fixed within the stent or advanced through an opening **406** at the proximal end of the stent. The flush tube allows delivery

of fluids to the distal end of the clot or through the clot when optional ports **408** are employed.

[0190] The entire stent structure can optionally be made radiopaque (e.g., using the DFT described above), enabling the physician to visualize the entire stent under fluoroscopy. By observing blood flow along with the structure of the stent under fluoroscopy, the physician can determine if the entire stent structure is narrowing (e.g., via a vessel or clot) or if the clot is pushing through the stent. Such an observation would be difficult or impossible using a conventional stent structure with radiopaque markers.

[0191] The proximal end of a delivery shaft of the infusion stent can have a luer with a standard fitting. This luer can accept a commercially available .010" guidewire (or .010"distal/.012"proximal guidewire). The wire can be used for initial delivery of the stent, and then removed once the stent is deployed. At anytime during the procedure the guidewire can be reinserted and re-advanced to the location of the stent to maintain wire position across the clot should the stent need to be recaptured and repositioned. Fig. 17C shows an infusion stent with a guidewire **104** inserted in the through-lumen **406.**

[0192] The devices described herein can also be modified or used as described below to provide additional options for improved removal of an obstruction from a body lumen, vessel, or other region.

[0193] For example, Figs. 18A to 18C show one variation of system **200** including a longitudinal stent **400** combined with additional features as described above. In the variation shown in Fig. 18A, the stent **400** is can be delivered as shown above in Figs. 17A to 17D where the stent **400** is delivered to the site of the clot **2** through the microcatheter **12** in a constrained state. Deployment of the stent **400** can occur in any number of ways. For example, the microcatheter **12** can advance distally beyond the occlusion **2** so that the stent is deployed from the microcatheter **12** and distal to the occlusion **2**. In such a case, the physician withdraws the stent **400** to engage the occlusion **2**. Alternatively, and as shown in Figs. 17A to 17C, the microcatheter **12** can be advanced distally to the occlusion **2**, so that a distal end of the stent **400** is distal to the occlusion **2**, then the physician withdraws the microcatheter **2** to expose and deploy the stent **400** within the occlusion **2**.

[0194] Next, as shown in Fig. 18A, the procedure can include a system **200** having a distal capture portion **226** (or any other type of basket) deployed through a lumen **406** of the stent **400** as well as through the microcatheter **12**. In one variation, the distal capture portion **226** functions as a distal protection device to trap and prevent debris from flowing downstream of the occlusion **2** as the stent **400** engages the occlusion **2**..

[0195] In some variations, when the microcatheter **2** is moved proximal to the clot **2** the stent **400** self-expands (or can be acutated via a spring release or other expansion mechanism). As shown in Fig. 17D, the expanded stent **400** pushes the occlusion **2** aside, providing some degree of immediate recanalization to the vessel **6** and, as a result, flow to the distal territories. However, the distal capture portion **226** (or other distal structure) can also assist in expanding the stent **400** when attempting to re-establish flow. In such cases, and as shown in Fig. 18B, the physician withdraws the distal capture portion **226** against the stent **400** while maintaining the stent **400** at the site of the obstruction **2**. Movement of the distal capture portion **226** against the stent **400** causes axial compression of the stent **400**. This axial compression results in radial expansion and further increases the force of the stent **400** against the occlusion **2**. This action can occur if the stent **400** is placed within the occlusion **2** or on a side of the occlusion **2** adjacent to a vessel wall.

[0196] Fig. 18C illustrates yet another conversion feature of systems **200** described herein and employing a stent **400** having a sufficient axial length to traverse an obstruction. In this variation, the physician withdraws the stent **400** within the microcatheter **12** to a sufficient degree where the remaining un-covered portion of the stent **400** forms a basket-type structure. This partially deployed portion of the stent **400** converts the system **200** to function as the dual-basket system described above.

[0197] In addition, the stent structure **400** includes a lumen **406** for delivery of the guidewire, fluids, or other devices as necessary. For example, as shown in Fig. 17E, the stent structure can further include a flush tube or lumen extending therethrough. The tube can either be fixed within the stent or advanced through an opening **406** at the proximal end of the stent. The flush tube allows delivery of fluids to the distal end of the clot or through the clot when optional ports **408** are employed.

[0198] Fig. 19A to 19C illustrate additional variations of systems **200** according to the present disclosure. In this example, the systems **200** include a stent structure **400** with an additional proximal structure. The additional proximal structure can be mounted coaxial and proximal to the stent so that the stent **400** engage the obstruction. However, after mobilizing the obstruction, the stent **400** brings the obstruction into engagement with the proximal structure. In this manner, the proximal structure prevents embolization of the obstruction.

[0199] Fig. 19A illustrates a first variation where the stent **400** includes a proximal basket portion **260** as shown above mounted on a microcatheter. In this variation, the stent **400** engages the obstruction (not shown) and moves the obstruction between the stent **400** and proximal capture portion **260**.

[0200] Fig. 19B illustrates a variation where a first stent **400** is combined with a proximal structure comprising a second proximal capture stent **404**. As shown, the second stent **406** can optionally include a flared opening **406**. This flared opening **406** assist in securing an obstruction that is captured about or within the first stent **400**. As the first stent **400** is withdrawn into the proximal capture stent **406**, the flared opening **406** serves as a funnel.

[0201] Fig. 19C shows another variation of a stent **400** including a proximal structure comprising a funnel or capture mesh as described above. However, in this variation, the funnel **350** is sized to reside on a proximal shaft or a microcatheter such that when the stent **400** mobilizes the obstruction, proximal movement brings the obstruction and stent **400** into the funnel. This allows immediate securing of the obstruction so that the obstruction remains secured as it is moved proximally along the vessel path until it encounters a distal access catheter or similar catheter in a larger vessel.

[0202] Furthermore, as shown in Fig. 19D, the funnel **350** and stent **400** can comprise a single combination device **448** where the funnel **350** and stent **400** are coupled to a single handle **450** which has a portion for controlling the funnel **452** and a portion for controlling the stent **454**. Accordingly, the stent **400** is moveable relative to the funnel **350** and can be withdrawn into the funnel **350** to remove debris. The combination device travels as a single device through the vessel or through a catheter. The funnel and stent

described herein can comprise any construction described herein or as known by those skilled in the art.

[0203] In another variation of the devices and method described herein, the elongated stents **400** are designed to expand within or adjacent to an obstruction to either re-establish blood flow within the vessel or to enmesh the stent **400** within the obstruction so that the stent and obstruction can be removed from the body.

[0204] Fig. 20A illustrates another variation of a system **200** for removing an obstruction from a body lumen. In this variation, the system **200** comprises at least any number of significant components (the number of components can vary depending on the particular application). As shown, the system **200** includes: a stent **400**, as described above, slidably positioned through a microcatheter (not shown). The microcatheter is located within a catheter **410** having a funnel or mesh **350** located at the end of the catheter **410**. This exit funnel **350** can either be affixed to the distal end of the catheter **410** or can be deployable through or from the catheter **410**. The catheter is then slidably postioned within a guide catheter **108**. The use of a catheter **410** permits placement of the funnel **350** in closer proximity to a clot or obstruction than otherwise would be possible with use of a guide catheter **108** alone. Variations of the system **200** also include the use of a funnel or reentry sheath at the distal end of the guide catheter **108**.

[0205] Fig. 20B shows a variation of the system shown in Fig. 20A when removing an obstruction **2** from a body lumen **6** or vessel. As shown and described above, a physician advances guide catheter **108** and/or a microcatheter (not shown) to position a stent **400** adjacent to the obstruction **2**. As described above, although the illustrated system **200** only includes a guidewire **104** rather than a distal capture portion, variations of the system include the use of one or more types of distal capture portions.

[0206] Turning back to Fig. 20B, the distance between the occlusion **2** and guide catheter **108** is for illustrative purposes only. In actual use the distance could be much greater or less than that shown. In any case, as the stent **400** begins to move the occlusion **2** from the target site to the guide catheter **108**, this movement creates a risk that the obstruction or parts of the obstruction will disengage from the stent **400** and cause further blood flow interruptions further along the vasculature. Accordingly, Fig. 20C illustrates advancement of a funnel or exit mesh **350** from the guide sheath **108** to a region

proximate to the obstruction **2** and stent **400**. The exit mesh **350** can be advanced through a catheter **410** as shown. Alternatively, the mesh **350** can be advanced using its own shaft (or other means) with or without a catheter **410**. Again, variations of the system **200** can include an alternate (or an additional) funnel/guide sheath located on the guide catheter **108**.

[0207] Fig. 20D shows the obstruction **2** secured within the exit mesh **350** where the stent **400** is withdrawn into the catheter **410** so that the exit mesh **350** and catheter **410** can be further withdrawn into the guide catheter **108**, as shown in Fig. 20E to remove the obstruction **2** from the body.

[0208] Fig. 20F shows another example where a catheter **410** can be positioned in the M1 segment of a middle cerebral artery. Variations of the method include any type of catheter, such as a second small guide catheter, an intermediate guide catheter, or some smaller catheter that can be advanced distally in small vasculature that is too small for the main guide catheter **108**. The distal end of the catheter **410** can reside in the M1 segment near the obstruction **2**. In such a case, the exit funnel **350** is then sized to pass through the catheter **410** so that it can receive the stent **400** and clot **2** at or close to the original obstruction site. In the illustrated figure, the exit funnel **350** is being advanced towards the obstruction **2**. However, variations of the procedure include positioning the exit funnel **350** anywhere from the obstruction **2**, to the opening of the guide catheter **108**.

[0209] Figs. 21A to 21B illustrate a variation of a funnel/reentry device **350** for use as describe above. Additionally, the funnel device **350** can be used with any obstruction retrieval device not limited to the retrieval baskets and stents described herein. The illustrated variation of the reentry device or funnel **350** can be used where the physician desires to shield the obstruction being removed from the frictional effects of the arteries or from the local anatomy (e.g., branching vessels, tortuous anatomy, or other substances on the vessel walls). As noted herein, the funnels **350** can be used as a stand alone device or can be integrated proximally to any of the retrieval devices described above or known to those skilled in the art. In use, the funnels can be sized for use with guide catheters, micro-catheters, and/or distal access catheters. The funnels can include any number of radiopaque marker bands to allow non-invasive imaging of the device (see marker **390** in Fig. 22B as one example). In any case, once the retrieval device captures a clot or

obstruction, as described above, the device and clot are withdrawn into the funnel so that the funnel eliminates or reduces direct contact between the interior of the wall of the vessel and the clot.

[0210] Figs. 21A to 21C show a variation in which a funnel is created from one or more mesh tubes **372**. Fig. 21B illustrates inversion of the tube **372** so that a first end **374** is drawn over the tube **372** towards a second end **376**. As shown in Fig. 21C, this creates a double walled funnel having an exterior wall **378** separated from an interior wall **380**. In one example, such a spacing or gap could range between 0.002 inches to 0.060 inches. However, any range is contemplated within alternative variations of the device. In some variations the inverted funnel **350** is heat set to maintain a separation between layers or walls **378 380** of the funnel **350**. Typically, if the funnel **350** is not created from a radiopaque material, a marker band will be placed on the proximal end **376** and adjacent to a shaft or catheter to which the funnel **350** is attached. In some variations the construction of the mesh material is compliant to allow for movement of a first part of the mesh relative to a second part of the mesh through compression and expansion of the mesh material. In such a case, the individual strands forming the mesh are moveable relative to one another to cause the mesh to be naturally compliant. Accordingly, this construction permits the inner wall **380** to move or deflect with the retrieval device and/or obstruction as the device is withdrawn into the funnel **350**. In some variations, both ends of the mesh **374** and **376** are affixed to the catheter or shaft. One benefit of the mesh funnel design is that the funnel can be inverted so that it can be loaded into a device (such as a peel away sheath). Alternatively, the funnel can be folded and fed into the proximal opening of a catheter. Moreover, the funnel can have any number of walls.

[0211] In many variations, the funnel mesh is selected to minimize friction when the interior layer **380** moves against the exterior layer **378**. For example, the braid pattern, wire, wire diameter, angle of the braid and or other features can be selected to reduce friction between the outer layer **378** and inner layer **380**. This permits the inner layer **380** to move proximally with a retrieval device while the outer layer remains stationary. Again, as discussed above, the construction of the mesh permits compression and expansion of the mesh layer to permit movement of the inner layer while the outer layer remains affixed when engaged against the vessel wall. In certain variations, the funnel is

heat set so that the inner layer has cushioning and the ability to deflect to assist in movement of the inner layer.

[0212] Figs. 21D to 21L illustrate additional variations of funnel construction to produce funnels having more than two walls. For example, a mesh tube **372** is everted or drawn over a second end **376** in the direction **420**. As shown in Fig. 21E this produces a dual layer funnel having a open ends **422** and **424** and a folded end **426**. The dual layer tube is then folded over again in the direction **420**. This creates a funnel construction with an exterior layer **378** and an interior layer **380** as well as a first intermediate layer **381** and a second intermediate layer **383**. As shown in Fig. 21F, the funnel can be set to assume the tapered shape having an opening at the first end **374** that is flared with the ends of the mesh at the second end **372**, which are ultimately affixed to a shaft or other catheter device as described herein.

[0213] Fig. 21G illustrates another example of a funnel construction. As shown, a first mesh tube **372** is placed coaxially with a second tube **372**. The concentric tubes are then everted in direction **420** to produce a four layer funnel. As shown in Fig. 21H, the funnel can comprise an interior mesh layer **380**, and exterior mesh layer **378** as well as any number of intermediate layers **381**, **383** depending on the number of tubes that are initially used. The second end **372** of the funnel **350** includes four unconnected ends of the mesh tubes that can be affixed to a shaft or tube as discussed herein, while the first end **374** of the funnel **350** can be shape set to taper from the opening.

[0214] Figs. 21I to 21L illustrate another example of the construction of a multi-wall funnel. As shown in Fig. 21I, a first end **374** of a mesh tube **372** is everted over and beyond a second end **376** in direction **420** to produce the configuration of Fig. 21J. Next, the first end **374** is everted or folded back in direction **420** to produce the configuration of Fig. 21K. Finally, the first end **374** is folded again in direction **420** so that the ends **374** and **376** are even to produce the funnel configuration shown in Fig. 21K. Again, one end of the funnel **350** can be set to form the tapered shape while the other respective end can be affixed to a catheter or shaft.

[0215] Although the funnels of the present disclosure are presented without additional structures, it should be noted that these funnels are coupled with a shaft or other member

so that the funnel can be advanced within the target anatomy to assist in removal of a device, structure, or debris from the site.

[0216] Figs. 22A to 22C show addition variations of funnels **350**. Fig. 22A illustrates a funnel in which the funnel wall as defined by the inner layer **380** and outer layer **378** is set in a shape that varies along a length of the funnel. For example, the end adjacent to the funnel opening **382** can be set to a bulbous shape. Such a configuration assists in maintaining separation of layers **378** and **380**, which aids in re-entry of the retrieval device. Additional configurations of funnel walls that vary in thickness are within the scope of this disclosure.

[0217] One of the benefits of using a funnel **350** as described herein is that the funnel reduces flow through the vessel when deployed so that the retrieval device can remove the obstruction without the full force of the flow of blood opposing the obstruction. Typically, conventional devices relied upon the use of an inflated balloon to obstruct flow. However, use of a funnel eliminates the need for total occlusion of blood flow. Fig. 22B illustrates a further improvement on a funnel **350** that aids in flow reduction. As shown, the funnel **350** includes a dense region **386** and a relatively less dense region **384**. This configuration permits greater blood flow through the region **385** while region **386** reduces or prevents blood flow. Furthermore, the distal section of the funnel is more flexible and conformable. Additional mesh layers can be added to any of the funnel designs to alter flow characteristics or even provide reinforcement to the funnel. Alternatively, or in combination, the braid density can be altered to adjust the porosity of the braid at different sections. Furthermore, additional braid layers can also be used to affect porosity of portions of the funnel or even the entire funnel. Deployment of a funnel can reduce blood flow by 30% to 40%. Adding additional layers or coatings can additionally reduce flow.

[0218] Fig. 22C shows another variation of a funnel **350** in which the mesh partially or totally is obscured using a polymeric coating **388** that reduces the permeability of the mesh design. Furthermore, drugs or other substances can be placed within the funnel wall of any of the funnels or can be deposited on the funnel using the polymeric coatings. In some examples, the funnels described herein can range from a length of 35 mm up to 50 mm. The OD at the opening of the funnel can range from 7 mm and could range

between 4 mm to 10 mm. Again, any range of dimensions is contemplated within the disclosure.

[0219] The funnels described herein can further be stacked on a device. For example, two or more funnels can be placed on a device to provide added protection.

[0220] The funnel/rentry devices described herein can be constructed of any material currently used in vascular applications, including those discussed above. Furthermore, fabrication of the funnel from a DFT material can provide additional benefits as the entire funnel remains radiopaque and can be imaged non-invasively imaged or viewed. Furthermore, the funnels can be provided with any type of medicament or bioactive substance either in a polymer that coats the mesh or in a delivery agent within the mesh or between layers. Such substances include tpa, urokinase, IIb/IIIa inhibitors, and other clot disruptors or inhibitors.

[0221] Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. Also, any optional feature of the inventive variations may be set forth and claimed independently, or in combination with any one or more of the features described herein. Accordingly, the invention contemplates combinations of various aspects of the embodiments or combinations of the embodiments themselves, where possible. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said," and "the" include plural references unless the context clearly dictates otherwise.

[0222] It is important to note that where possible, aspects of the various described embodiments, or the embodiments themselves can be combined. Where such combinations are intended to be within the scope of this disclosure.

CLAIMS

We claim

1. A funnel device for securing debris and/or devices within a vessel, the funnel device comprising:

   a shaft having a flexibility to navigate through tortuous anatomy and having a lumen extending therethrough;

   a funnel comprising a distal opening and a proximal portion connected to the shaft and a cavity therebetween such that when the funnel is expanded the funnel tapers in a proximal direction towards the shaft, the funnel comprising a mesh material secured to the shaft such that when expanded the mesh material forms a funnel configuration having at least an exterior mesh wall and an interior mesh wall that are shape; and

   where at least a portion of the mesh material is porous to permit fluid flow therethrough.

2. The device of claim 1, where the funnel is shape set such that there is a gap between the interior and exterior wall.

3. The device of claim 1, where the funnel is shape set such that the exterior mesh wall is in contact with the interior mesh wall proximal of the opening.

4. The device of claim 1, where the mesh material is compliant and where the interior mesh wall and exterior mesh wall are slidable relative to each other such that withdrawal of the device or debris proximally into the interior mesh wall of the funnel causes movement of the interior mesh wall while a portion of the exterior mesh wall remains stationary when positioned against the vessel.

5. The device of claim 1, where the mesh material comprises a first and second end where at least either the first or second end is affixed to the shaft and a medial portion that forms a perimeter of the distal opening.

6. The device of claim 5, both the first and second end of the mesh material is affixed to the shaft.

7. The device of claim 1, where the funnel is self expanding.

8. The device of claim 1, further comprising a lumen extending through the shaft and exiting at a distal portion of the shaft.

9. The device of claim 1, where the mesh material is flexible to permit flexible everting of the funnel over the shaft to permit insertion of the everted funnel and shaft into a secondary device.

10. The device of claim 1, where a portion of the funnel at or adjacent to the distal opening comprises a bulbous shape.

11. The device of claim 1, where the funnel comprises a first porous section having a first porosity and at least a second porous section having a second porosity, where the first and second porosity are different such that the ability of fluid to flow through the first porous section and second porous section differs.

12. The device of claim 11, where the first porous section comprises a first braid density and the second porous section comprises a second braid density.

13. The device of claim 11, where the first porous section comprises an additional braid layer.

14. The device of claim 11, where the first porous section prevents fluid from flowing therethrough.

15. The device of claim 11, where the first porous section is distal to the second porous section and where the first porosity is greater than the second porosity.

16. The device of claim 11, where the first porous section comprises a circumferential area of the funnel.

17. The device of claim 1, further comprising at least one polymeric layer on or adjacent to a region of the funnel.

18. The device of claim 17, further comprising at least one medicament on or in the polymeric layer.

19. The device of claim 1, further comprising at least one radiopaque marker on a distal end of the shaft.

20. The device of claim 1, where the mesh material comprises a single continuous wire.

21. The device of claim 1, where at least a portion of the mesh material is fabricated from a drawn filled tube material.

22. The device of claim 1, where at least a portion of the mesh material is fabricated from a radiopaque material.

23. The device of claim 1, where funnel comprises at least one additional wall.

24. An obstruction removal system for removing obstructions from a body lumen; the removal system comprising:

a retrieval device for securing the obstruction;

a shaft having a flexibility to navigate through tortuous anatomy and having a lumen extending therethrough; where the retrieval device is axially advanceable through the lumen;

a funnel comprising a distal opening and a proximal portion connected to the shaft and a cavity therebetween such that when the funnel is expanded the funnel tapers in a proximal direction towards the shaft, the funnel comprising a mesh material secured to the shaft such that when expanded the mesh material forms a funnel configuration having at least an exterior mesh wall and an interior mesh wall that are shape set; and

where at least a portion of the mesh material is porous to permit fluid flow therethrough.

25. The system of claim 24, where the funnel is shape set such that there is a gap between the interior and exterior wall.

26. The system of claim 24, where the funnel is shape set such that the exterior mesh wall is in contact with the interior mesh wall proximal of the opening.

27. The system of claim 24, where the mesh material is compliant and where the interior mesh wall and exterior mesh wall are slidable relative to each other such that withdrawal of the device or debris proximally into the interior mesh wall of the funnel causes movement of the interior mesh wall while a portion of the exterior mesh wall remains stationary when positioned against the vessel.

28. The system of claim 24, where the mesh material comprises a first and second end where at least either the first or second end is affixed to the shaft and a medial portion that forms a perimeter of the distal opening.

29. The system of claim 28, both the first and second end of the mesh material is affixed to the shaft.

30. The system of claim 24, where the funnel is self expanding.

31. The system of claim 24, further comprising a lumen extending through the shaft and exiting at a distal portion.

32. The system of claim 24, where the mesh material is flexible to permit flexible everting of the funnel over the shaft to permit insertion of the everted funnel and shaft into a secondary device.

33. The system of claim 24, where a portion of the funnel adjacent to the distal opening comprises a bulbous shape.

34. The system of claim 24, where the funnel comprises a first porous section having a first porosity and at least a second porous section having a second porosity, where the first and second porosity are different such that the ability of fluid to flow through the first porous section and second porous section differs.

35. The device of claim 34, where the first porous section comprises a first braid density and the second porous section comprises a second braid density.

36. The device of claim 34, where the first porous section comprises an additional braid layer.

37. The system of claim 24, further comprising at least one additional mesh layer.

38. The device of claim 34, where the first porous section prevents fluid from flowing therethrough.

39. The device of claim 38, where the first porous section is distal to the second porous section and where the first porosity is greater than the second porosity.

40. The device of claim 34, where the first porous section comprises a circumferential area of the funnel.

41. The system of claim 24, further comprising at least one polymeric layer on or adjacent to a region of the funnel.

42. The device of claim 41, further comprising at least one medicament on or in the polymeric layer.

43. The system of claim 24, further comprising at least one radiopaque marker on a distal end of the shaft.

44. The system of claim 24, where the mesh material comprises a single continuous wire.

45. The system of claim 24, where at least a portion of the mesh material is fabricated from a drawn filled tube material.

46. The system of claim 24, where at least a portion of the mesh material is fabricated from a radiopaque material.

47. The system of claim 24, where the mesh material comprises a plurality of wires, where at least one wire is selected from the group consisting of a drawn filled tube, a radiopaque wire, a super elastic wire.

48. The system of claim 24, where the retrieval device comprises a debris capturing portion comprising an elongate woven stent structure, where the woven stent structure has an open distal end and a fluid permeable proximal end.

49. The system of claim 24, where the retrieval device comprises a basket structure having an open proximal end and a fluid permeable distal end.

50. The system of claim 24, further comprising a guide catheter, where the guide catheter comprises a guide catheter lumen, and where the retrieval catheter body and funnel are slidably advanceable from the guide

51. A method of retrieving an obstruction from a vessel, the method comprising:

advancing an obstruction capture device into the blood vessel;

engaging the obstruction capture device with the obstruction;

deploying a multi-wall funnel having a plurality of walls, proximal to the obstruction capture device, where the multi-wall funnel comprises at least an exterior wall separated from an interior wall when the multi-wall funnel is expanded, the exterior and interior wall defining an opening and a cavity where the multi-wall funnel tapers in a proximal direction;

withdrawing the obstruction capture device proximally into the opening and cavity of the multi-wall wall funnel;

securing at least a portion of the obstruction capture device within the multi-wall funnel by engaging the obstruction capture device with the interior wall of the multi-wall funnel, where continued proximal movement of the obstruction capture device causes the interior wall to move in an axially proximal direction.

52. The method of claim 51, where the obstruction capture device comprises an elongate stent; and where engaging the obstruction capture device comprises expanding the elongate stent within the obstruction.

53. The method of claim 51, where the obstruction capture device comprises a distal basket and a proximal basket, and where engaging the obstruction capture device comprises placing the distal basket and proximal basket on either side of the obstruction.

54. The method of claim 51, where the funnel comprises an exterior wall and an interior wall that are set in shape such that a gap separates the walls at a distal portion of the

funnel when expanded, and where withdrawing the obstruction capture device within the multi-wall funnel comprises engaging the interior wall causing movement of the interior wall independently of exterior wall..

55. The method of claim 51, where the mesh material is compliant and where a first interior mesh wall and a second exterior mesh wall are slidable relative to each other such that withdrawal of the obstruction proximally into the interior mesh wall of the funnel causes movement of the interior mesh wall while a portion of the exterior mesh wall remains stationary when positioned against the vessel

56. The method of claim 51, where the multi-wall funnel is advanced through a catheter such that the obstruction capture device is advanced distally into cerebral vasculature and where the multi-wall funnel is advanced adjacent to the obstruction capture device.

57. A retrieval device comprising:

an elongated stent extending from an inner connection wire, where the inner connection wire is coupled to a handle;

a funnel extending from a outer shaft, where the elongated stent and inner connection wire are moveable through the outer shaft, and where the outer shaft is coupled to the handle;

a control member coupled to the elongated stent, where relative movement of the handle and control member permit independent motion of the elongated stent with respect to the funnel.

58. The device of claim 57, where the funnel comprises a funnel as described in any of claims 1 to 50.

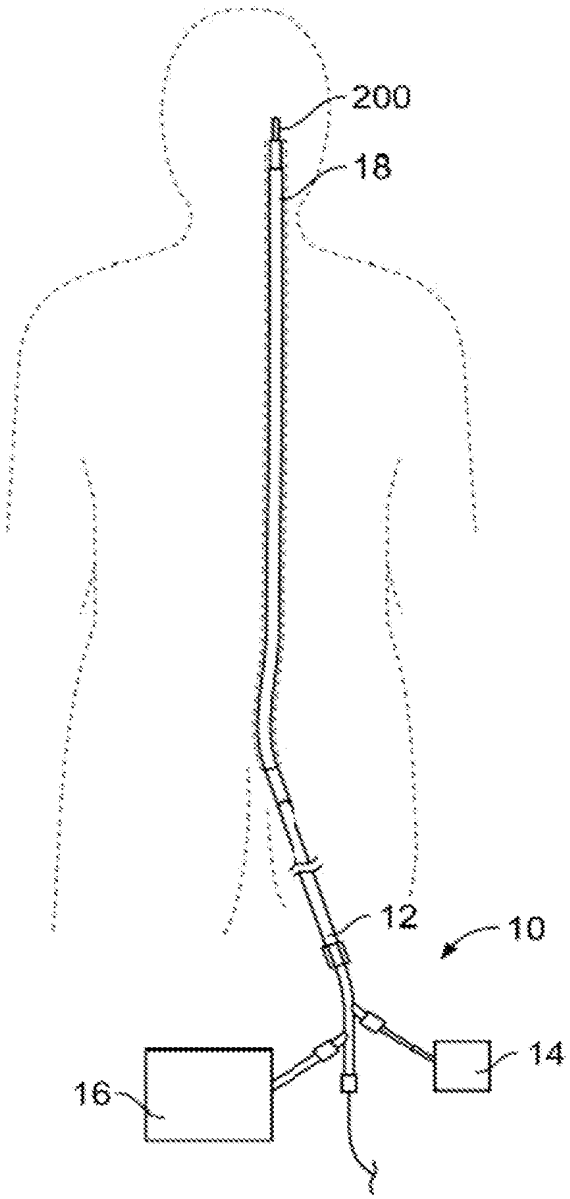


FIG. 1A

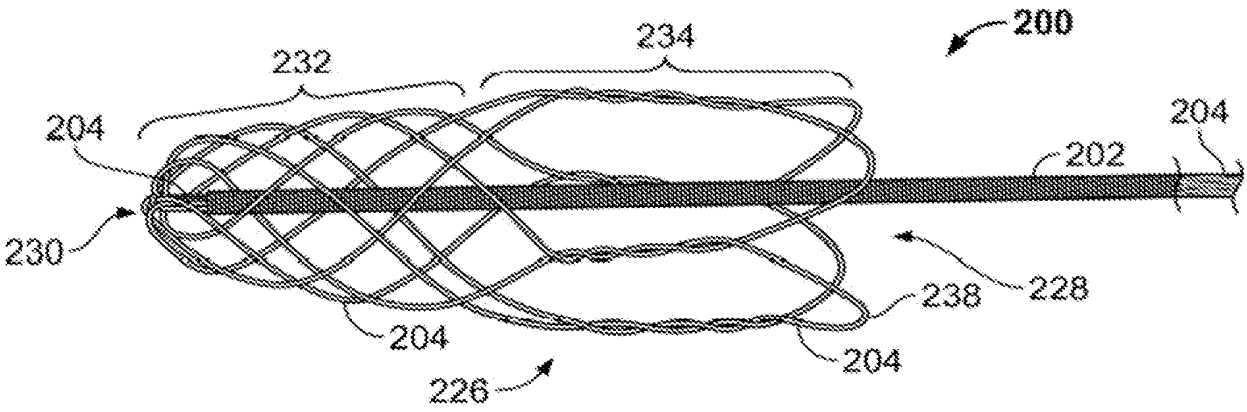

200
234
232
204
204
202
230
238
228
204
204
226

FIG. 1B

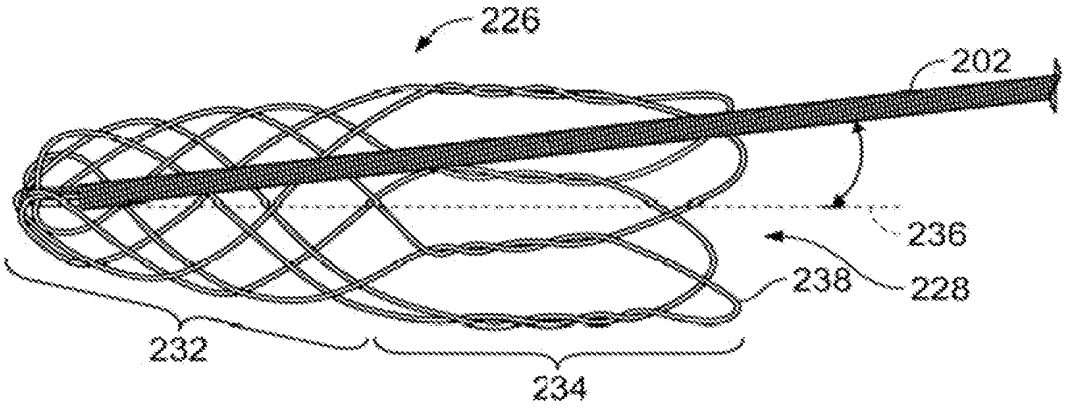

226
202
236
238
228
232
234

FIG. 1C

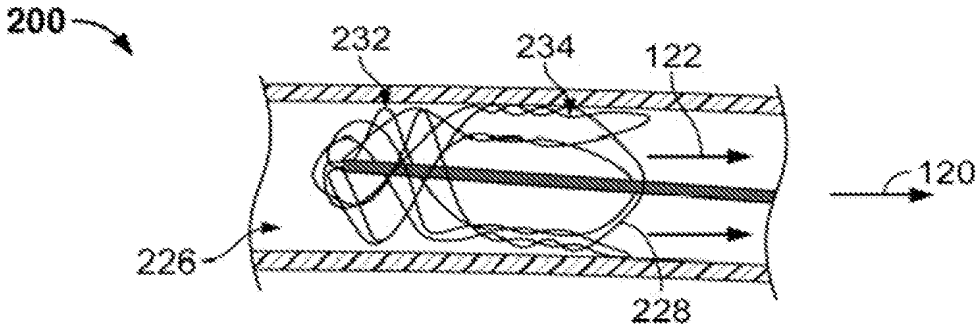


FIG. 2A

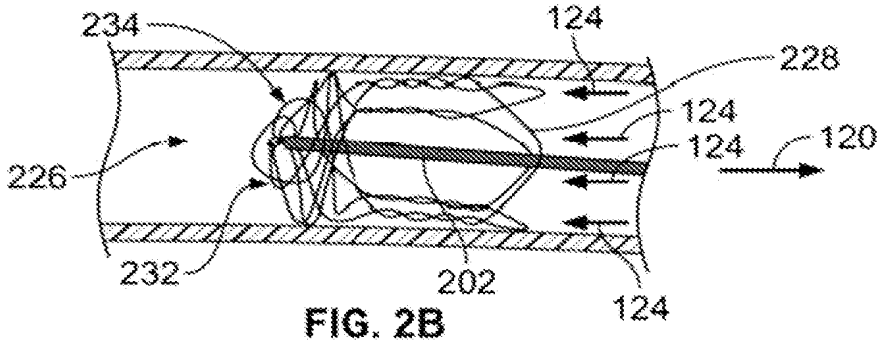


FIG. 2B

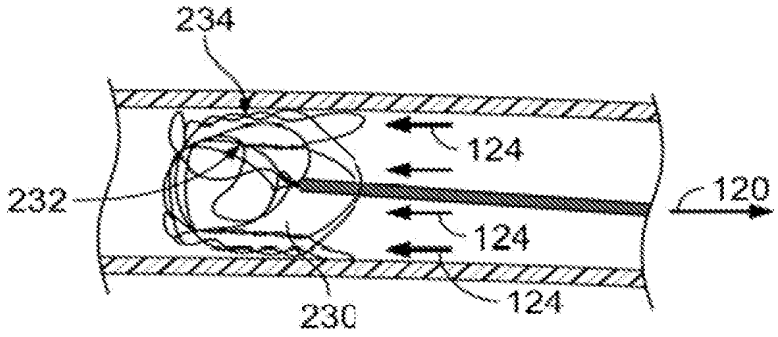


FIG. 2C

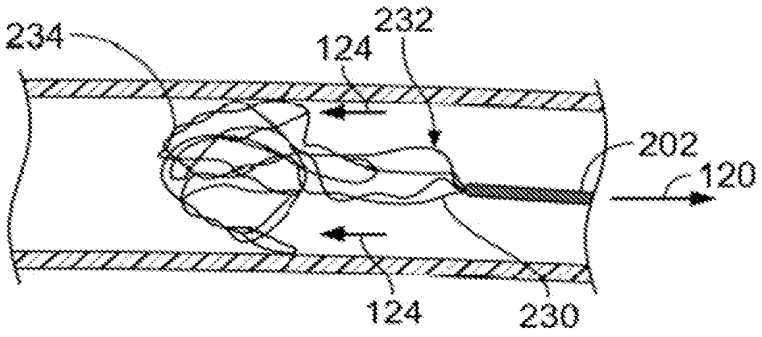


FIG. 2D

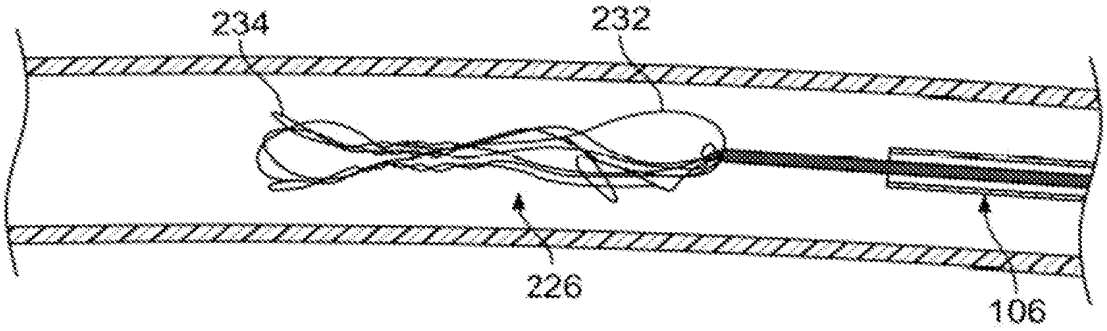


FIG. 2E

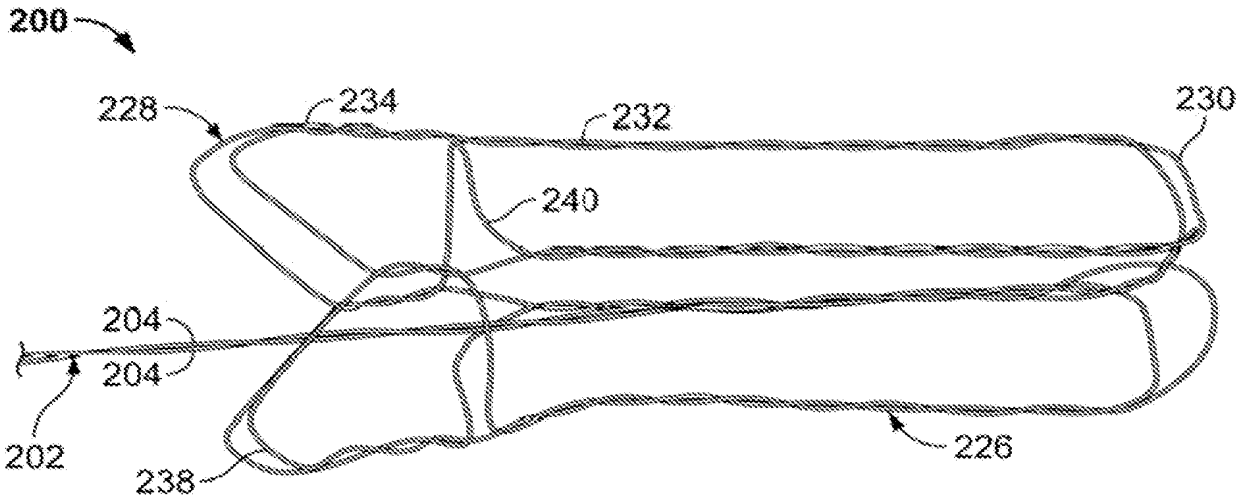

200
228
234
232
230
240
204
204
202
238
226

FIG. 3A

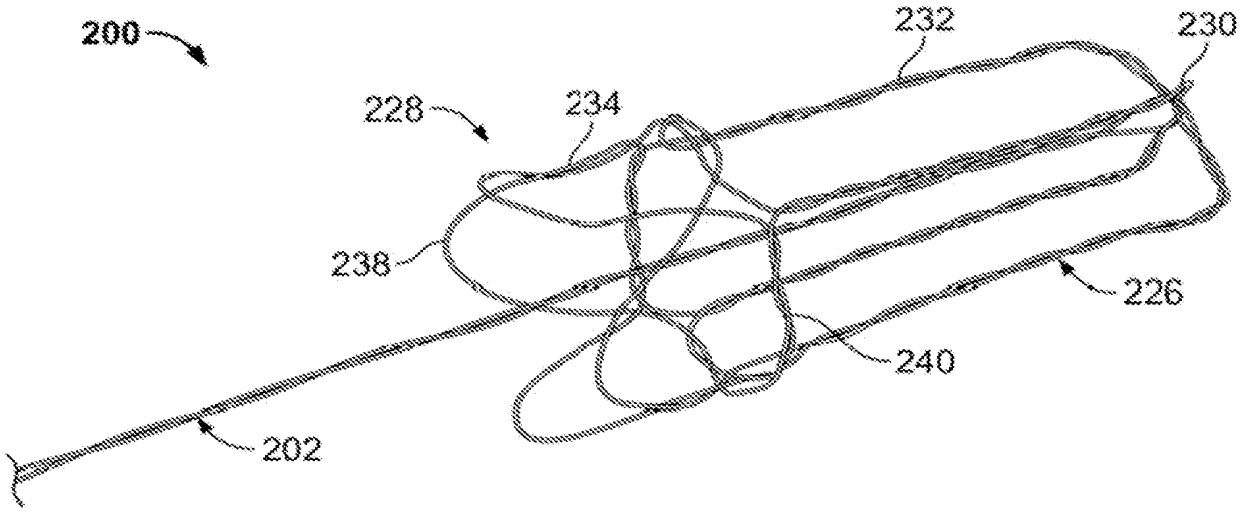

200
232
230
228
234
238
226
240
202

FIG. 3B

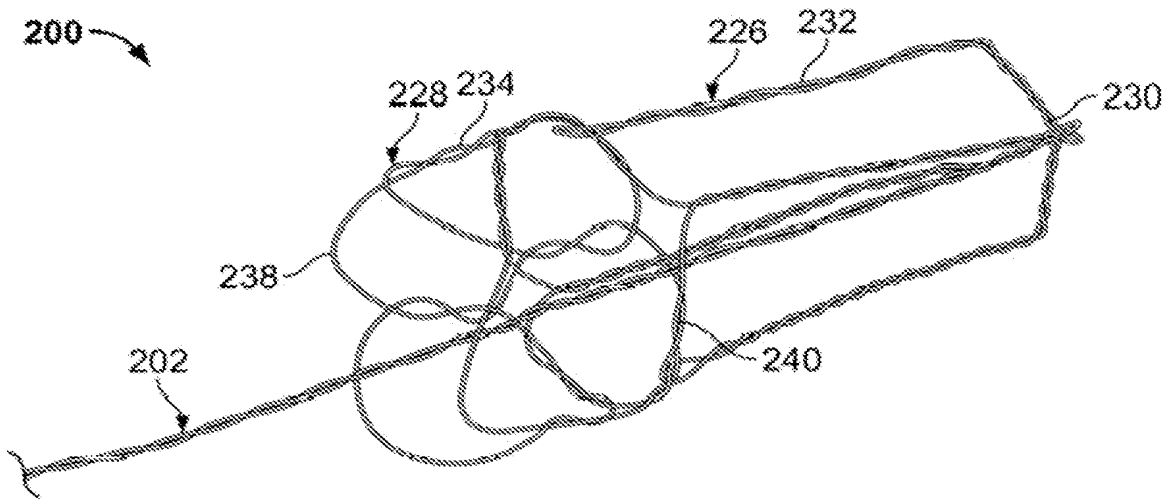


FIG. 3C

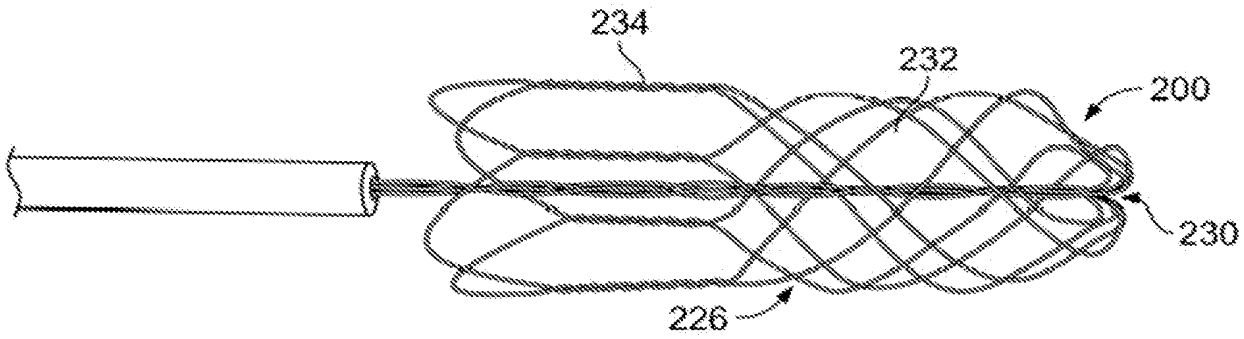


FIG. 3D

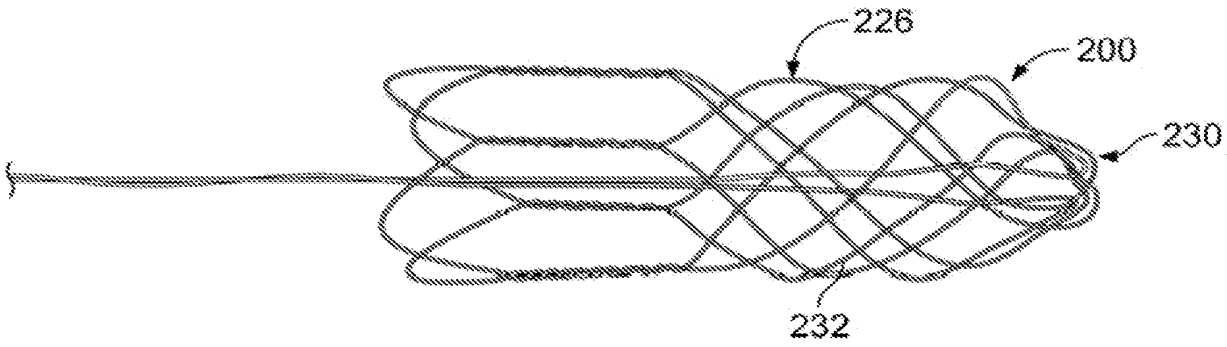


FIG. 3E

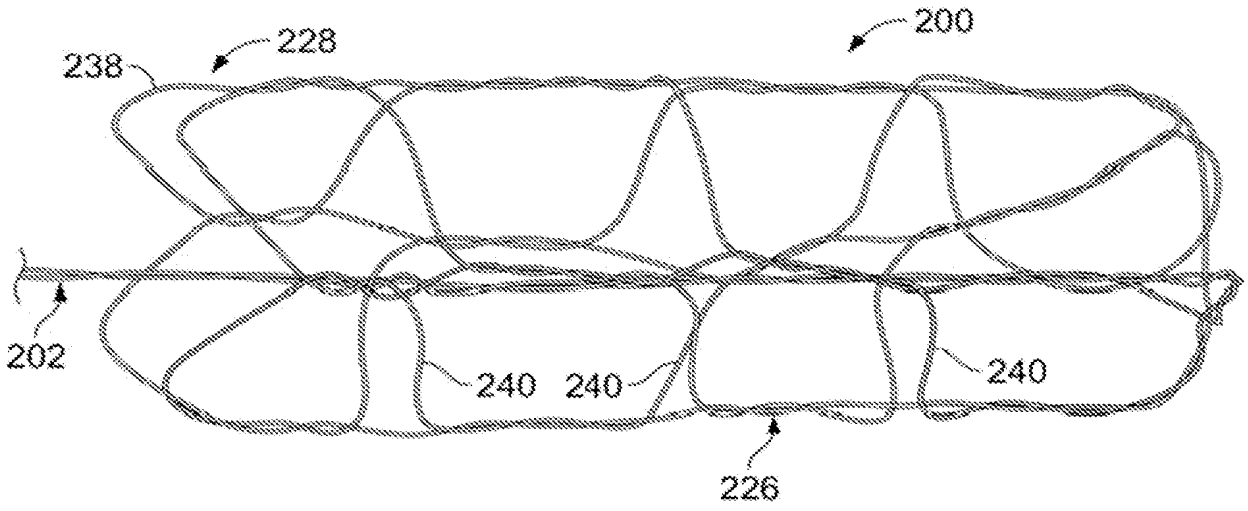


FIG. 3F

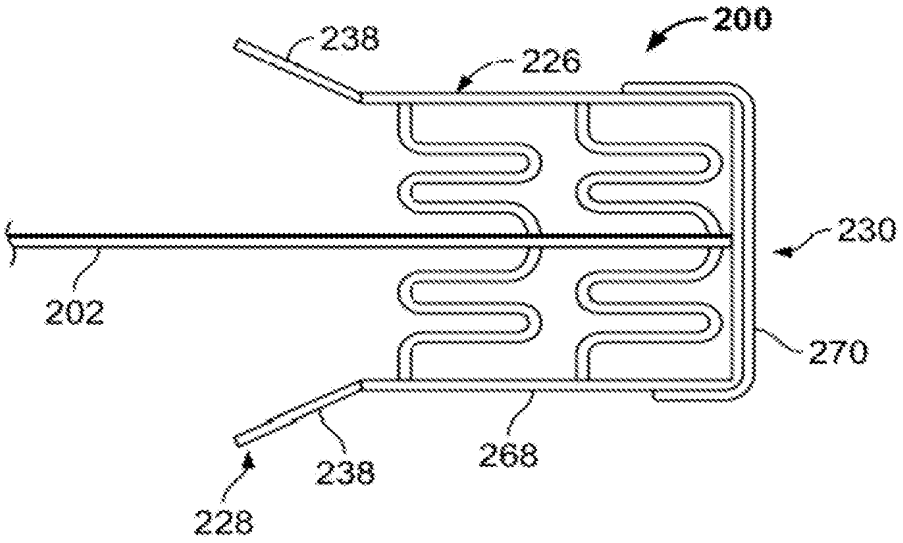


FIG. 3G

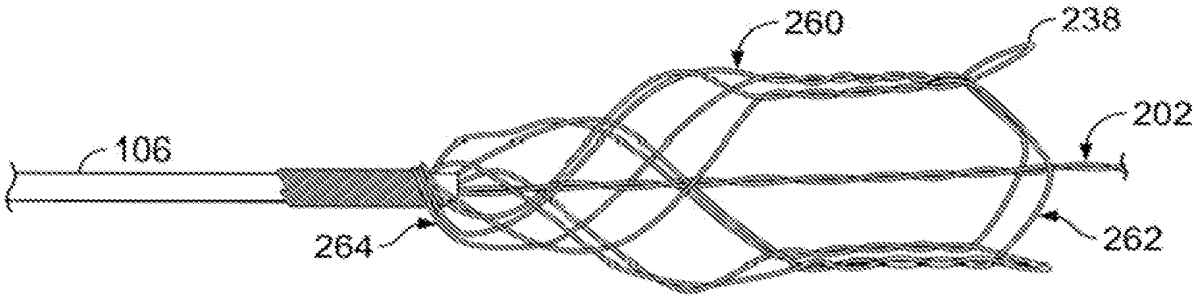


FIG. 3H

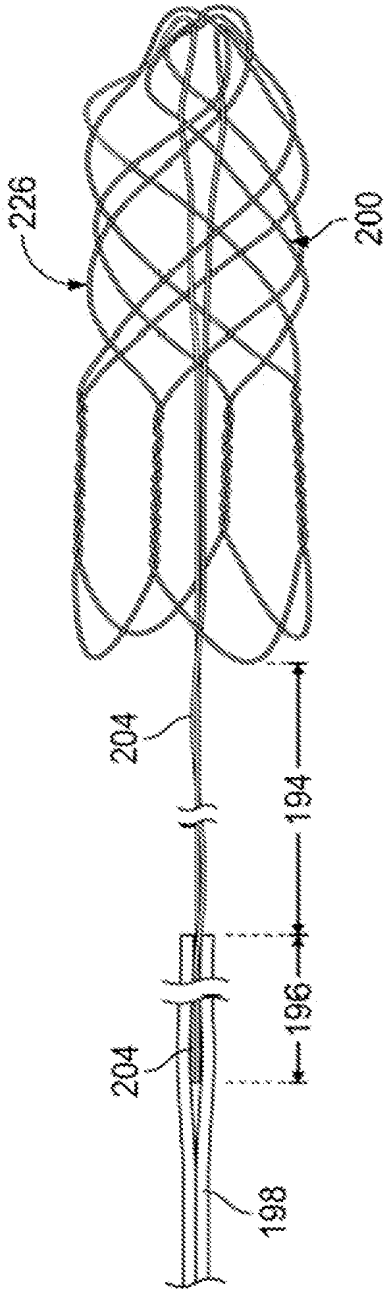


FIG. 4A

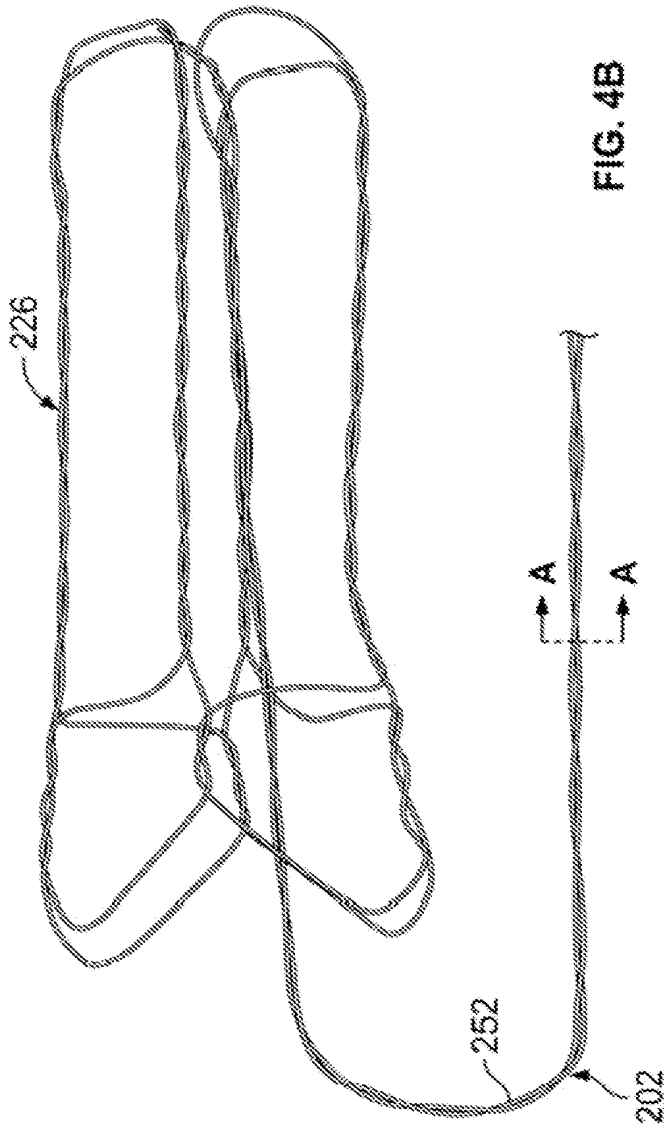


FIG. 4B

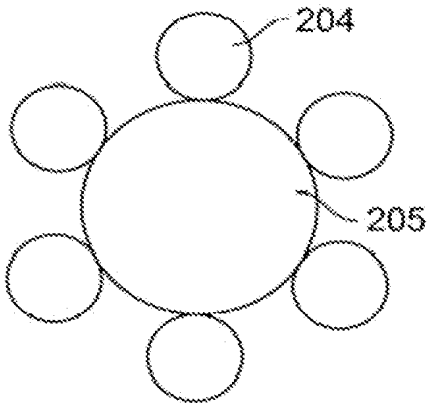


FIG. 4C

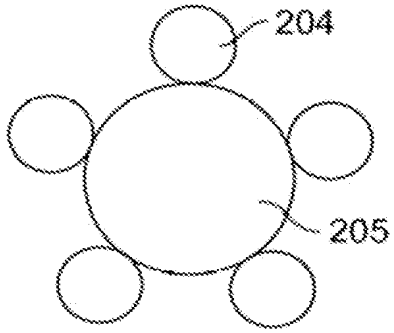


FIG. 4D

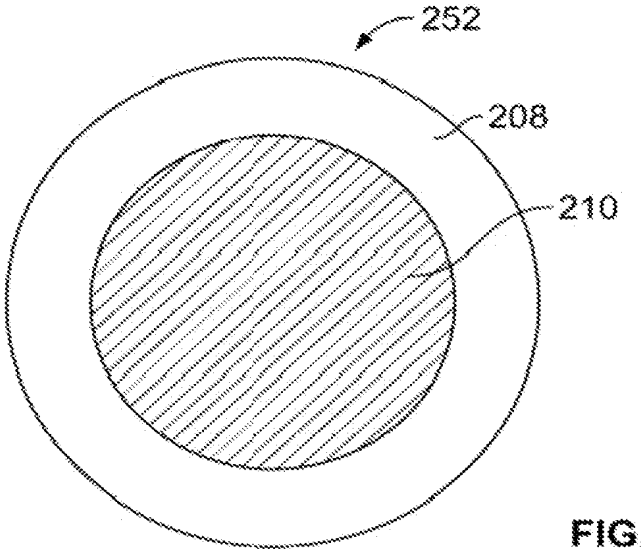


FIG. 4E

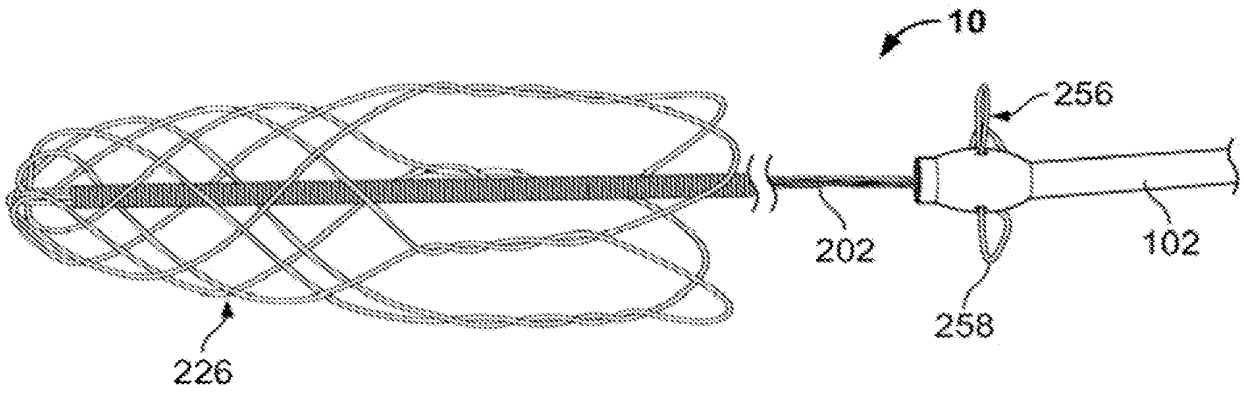


FIG. 5A

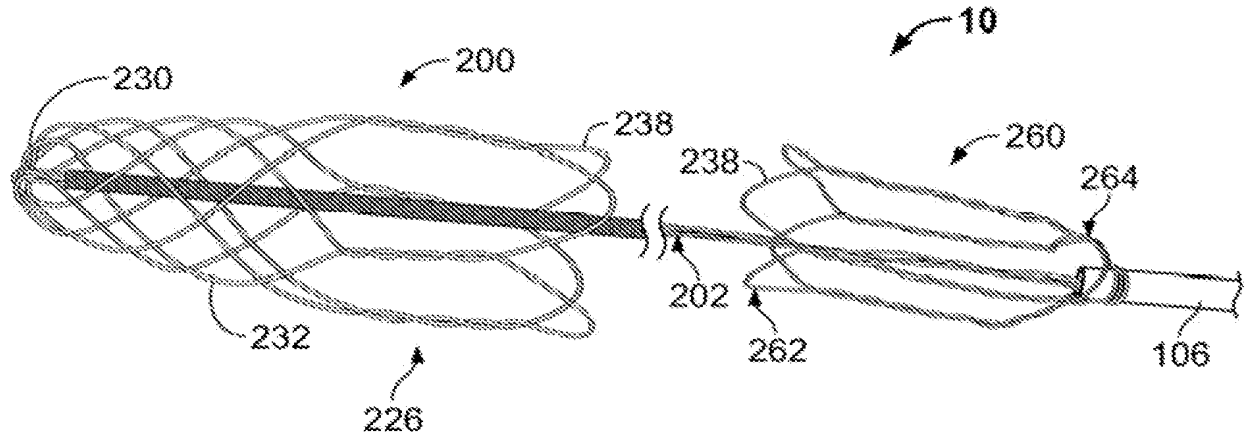


FIG. 5B

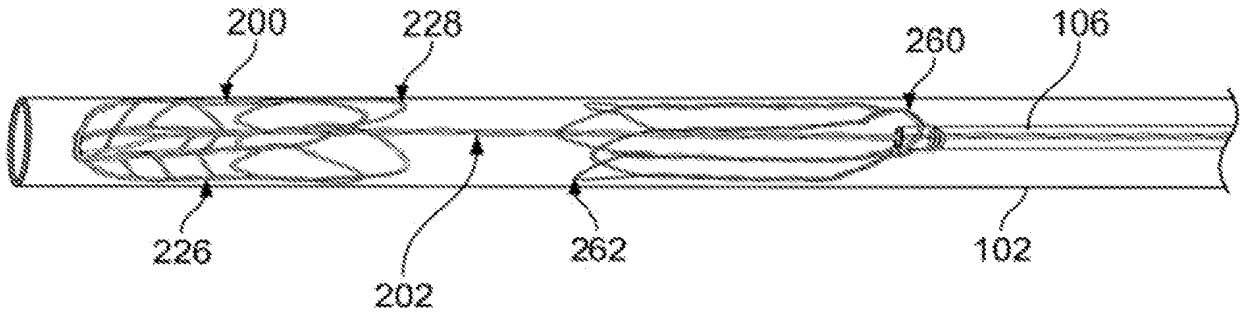


FIG. 5C

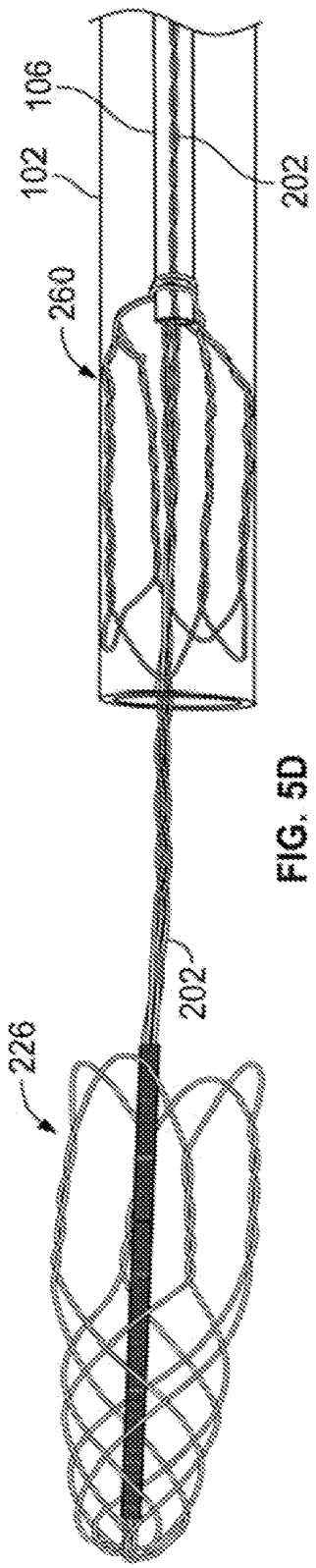


FIG. 5D

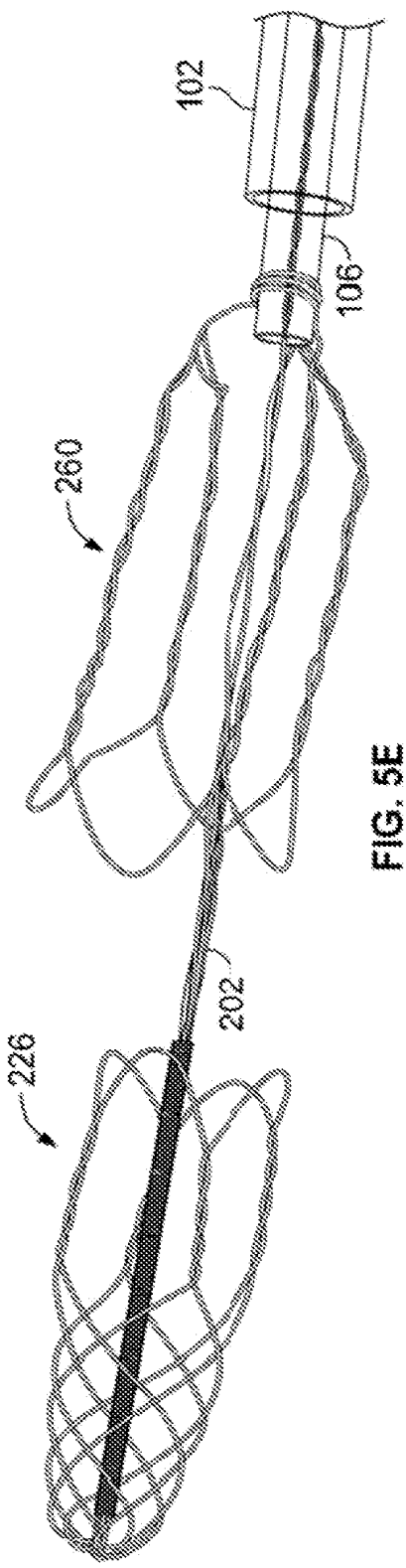


FIG. 5E

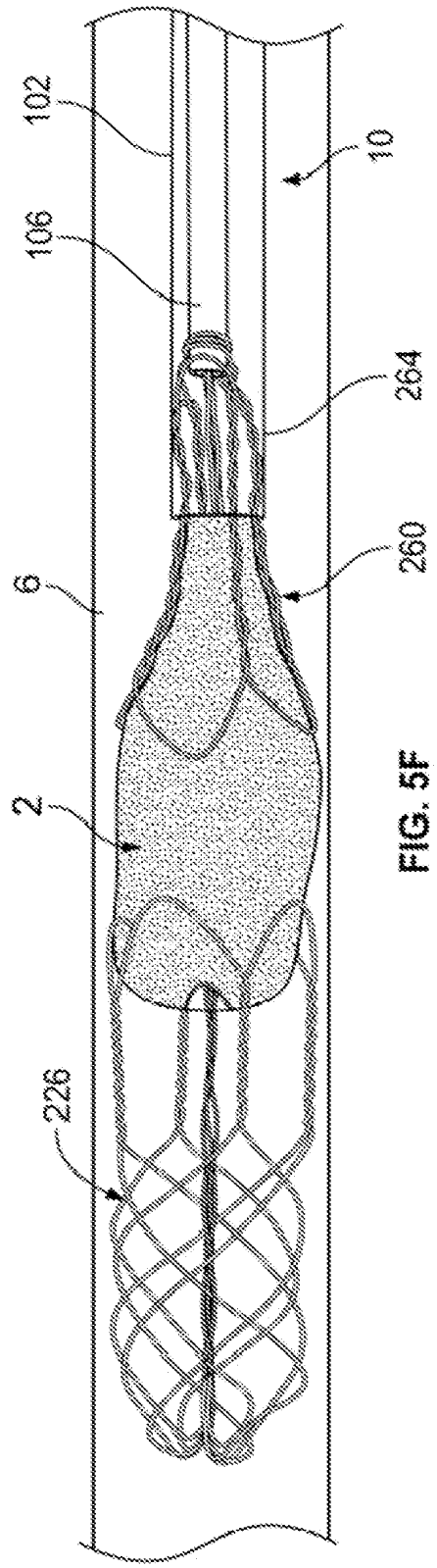


FIG. 5F

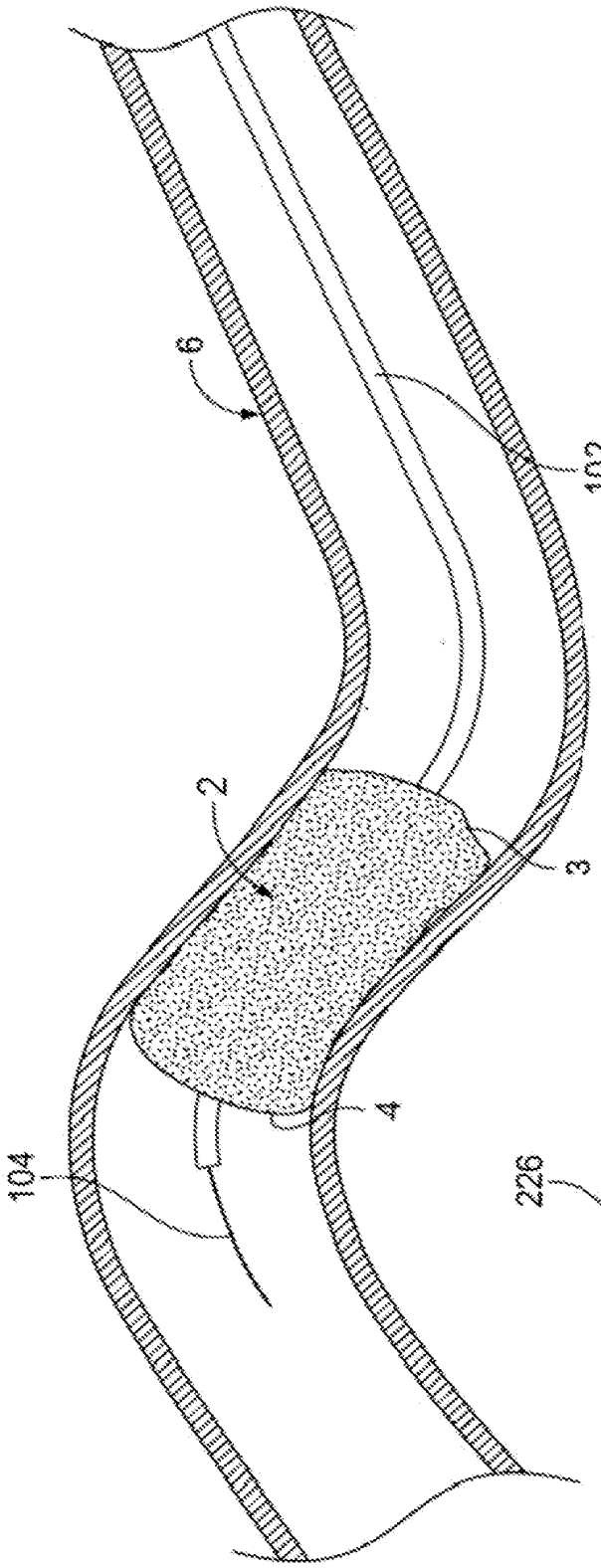


FIG. 6A

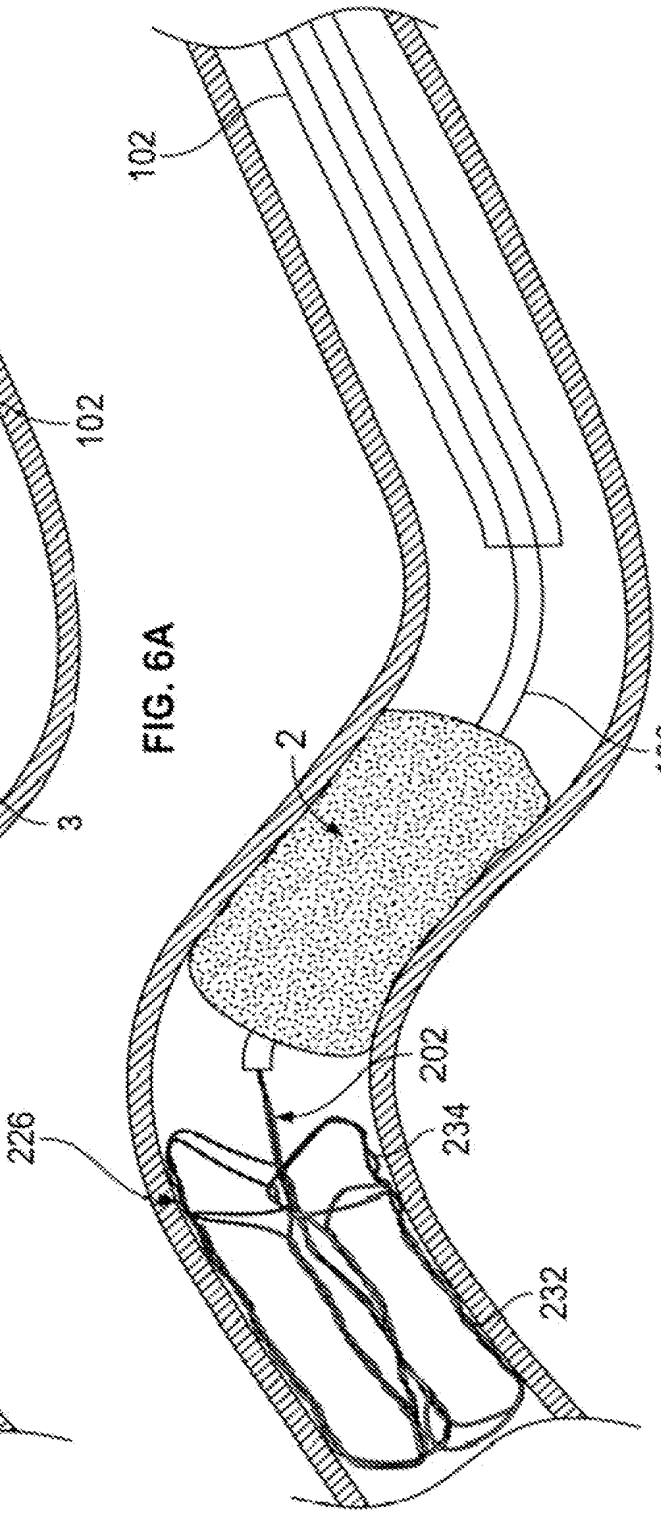


FIG. 6B

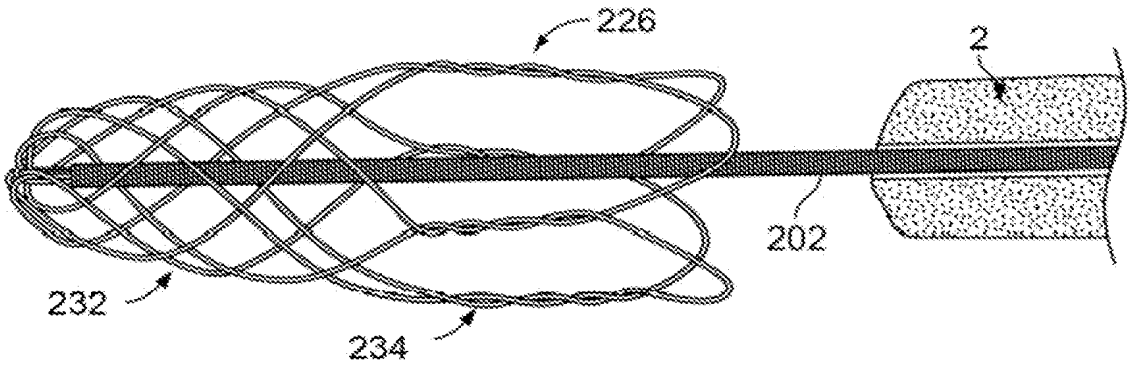


FIG. 7A

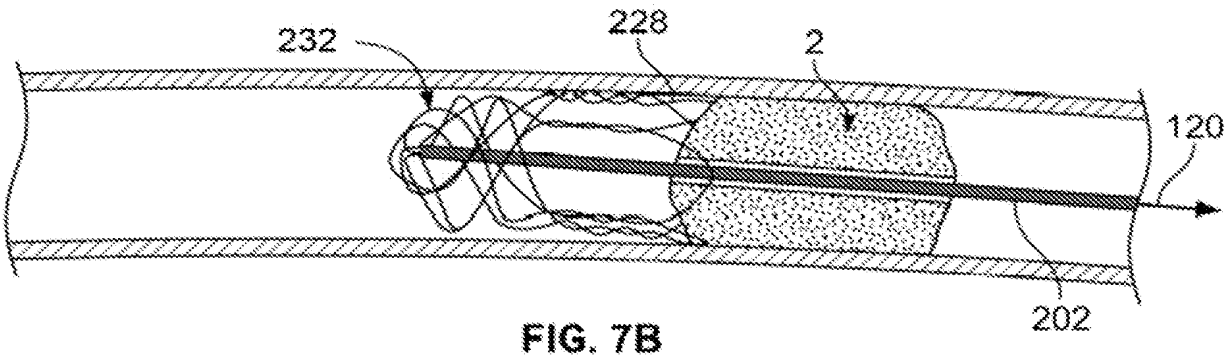


FIG. 7B

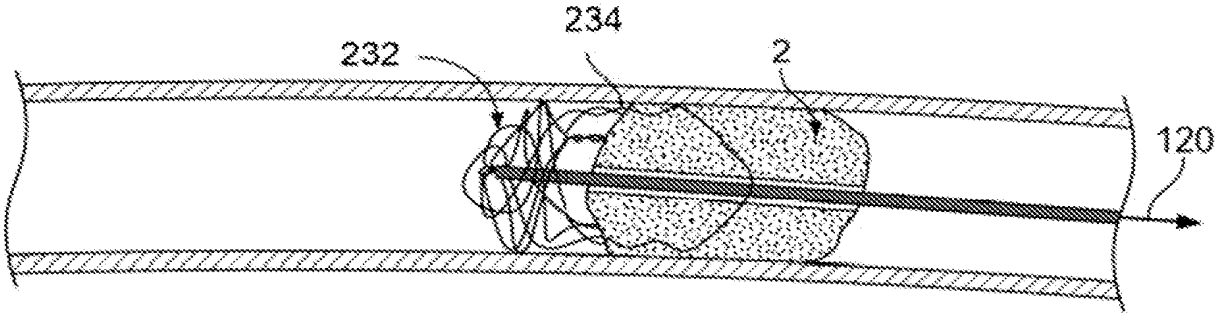


FIG. 7C

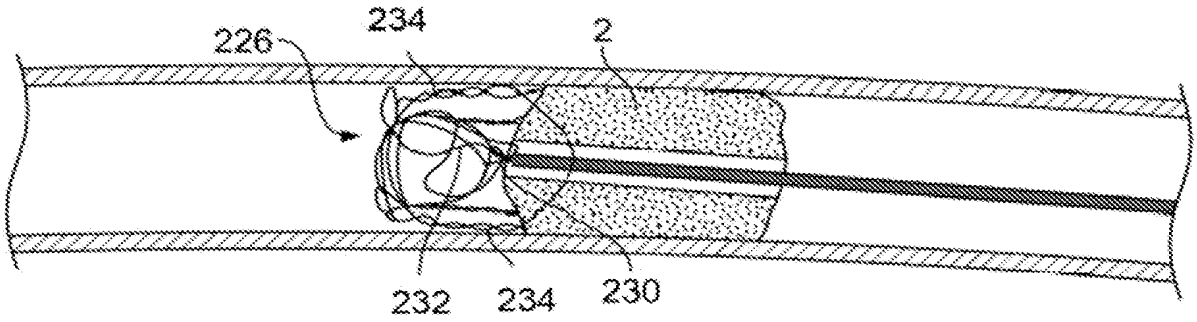


FIG. 7D

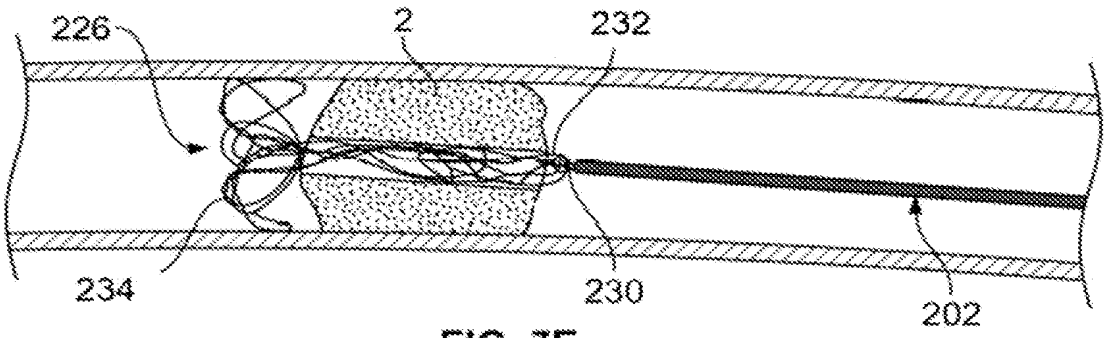


FIG. 7E

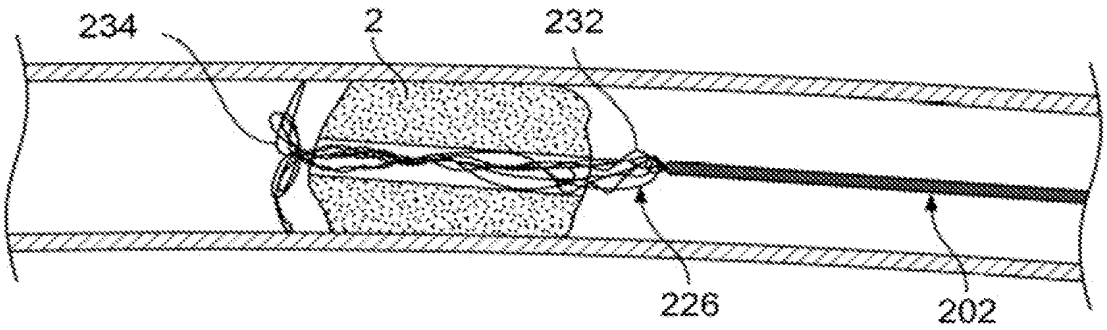


FIG. 7F

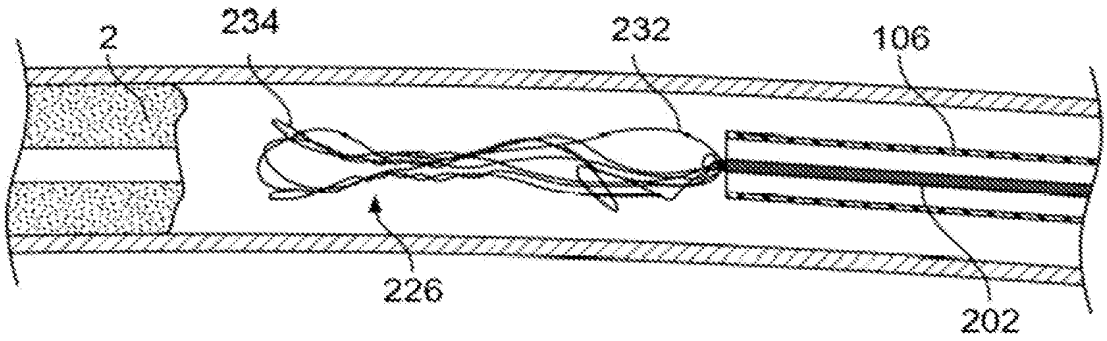


FIG. 7G

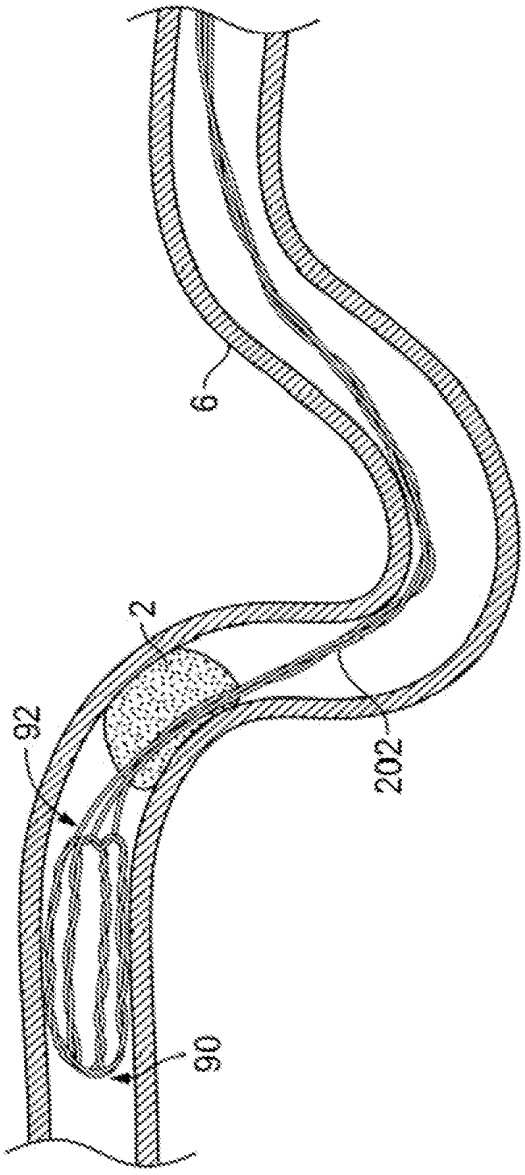


FIG. 8A

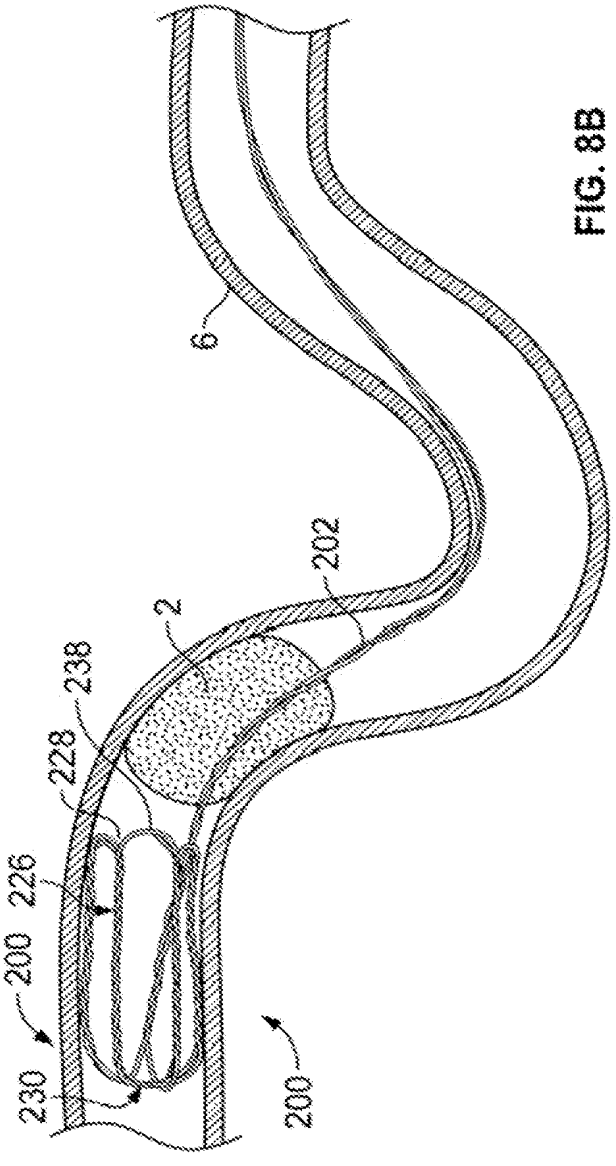


FIG. 8B

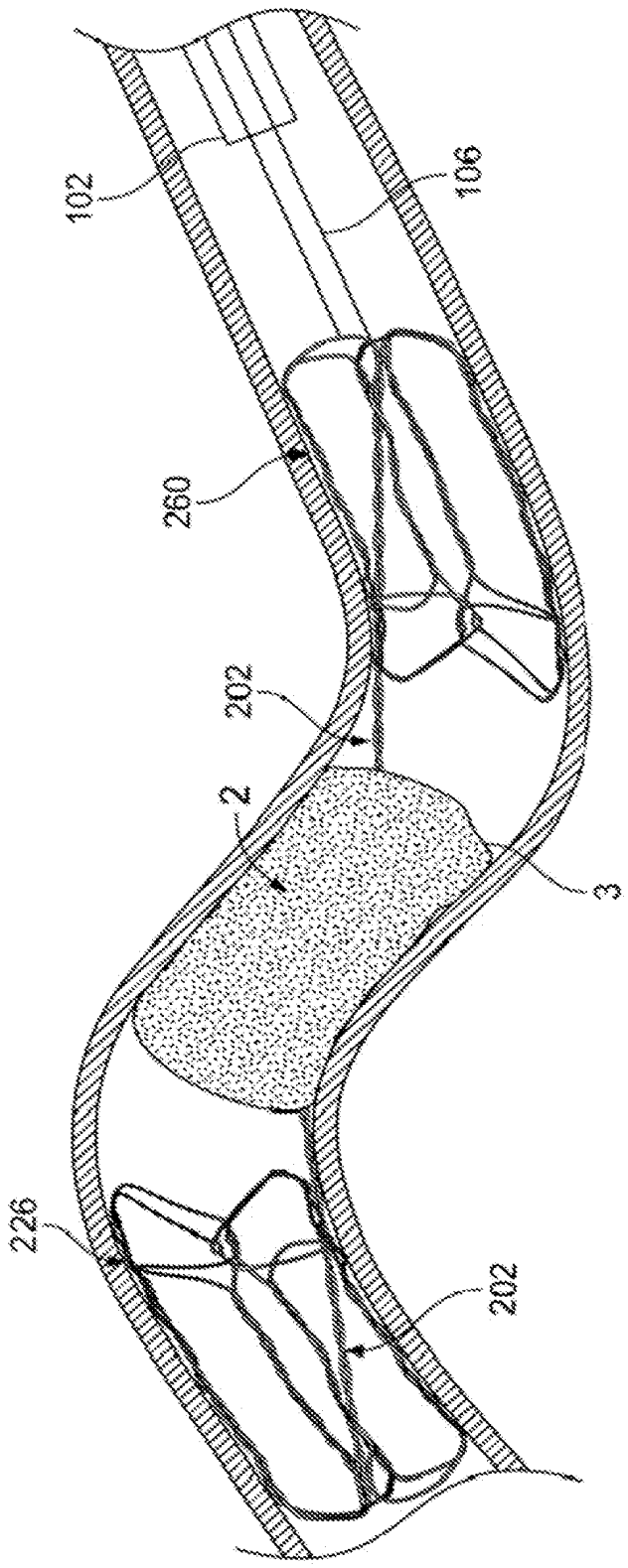


FIG. 8C

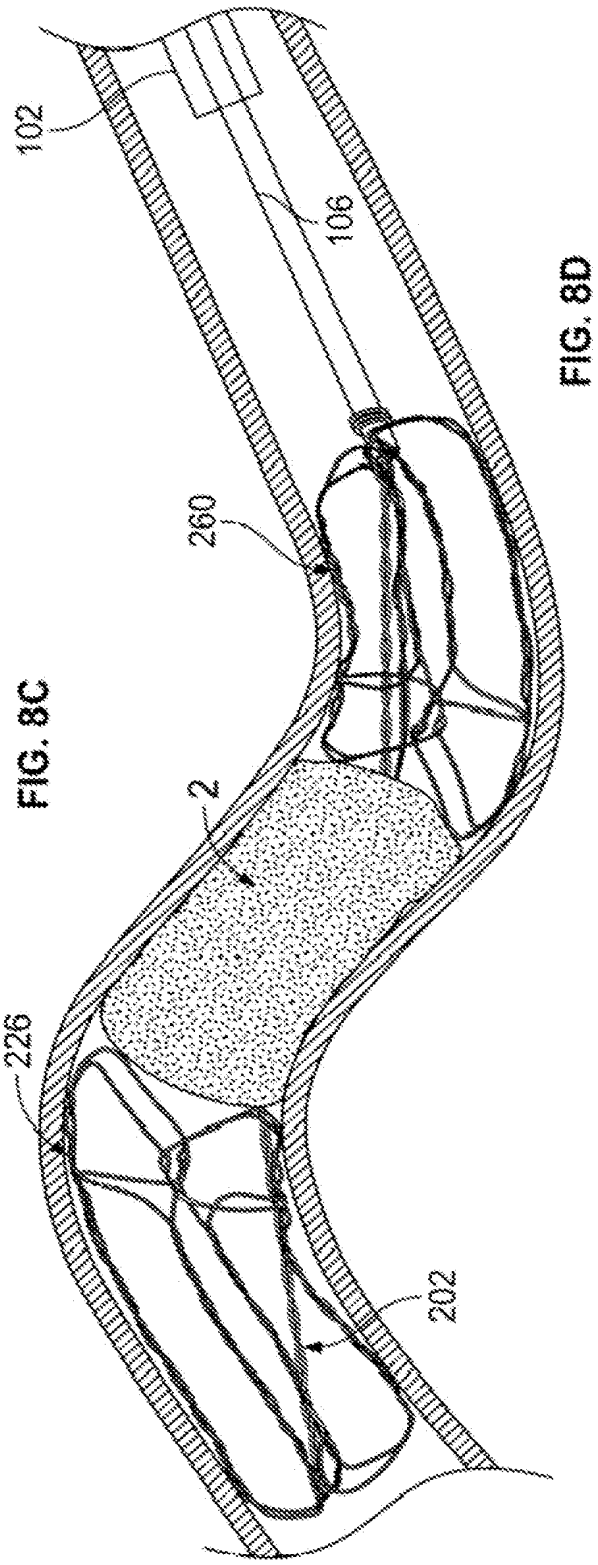


FIG. 8D

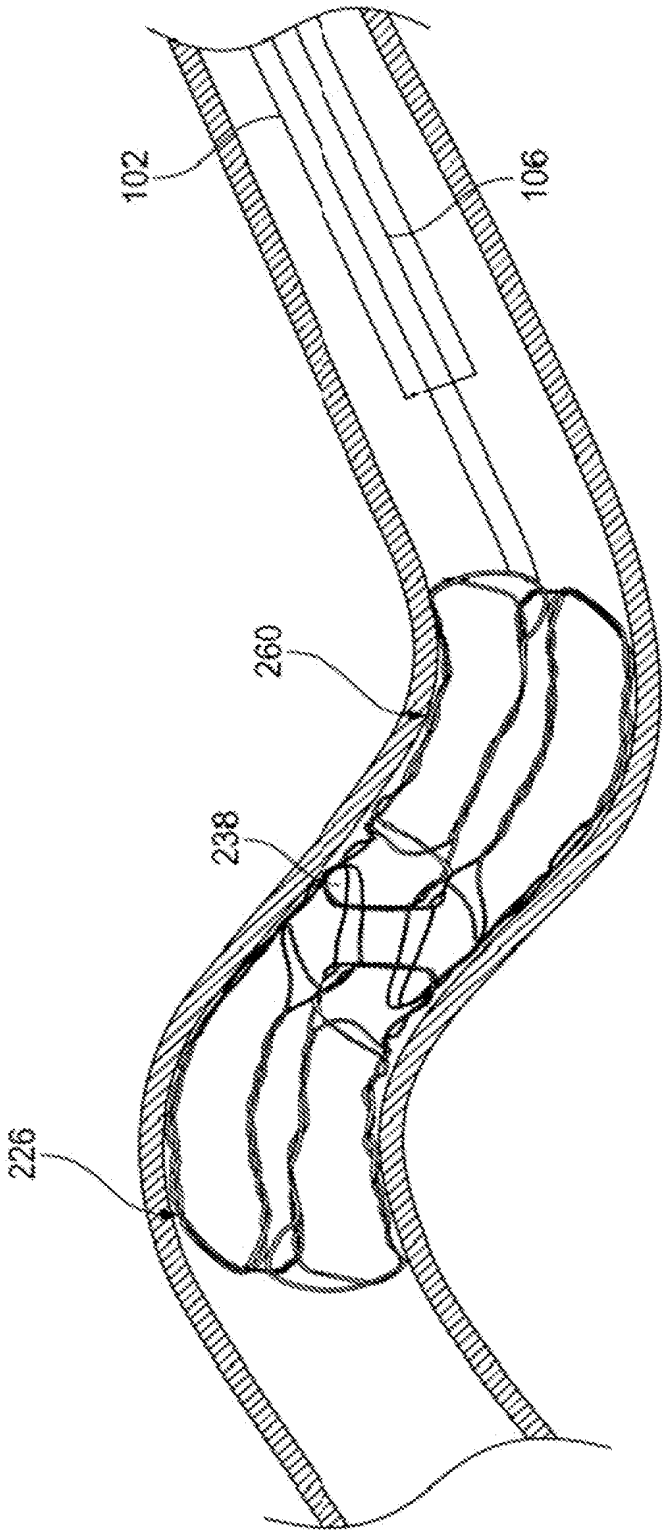


FIG. 8E

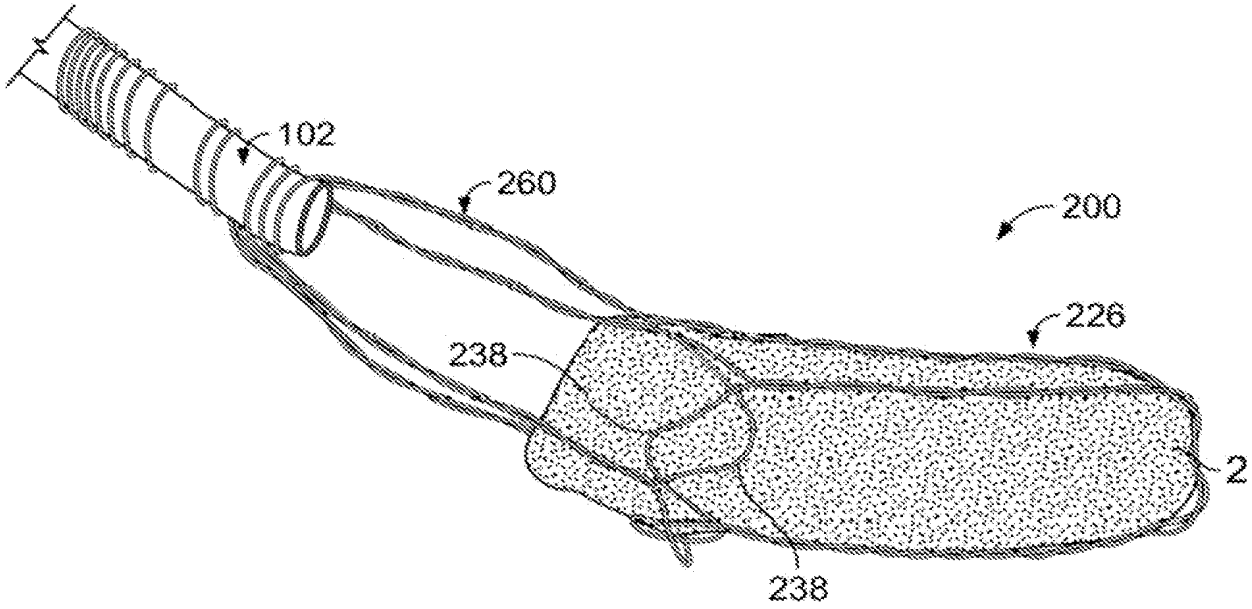


FIG. 8F

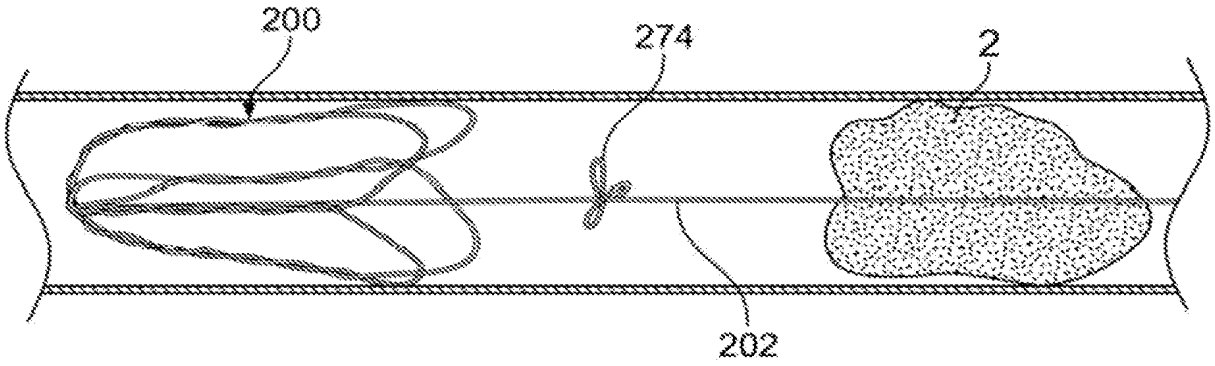


FIG. 9

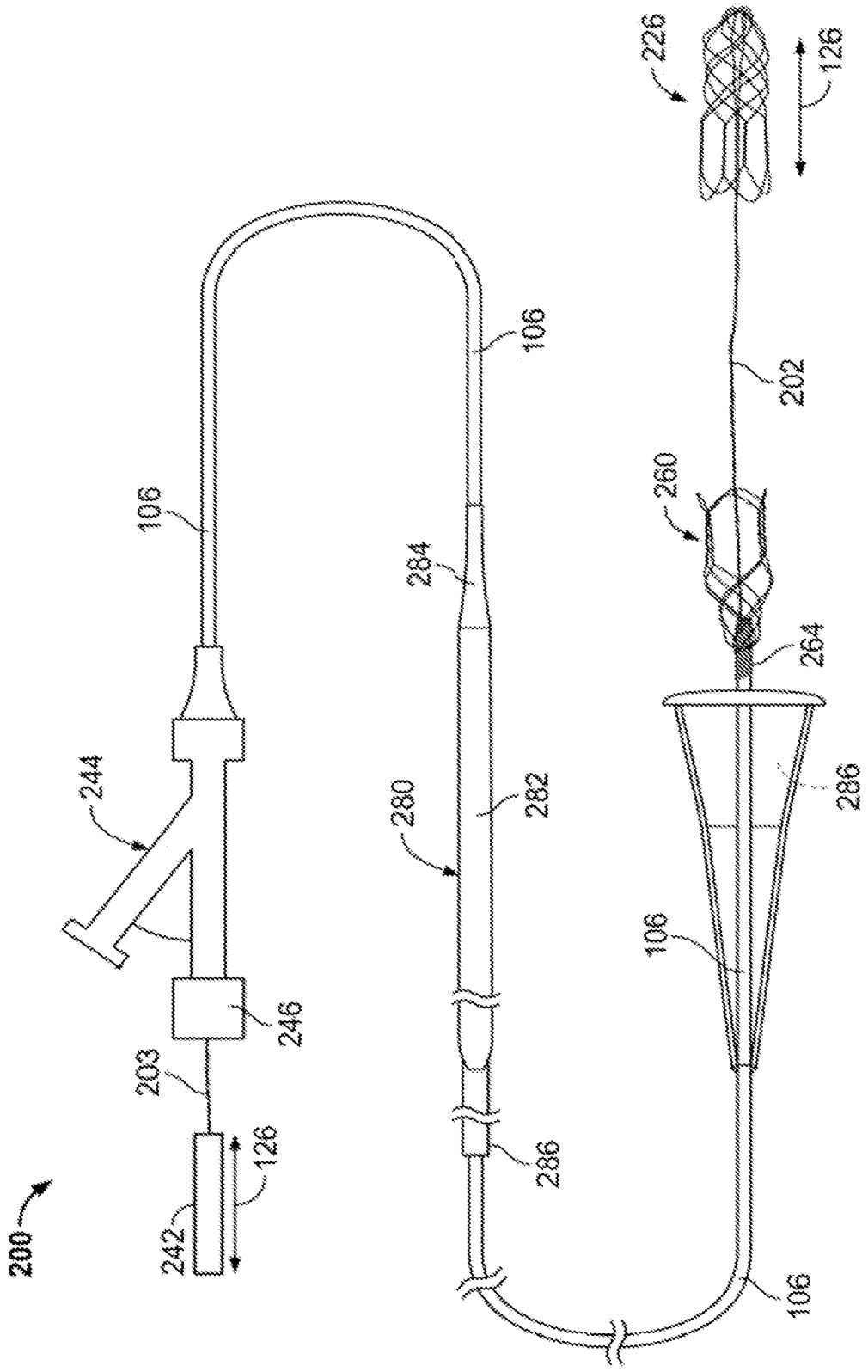

200
242
126
203
246
244
106
106
284
280
282
286
286
106
106
260
264
226
126
202

FIG. 10

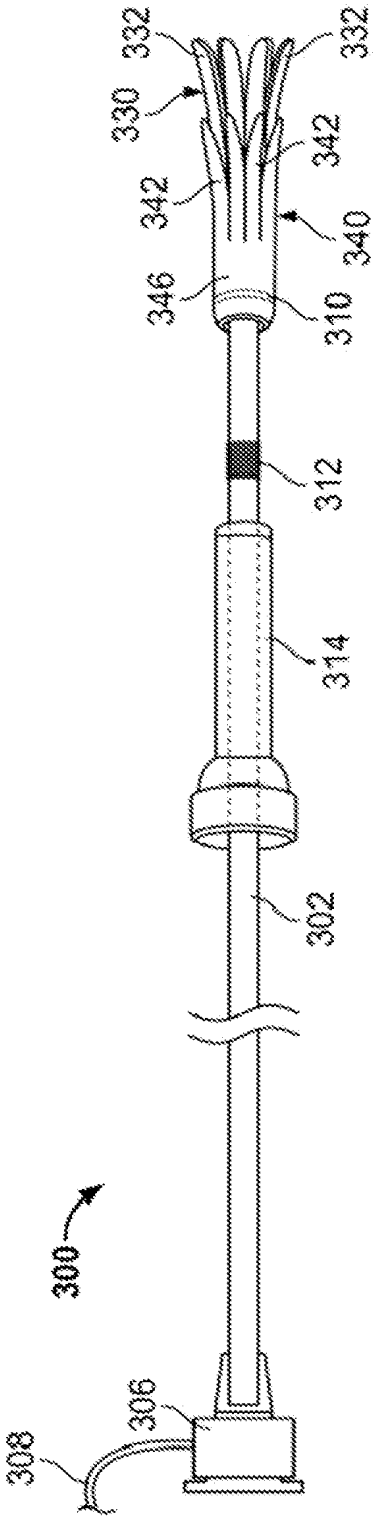


FIG. 11A

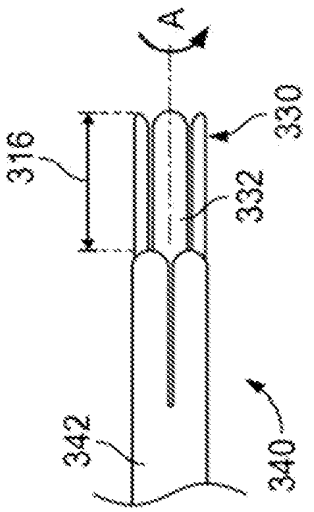


FIG. 11C

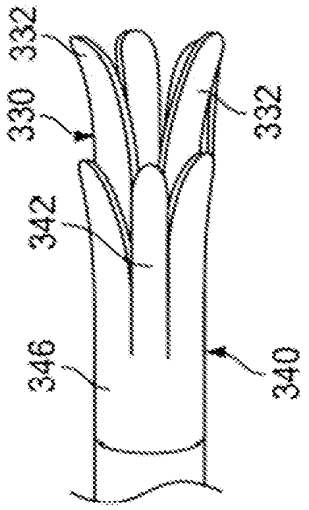


FIG. 11B

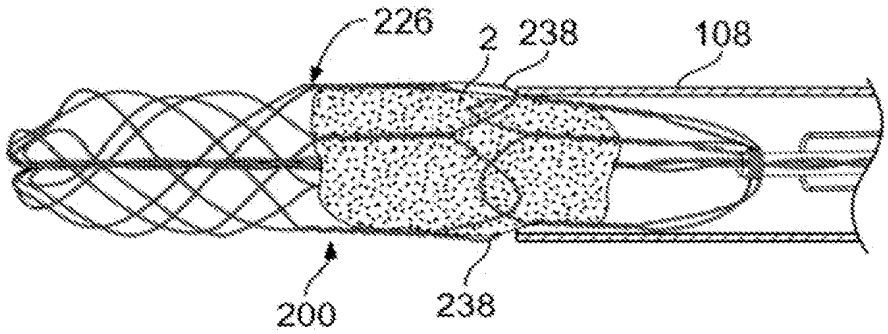


FIG. 12A

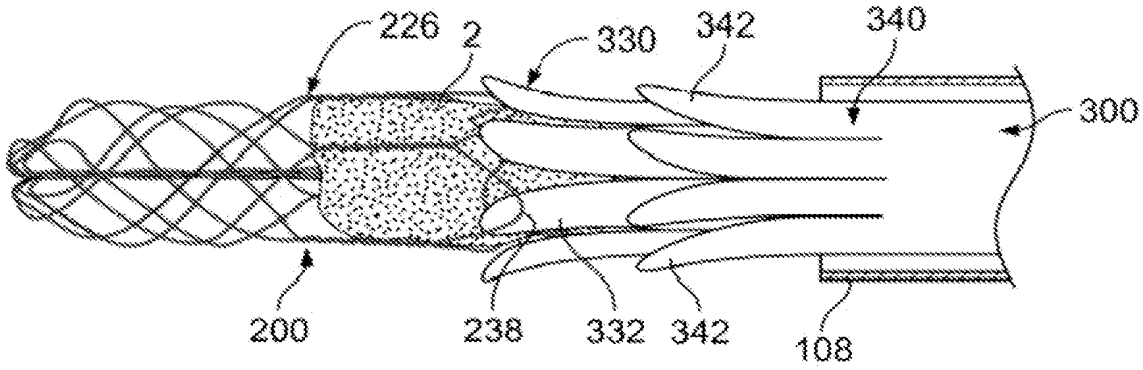


FIG. 12B

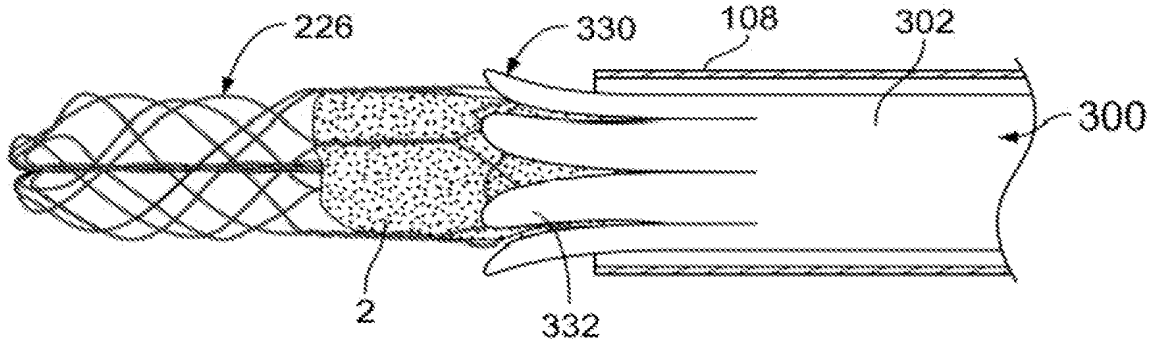


FIG. 12C

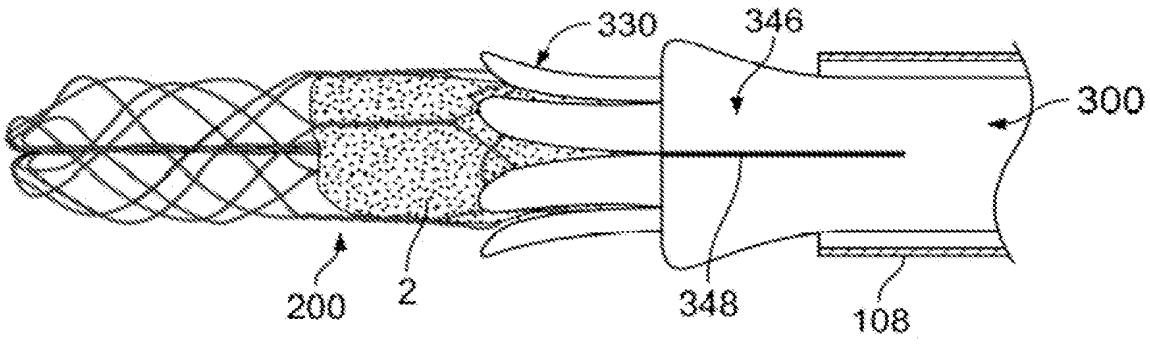


FIG. 12D

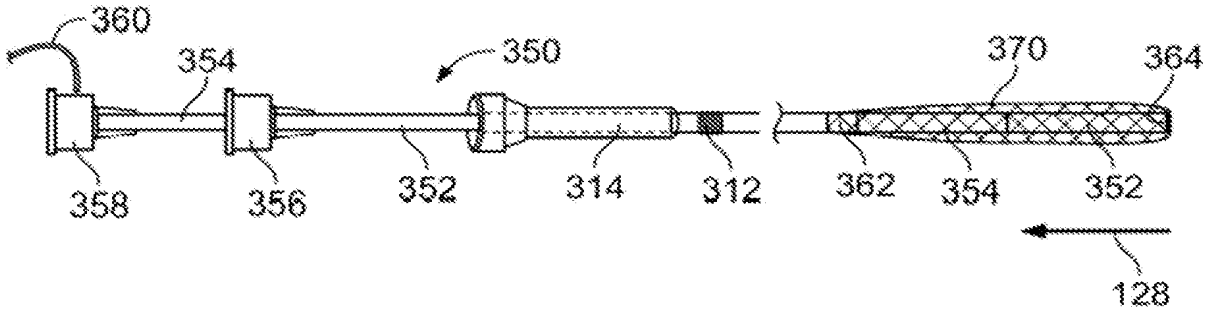


FIG. 13A

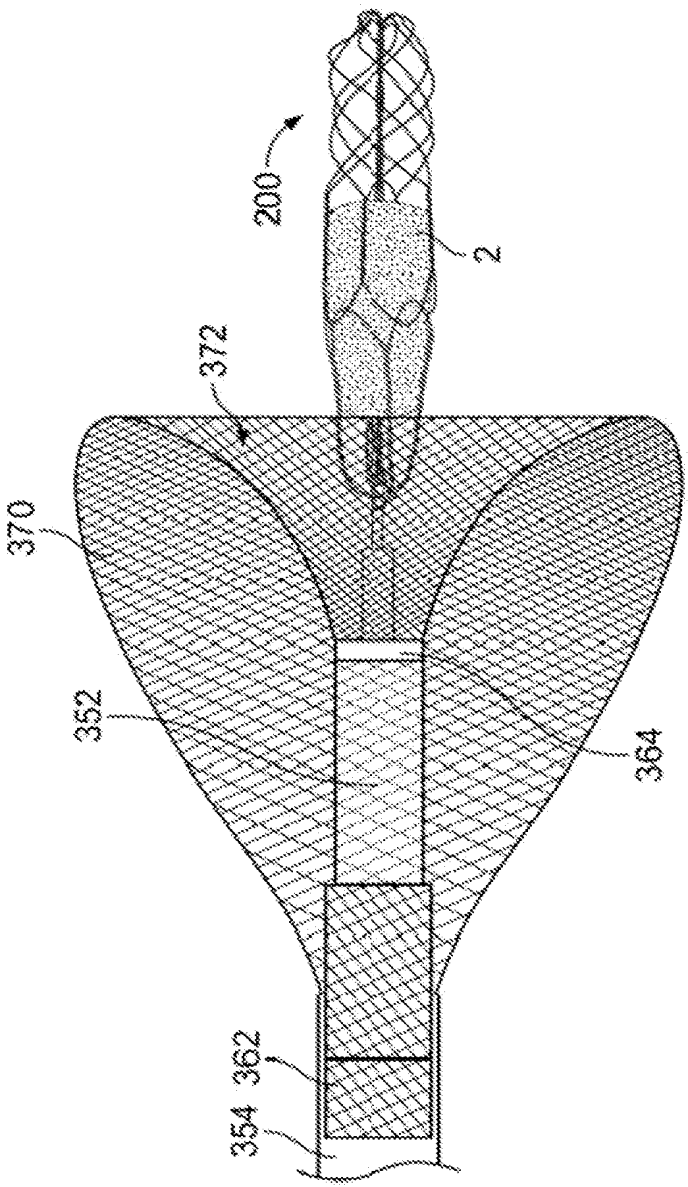


FIG. 13B

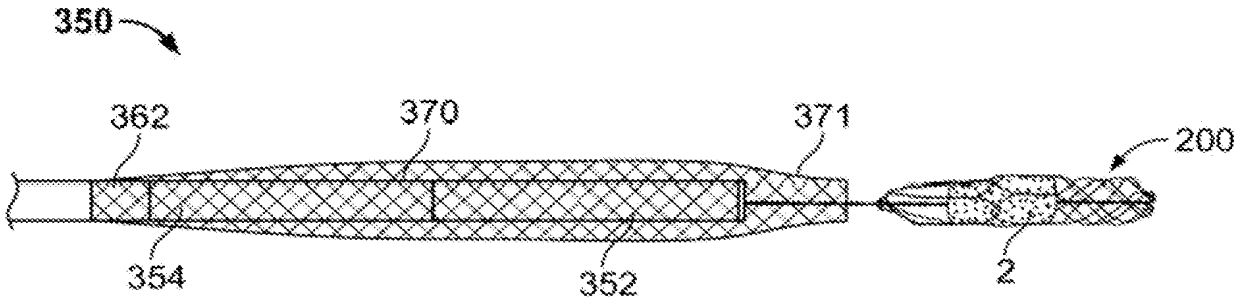


FIG. 13C

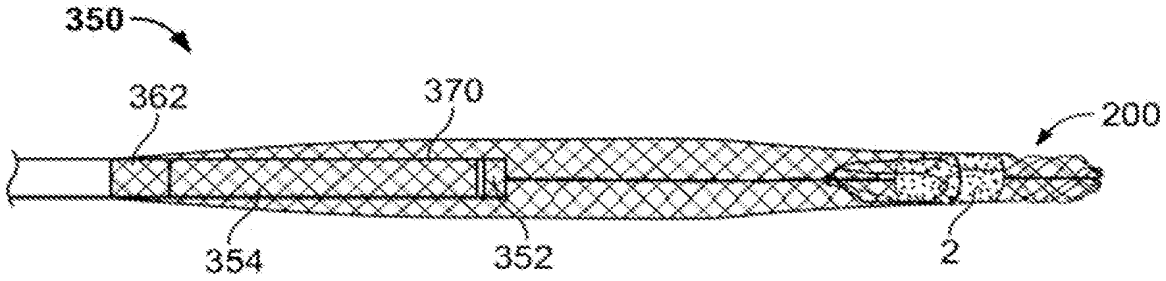


FIG. 13D

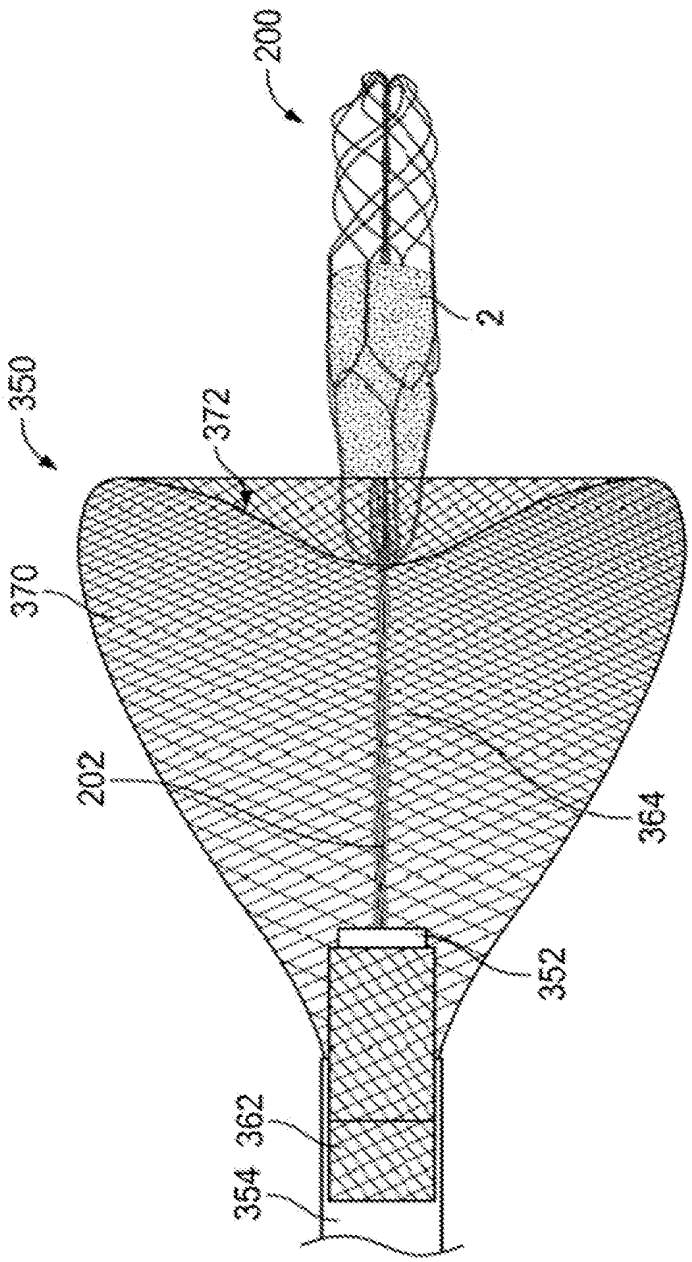


FIG. 13E

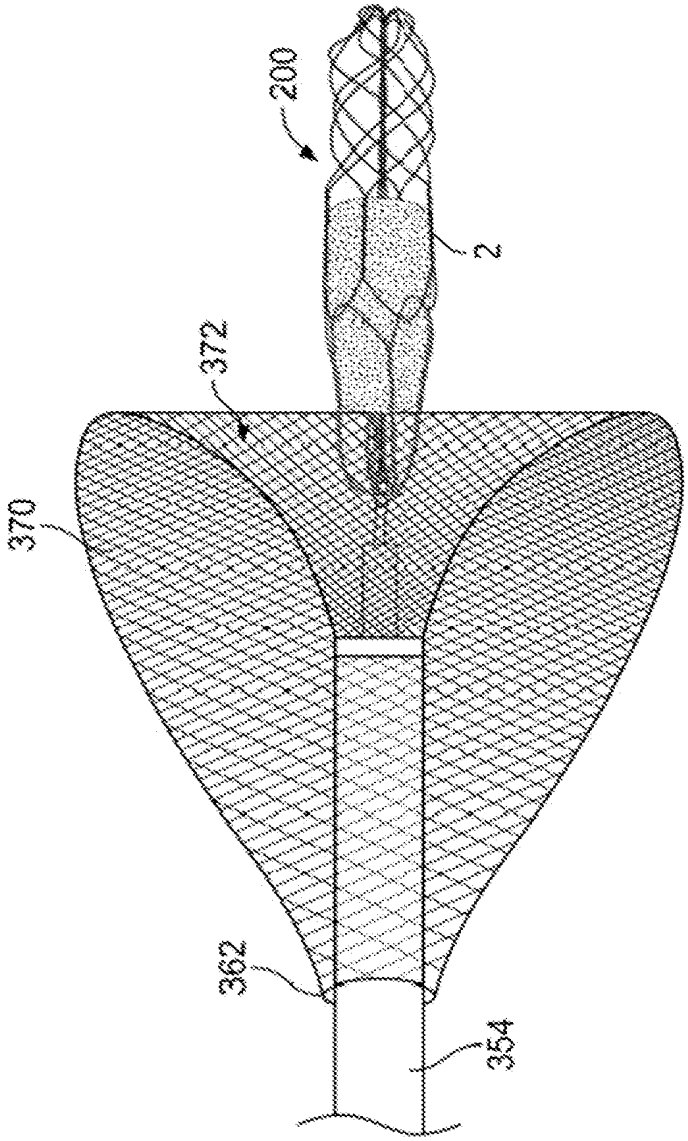


FIG. 13G

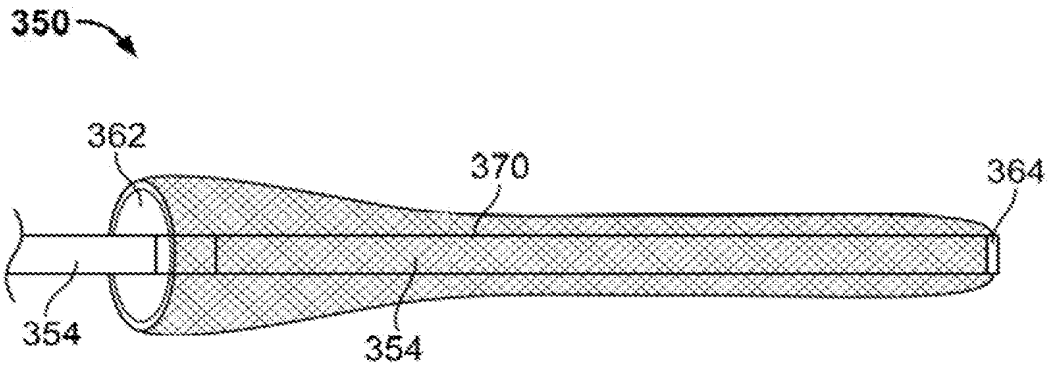


FIG. 13F

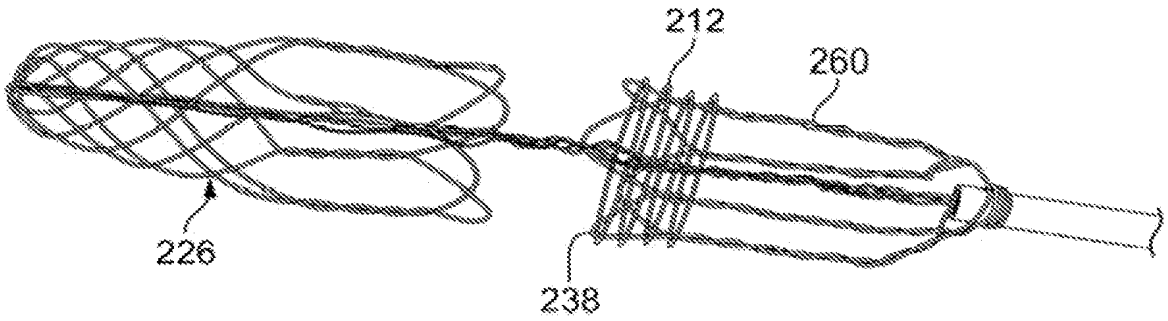


FIG. 14A

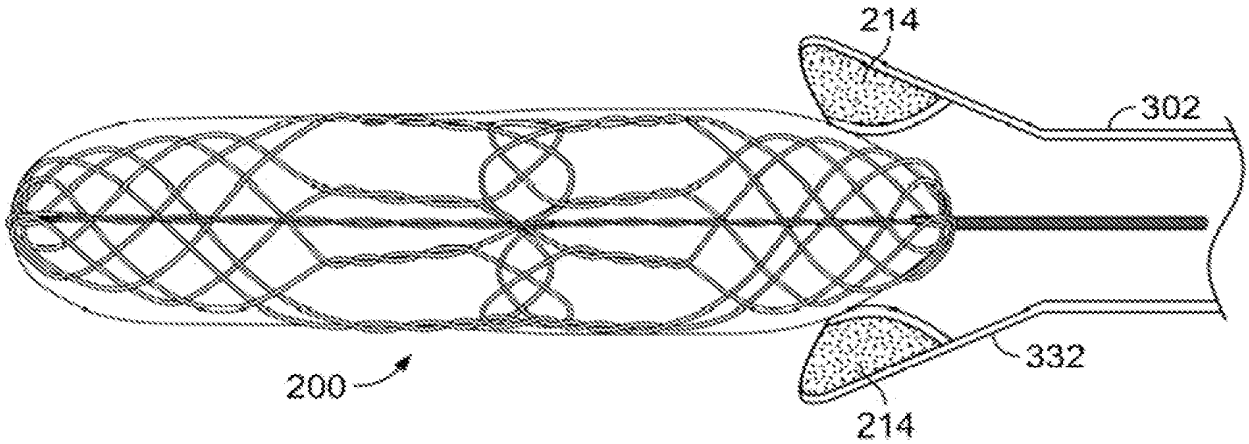


FIG. 14B

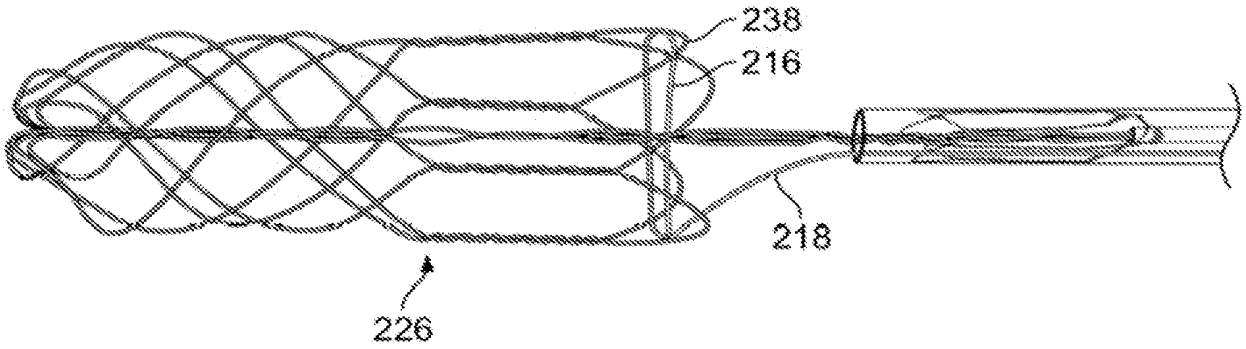


FIG. 14C

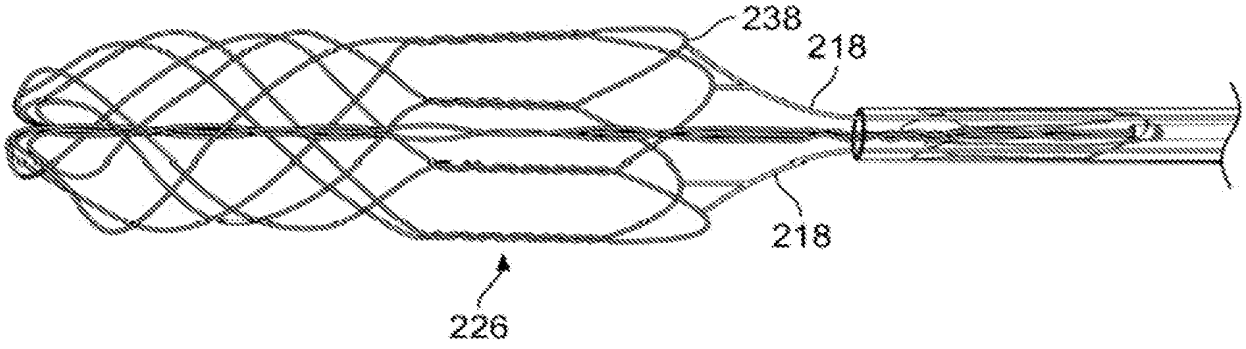


FIG. 14D

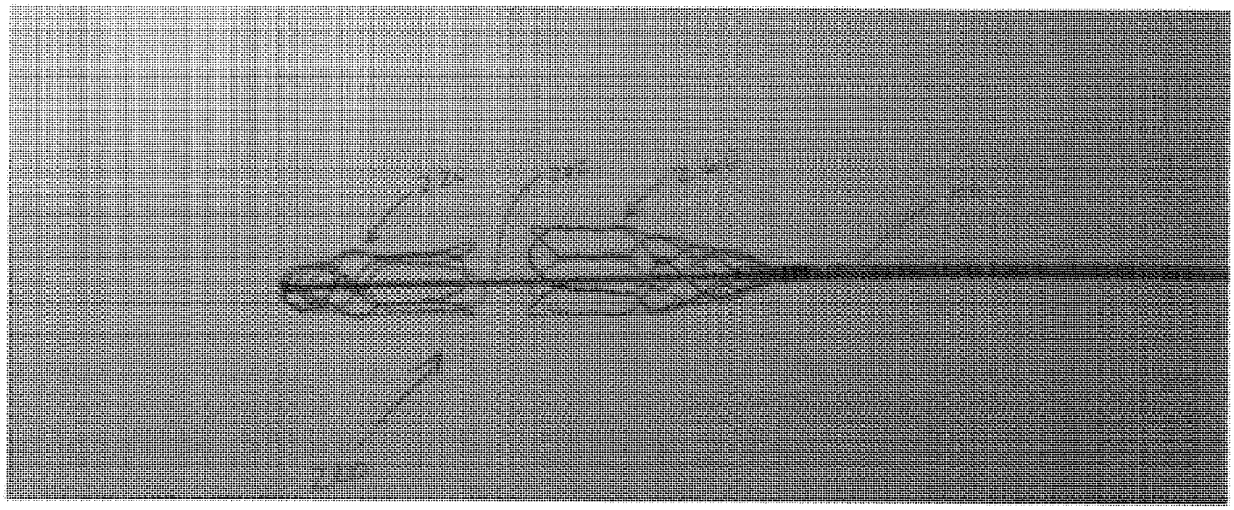


Fig 15A

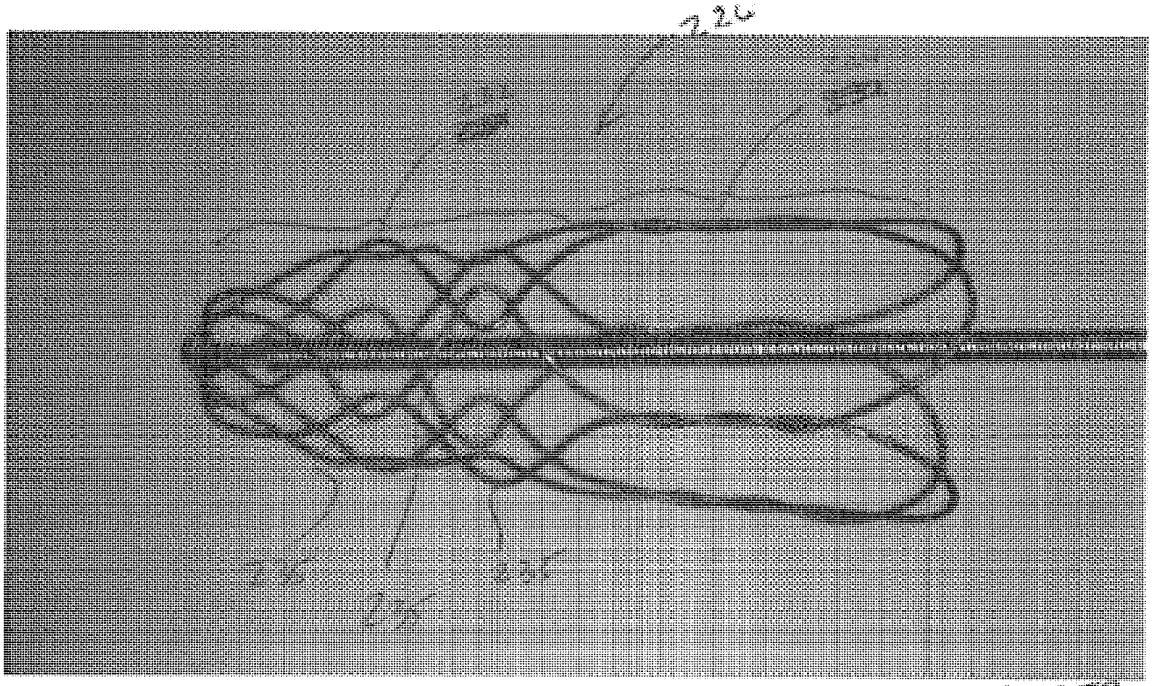


Fig 15B

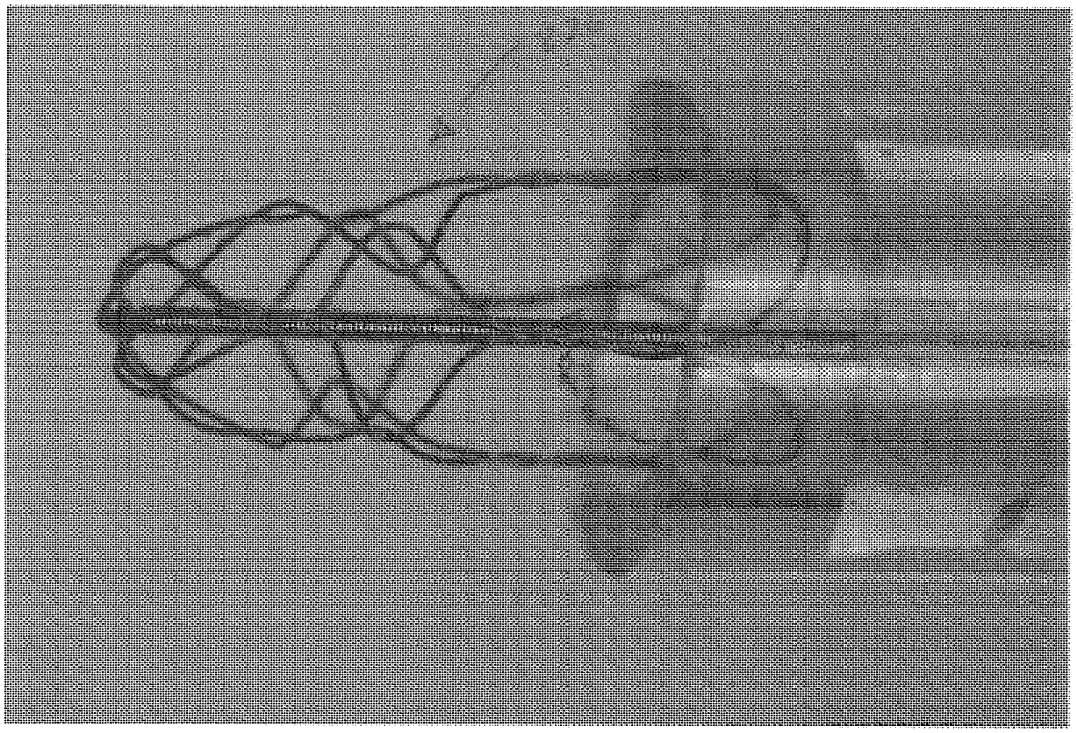


Fig 15C

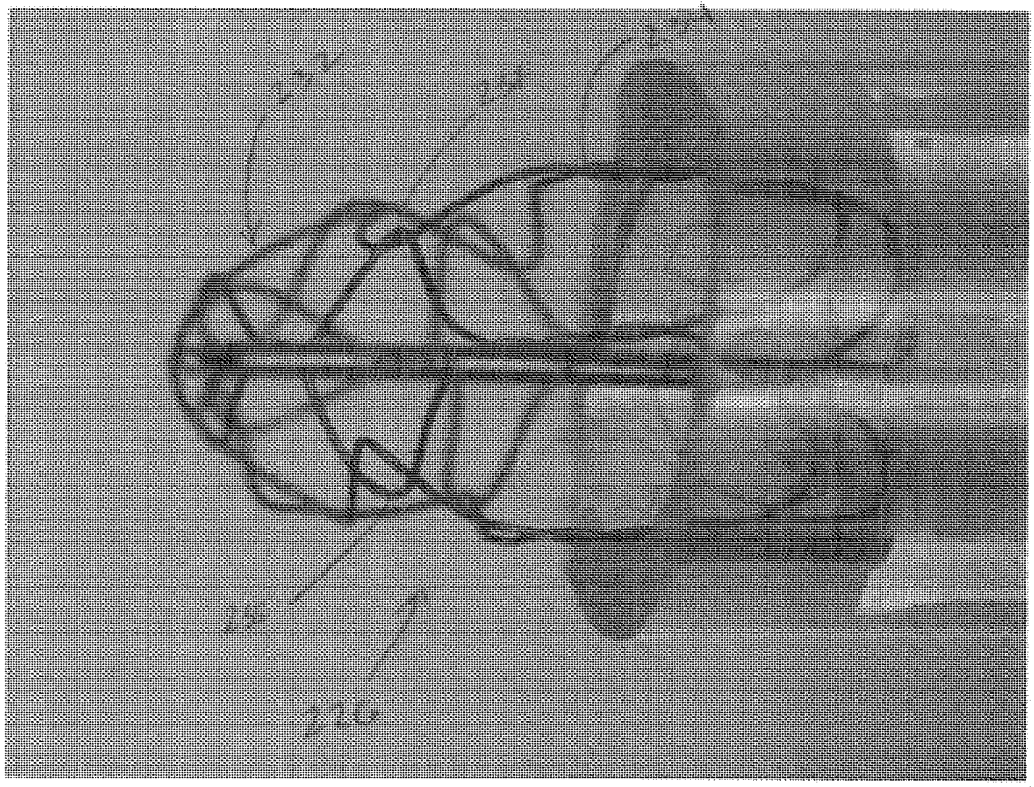


Fig 15C

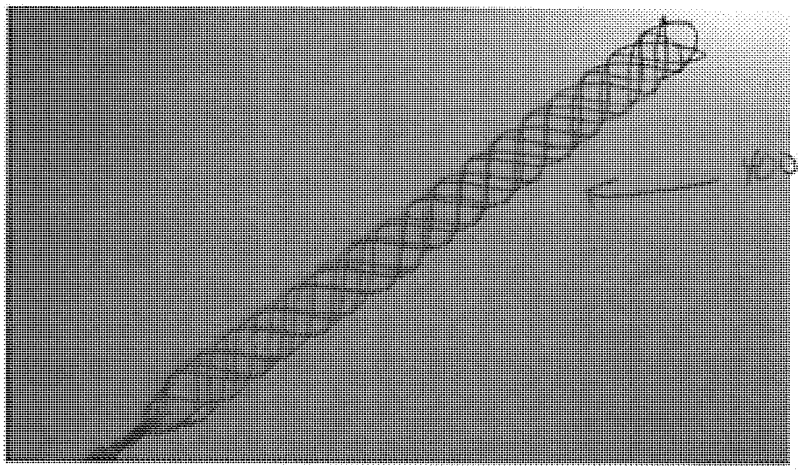


Fig 16A

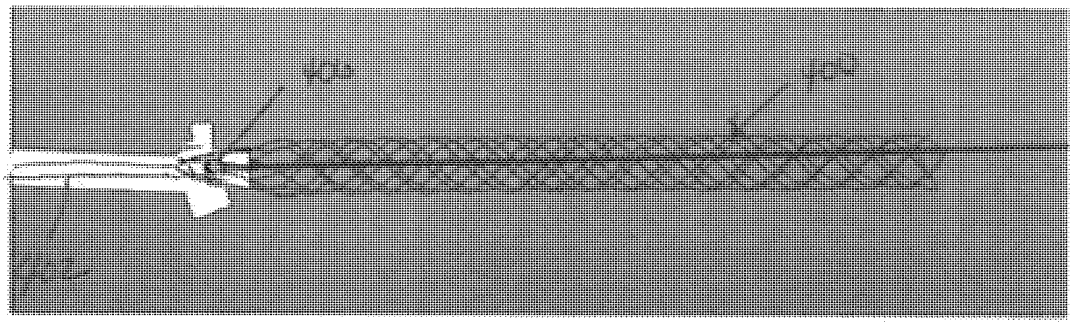


Fig 16B

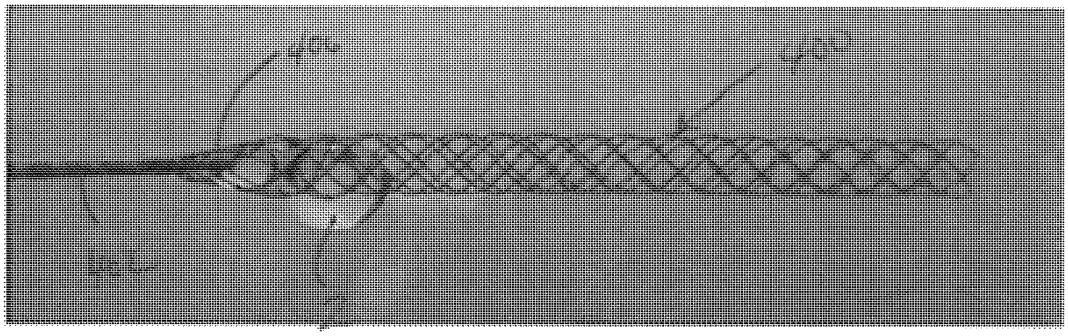


Fig 16C

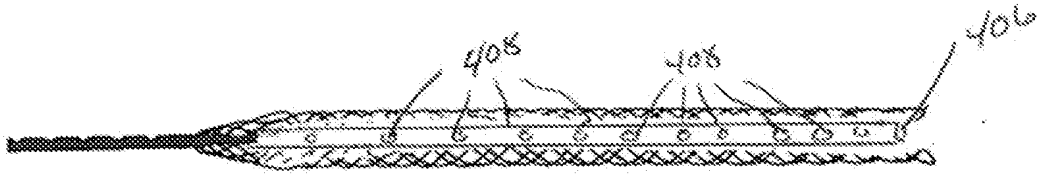


Fig 16D

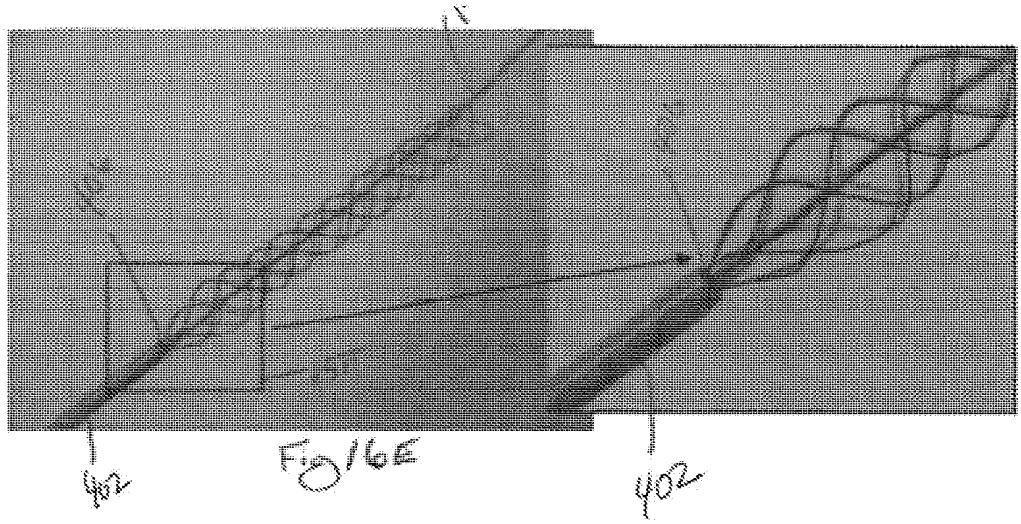


FIG 16E FIG 16F

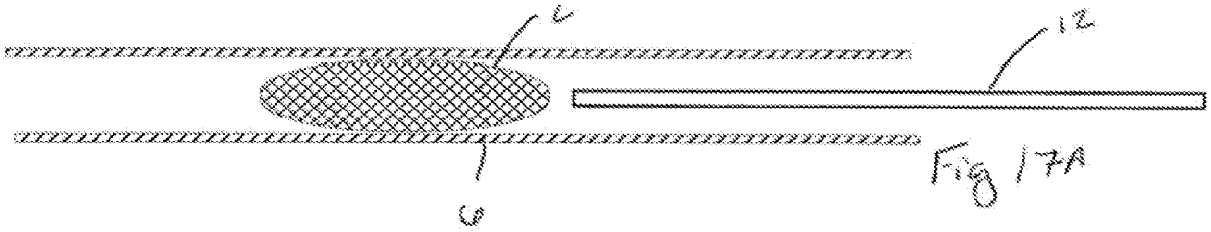


Fig 17A

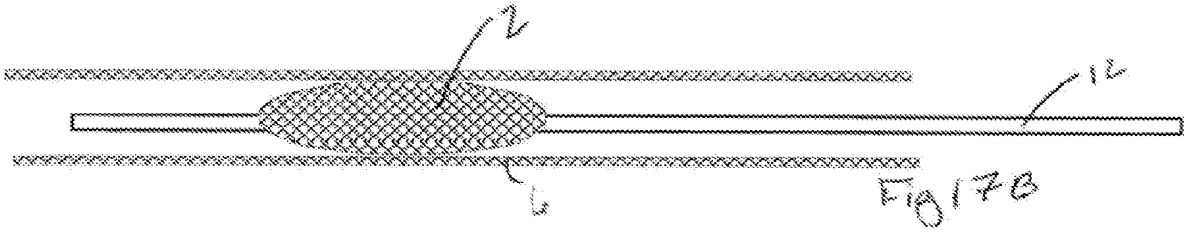


Fig 17B

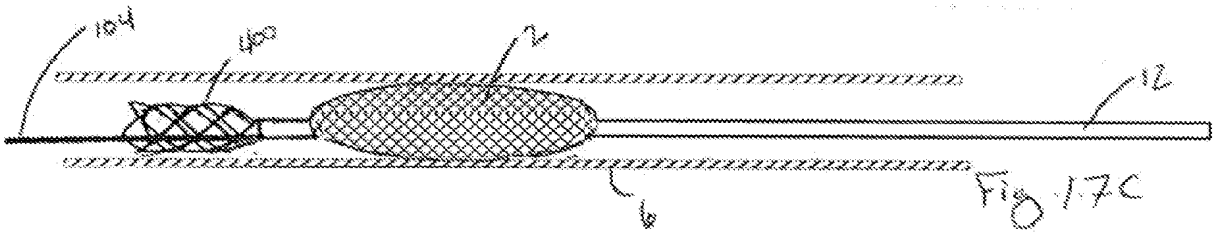


Fig 17C

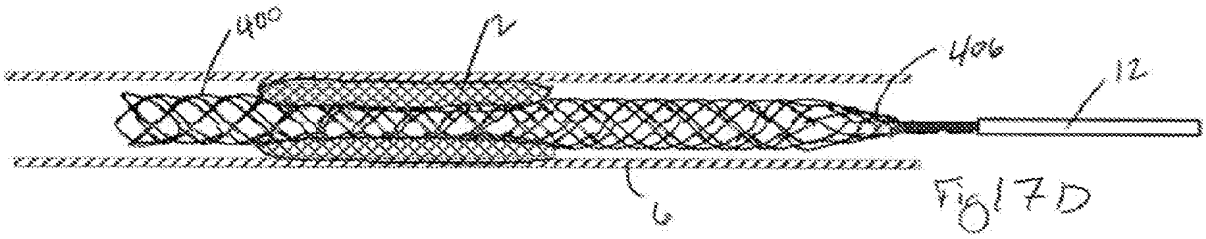


Fig 17D

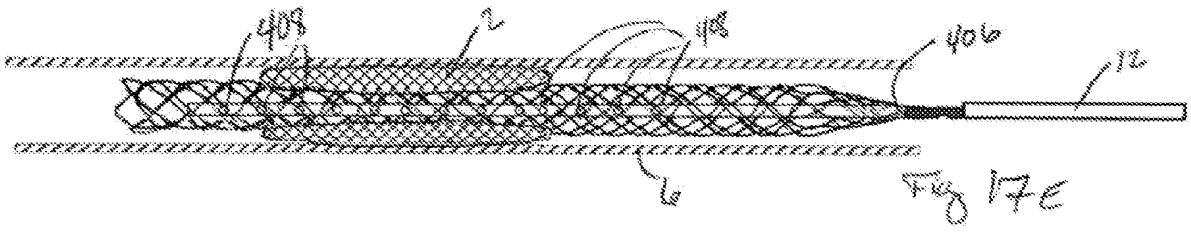


Fig 17E

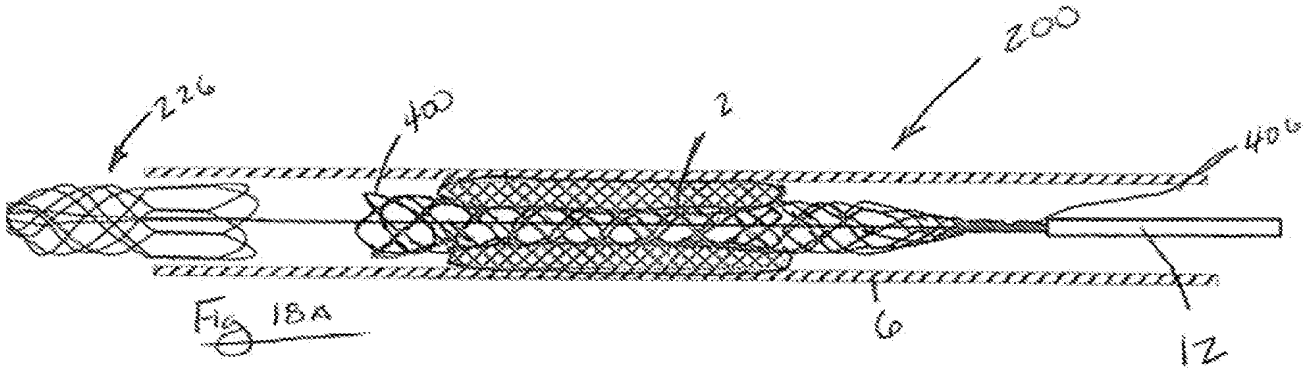


Fig 18A

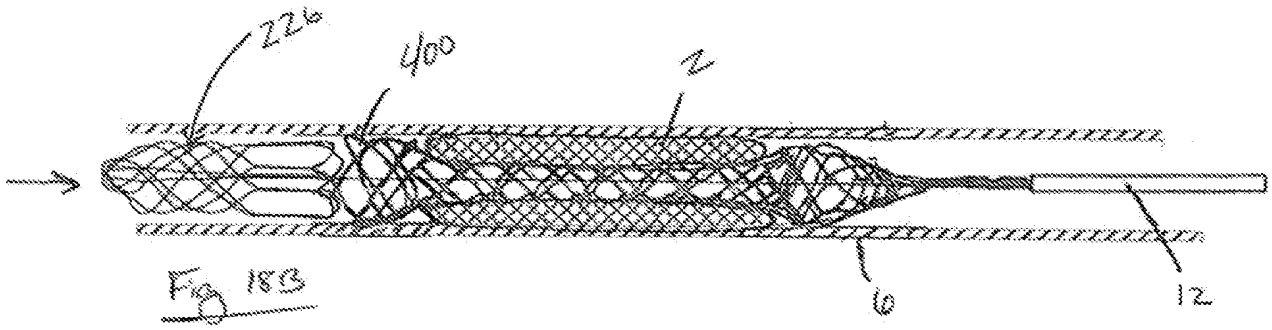


Fig 18B

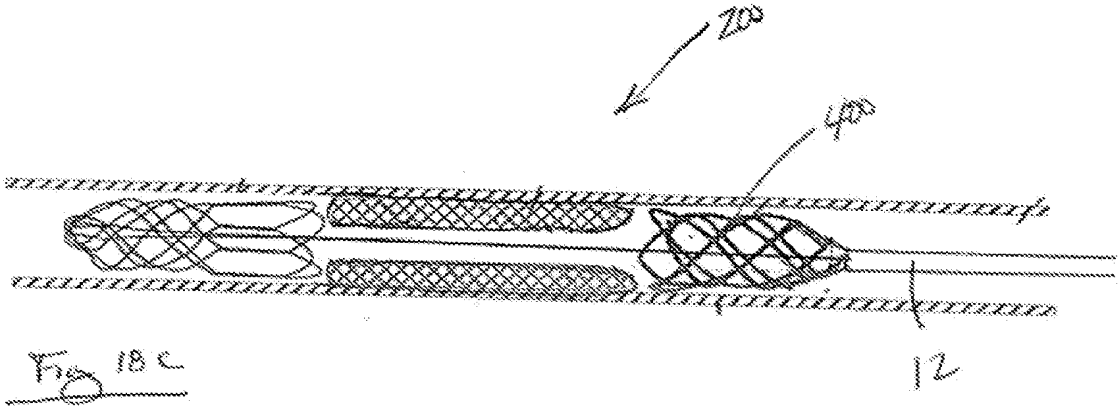


Fig 18C

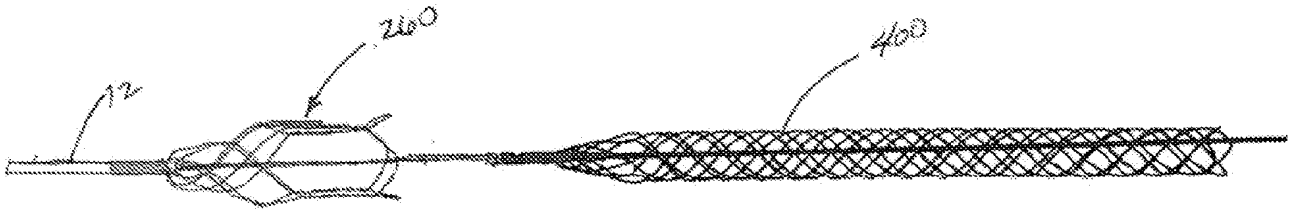


FIG 19A

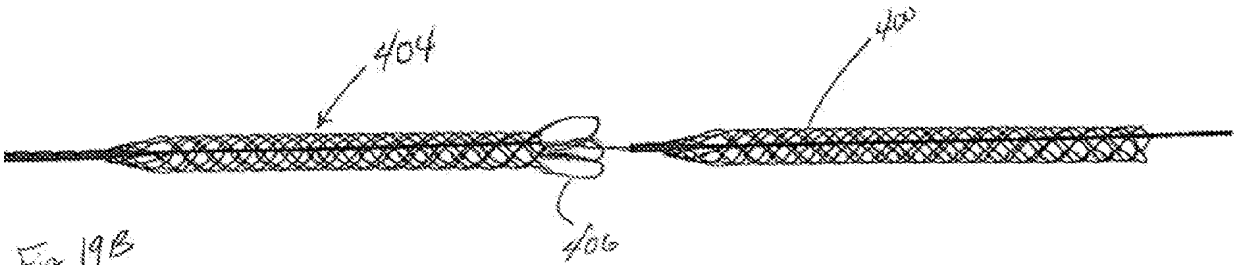


FIG 19B

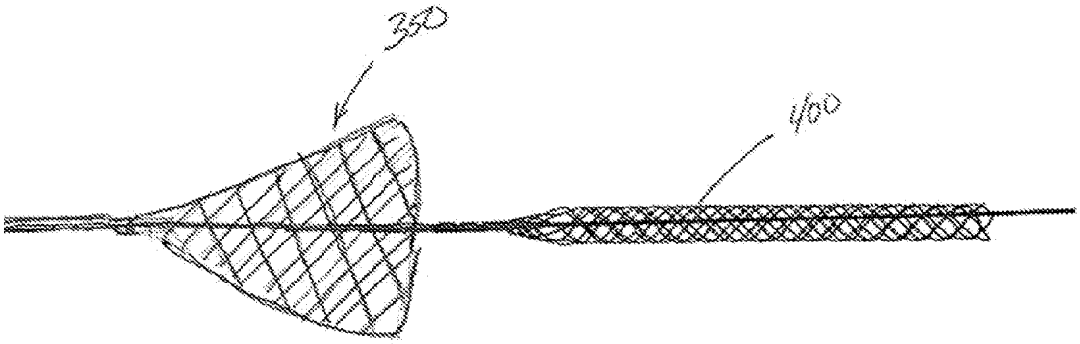


FIG 19C

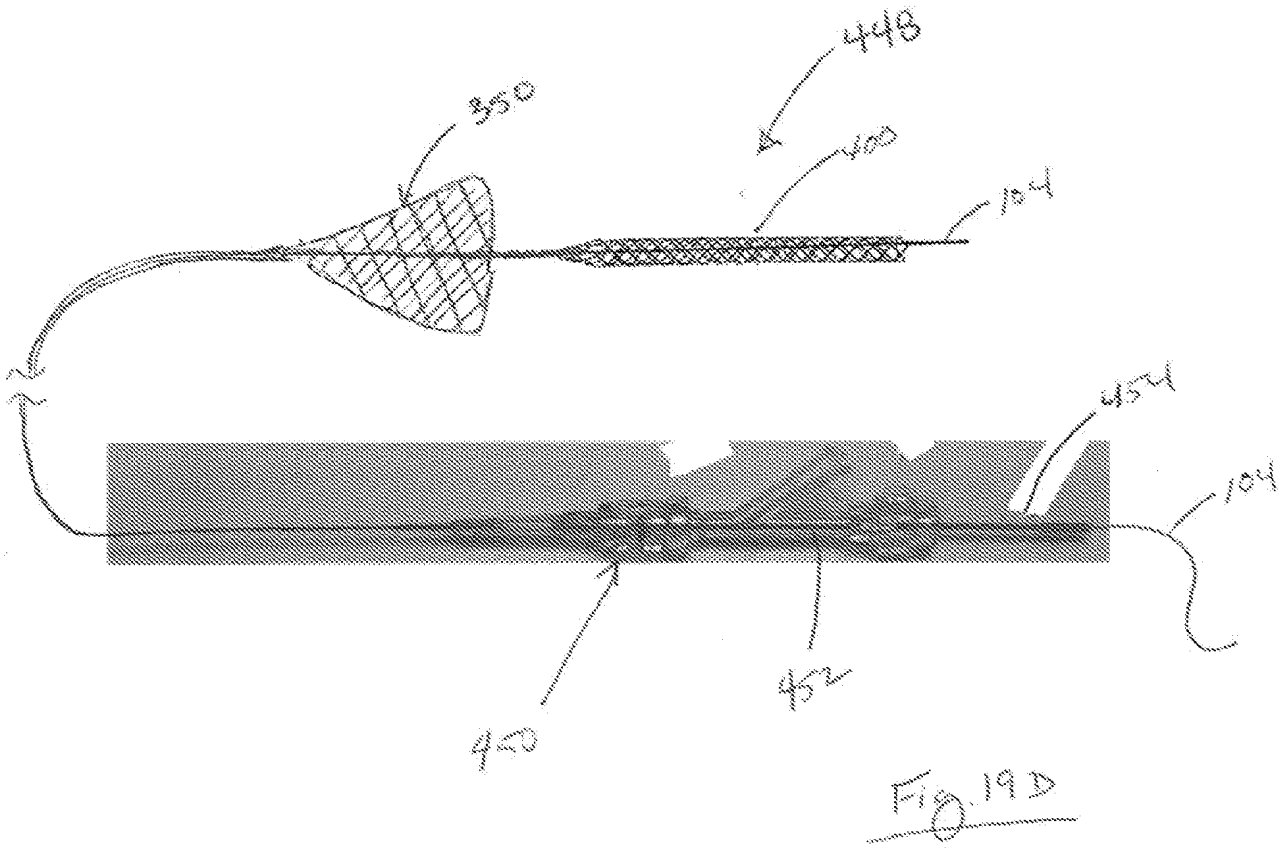


FIG. 19D

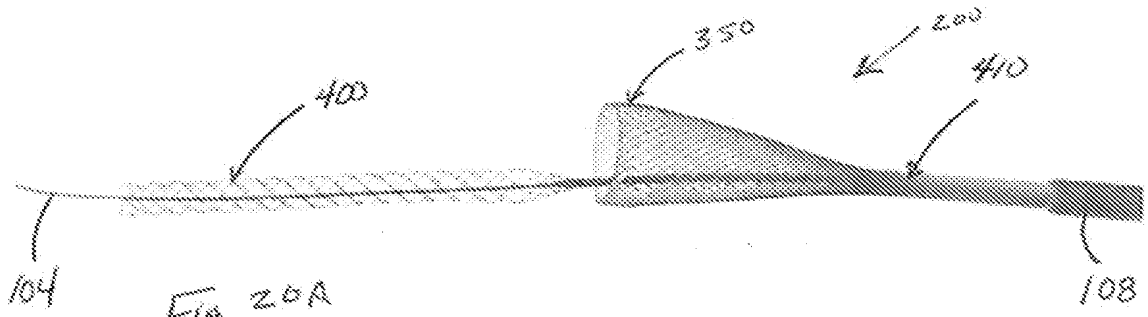


Fig 20A

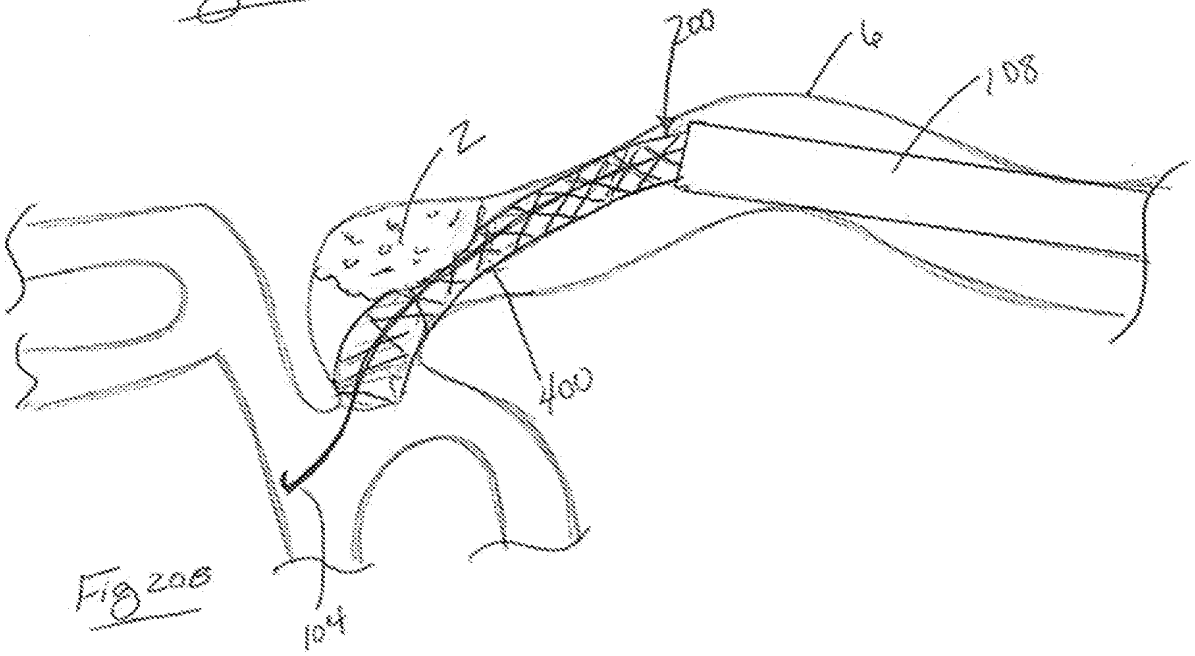


Fig 20B

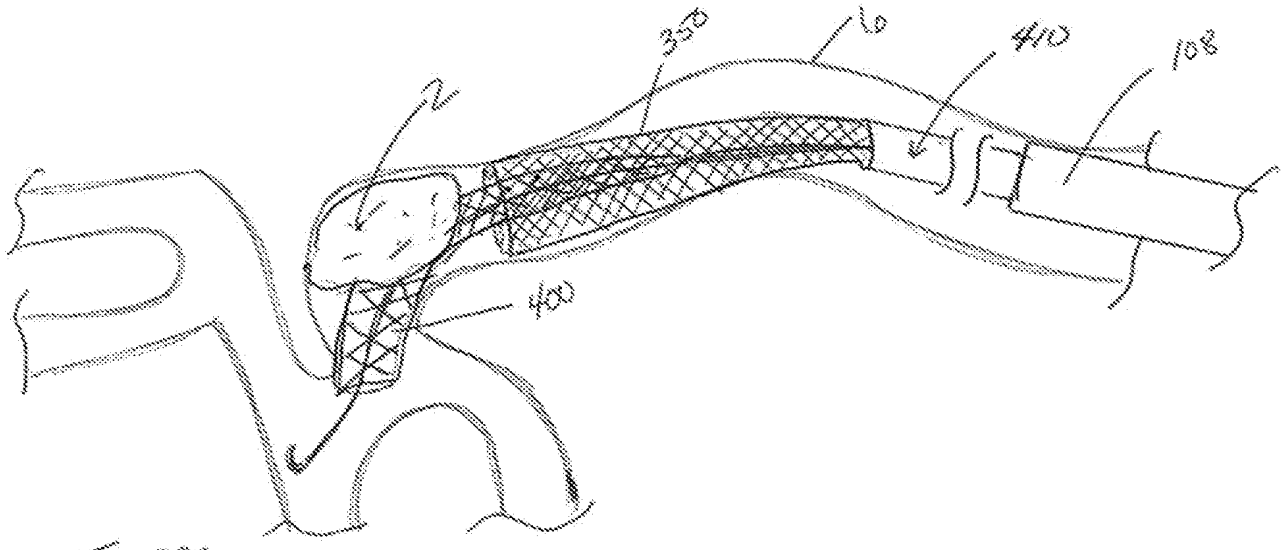


Fig 20C

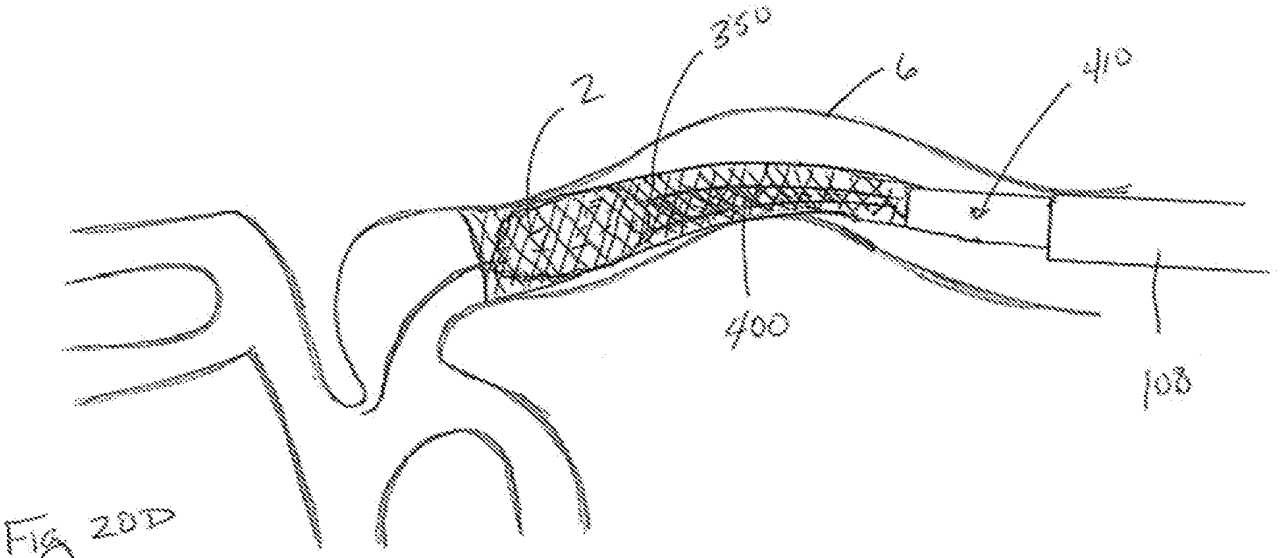


Fig 20D

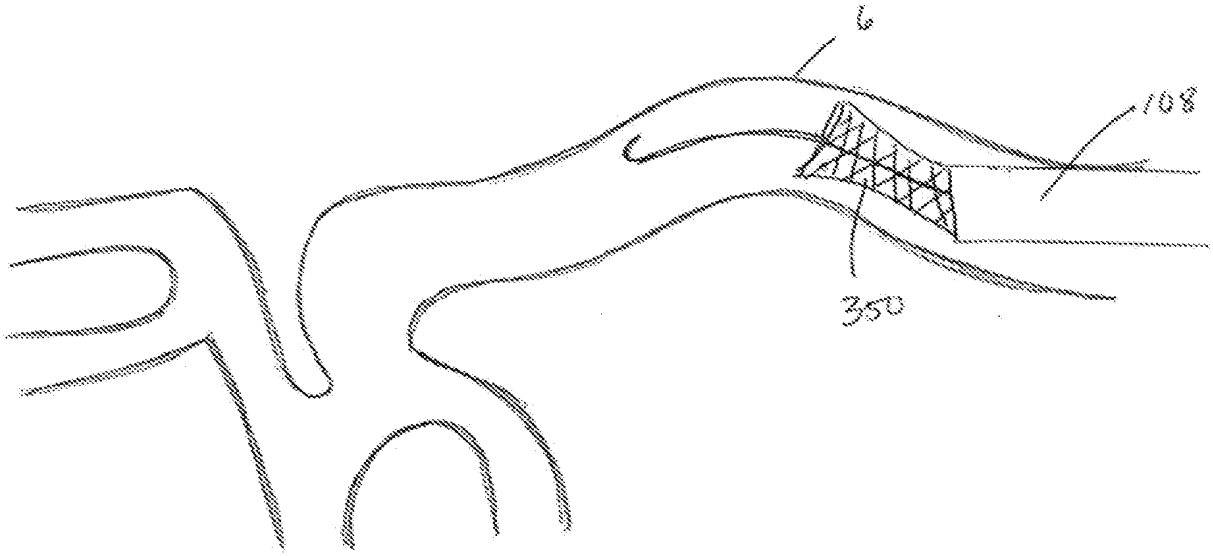


Fig 20E

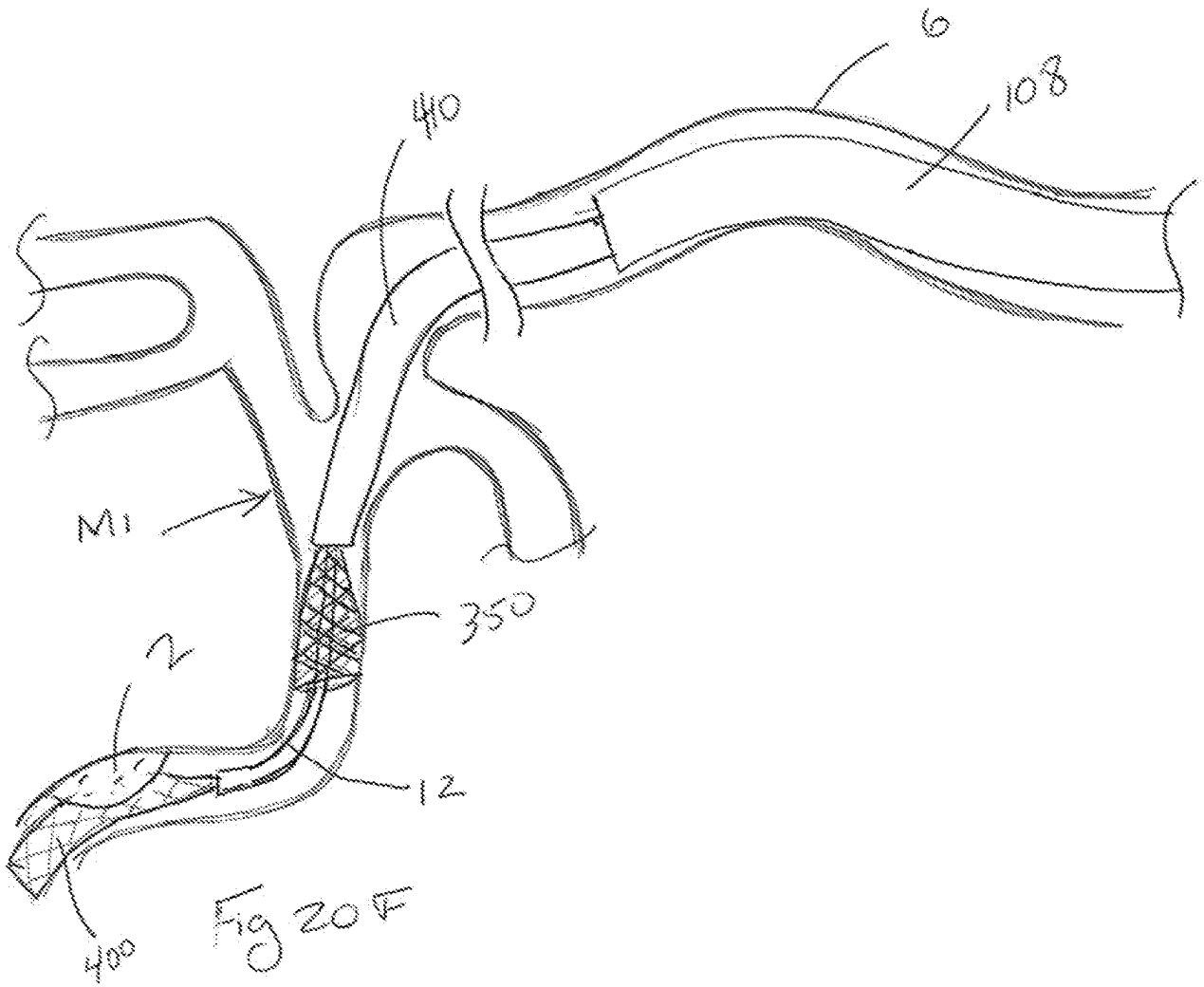


Fig 20F

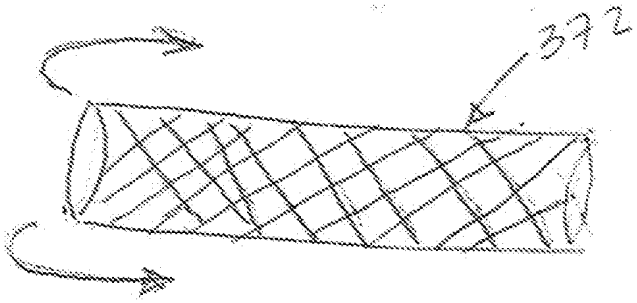


Fig. 21A

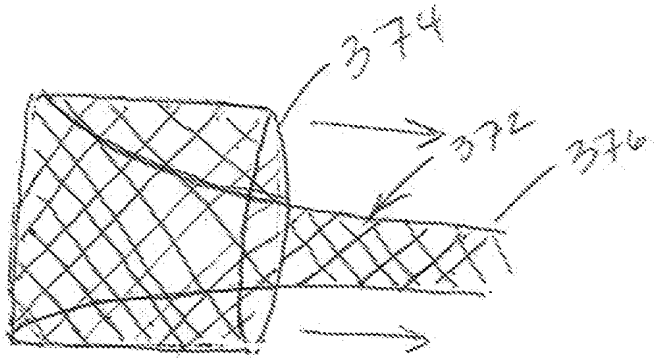


Fig. 21B

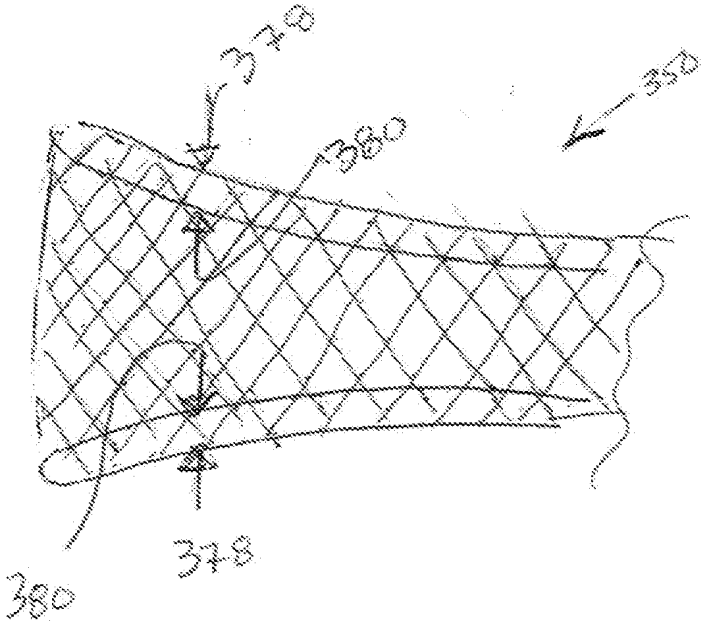


Fig. 21C

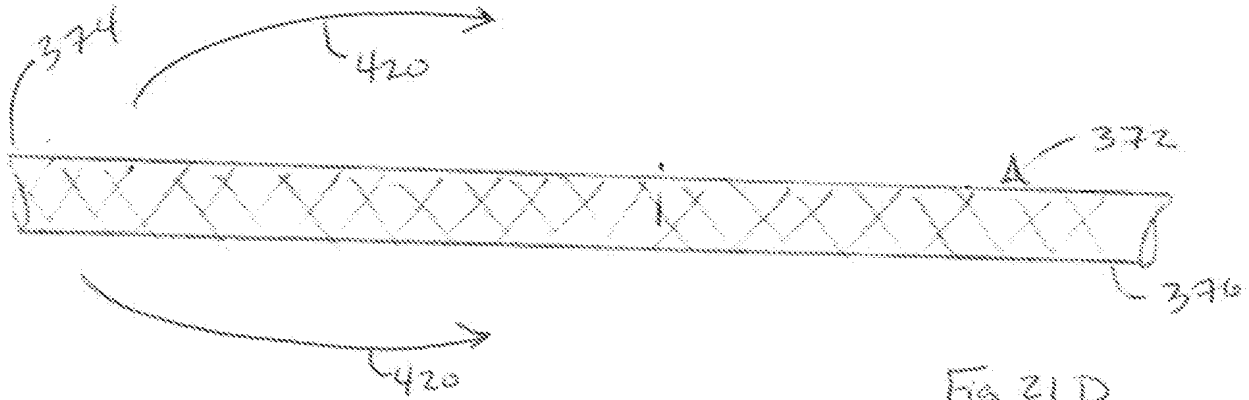


Fig 21D

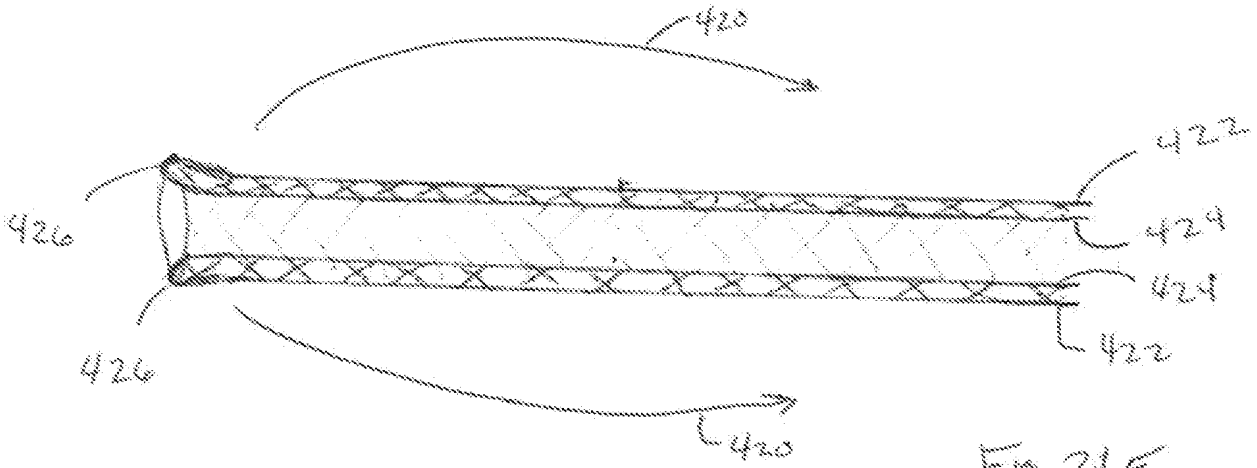


Fig 21E

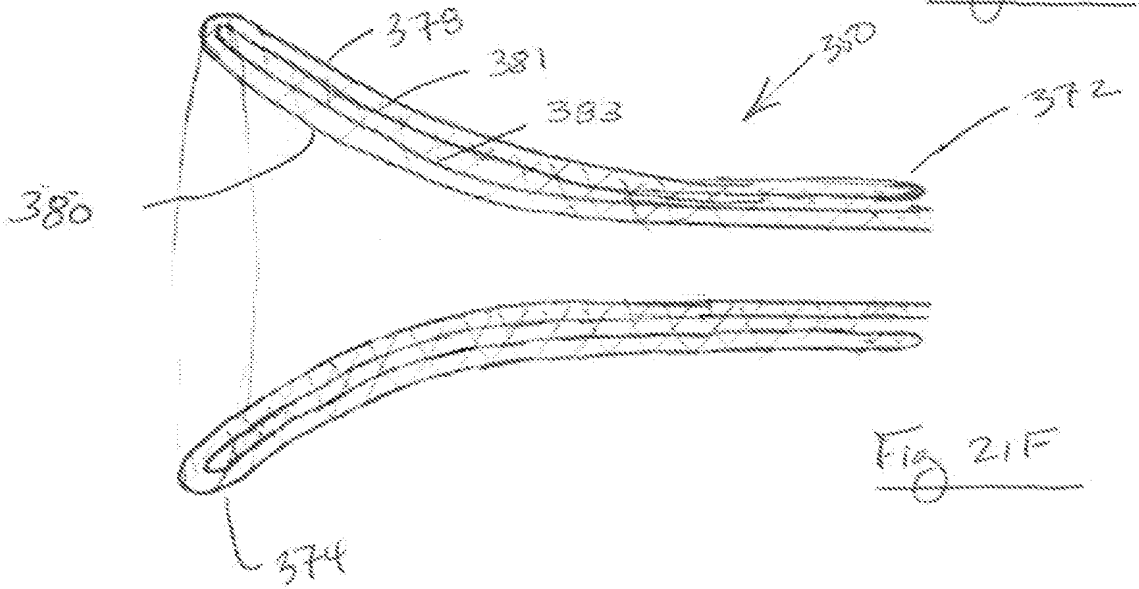


Fig 21F

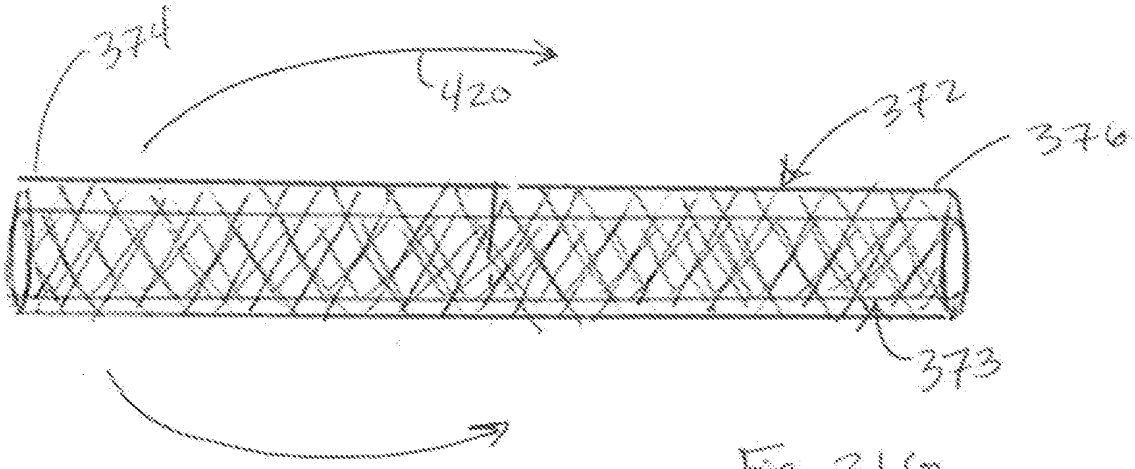


Fig 21G

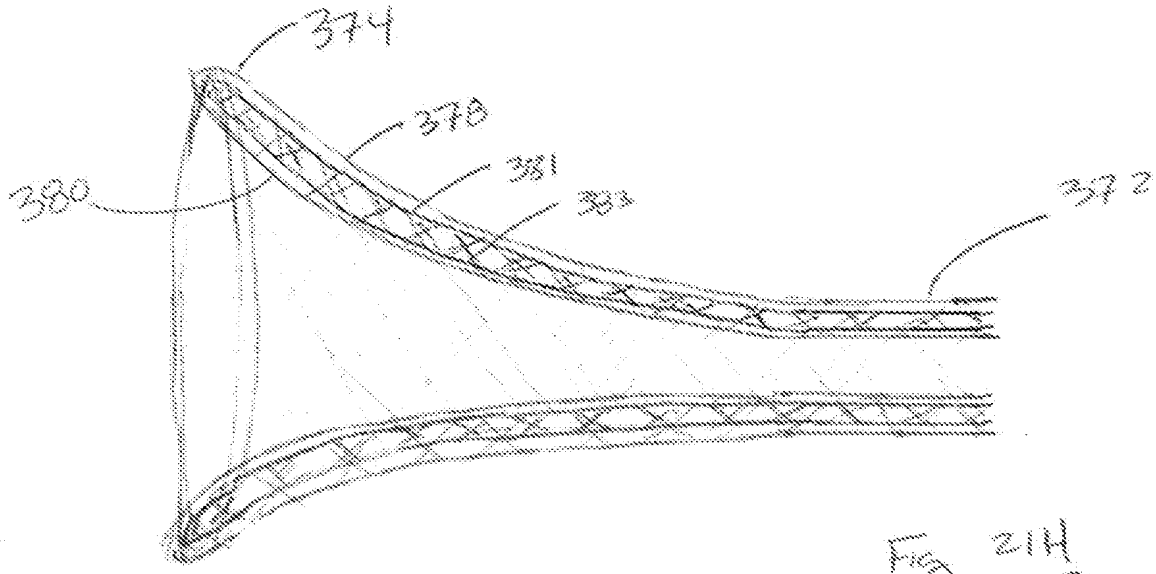


Fig 21H

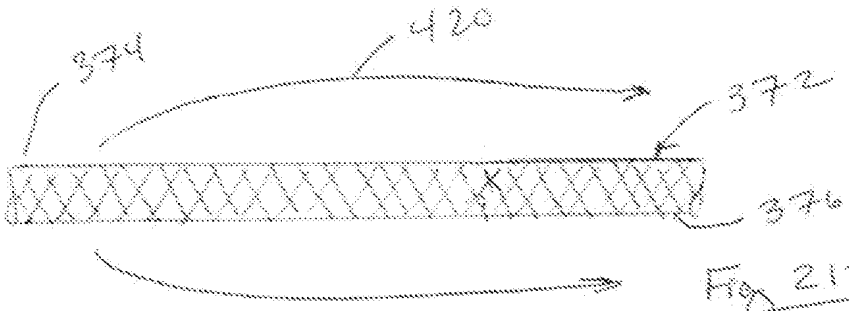


Fig 21I

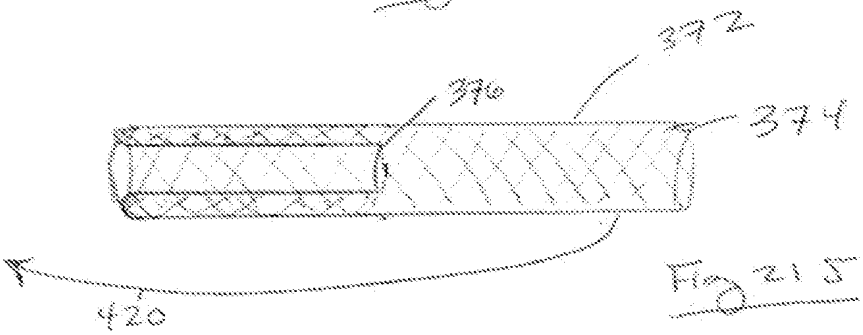


Fig 21J

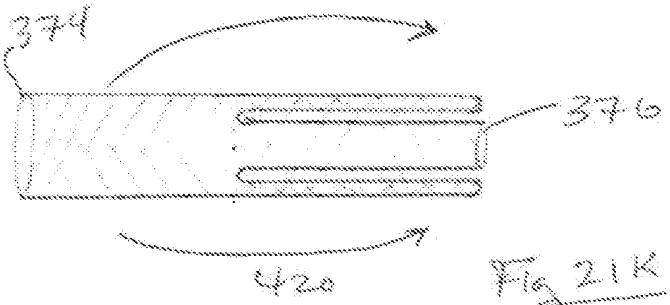


Fig 21K

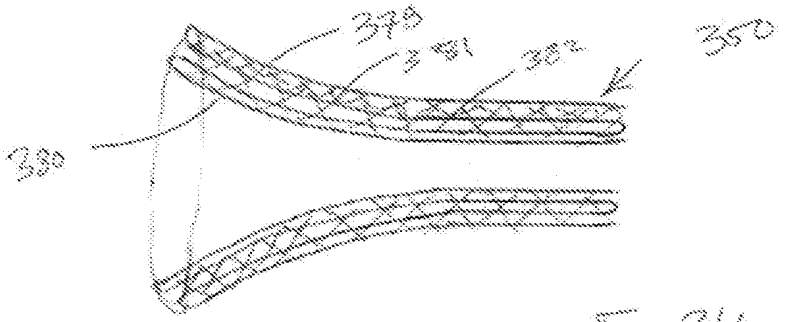


Fig 21L

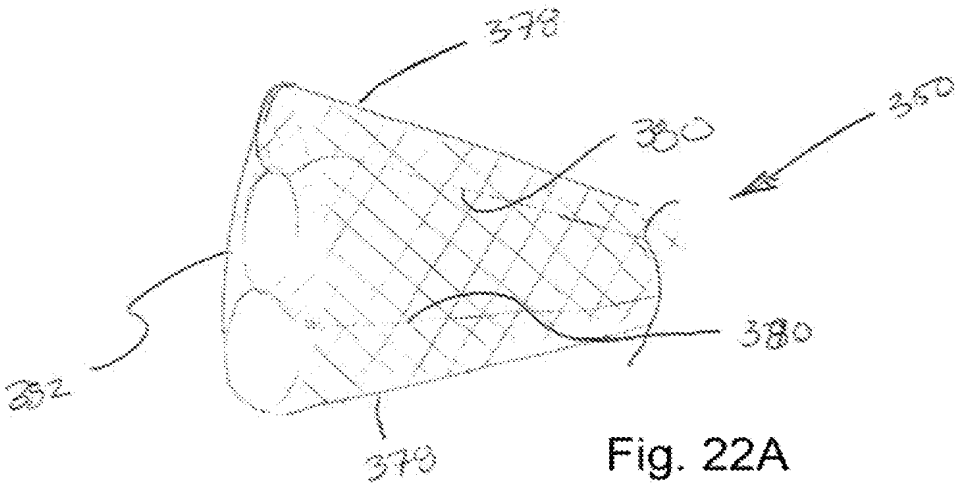


Fig. 22A

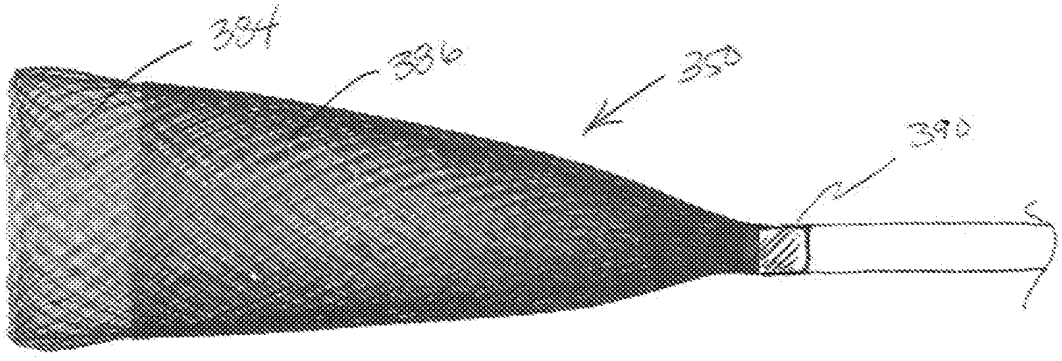


Fig. 22B

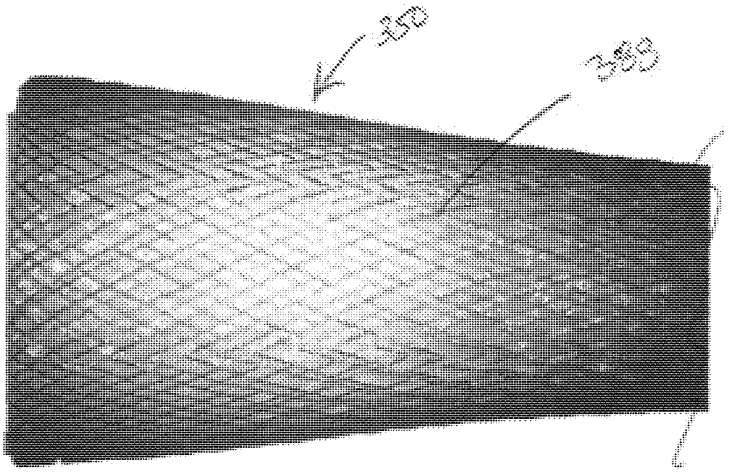


Fig. 22C

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 March 2014 (27.03.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/047650 A1

(51) International Patent Classification:
A61B 17/22 (2006.01)

(21) International Application Number:
PCT/US2013/061470

(22) International Filing Date:
24 September 2013 (24.09.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/705,129	24 September 2012 (24.09.2012)	US
61/728,775	20 November 2012 (20.11.2012)	US
61/750,277	8 January 2013 (08.01.2013)	US
61/845,796	12 July 2013 (12.07.2013)	US
61/864,356	9 August 2013 (09.08.2013)	US

(71) Applicant: **INCEPTUS MEDICAL LLC** [US/US]; 8 Argonaut Suite 100, Aliso Viejo, CA 92656 (US).

(72) Inventors; and

(71) Applicants *(for US only)*: **COX, Brian, J.** [US/US]; 3 Novilla, Laguna Niguel, CA 92677 (US). **LUBOCK, Paul** [US/US]; 11 Santa Lucia, Monarch Beach, CA 92629 (US). **ROSENBLUTH, Robert, F.** [US/US]; 24161 Cherry Hills Place, Laguna Niguel, CA 92677 (US).

(74) Agent: **INSKEEP, James, W.**; Inskeep Intellectual Property Group, Inc., 2281 W. 190th Street, Suite 200, Torrance, CA 90504 (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, 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**: DEVICE AND METHOD FOR TREATING VASCULAR OCCLUSION

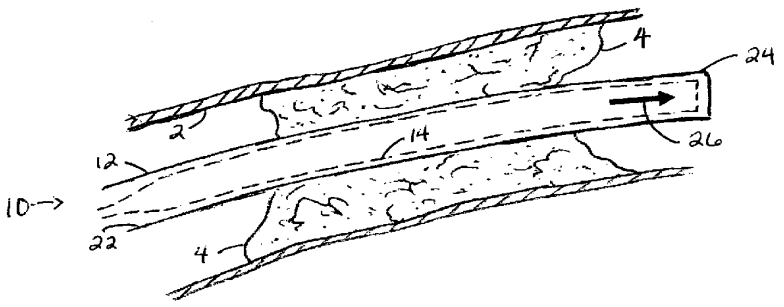


Fig. 1

(57) **Abstract**: A system and method for managing an occlusion, such as a blood clot, within a lumen or passageway of a patient. More particularly, a system and method for rapidly restoring blood flow through an occlusion including a self-expanding, tubular member through which blood may flow when in an expanded state. The tubular member has a structure configured to engage the occlusive material, thereby allowing for extraction of at least a portion of the occlusive material. The system may further employ a material extraction member that is deployed distally of the tubular member.

WO 2014/047650 A1

DEVICE AND METHOD FOR TREATING VASCULAR OCCLUSION

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Serial No. 61/864,356 filed August 9, 2013 entitled *Devices and Methods for Treatment of Vascular Occlusion*; U.S. Provisional Application Serial No. 61/845,796 filed July 12, 2013 entitled *Devices and Methods for Treatment of Vascular Occlusion*; U.S. Provisional Application Serial No. 61/750,277 filed January 8, 2013 entitled *Devices and Methods for Treatment of Vascular Occlusion*; U.S. Provisional Application Serial No. 61/728,775 filed November 20, 2012 entitled *Devices and Methods for Treatment of Vascular Occlusion*; and U.S. Provisional Application Serial No. 61/705,129 filed September 24, 2012 entitled *Devices and Methods for Treatment of Vascular Occlusion*; each of which are incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

[0002] This invention relates to a system and method for endovascular treatment of blood clots obstructing passageways in the circulatory system.

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. Moreover, such agents can cause hemorrhage in a patient.

[0009] And the known mechanical devices for removing an embolism are typically highly complex and prone to cause undue trauma to the vessel. Moreover, such known devices are difficult and expensive to manufacture.

[0010] 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.

OBJECTS AND SUMMARY OF THE INVENTION

[0011] The above described shortcomings of the existing systems and approaches for treating an occlusion in a lumen of a patient, such as a thromboembolism and particularly a pulmonary embolism, are improved upon by the systems and methods of the present invention. These improvements are achieved in certain embodiments of the present invention, in part, by providing an occlusion management system comprising a catheter, a pusher, and a tubular member reversibly restrained in a compressed state within a lumen of the catheter and radially expanded from the compressed state upon retraction of the catheter relative to the pusher.

[0012] These improvements are further achieved in certain embodiments of the present invention, in part, by providing occlusion management system comprising a catheter, a pusher, a tubular member attached to a distal end of the pusher, and an extraction member extending distally of a distal end of the cylindrical member having a diameter larger than a diameter of the cylindrical member.

[0013] These improvements are further achieved in certain embodiments of the present invention, in part, by a method for management of an occlusion in a lumen comprising the steps of: creating a passage for fluid flow through occlusive material in a lumen of a patient, engaging a portion of the occlusive material with at least a portion of a tubular member; and extracting a portion of the occlusive material from the lumen of the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which

[0015] Fig. 1 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0016] Fig. 2 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0017] Fig. 3 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0018] Fig. 4 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0019] Fig. 5 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0020] Fig. 6 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0021] Fig. 7 is a side elevation view of a portion of an occlusion management system according to one embodiment of the present invention.

[0022] Fig. 8 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0023] Fig. 9 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0024] Fig. 10 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0025] Fig. 11 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0026] Fig. 12 is a partial cutaway elevation view of a portion of an occlusion management system according to one embodiment of the present invention.

[0027] Fig. 13 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0028] Fig. 14 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0029] Fig. 15 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0030] Fig. 16 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0031] Fig. 17 is a partial cutaway view of a portion of an occlusion management system according to one embodiment of the present invention.

[0032] Fig. 18 is a partial cutaway view of a portion of an occlusion management system according to one embodiment of the present invention.

[0033] Fig. 19 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0034] Fig. 20 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0035] Fig. 21 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0036] Fig. 22 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0037] Fig. 23 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0038] Fig. 24 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0039] Fig. 25 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0040] Fig. 26 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0041] Fig. 27 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0042] Fig. 28A is an elevation view of a portion of an occlusion management system according to one embodiment of the present invention.

[0043] Fig. 28B is a partial cutaway view of a portion of an occlusion management system within lumen of a patient according to one embodiment of the present invention.

[0044] Fig. 29 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0045] Fig. 30 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0046] Fig. 31 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0047] Fig. 32 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0048] Fig. 33 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0049] Fig. 34 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0050] Fig. 35 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0051] Fig. 36 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0052] Fig. 37 is a partial cutaway view of a portion of an occlusion management system within a lumen of a patient according to one embodiment of the present invention.

[0053] Fig. 38 is an elevation view of a portion of an occlusion management system according to one embodiment of the present invention.

[0054] Fig. 39 is a perspective view of a portion of an occlusion management system according to one embodiment of the present invention.

[0055] Fig. 40A-40C are elevation views of portions of an occlusion management system according to one embodiment of the present invention.

DESCRIPTION OF EMBODIMENTS

[0056] Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention 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 invention 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 invention. In the drawings, like numbers refer to like elements.

[0057] Methods and systems according to the present invention are broadly directed to treating a blood vessel or other body lumen. More particularly, the present invention is directed to systems and methods for disrupting, dissolving, and/or otherwise removing occlusive materials, such as thrombus, from a treatment site, such as a blood vessel.

[0058] With reference to Figs. 1-6, in one embodiment of the present invention, an occlusion management system 10 employs a catheter 12 and a flow restoration member 14. The flow restoration member 14 is radially expandable from a compressed delivery

state, to a radially expanded, minimum energy state having at least, in part, a hollow cylindrical or tubular shape. A distal end 18 of a pusher 16 is attached to a proximal portion 20 of the flow restoration member 14.

[0059] The flow restoration member 14 may be formed of a porous mesh or scaffold. The mesh or scaffold may be formed at least in part by a braid of filaments or fabricated by methods known in the art of stent manufacturing including but not limited to conventional machining, laser cutting, electrical discharge machining (EDM) and photo-chemical etching.

[0060] In operation, the pusher 16 and the attached compressed flow restoration member 14 are inserted into a lumen 22 of the catheter 12. The catheter 12 is advanced through a lumen 2 of a patient, e.g. a blood vessel 2, to a site within the lumen 2 at which occlusive material 4, such as a thrombus or an embolus, is located. The catheter 12 is advanced in the direction of arrow 26 through the occlusive material 4 until a distal end 24 of the catheter 12 passes entirely through the occlusive material 4, as shown in Fig. 1.

[0061] With reference to Fig. 2, the catheter 12 is then retracted relative to the pusher 16 and flow restoration member 14 in the direction of arrow 28. As the flow restoration member 14 is exposed from the retracting distal end of the catheter 12, the flow restoration member 14 radially expands within the occlusive material 4 to an intermediate diameter larger than a diameter of the member 14 in the compressed delivery state and smaller than a diameter of the member 14 in the expanded, minimum energy state. The structure and outer surface of the flow restoration member 14 is configured such that the mesh or scaffold of the flow restoration member 14 engages the occlusive material 4 when it is exposed from the constraint of the catheter 12. As shown in Fig. 2, the catheter 12 is retracted in the direction of arrow 28 to an extent that allows for the radial expansion of an entire length of the flow restoration member 14.

[0062] As shown in Fig. 3, when catheter 12 is retracted sufficiently to allow expansion of the entire length of the flow restoration member 14, fluid or blood may enter the open, proximal portion 20 of the flow restoration member 14 in the direction of arrows 30, flow through the hollow interior of the flow restoration member 14, and exit

through a open, distal portion 34 of the flow restoration member 14. Thereby, allowing for a rapid restoration of blood flow through the lumen 2.

[0063] As shown in Fig. 4, the pusher 16 is then retracted relative to the catheter in the direction of the arrow 28, thereby pulling the length of the flow restoration member 14 through the occlusive material 4. The pusher 16 is retracted such that the flow restoration member 14 is pulled towards the distal end 24 of the catheter 12 and back into the lumen 22 of the catheter 12. As the flow restoration member 14 is pulled through the occlusive material 4, the occlusive material 4 engaged with the flow restoration member 14 is also pulled along and removed. Hence, while restoring flow through the lumen 2, the flow restoration member 14 may also function to remove or extract at least a portion of the occlusive material 4 from the lumen 2. Finally, the flow restoration member 14 and the engaged occlusive material 4 is pulled back into the lumen 22 of the catheter 12 and the system 10 is withdrawn from the patient.

[0064] In one embodiment of the present invention, as shown in Figs. 5-7, the occlusion management system 10 may further employ an extraction member 38 for extraction or removal of the occlusive material 4, such as an embolus. The extraction member 38 may have an umbrella-like configuration, as shown in Fig. 5; a conical configuration, as shown in Fig. 6; or a cup-like configuration, as shown in Fig. 7. The extraction member 38 expands from a compressed diameter to an expanded diameter that is greater than a diameter of the expanded flow restoration member 14 and approximately equal to a diameter of the lumen 2.

[0065] The extraction member 38 may be attached directly to the flow restoration member 14 or to a separate structure that is deployed through the flow restoration member 14 either before or after deployment of the flow restoration member 14. For example, as shown in Figs. 5 and 6, a distal portion 44 of the extraction member 38 may be attached to a distal end 46 of a delivery element 42. The delivery element 42 may be formed of a separate, transposable element that is located within a lumen of the pusher 16. One or more tethers 40 may statically attach a proximal periphery 48 of the extraction member 38 to the delivery element 42 proximally of the distal end 46 of the delivery element 42. The tethers 40 facilitate compression and retraction of the extraction member 38 back into the catheter 12. Alternatively, the tethers 40 may be

transposable independent of the delivery element 42. For example, the tethers 40 may be attached to a coaxial tube located within the lumen of the pusher 16 around the delivery element 42.

[0066] In operation, the extraction member can be deployed either prior to complete deployment of the flow restoration member 14 or after complete deployment of the flow restoration member 14.

[0067] In certain embodiments, as shown in Fig. 25, the extraction member 38 is a balloon 56 that is attached to a distal end 46 of a delivery element 42. The delivery element 42 has a lumen formed therethrough for inflation and deflation of the balloon 56. The balloon 56 having a diameter that is substantially equal to or greater than a diameter of the vessel 2.

[0068] In certain other embodiments, as shown in Fig. 26, the extraction member 38 is formed by a malecot-type formation of the distal end 46 of the delivery element 42. The malecot-type formation may be covered with a fabric, polymer, or braided covering. The malecot-type formation has a diameter that is substantially equal to or greater than a diameter of the vessel 2.

[0069] In certain other embodiments, as shown in Fig. 29 the extraction member 38 is formed of a braided structure having a disc-like form that is attached to a distal end 46 of a delivery element 42. The disc-like structure has a diameter that is substantially equal to or greater than a diameter of the vessel 2.

[0070] In one embodiment of the present invention, as shown in Fig. 7, the delivery element 42 is not employed in the system 10 and extraction member 38 is attached directly to the flow restoration member 14 by the tethers 40. More particularly, proximal ends of the tethers 40 are attached to the distal portion 34 of the flow restoration member 14 and distal ends of the tethers 40 are attached to the proximal periphery 48 of the extraction member 38.

[0071] In operation, after the catheter 12 is advanced through the occlusive material 4 until a distal end 24 of the catheter 12 passes entirely through the occlusive material 4, the catheter 12 is then retracted relative to the pusher 16. As the extraction member 38 is

exposed from the retracting distal end 24 of the catheter 12, the extraction member 38 radially expands distally of the occlusive material 4. As the catheter 12 is further retracted, the flow restoration member 14 radially expands within the occlusive material 4.

[0072] After complete expansion of the flow restoration member 14, the pusher 16 is retracted relative to the catheter, thereby pulling the flow restoration member 14 through the occlusive material 4 and pulling the extraction member 38 into and around the occlusive material 4. The occlusive material 4 is thereby captured within the extraction member 38. Retraction of the pusher 16 is continued until the flow restoration member 14 and extraction member 38 with captured occlusive material 4 are pulled back into the lumen 22 of the catheter 12. The system 10 is then withdrawn from the patient.

[0073] The extraction member 38 may be formed at least in part by a braid of filaments or fabricated by methods known in the art of stent manufacturing including but not limited to conventional machining, laser cutting, electrical discharge machining (EDM) and photo-chemical etching.

[0074] In one embodiment of the present invention, as shown in Figs. 8-11, the flow restoration member and the extraction member of the occlusion management system 100 are formed of a substantially continuous structure. For example, as shown in Fig. 10, a distal portion 134 of a flow restoration member 114 is biased to evert to a relaxed state that turns in a proximal direction back towards a proximal portion 120 of the flow restoration member 114, thereby forming an extraction member 138. One or more tethers 140 are eccentrically coupled or attached to the distal portion 134 of a flow restoration member 114. In certain embodiments, a radially expandable connector member 150 may hold ends of the filaments that may be present at the distal portion 134 of a flow restoration member 114.

[0075] Proximal ends of the tethers 140 may extend proximally within the lumen 22 of the catheter 12 and may be manipulated by a physician in order to facilitate the formation of the everted distal portion 134 and extraction member 138 of the flow restoration member 114. In certain embodiments, the tethers 140 do not extend to a proximal end of the system 100 but rather are connected to an elongate retraction member that in turn extends proximally for manipulation by a physician. As shown in

Fig. 10, the tethers 140 may further function to cut through the occlusive material 4 as the extraction member 138 is formed or when the pusher 16, the flow restoration member 114, and the extraction member 138 are retracted relative to the catheter 12.

[0076] In certain embodiments, as shown in Fig. 27, the flow restoration member 114 having everted distal portion 134 need not necessarily employ the tethers 140.

[0077] In certain other embodiments, as shown in Figs. 21-24, 28A, and 28B, the mesh or scaffold structure forming the flow restoration member 114 employs an enlarged diameter distal portion 134 that does not necessarily evert. For example, Fig. 21 shows a partially deployed and Fig. 23 shows completely deployed flow restoration member 114 having a flared or expanded distal portion 134. Fig. 24 shows the flow restoration member 114 having a bulbous, expanded distal portion 134 which may or may not employ a guide wire passage through a distal end.

[0078] In certain other embodiments, as shown in Fig. 28A and 28B, the extraction member 38 is a wireform attached to the delivery element, such as delivery element 42 described above, or alternatively attached directly to the flow restoration member 114 to form an expanded distal portion 134 of the flow restoration member 114. The wire form may also be covered with a braid.As shown in Figs. 8-11, operation of the occlusion management system 100 is substantially the same as described above regarding the occlusion management system 10 employing the extraction member 38.

[0079] In one embodiment of the present invention, as shown in Fig. 12, the pusher 16 may be formed of a wire, tube, or catheter.

[0080] In one embodiment of the present invention, as shown in Figs. 13-19, a method for operation of system 10, 100 is shown. First, retrieval of occlusive matter 4 includes first advancing a guidewire 6 through a lumen 2 to the site of the occlusive material 4 and through the occlusive material 4. The catheter 12 is then advanced over the guidewire 6 to the site of the occlusive material 4 and through the occlusive material 4, as shown in Figs. 13 and 14. The guidewire 6 is withdrawn from the patient. As shown in Fig. 15, the catheter 12 is then retracted relative to the pusher 16, thereby allowing the flow restoration member 14 to expand to a more relaxed state and engage the occlusive material 4.

[0081] In certain embodiments, as shown in Fig. 17, the catheter 12 may be passed through a lumen of a sheath 8. The sheath 8 may function to provide suction, vacuum, or irrigation, in the direction of arrows 26, within the lumen 2 near the site of the occlusive material 4. Alternatively, as shown in Fig. 18, one or more holes 52 may be formed in the catheter 12 so that the suction, vacuum, or irrigation may originate from a proximal end of the catheter 12 and be simultaneously generated through the proximal portions of both the lumen 22 of the catheter 12 and the lumen of the sheath 8.

[0082] With the assistance of such suction, vacuum, or irrigation, as shown in Fig. 19, it may be possible for the flow restoration member 14 to sufficiently engage the occlusive material 4 such that the occlusive material 4 is released from the lumen 2 and can be extracted in substantially its entirety from the lumen 2 of the patient.

[0083] In one embodiment of the present invention, as shown in Fig. 20, in order to further assist in the generation and efficacy of such suction, vacuum, or irrigation, an annular balloon 54 may be attached to an exterior of the catheter 12 near the distal end 24 of the catheter 12. The balloon 54 is sized so as to contact a circumference of an interior surface of the lumen 2. Accordingly, the balloon 54 provides a seal against the flow of fluid, such as blood, through the lumen 2 and enhances the efficacy of the suction, vacuum, or irrigation. Fig. 22 shows the flow restoration member 114 of Fig. 23 being deployed through a catheter 12 having an inflated balloon 54 near the distal end 24 of the catheter 12. In order to inflate and deflate the balloon 54, inflation lumens may be formed within the wall of the catheter 12 according to techniques known in the art.

[0084] In one embodiment of the present invention, as shown in Figs. 30-35, an occlusion management system 200 employs a flow restoration member 214, such as that described above with respect to the flow restoration members 14 or 114 that is advanceable through a proximal capture member 260.

[0085] The proximal capture member 260 is radially expandable from compressed delivery state within a lumen 258 of a sheath 208, to a radially expanded, minimum energy state having a generally cylindrical or tubular shape. When in the expanded minimum energy state, the proximal capture member 260 may have a diameter that is

larger or substantially equal to the diameter of the patient's lumen 2 in which the system 200 will be employed.

[0086] The proximal capture member 260 is attached to a capture member pusher 262 that is also inserted through the lumen 258 of the sheath 208. The proximal capture member 260 may be formed of a mesh or scaffold. The mesh or scaffold may be formed at least in part by a braid of filaments or fabricated by methods known in the art of stent manufacturing including but not limited to conventional machining, laser cutting, electrical discharge machining (EDM) and photo-chemical etching.

[0087] The flow restoration member 214 is attached to the pusher 16 and the flow restoration member 214 and the pusher 16 are positioned within the lumen 22 of the catheter 12. The catheter 12 is, in turn, positioned within a lumen of the proximal capture member 260. A diameter of the proximal capture member 260 may be approximately equal to or greater than a diameter of the lumen 2.

[0088] In operation, the capture member pusher 262 and attached proximal capture member 260 are inserted into the lumen 258 of the sheath 208. A guidewire may be advance through the occlusion material 4, such as a thrombus or embolus. The sheath 208 is then advanced over the guidewire to a position proximal of the occlusion material 4. The guidewire may but need not necessarily be retracted at this time.

[0089] As shown in Figs. 30 and 31, the sheath 208 is retracted, in the direction of arrow 28, proximally relative to the capture member pusher 262, thereby exposing the proximal capture member 260 at a distal end 266 of the sheath 208 and allowing the proximal capture member 260 to radially expand from its collapsed state within the lumen 258 of the sheath 208.

[0090] The pusher 16 and attached flow restoration member 214 are then inserted into the lumen 22 of the catheter 12. As shown in Fig. 32, the catheter 12 is then advanced through the lumen 258 of the sheath 208 and the lumen of the proximal capture member 260 until a distal end 24 of the catheter 12 is positioned distally of the occlusive material 4. As shown in Figs. 33 and 34, the catheter 12 is then retracted, in the direction of arrow 28, proximally relative to the flow restoration member 214, thereby

exposing the flow restoration member 214 and allowing the flow restoration member 214 to radially expand from its collapsed state within the lumen 22 of the catheter 12.

[0091] As shown in Fig. 35, after complete expansion of the flow restoration member 214, the pusher 16 is retracted relative to the catheter 12, thereby pulling the flow restoration member 214 through the occlusive material 4 and pulling an extraction member, if present, into and around the occlusive material 4. The occlusive material 4 is thereby captured within the flow restoration member 214 and extraction member, if present. Retraction of the pusher 16 is continued until the flow restoration member 214 and extraction member, if present, with captured occlusive material 4 are pulled at least partially back into the lumen 22 of the catheter 12. The catheter 12 and the flow restoration member 214 and extraction member, if present, with captured occlusive material 4 are then pulled back into the lumen 264 of the proximal capture member 260. The proximal capture member 260 is then pulled back into the lumen 258 of the sheath 208. The system 200 is then withdrawn from the patient.

[0092] The order of deployment of the proximal capture member 260 and flow restoration member 214 as described above may be reversed as seen fit by the physician. Furthermore, therapeutic agent(s) such as thrombolytics or anticoagulants may be infused through the lumen 258 of the sheath 208 or lumen 22 of catheter 12 during the course of the procedure.

[0093] In one embodiment of the present invention, the occlusion management systems 10, 100, 200 is configured for removal of at least a portion of the occlusive material 4, such as an embolus or thrombus, that is located at a bifurcation, trifurcation or multi-lumen plexus of the lumen 2, such as a blood vessel. By way of example, as shown in Figs. 36 and 37, a sheath 8, through which multiple catheters 12 are inserted, is advanced through the lumen 2 to the bifurcation at which occlusive material 4 is present. The catheters 12 are independently advanced distally from the sheath 8 through the occlusive material 4 within the different lumens 2 of the bifurcation. Flow restoration and extraction of the occlusive material 4 is conducted as described above.

[0094] In certain embodiments of the present invention, the flow restoration member 14, 114, 214, extraction member 38, 138, and the proximal capture member 260 may

comprise a braided mesh of filaments or wires 70. The braids for the mesh components may have a generally constant braid angle over an entire length of the member or may be varied to provide different zones of pore size and radial stiffness.

[0095] The braided mesh may be formed over a mandrel as is known in the art of tubular braid manufacturing. A braid angle α (alpha), shown in Figure 38, may be controlled by various means known in the art of filament braiding. In certain embodiments, the braid angle α is, for example, between about 45 degrees and about 60 degrees. The tubular braided mesh may be further shaped using a heat setting process. As known in the art of heat setting nitinol wires, a fixture, mandrel or mold may be used to hold the braided tubular structure in its desired configuration then subjected to an appropriate heat treatment such that the resilient filaments of the braided tubular member assume or are otherwise shape-set to the outer contour of the mandrel or mold.

[0096] In certain embodiments, the filamentary elements of the mesh member may be held by a fixture configured to hold the member in a desired shape and heated to about 475-525 degrees Celsius for about 5 to 30 minutes to shape-set the structure. In certain embodiments, the braid may be a tubular braid of fine metal wires 70 such as Nitinol, platinum, cobalt-chrome alloys, 35N LT, Elgiloy, stainless steel, tungsten or titanium.

[0097] In certain embodiments, the member can be formed at least in part from a cylindrical braid of elastic filaments. Thus, the braid may be radially constrained without plastic deformation and will self-expand on release of the radial constraint to an unrestrained diameter or diameter at its lowest energy state. Such a braid of elastic filaments is herein referred to as a "self-expanding braid."

[0098] In certain embodiments, the thickness of the braid filaments is less that about 0.5 millimeters. In certain embodiments, the braid may be fabricated from wires 70 with diameters ranging from about 0.015 millimeters to about 0.40 millimeters. In certain embodiments, the braid may be fabricated from wires with diameters ranging from about 0.02 millimeters to about 0.15 millimeters.

[0099] In certain embodiments, the member has a high braid angle zone where the braid angle α is greater than about 60 degrees. More particularly, the higher braid angle

portion or zone may have a braid angle α that is between 60 and 80 degrees. The high braid angle portion may have higher radial stiffness that may provide, for example, improved extraction of occlusive material 4. Furthermore, as the member is retracted the portion of the member with a high braid angle elongates to a greater amount relative to the remainder of the member, thereby providing a longer surface for retraction through the occlusive material.

[00100] In certain embodiments, the system may comprise a braided member where the braid is formed from a mixture of more than one diameter wire 70, as shown in Fig. 38. A braid showing two wire diameters, wire 70a and wires 70b having a smaller diameter than the diameter of the wires 70a, is shown in Figure 39.

[00101] A braided member may also comprise a plurality of layers. In certain embodiments, the system may comprise a braided member where the braid configuration changes over the length of the member forming a tubular structure with two or more zones of different braid. The parameters that may be changed to manipulate the braid include but are not limited to braid angle α, combinations of different diameters of wire 70 (e.g. a combination of small and large diameters) and wire loading (e.g. alternating wire size in a 1 by 1 or 2 by 2 pattern). Changing the braid parameters allows for zones of different mechanical properties (e.g. radial stiffness and compliance) along one continuous braid. In certain embodiments, the member may have one zone with a braid angle α between about 35 degrees and 55 degrees and another zone with a braid angle α between about 50 degrees and 70 degrees. In certain embodiments, the member may have one zone with a radial stiffness that is at least about 25% greater than the radial stiffness of a second zone.

[00102] In one embodiment of the present invention, as shown in Figs. 40A-40C, the flow restoration member may be formed by machining or laser cutting a stent-like pattern either directly in a tube or in a flat sheet that is subsequently formed into a tube. The sheet may be rolled or otherwise formed into a generally tubular configuration and then welded, soldered or joined in order to fix the tubular shape. Figure 40A shows an exemplary flat pattern. Figure 40B shows the tube form of the stent-like pattern and Figure 40C shows the stent-like tube attached to the distal end of a pusher or deleviery element.In certain other embodiments, as shown in Fig. 27, the extraction member 138

is a braided structure extension of flow restoration member 114 that has been everted and curled back on itself forming an expanded distal portion.In any of the above described embodiments, the system 10, 10, 200 may include additional devices or components to facilitate thrombus maceration or disruption including but not limited to mechanical maceration members (auger, drill bit, screw, impellor, burr, pick, etc.), vibration members, ultrasonic energy, radiofrequency energy, microwave energy, thermal energy, cavitiation, flow jets or perfusion apparatus. For example, in certain embodiments, the system 10, 100, 200 may comprise a boring member to facilitate penetration of the occlusive material 4. In certain embodiments, the system 10, 100, 200 may comprise an auger device to facilitate retraction of the occlusive material 4, such as thrombus along a central path coaxial with the flow restoration member 14, 114, 214.

[00103] In any of the above described embodiments, the system 10, 100, 200 may include a drug or bioactive agent to enhance the thrombus extraction performance and/or reduce the propensity to produce clotting. In certain embodiments, the system 10, 100, 200 and more particularly the flow restoration member 14, 114, 214, extraction member 38, 138, and the proximal capture member 260 may employ textures, surface features, coatings, or the like to enhance the engagement and/or attachment of the occlusive material 4, such as thrombus. In certain embodiments, the device may include an antiplatelet agent, a lytic agent or an anticoagulant.

[00104] In any of the above described embodiments, a delivery system may be provided or integrated into the catheter 10 and/or sheath 8, 208. The delivery system may include an introducer sheath for access into the appropriate vein such as the subclavian vein, jugular vein, femoral vein or radial vein. In certain embodiments, the catheter 10 and/or sheath 8, 208 may be placed through the introducer sheath to pass through the access vein such as the right subclavian vein or jugular vein into the superior vena cava through the right atrium through the tricuspid valve, through the right ventricle, through the pulmonic valve, to thrombus or occlusive embolus situated in the pulmonary artery or branches of the pulmonary artery. In some embodiments, the catheter 10 and/or sheath 208may be placed through the introducer sheath to pass through the access vein such as the femoral vein into the inferior vena cava through the right atrium through the tricuspid valve, through the right ventricle, through the pulmonic

valve, to thrombus or occlusive embolus situated in the pulmonary artery or branches of the pulmonary artery.

[00105] 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 claimed 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. An occlusion management system comprising:

a catheter;

a pusher; and

a tubular member reversibly restrained in a compressed state within a lumen of the catheter and radially expanded from the compressed state upon retraction of the catheter relative to the pusher.

2. The system of claim 1 wherein a distal end of the pusher is attached to a proximal portion of the tubular member.

3. The system of claim 1 wherein a diameter of the member is largest at a distal portion of the tubular member.

4. The system of claim 1 wherein a distal portion of the tubular member is flared in a radially expanded state.

5. The system of claim 1 wherein a distal portion of the tubular member is bulbous in a radially expanded state.

6. The system of claim 1 further comprising an extraction member attached to a distal portion of the member.

7. The system of claim 1 wherein a distal portion of the tubular member is everted toward a proximal portion of the member.

8. The system of claim 1 further comprising a sheath having a lumen through which the catheter is advanced.

9. The system of claim 1 further comprising a sheath having a lumen through which a proximal tubular member is advanced.

10. The system of claim 1 wherein the catheter comprises an annular balloon near a distal end of the catheter.

11. An occlusion management system comprising:

a catheter;

a pusher;

a tubular member attached to a distal end of the pusher; and

an extraction member extending distally of a distal end of the cylindrical member having a diameter larger than a diameter of the cylindrical member.

12. The system of claim 11 wherein the extraction member is attached directly to the tubular member.

13. The system of claim 1 further comprising a sheath having a lumen through which the catheter is advanced.

14. The system of claim 1 further comprising a sheath having a lumen through which a proximal tubular member is advanced.

15. A method for management of an occlusion in a lumen comprising the steps of:

creating a passage for fluid flow through occlusive material in a lumen of a patient;

engaging a portion of the occlusive material with at least a portion of a tubular member; and

extracting a portion of the occlusive material from the lumen of the patient.

16. The method of claim 15 wherein the step of creating a passage for fluid flow through occlusive material in a lumen of a patient comprises expanding the tubular member.

17. The method of claim 15 wherein the step of engaging a portion of the occlusive material with at least a portion of the tubular member comprises retracting a catheter relative to the tubular member.

18. The method of claim 15 wherein the step of engaging a portion of the occlusive material with at least a portion of a tubular member comprises expanding the tubular member.

19. The method of claim 15 wherein the step of extracting a portion of the occlusive material from the lumen of the patient comprises expanding an extraction member distally of the tubular member.

20. The method of claim 15 wherein the step of extracting a portion of the occlusive material from the lumen of the patient comprises retracting the tubular member in to a catheter.

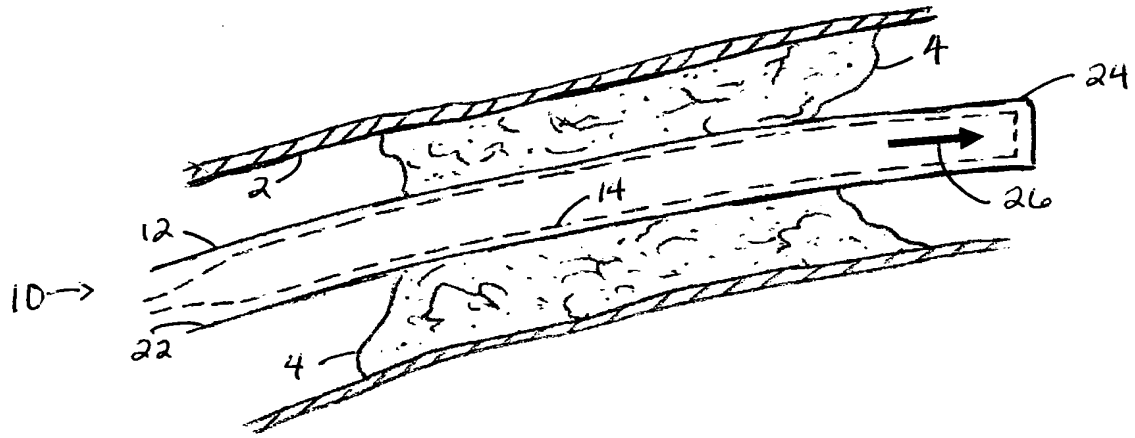


Fig. 1

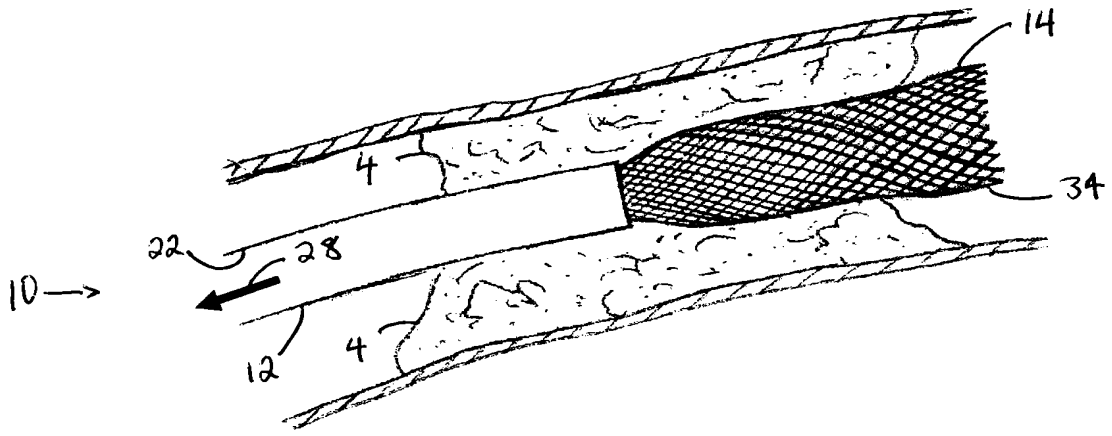


Fig. 2

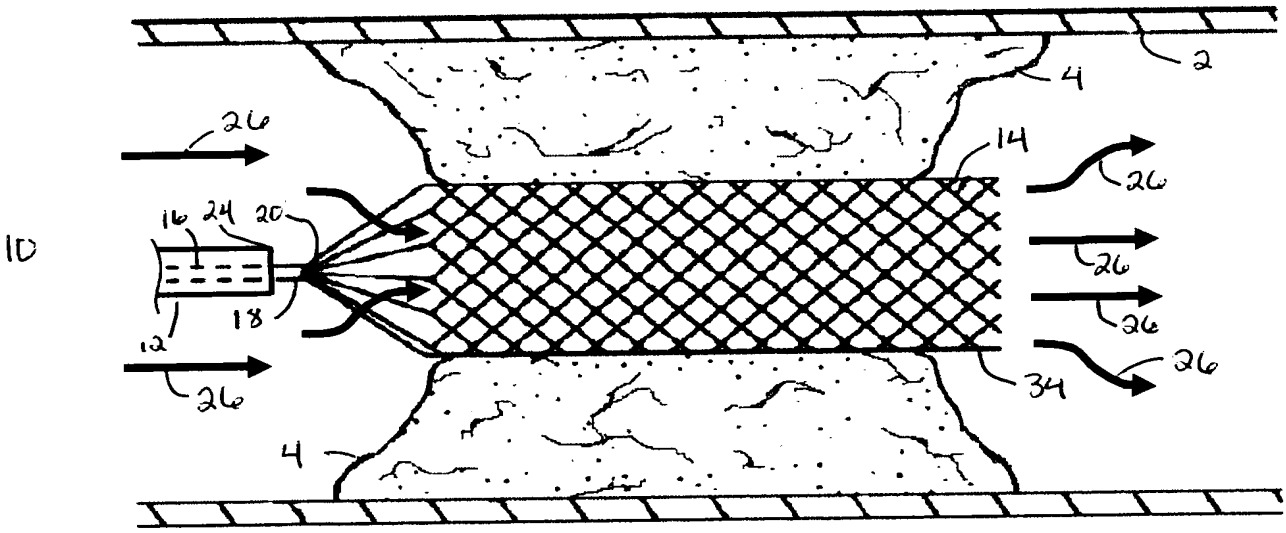


Fig. 3

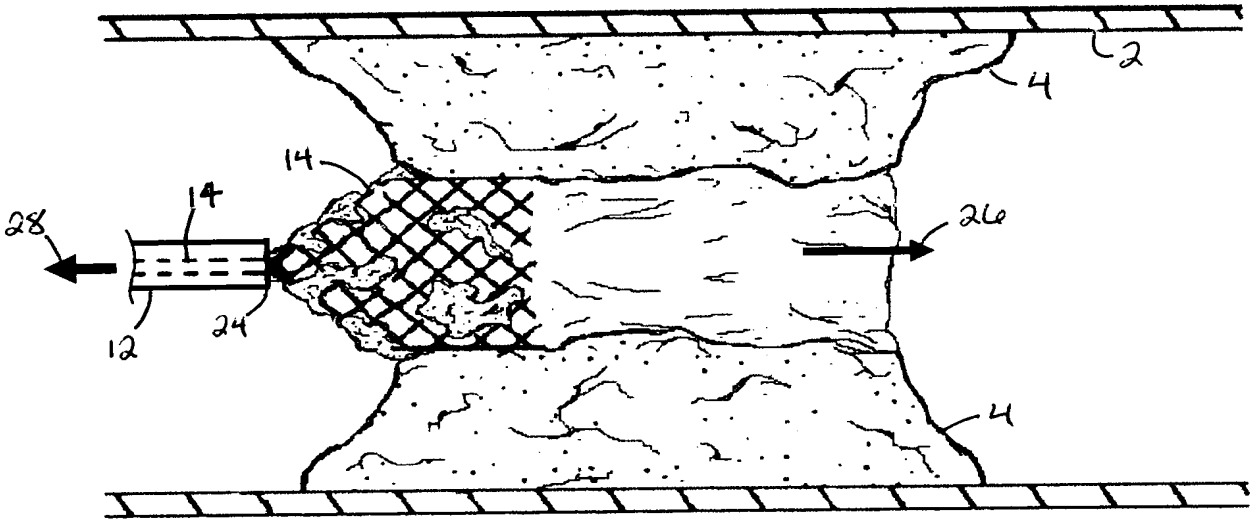


Fig 4

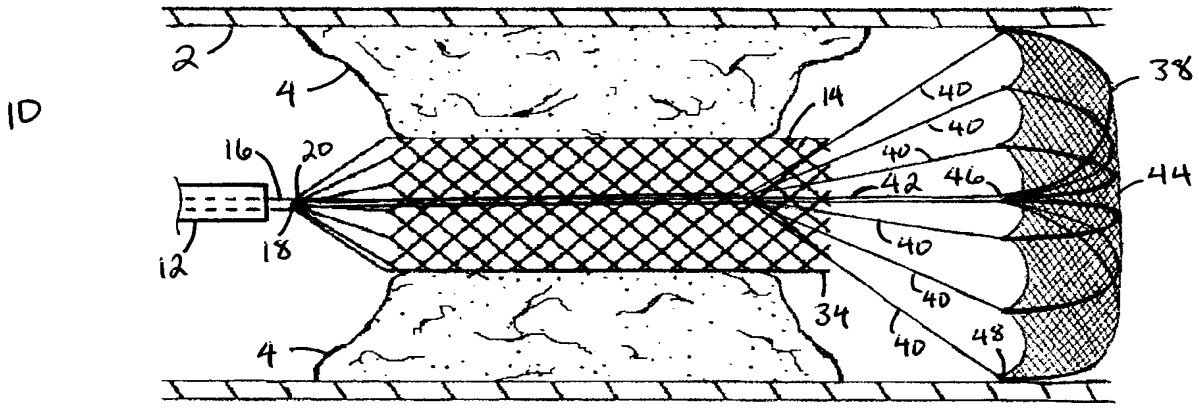

10
2
4
14
16
20
12
18
34
38
40
42
44
46
48

Fig. 5

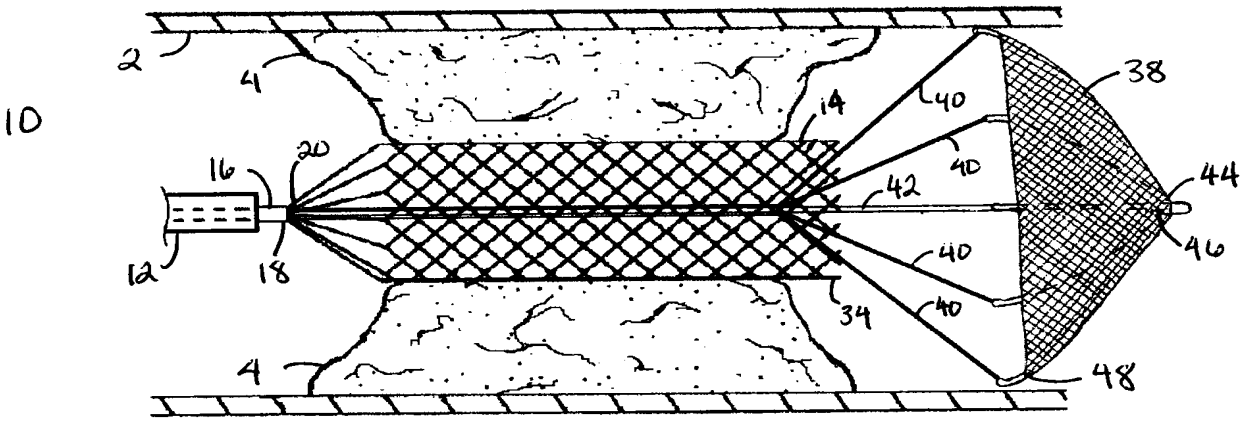

10
2
4
14
16
20
12
18
34
38
40
42
44
46
48

Fig. 6

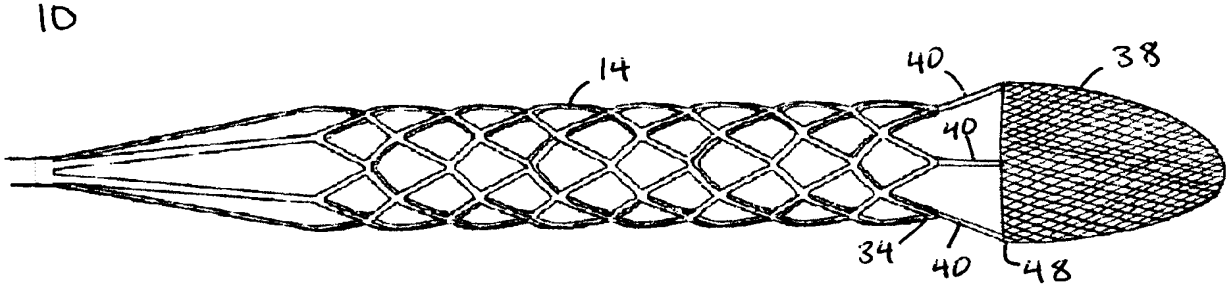


Fig. 7

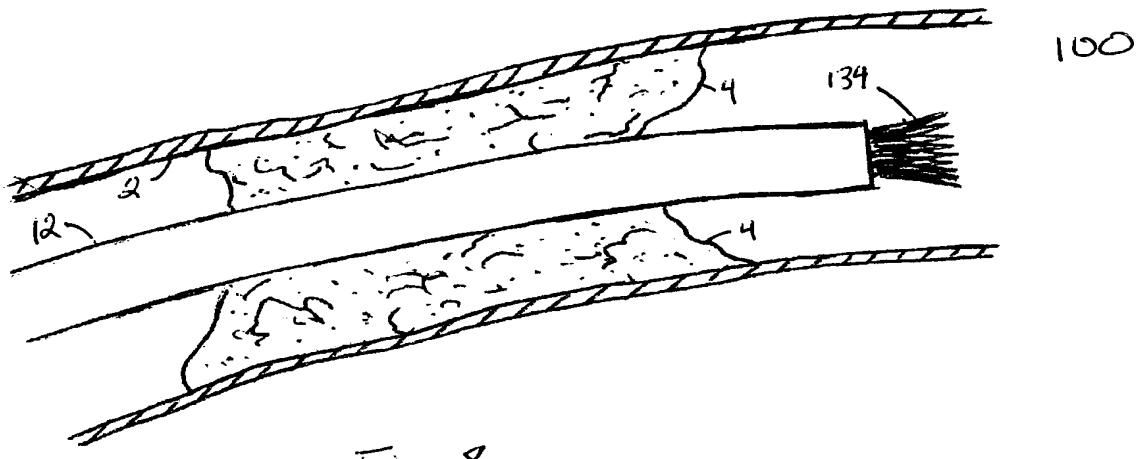


Fig. 8

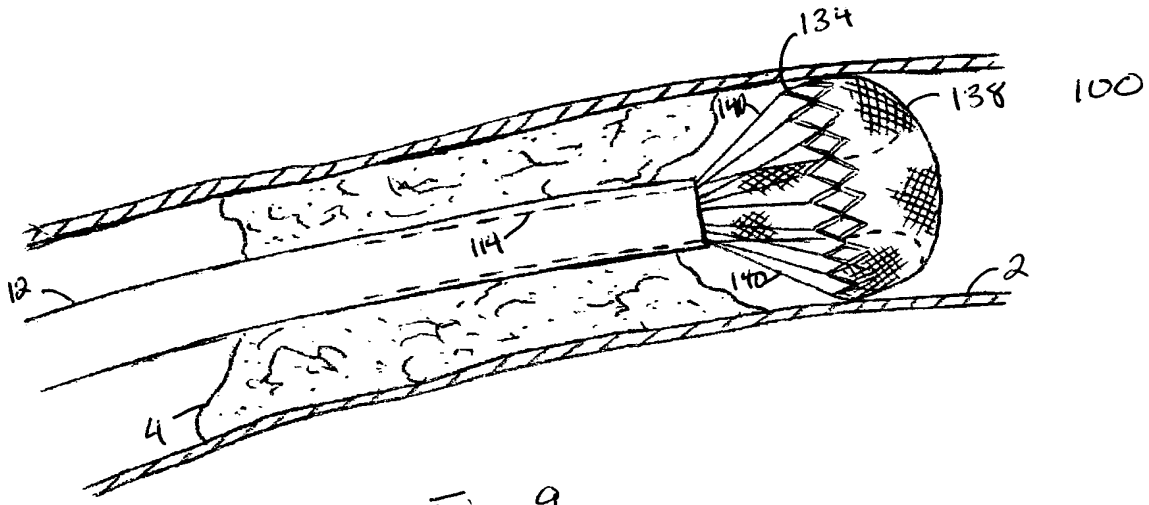

134
138
100
140
114
12
140
2
4

Fig. 9

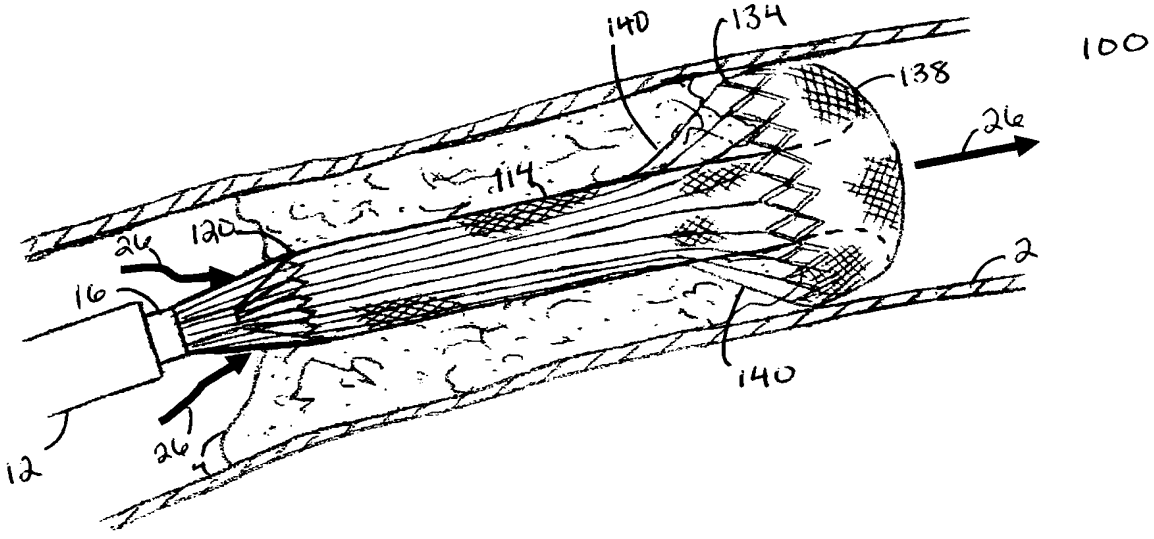

140
134
100
138
26
114
26
120
2
16
140
12
26

Fig. 10

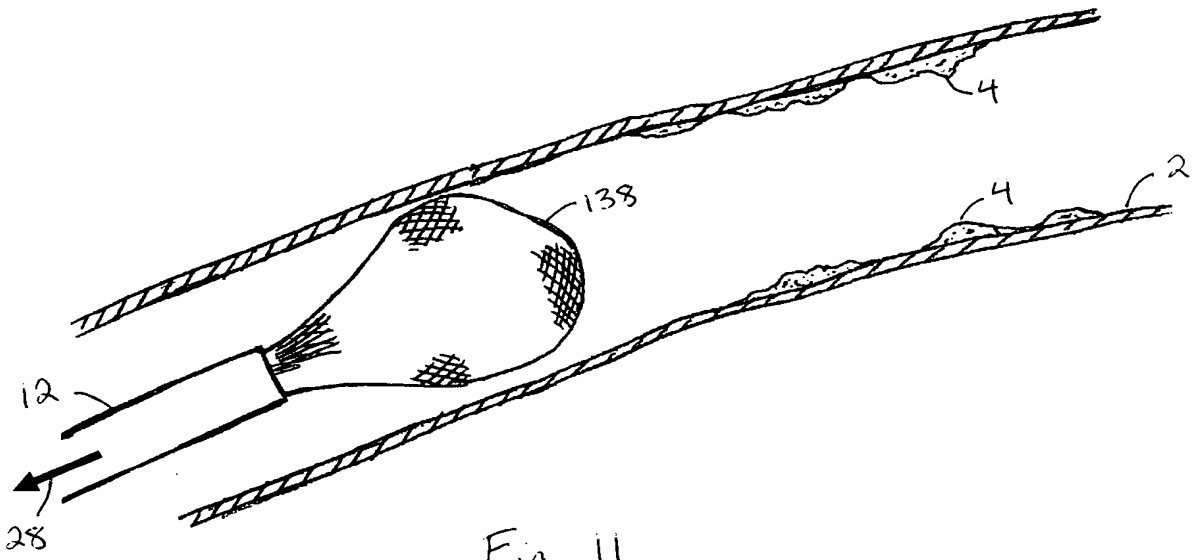


Fig. 11

Fig. 12

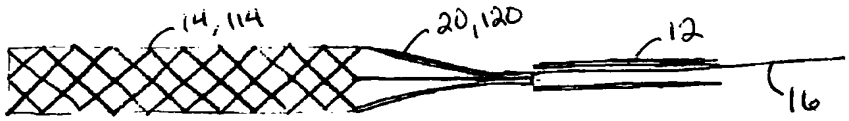


Fig. 13

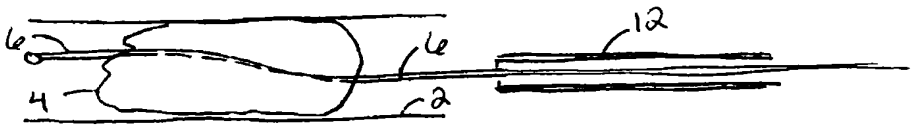


Fig. 14

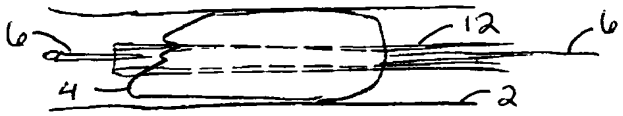


Fig. 15

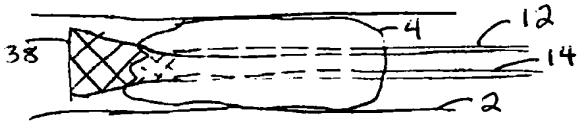


Fig. 16

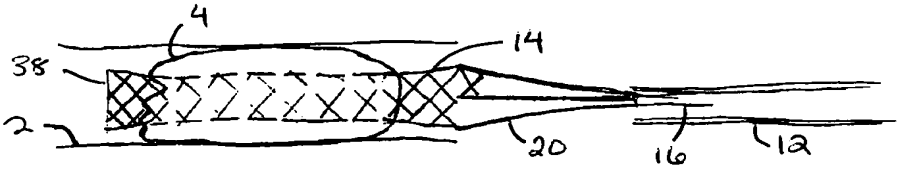


Fig. 17

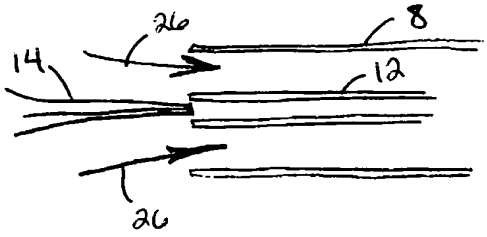


Fig. 18

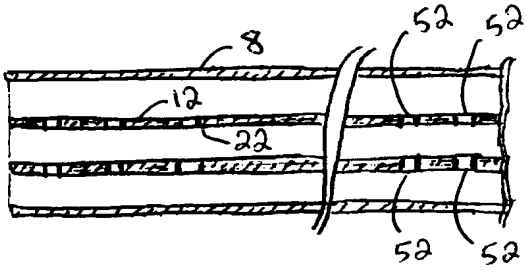


Fig. 19

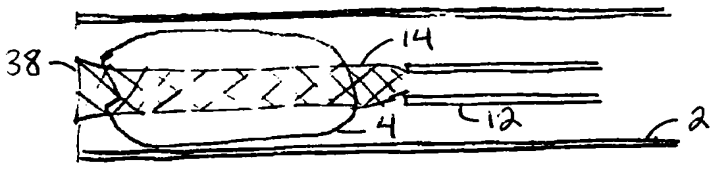


Fig. 20

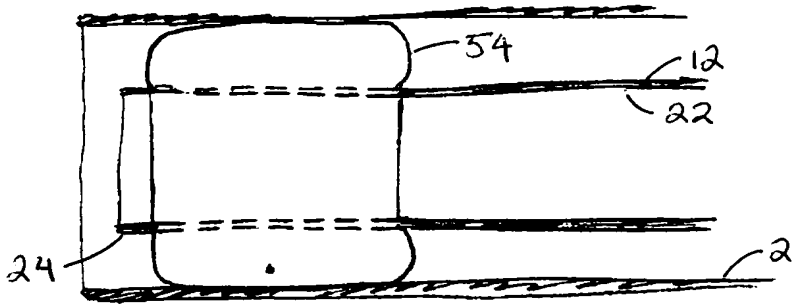


Fig. 21

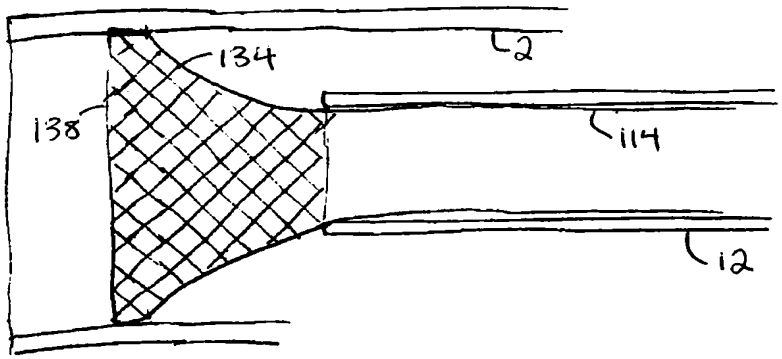


Fig. 22

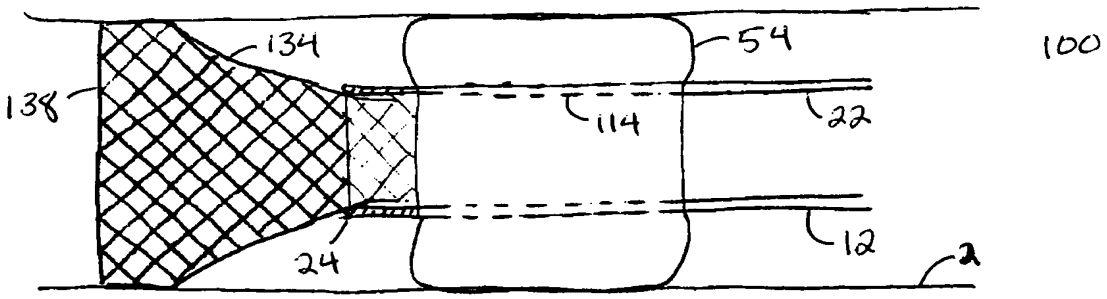


Fig. 23

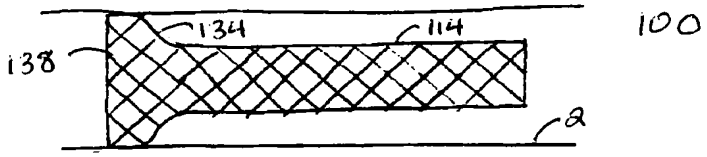


Fig. 24

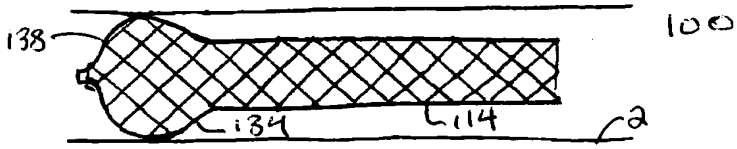


Fig. 25

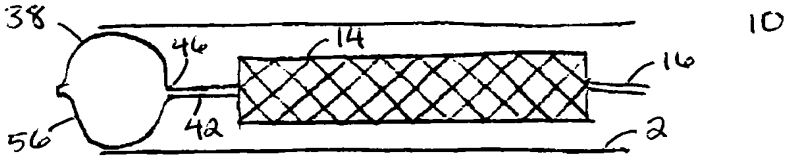


Fig. 26

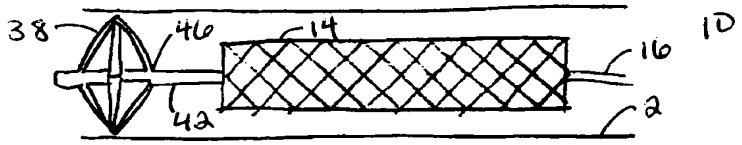


Fig. 27

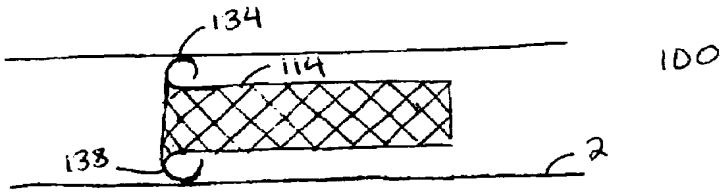
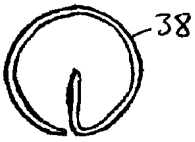


Fig. 28A



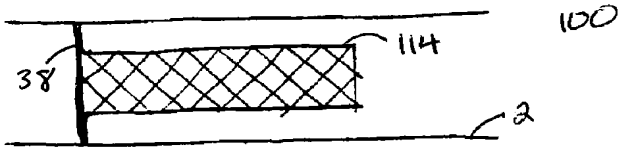
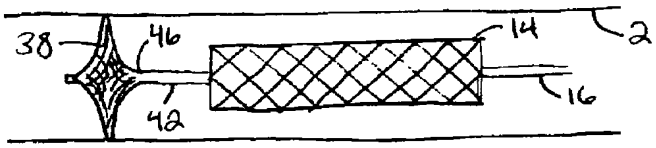


Fig. 28B

Fig. 29



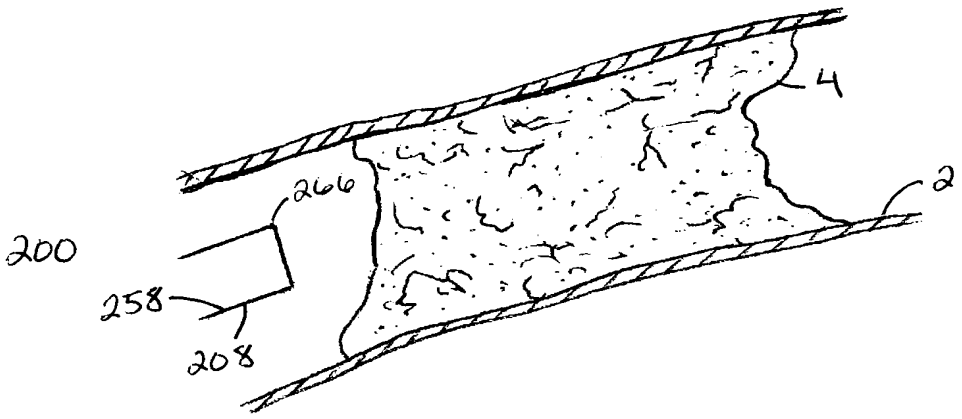


Fig. 30

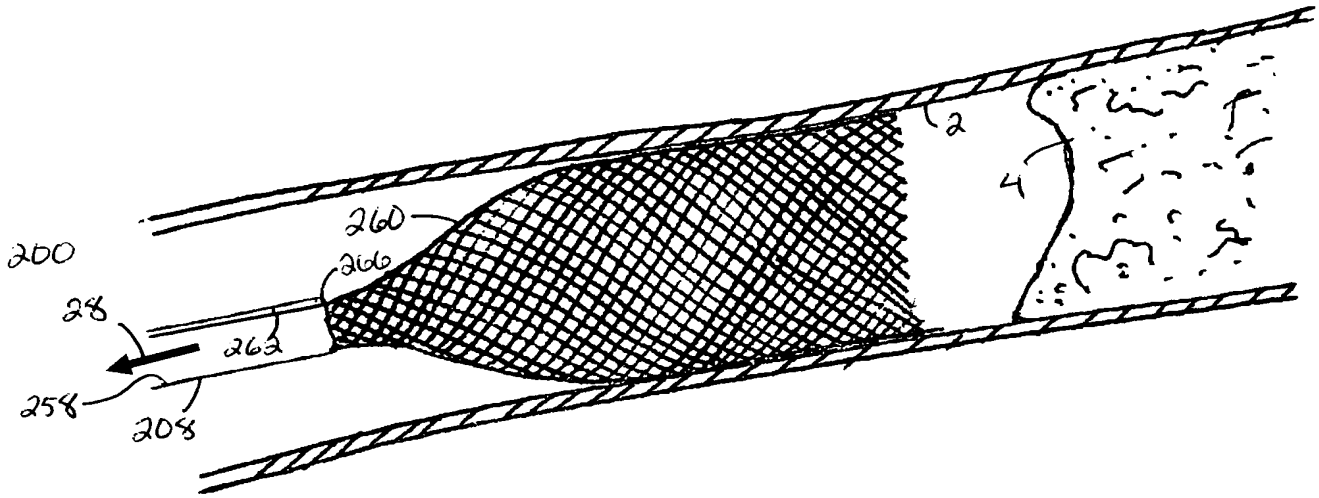


Fig. 31

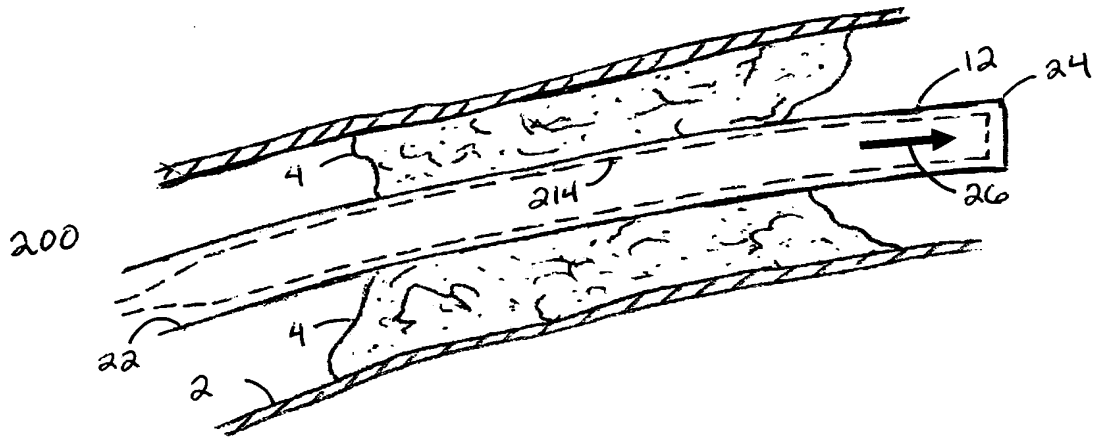


Fig. 32

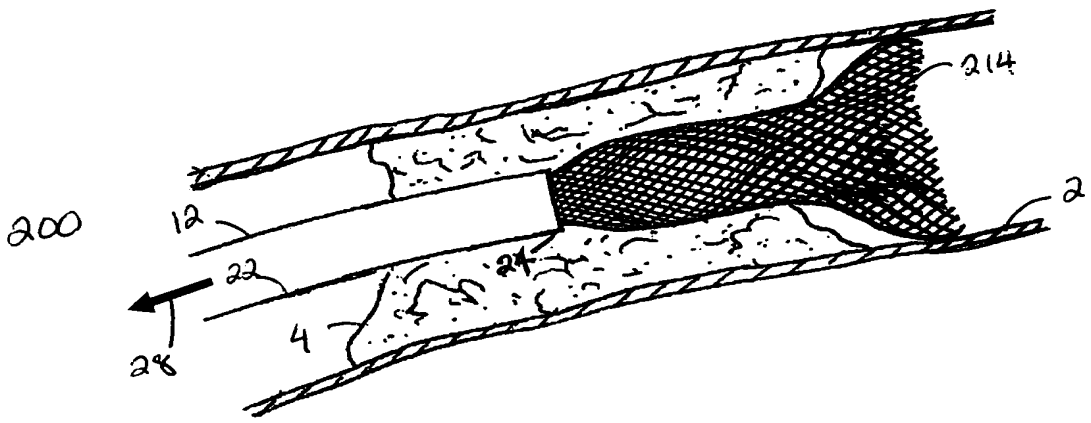


Fig. 33

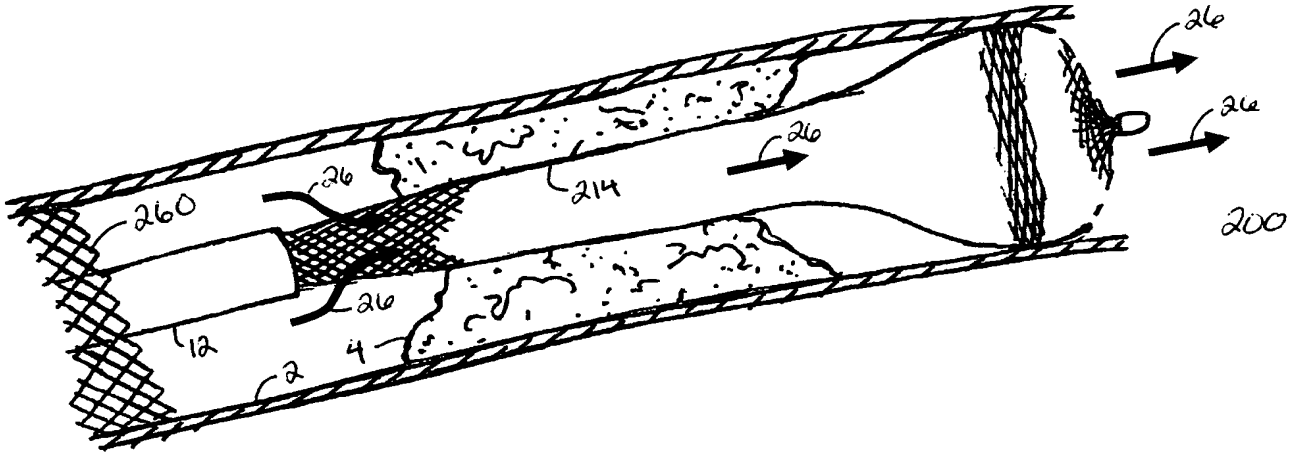


Fig. 34

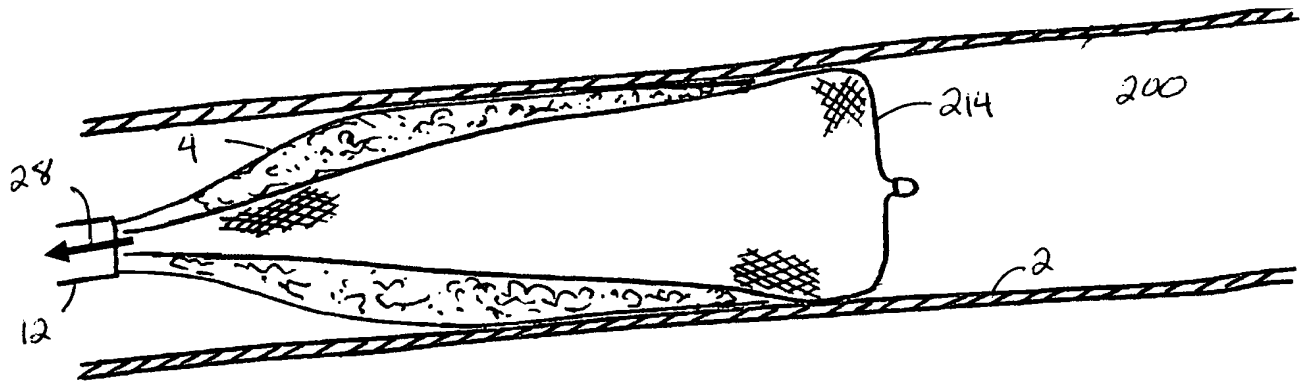


Fig. 35

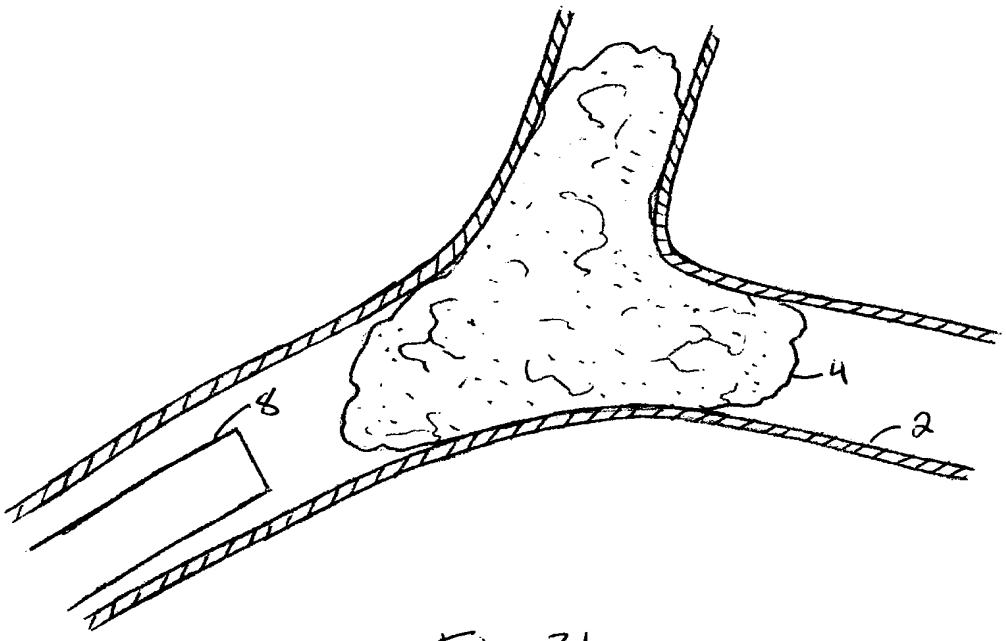


Fig. 36

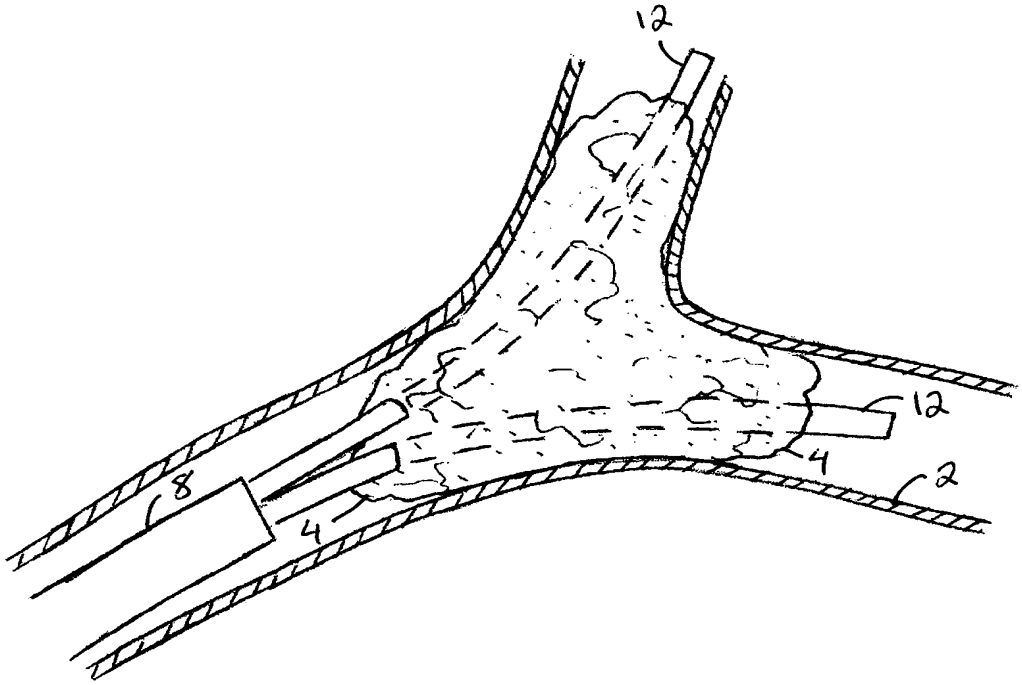


Fig. 37

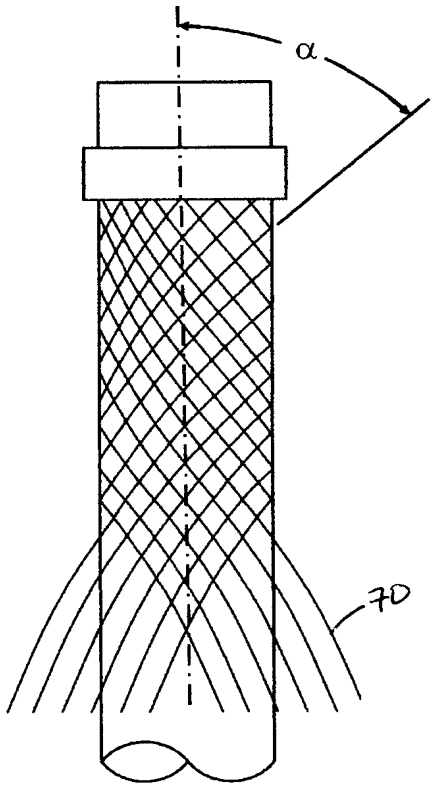


Fig. 38

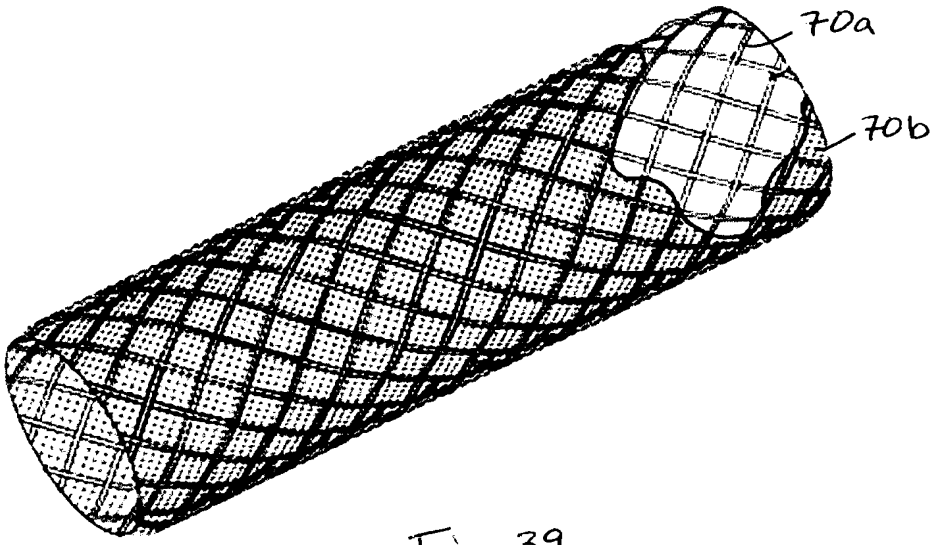


Fig. 39

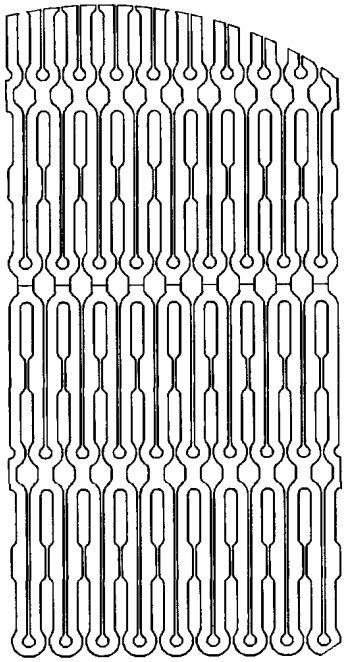


Fig. 4DA

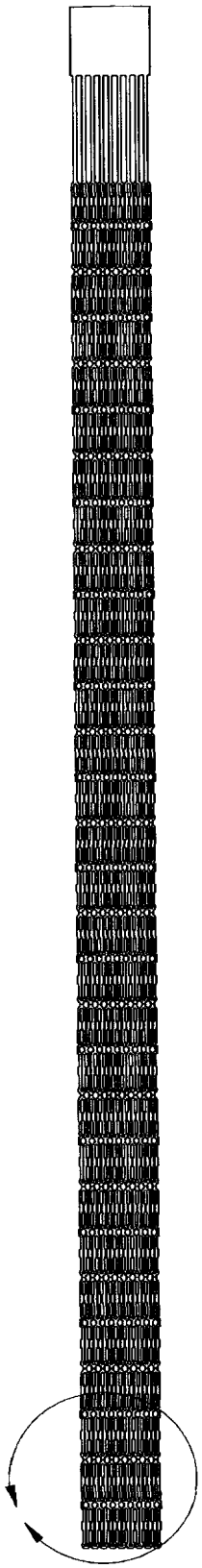


Fig. 4DB

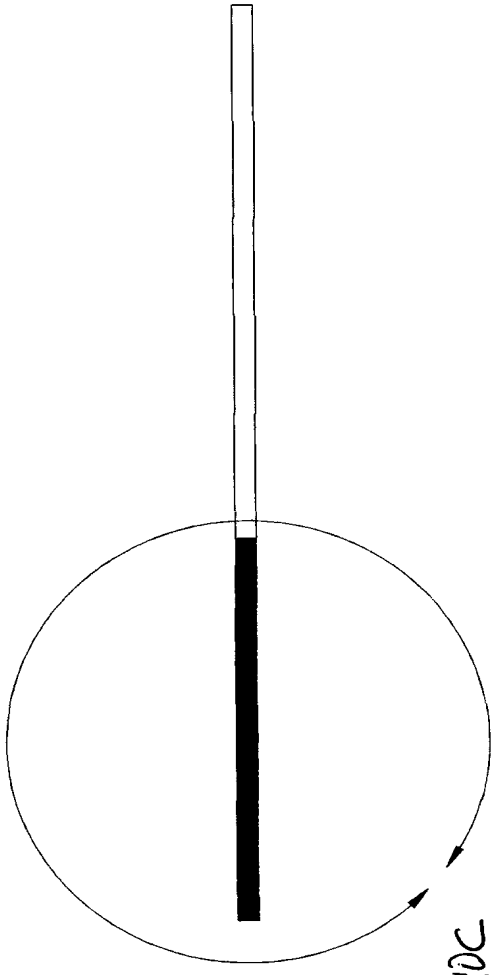


Fig. 4DC

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 13/61470

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/22 (2013.01)
USPC - 606/159; 604/22
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) - A61B 17/22 (2013.01)
USPC - 606/159; 604/22

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
606/167, 170, 200; 600/564; 623/1.11
(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: Atherectomy, atherosclorosis, angioplasty, thrombectomy, stenosis, stenotic, occlusion, plaque, embolism, expandable, evert, eversion, intussucscept, filter, trap, distal protection, passage, hole, path, through, across

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 2012/0089216 A1 (RAPAPORT et al.) 12 April 2012 (12.04.2012) Entire document, especially Abstract, para[0051] para-[0068], para[0094], para[0103]- para[0110] and FIGS. 1-2D, 7A, 9	1-4, 6, 11-12 and 15-20 --- 13-14
X	US 2007/0208367 A1 (FIORELLA et al.) 06 September 2007 (06.09.2007) Entire document, especially Abstract, para[0026] and FIGS. 6-8.	1, 5
X	US 2010/0249815 A1 (JANTZEN et al.) 30 September 2010 (30.09.2010) Entire document, especially Abstract, para[0026]-[0030] and FIGS. 1-9.	1, 7
X -- Y	US 5,972,019 A (ENGELSON et al.) 26 October 1999 (26.10.1999) Entire document, especially Abstract, col 6, ln 20-49 and FIGS. 2, 19A-19E.	1, 8-11 --- 13-14
X	US 2009/0292307 A1 (RAZACK) 26 November 2009 (26.11.2009) Entire document, especially Abstract and FIGS. 12-15.	1
X	US 2007/0208361 A1 (OKUSHI et al.) 06 September 2007 (06.09.2007) Entire document, especially Abstract and FIGS. 1, 11-12, 24.	1

☐ 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
18 November 2013 (18.11.2013)	17 JAN 2014
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

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :		(11) International Publication Number:
A61B 5/00, 17/22, A61D 1/02, A61M 29/00	A1	WO 97/17889
		(43) International Publication Date: 22 May 1997 (22.05.97)

(21) International Application Number: PCT/US96/17598

(22) International Filing Date: 4 November 1996 (04.11.96)

(30) Priority Data:
08/559,076 16 November 1995 (16.11.95) US

(71) Applicant: APPLIED MEDICAL RESOURCES CORPORATION [US/US]; Suite 103, 26051 Merit Circle, Laguna Hills, CA 92653 (US).

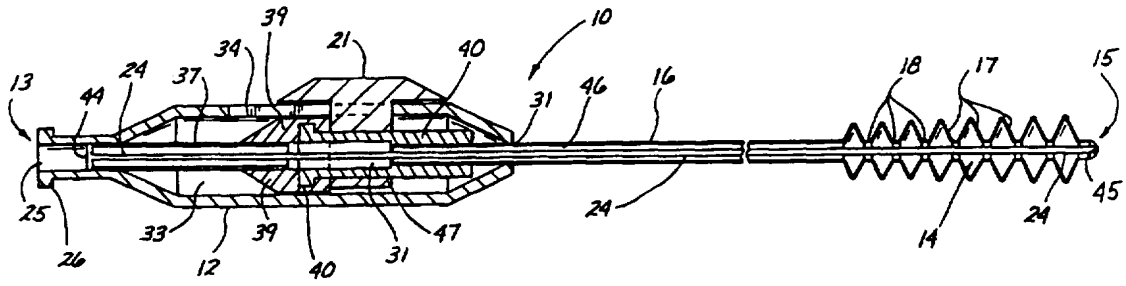
(72) Inventor: HART, Charles, C.; 8252 Mandeville, Huntington Beach, CA 92646 (US).

(74) Agent: MYERS, Richard, L.; Suite 103, 26051 Merit Circle, Laguna Hills, CA 92653 (US).

(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: INTRALUMINAL EXTRACTION CATHETER



(57) Abstract

The expandable intraluminal catheter (10) is used for removing occlusive material from a body passage. The catheter includes a handle (12) having both a proximal handle end and a distal handle end. Attached to the distal handle end is an elongate tubular body (16) which includes a proximal elongate tubular body end and a distal elongate tubular body end (15). The elongate tubular body further includes a lumen (46) between the proximal elongate tubular body end and the distal elongate tubular body end. A number of radially expandable segments (17) are disposed on the elongate tubular body near the distal elongate tubular body end. These radially expandable segments can be mechanically activated by a user when the distal elongate tubular body end is within a blood vessel, to thereby contact and partition occlusive material within the blood vessel. The partitioned occlusive material within the blood vessel can then be removed.

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.

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

INTRALUMINAL EXTRACTION CATHETER

Background of the Invention

The present invention relates generally to catheters and, more particularly, to an expandable intraluminal catheter for removing occlusive material from a body passage.

Expanding diameter catheters are commonly used in surgical procedures. A well-known mechanism for expanding the diameter of the catheter is inflation. These balloon-type embolectomy catheters are disclosed in U.S. Patent No. 3,435,826, U.S. Patent No. 3,467,101, and U.S. Patent No. 5,320,604 for use in removing blood clots and thrombus from blood vessels. In addition to balloon-type embolectomy catheters, other mechanisms have been proposed by the prior art in an attempt to improve the procedure of removing clots and thrombus or plaque from blood vessels. U.S. Patent No. 5,282,484 and U.S. Patent No. 5,284,486 disclose a catheter having rotating blades. U.S. Patent No. 5,370,653 discloses a catheter having a brush for removal of material from a blood vessel. U.S. Patent No. 5,192,290, which is assigned to the assignee of the present invention, discloses a catheter having an expanding elastomeric foam.

All of these prior art embolectomy catheters have intrinsic problems and complications connected with use in delicate blood vessels, regardless of whether balloons, blades, or bushes are used. Balloons may rupture or may transmit excessive force to the delicate blood vessel. Blades or brushes may cause extensive damage to the fragile lining of the delicate blood vessel. An elastomeric foam member, such as that disclosed in U.S.

Patent No. 5,192,290, provides a mechanical activation of the expansion means. Although this mechanical activation provides a safety measure by giving the user a tactile feel, the elastomeric foam expansion member does not have the removal capabilities of the above-mentioned balloons, blades, and brushes.

Another problem commonly shared by all of the prior art embolectomy catheters stems from a removal method which is inherently engineered into these devices. A common principle is implemented by each of the prior art devices. Specifically, the expanding members of these prior art devices are advanced beyond the occlusive material to be removed or treated in the blood vessel, and the occlusive material is then forced as a whole along a retrieval path through the blood vessel to a collection site. If the occlusive material is well-attached to the blood vessel wall, the shear forces required to dislodge this material may be damaging to the blood vessel. Since the expanding member basically contacts a perimeter portion of the occlusive material and pushes this material through the vessel to the collection site, a resulting compression of the occlusive material often results. This compression may necessitate the application of additional, excessive force for the removal of the occlusive material, resulting in further damage to the delicate intimal lining of the blood vessel. A need thus exists in the prior art for an embolectomy catheter, that is able to capture and remove occlusive material from a delicate blood vessel without damaging the intimal lining or causing traumatic injury to that blood vessel.

Summary of the Invention

The expansion member of the intraluminal catheter of the present invention harnesses a mechanical activation of the expansion member, and thus does not suffer from the

problems associated with prior art balloons, blades, and brushes. This mechanical activation of the expansion member provides the user with a tactile feel. Additionally, the expandable intraluminal catheter of the present invention does not rely on the removal mechanism of the prior art. Specifically, the expandable intraluminal catheter of the present invention does not contact and push only the outer parameter of the occlusive material in the blood vessel. The expandable intraluminal catheter of this invention contacts the occlusive material along the entire length of the occlusive material within the blood vessel to thereby minimize the compression effect suffered by the prior art. The resulting force required to dislodge or mobilize the occlusive material at any one point within the blood vessel is significantly reduced, since compression is reduced and the mobilizing force is distributed over a large surface area. Since the occlusive material is contacted, and partitioned, at a number of points along the length of the occlusive material within the blood vessel, a risk that the occlusive material may be lost, left behind, or swept into the flow of the blood vessel is also reduced.

The expandable intraluminal catheter is used for removing occlusive material from a body passage. The catheter includes a handle having both a proximal handle end and a distal handle end. Attached to the distal handle end is an elongate tubular body, which includes a proximal elongate tubular body end and a distal elongate tubular body end. The elongate tubular body further includes a lumen between the proximal elongate tubular body end and the distal elongate tubular body end. A number of radially-expandable segments are disposed on the elongate tubular body near the distal elongate tubular body end. These radially-expandable segments can be mechanically activated by a user when the distal elongate

tubular body end is within a blood vessel, to thereby contact and partition occlusive material within the blood vessel. The partitioned occlusive material within the blood vessel can then be removed. The mechanism for mechanically activating the radially-expandable segments includes a wire disposed within the lumen of the elongate tubular body. A proximal end of the wire is connected to the proximal handle end, and a distal end of the wire is connected to the distal elongate tubular body end. This connection of the wire between the handle and the distal elongate tubular body end fixes the length therebetween. An actuator, connected to the proximal elongate tubular body end, can be actuated by the user to move the proximal elongate tubular body end toward the relatively stationary distal elongate tubular body end. This movement results in an expansion of the radially-expandable segments. Similarly, the user can reverse the direction of the actuator to increase the distance between the proximal elongate tubular body end and the distal elongate tubular body end to thereby decrease the diameters of the radially-expandable segments.

In addition to the partitioning effect caused by the number of radially-expandable segments contacting the occlusive material at a corresponding number of points within the blood vessel, the expandable intraluminal catheter of the present invention utilizes a peristaltic effect among the number of radially-expandable segments. Specifically, the radially-expandable segments closer to the distal elongate tubular body end may be configured to expand before other radially-expandable segments adjacently proximal thereto. This progressive deployment of the radially-expandable segments captures and mobilizes the occlusive material, progressively, in a direction toward the collection site.

These radially-expandable segments may be formed of a tubular woven, braided, or meshed material having tiny apertures therein. When the radially-expandable segments are activated, the small apertures become larger to thereby allow for liquids or small particles to pass therethrough. Thus, solvents or other medications may be administered through the lumen of the expandable intraluminal catheter, to thereby exit through the apertures of the radially expandable members. Suction may also be applied through the lumen to draw fluids back through the apertures. This suction may aspirate, desiccate, or in other ways mechanically attach portions of chemically treated occlusive material to the radially-expandable segments to thereby facilitate removal of the occlusive material from the blood vessel.

The mechanical activation of the plurality of radially-expandable segments, in addition to providing a tactile feel to the user, provides an expansion mechanism which has a relatively smooth outer surface for non-destructive insertion into the blood vessel, and subsequently provides relatively rigid enlarged-diameter segments for removal of the occlusive material from the blood vessel. According to another feature of the present invention, an expandable distal member, formed of elastomeric foam, can be placed at the distal elongate tubular body end of the expandable intraluminal catheter tube to further facilitate effective removal of the occlusive material from the blood vessel.

The present invention, together with additional features and advantages thereof, may best be understood by reference to the following description taken in connection with the accompanying illustrative drawings.

Brief Description of the Drawings

Figure 1a is a side view of the expandable intraluminal catheter of the presently preferred embodiment in an undeployed configuration;

Figure 1b is a side view of the expandable intraluminal catheter of the presently preferred embodiment in a deployed or expanded configuration;

Figure 2a is a partial cross-sectional view of the expandable intraluminal catheter of the presently preferred embodiment in the undeployed configuration;

Figure 2b is a partial cross-sectional view of the distal portion of the expandable intraluminal catheter in an expanded configuration, according to the presently preferred embodiment;

Figure 3a is a cross-sectional view of the expandable intraluminal catheter in an undeployed condition, according to the presently preferred embodiment;

Figure 3b is a cross-sectional view of the expandable intraluminal catheter in a deployed condition, according to the presently preferred embodiment;

Figure 4 is a distal-end view of the expandable intraluminal catheter in the expanded configuration, according to the presently preferred embodiment;

Figure 5a is an enlarged view of the handle portion of the expandable intraluminal catheter in the position shown in Figure 3a;

Figure 5b is an enlarged view of the handle portion of the expandable intraluminal catheter in the position shown in Figure 3b;

Figures 6a-6c illustrate the use of the expandable intraluminal catheter of the present invention to remove occlusive material from a body passage;

Figure 7a and 7b are enlarged views of Figures 6b and 6c, respectively;

Figures 8a and 8b are side views of the expandable intraluminal catheter with an elastomeric expandable foam member attached thereto, according to an alternative embodiment of the present invention; and

Figures 9a and 9b illustrate use of the expandable intraluminal catheter within a blood vessel, according to the alternative embodiment.

Detailed Description of the Preferred Embodiments

An expandable intraluminal catheter of the presently preferred embodiment is illustrated in Figure 1 and designated generally by the reference numeral 10. The expandable intraluminal catheter 10 comprises a handle 12 and an elongate tubular body 16. The elongate tubular body 16 fits into an aperture 31 of the handle 12. A segmented distal portion 14 is located near the distal end 15 of the elongate tubular body. This segmented distal portion 14 preferably comprises a number of expandable segments 17 separated by a number of non-expandable segments 18. Each expandable segment 17 preferably comprises a tubular woven, braided, or meshed material. Each of the non-expandable segments preferably comprises a semi-rigid plastic tubing. The handle 12 is configured to be gripped by the hand of a user, and the actuator 21 is movable between a reverse position shown in Figure 1a and a forward position shown in Figure 1b. An opening or port 25 is located at the proximal end of the handle 12. This opening 25 preferably comprises a leur-type locking hub 26.

As shown in Figure 1b, movement of the actuator 21 into the forward position results in an expansion of the expandable segments 17. As each expandable segment 17 radially expands, a corresponding width of that expandable segment, measured in the direction of a longitudinal axis of the elongate tubular body 16, decreases. The non-

expandable segments 18 do not radially expand upon movement of the actuator 21 into the forward position and, further, do not decrease in width, measured along the longitudinal axis of the elongate tubular body 16.

Figure 2a illustrates a closer view of the segmented distal portion 14 of the elongate tubular body 16 in the non-activated configuration. In the presently preferred embodiment, the expandable segments 17 and the non-expandable segments 18 are formed of different materials, but comprise the same wall 50. The expandable segments 17 and the non-expandable segments 18 are fused together at fusion points 51 along the longitudinal axis of the tubular elongate body 16. Alternatively, a single expandable material may be fused at the fusion points 51, or non-expandable bands may be placed around the wall 50 to form the non-expandable segments 18. In the presently preferred embodiment, the locations of the fusion points 51 along the longitudinal axis of the elongate tubular body 16 are selected to correspond to predetermined expansion ratios. Each of the fusion points 51 is thus positioned to yield a deployed cone-shaped expandable segment 17 (Figure 2b) of a predetermined diameter and circumference.

In the presently preferred embodiment, the width of the expandable segments 17, measured along the longitudinal axis of the elongate tubular body 16, are progressively larger in the direction toward the distal end 15. This larger width of the expandable segments 17 in the direction of the distal end 15 results in expandable segments 17 near the handle 12 having smaller widths than expandable segments 17 near the distal end 15. As shown in Figure 2b, the expandable segments 17 near the distal end 15 with larger widths expand to greater diameters when activated, than the expandable segments 17 near the handle 12.

Figure 4 illustrates the segmented distal portion 14 in an expanded configuration, as shown on the distal end 15 looking down toward the handle 12. Each expandable segment 17 has a progressively smaller diameter 60 and circumference 61, according to its location away from the distal end 15. According to the presently preferred embodiment, the braided material which comprises the wall 50 has a characteristic which causes the expandable segments 17 having larger widths to expand before the expandable segments 17 having smaller widths. According to this presently preferred embodiment, a progressive deployment or expansion of the expandable segments 17 occurs upon activation by the actuator 21, in the direction from the distal end 15 toward the handle 12, to thereby capture and mobilize occlusive material 52 (Figure 6a) in a rearward direction toward the handle 12. The progressive deployment may also be from the distal and handle ends to the center of the expandable segments 17.

Turning to Figures 3a and 3b, a cross-sectional view of the expandable intraluminal catheter 10 is illustrated in both a non-expanded and an expanded configuration, respectively. The elongate tubular body 16 fits through the aperture 31 in the handle 12 and extends through the handle 12 to the proximal end 13. A wire 24 fits within a lumen 46 of the elongate tubular body 16. The wire 24 is connected to a distal connection point 45 at the distal end 15 of the elongate tubular body 16, and is also connected at a proximal point 44 within the handle 12. The wire 24 maintains a relatively fixed distance between the handle 12 and the distal connection point 45. The actuator 21 slides within the slot 34 between the backward position (Figure 3a) and the forward position (Figure 3b). This actuator 21 comprises a portion 47 which extends into the handle 12. The portion 47 of the actuator 21 connects to a cylindrical bushing 40. The

cylindrical bushing 40 is connected to the elongate tubular body 16, to thereby cause movement of the elongate tubular body 16 along the longitudinal axis of the elongate tubular body 16 with corresponding forward and reverse movement of the actuator 21 within the slot 34.

The cylindrical bushing 40 is connected at its proximal end to an elastomeric gasket or seal 39. A fixed tubular structure 37 is secured to the proximal point 44 at the handle 12. The cylindrical bushing 40 and the elastomeric gasket 39 slidably fit around the fixed tubular structure 37. Thus, movement of the actuator 21 from the reverse position (Figure 3a) to the forward position (Figure 3b) causes the bushing 40 and elastomeric gasket 39 to move along an outer surface of the fixed tubular structure 37 in the direction of movement of the actuator 21. The elastomeric gasket 39 maintains a seal between the lumen 46, which extends into the fixed tubular structure 37, and the general interior 33 of the handle 12. A watertight seal is thus formed from the opening 25, through the fixed tubular structure 37, elastomeric gasket 39, cylindrical bushing 40, and the elongate tubular body 16.

Movement of the actuator 21 toward the distal end 15 moves the end of the elongate tubular body 16, which is attached to the cylindrical bushing 40, toward the distal end 15. Thus, movement of the actuator 21 toward the distal end 15 results in a corresponding movement of the proximal elongate tubular body end toward the distal elongate tubular body end 15. The distal elongate tubular body end 15 does not move forward with forward movement of the actuator 21, since the wire 24 maintains the distance between the distal elongate tubular body end 15 and the handle 12. The reduction in distance between the proximal elongate tubular body end and the distal elongate tubular body end 15 results in a compression of the segmented

distal portion 14 from the relatively smooth, small-diameter configuration (Figure 3a) to the larger diameter configuration (Figure 3b). In other words, forward movement of the actuator 21 applies a compressive force to the segmented distal portion 14, which is relieved by expansion of the expandable segments 17, as the width of the expandable segments 17 decrease along the longitudinal axis of the elongate tubular body 16. Figures 5a and 5b are enlarged cross-sectional views of the handle 12 of Figures 3a and 3b, respectively.

Turning to Figure 6a, the segmented distal portion 14 of the elongate tubular body 16 is inserted through an incision or puncture 59 of a body passage 50. The body passage 50 may comprise a blood vessel, for example, having occlusive material 52 within the lumen 53 at an operation site 48. The occlusive material may be plaque, thrombi, emboli, or other potential clotting agents within the body passage 50. The segmented distal portion 14 is guided by the interior wall 54 of the body passage 50 to the operation site 48. As shown in Figure 6b, the segmented distal portion 14 is inserted through the occlusive material 52 with relative ease, since the expandable segments 17 and the non-expandable segments 18 have relatively similar diameters and circumferences. The expandable segments 17 are mechanically activated by the actuator 21 to thereby radially expand, as shown in Figure 6c. These expandable segments 17 sequentially expand in the direction from the operation site 48 toward the incision 59, to sequentially fill the lumen 53 and partition the occlusive material 52. Thus, once the distal end 15 is moved in the direction of arrow A1 beyond the occlusive material 52, the expandable segments 17 are radially expanded by the compression force resulting from forward movement of the actuator 21. The expandable segments 17 mobilize and capture the occlusive material 52

on a plurality of points along the interior wall 54. The method of mobilization and capture of the occlusive material 52 may be accomplished in several ways. The expandable segments 17 may be radially expanded and radially contracted to mechanically loosen the occlusive material 52 from the interior walls 54 of the body passage 50. Additionally, solvents or other medications may be administered through apertures formed in the expandable segments 17. These fluids are inserted through the opening 25 (Figure 1) of the expandable intraluminal catheter 10 and guided through the lumen 46 toward the segmented distal portion 14. Figures 7a and 7b illustrate closer views of Figures 6b and 6c. As shown in Figure 7b, the apertures 55 in the expandable segments 17 closest to the distal end 15, for example, allow the fluids to exit from the lumen 46 into the interior of the body passage 50. A suction may be applied to the opening 25 to remove the chemically treated occlusive material 52. The occlusive material 52 may thus be aspirated, desiccated, or in other ways mechanically attached to the expandable segments 17 by the negative internal pressure within the lumen 36.

Figure 9 illustrates the expandable intraluminal catheter 10 according to an alternative embodiment. This configuration comprises an expandable-contractible distal member 67 of an elongated shape 65. When the actuator 21 is moved to the forward position, the distal member 67 is compressed into a generally spherical shape 66. This expandable-contractible distal member 67 preferably comprises an elastomeric foam. The action required to perform the stretching and compression of this expandable-contractible distal member 67 is the same action required to expand and contract the expandable segments 17. The expandable-contractible distal member 67 provides an

additional function of further cleaning and removing small pieces of the occlusive material 52.

Although exemplary embodiments of the invention have been shown and described, many other changes, modifications and substitutions, in addition to those set forth in the above paragraph, may be made by one having ordinary skill in the art without necessarily departing from the spirit and scope of this invention.

CLAIMS

1. An expandable intraluminal catheter for removing occlusive material from a body passage, comprising:

a handle having a proximal handle end and a distal handle end;

an elongate tubular body having a proximal elongate tubular body end, a distal elongate tubular body end, and a lumen between the proximal elongate tubular body end and the distal elongate tubular body end, the proximal elongate tubular body end being connected to the distal handle end;

a plurality of radially-expandable segments disposed on the elongate tubular body near the distal elongate tubular body end;

a non-expandable member disposed within the lumen of the elongate tubular body, the non-expandable member having a proximal non-expandable member end connected to the proximal handle end and a distal non-expandable member end connected to the distal elongate tubular body end, the connection of the non-expandable member between the proximal handle end and the distal elongate tubular body end holding the distal non-expandable member end relatively stationary with regard to the proximal handle end; and

an actuator, connected to the proximal elongate tubular body end, for actuating the plurality of radially-expandable segments to radially expand and radially contract, the actuator actuating the plurality of radially-expandable segments to radially expand by moving the proximal elongate tubular body end toward the relatively stationary distal elongate tubular body end, the actuator actuating the plurality of radially-

expandable segments to radially contract by moving the proximal elongate tubular body end away from the relatively stationary distal elongate tubular body end.

2. The expandable intraluminal catheter according to Claim 1, wherein the plurality of radially expandable segments are progressively expanded upon actuation by the actuator, the plurality of expandable segments progressively expanding from a first, distally-located expandable segment to a last, proximally-located expandable segment.

3. The expandable intraluminal catheter according to Claim 1, wherein each of the plurality of radially expandable segments comprises one of a tubular woven, a tubular braided, and a tubular meshed material, and

wherein apertures are formed on each of the plurality of radially expandable segments, upon expansion of the segments by the actuator, to thereby allow for application of one of a pressure and a suction through the lumen to the apertures.

4. The expandable intraluminal catheter according to Claim 1, wherein the body passage comprises a blood vessel.

5. The expandable intraluminal catheter according to Claim 1, wherein the occlusive material comprises at least one of plaque, thrombi, emboli, and potential clotting agents within a blood vessel.

6. An expandable intraluminal catheter for removing occlusive material from a body passage, comprising:

an elongate tubular body having a proximal elongate tubular body end and a distal elongate tubular body end;

a plurality of radially-expandable segments disposed on the elongate tubular body near the distal elongate tubular body end; and

an actuator for actuating the plurality of radially-expandable segments to thereby cause the plurality of radially-expandable segments to progressively radially expand, the plurality of radially-expandable segments progressively radially expanding from a first distally-located expandable segment to a subsequent proximally-located expandable segment.

7. An expandable intraluminal catheter for removing occlusive material from a body passage, comprising:

an elongate tubular body having a proximal elongate tubular body end, a distal elongate tubular body end, and a longitudinal axis connecting the proximal elongate tubular body end and the distal elongate tubular body end;

a plurality of radially-expandable segments disposed on the elongate tubular body near the distal elongate tubular body end; and

an actuator for actuating the plurality of radially-expandable segments, to thereby cause, by means other than inflation, the plurality of radially-expandable segments to radially expand into semi-rigid enlarged-diameter segments.

8. The expandable intraluminal catheter according to Claim 7, wherein the plurality of radially-expandable segments are separated by a corresponding plurality of non-expandable segments, which are disposed

between the plurality of radially-expandable segments on the elongate tubular body near the distal elongate tubular body end.

9. The expandable intraluminal catheter according to Claim 8, wherein, when the radially-expandable segments are not radially expanded, the plurality of radially-expandable segments and the corresponding plurality of non-expandable segments form a relatively smooth surface on an exterior surface of the elongate tubular body to thereby allow the elongate tubular body to move within the body passage with relative ease.

10. The expandable intraluminal catheter according to Claim 9, wherein a width, measured in a direction parallel to the longitudinal axis of the elongate tubular body, of each of the plurality of radially-expandable segments is greater than a width of a corresponding adjacent one of the plurality of non-expandable segments.

11. The expandable intraluminal catheter according to Claim 10, wherein the actuator causes the plurality of radially-expandable segments to radially expand into semi-rigid enlarged-diameter segments, by moving the proximal elongate tubular body end and the distal elongate tubular body end toward one another,

wherein the larger widths, measured in a direction parallel to the longitudinal axis of the elongate tubular body, of the radially-expandable segments are attenuated as the radially expandable segments radially expand, and

wherein the smaller widths of the non-expandable segments do not attenuate as the non-expandable segments do not radially expand.

12. The expandable intraluminal catheter according to Claim 11, wherein the plurality of radially-expandable segments and the corresponding plurality of non-expandable segments are integrally formed with the exterior surface of the elongate tubular body, each radially-expandable segment being joined to an adjacent non-expandable segment at a bendable joint.

13. The expandable intraluminal catheter according to Claim 11, wherein each of the plurality of radially-expandable segments comprises an expandable, plastic, tubular braid and each of the corresponding plurality of non-expandable segments comprise a semi-rigid plastic tubing.

14. The expandable intraluminal catheter according to Claim 7, wherein a width of each of the plurality of radially-expandable segments is smaller than a width of an adjacent, distally-located, radially-expandable segment,

wherein each radially-expandable segment in the plurality of radially-expandable segments is progressively expanded upon actuation by the actuator, the plurality of expandable segments progressively expanding from a first distally-located expandable segment to a subsequent proximally-located expandable segment.

15. The expandable intraluminal catheter according to Claim 14, wherein the expandable intraluminal catheter further comprises:

a handle having a proximal handle end and a distal handle end; and

a wire disposed within the elongate tubular body, a proximal end of the wire being connected to the proximal handle end and a distal end of the wire being connected to the distal elongate tubular body end.

16. The expandable intraluminal catheter according to Claim 15, wherein the elongate tubular body has a lumen along the longitudinal axis of the elongate tubular body, the lumen accommodating the wire,

wherein the actuator is connected to the proximal elongate tubular body end, the actuator actuating the plurality of radially expandable segments to radially expand by moving the proximal elongate tubular body end toward the distal elongate tubular body end, the actuator actuating the plurality of radially expandable segments to radially contract by moving the proximal elongate tubular end away from the distal elongate tubular body end, while the non-expandable member maintains a constant distance between the proximal handle end and distal elongate tubular body end.

17. The expandable intraluminal catheter according to Claim 16, wherein each of the plurality of radially expandable segments comprises one of a tubular woven, a tubular braided, and a tubular meshed material, and

wherein apertures are formed on each of the plurality of radially expandable segments, upon expansion of the segments by the actuator, to thereby allow for application of one of a pressure and a suction to the apertures.

18. The expandable intraluminal catheter according to Claim 17, wherein the proximal handle end comprises a port, which is connected to the lumen, and

wherein one of a pressure and a suction is applied to the apertures through the port.

19. The expandable intraluminal catheter according to Claim 18, wherein the port in the proximal handle end comprises a luer type locking hub, which allows fluid to be inserted into the lumen to be excreted through the apertures, and which allows fluid to be drawn through the apertures and out of the lumen.

20. An expandable intraluminal catheter for removing occlusive material from a body passage, comprising:

a handle having a proximal handle end and a distal handle end;

an elongate tubular body having a proximal elongate tubular body end, a distal elongate tubular body end, and a lumen between the proximal elongate tubular body end and the distal elongate tubular body end, the proximal elongate tubular body end being connected to the distal handle end;

a plurality of radially-expandable segments disposed on the elongate tubular body near the distal elongate tubular body end;

an expandable distal member, located on the elongate tubular member between the distal elongate tubular body end and the plurality of radially-expandable segments;

a non-expandable member disposed within the lumen of the elongate tubular body, the non-expandable member having a proximal non-expandable member end and a distal

non-expandable member end, which is connected to the distal elongate tubular body end; and

an actuator for actuating the plurality of radially expandable segments to radially expand and radially contract, and for actuating the expandable distal member to radially expand and radially contract.

21. The expandable intraluminal catheter according to Claim 20, wherein the expandable distal member comprises a elastomeric foam, which, when expanded by the actuator, is deformable from an elongated shape into a generally spherical shape.

22. The expandable intraluminal catheter according to Claim 20, wherein the actuator causes the plurality of radially-expandable segments to progressively radially expand, the plurality of radially-expandable segments progressively radially expanding from a first distally-located expandable segment to a subsequent proximally-located expandable segment.

23. The expandable intraluminal catheter according to Claim 20, wherein the actuator causes the plurality of radially-expandable segments to progressively radially expand, the plurality of radially-expandable segments progressively radially expanding from both a first distally-located expandable segment and a second proximally-located expandable segment toward a central region to thereby move the occlusive material toward the central region.

24. The expandable intraluminal catheter according to Claim 20, wherein the expandable distal member comprises an inflatable balloon, which, when inflated, is deformable from an elongated shape into a generally spherical shape.

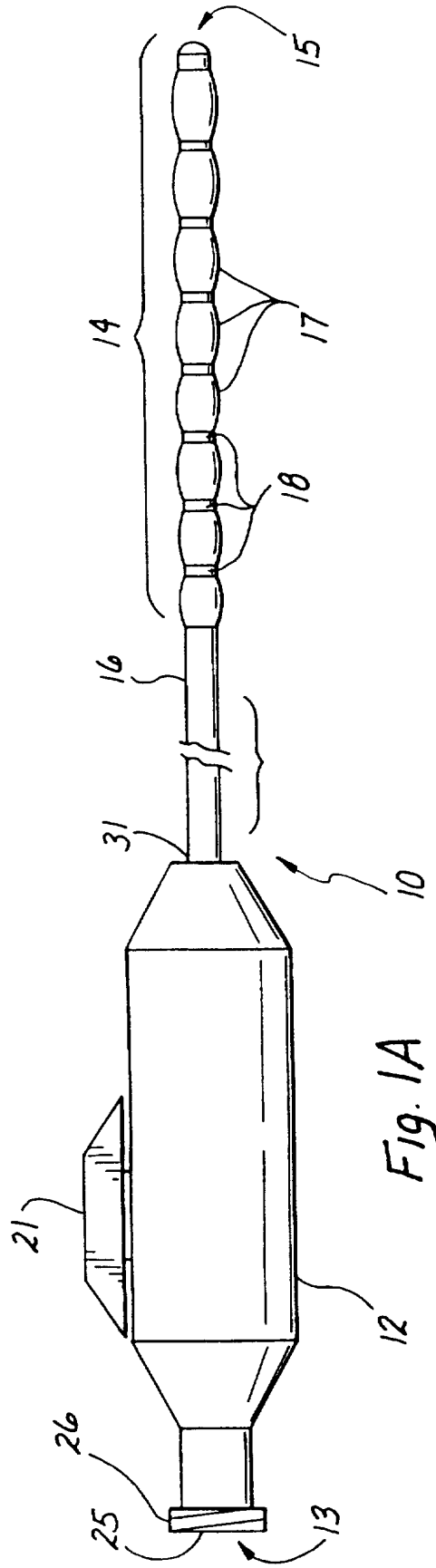


Fig. 1A

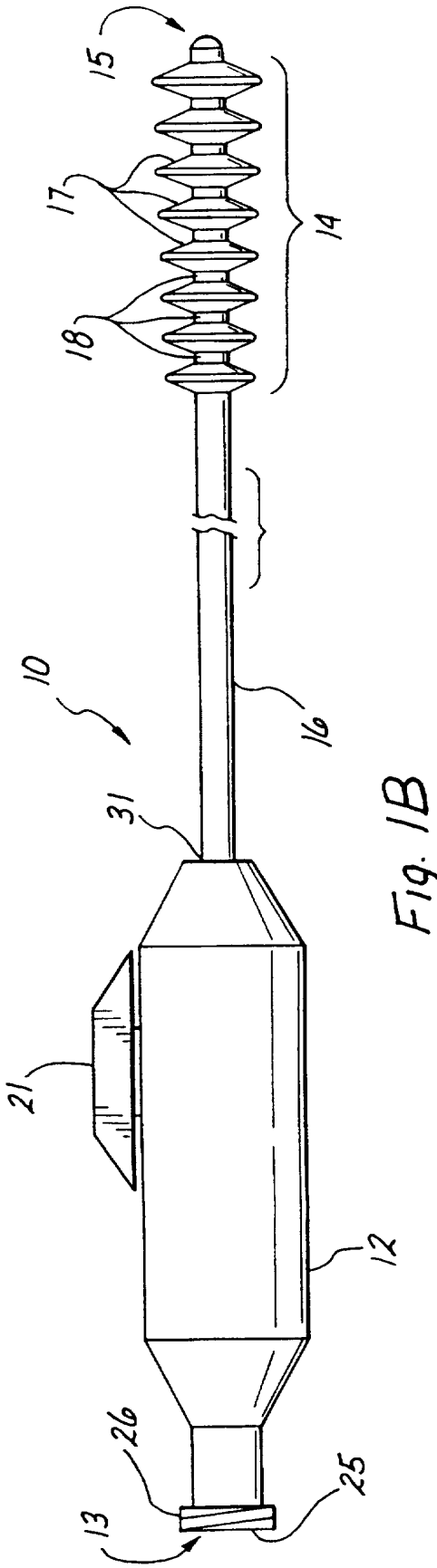


Fig. 1B

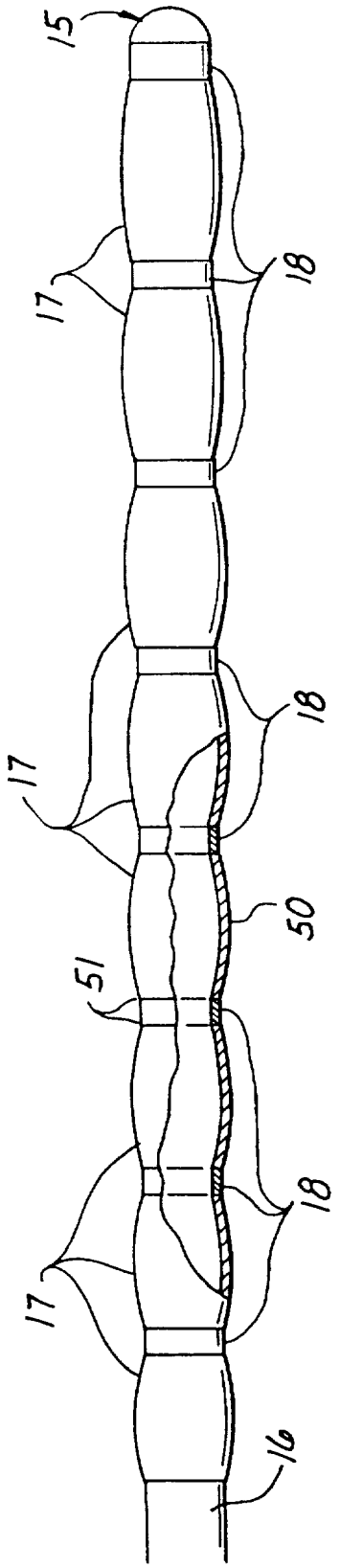


Fig. 2A

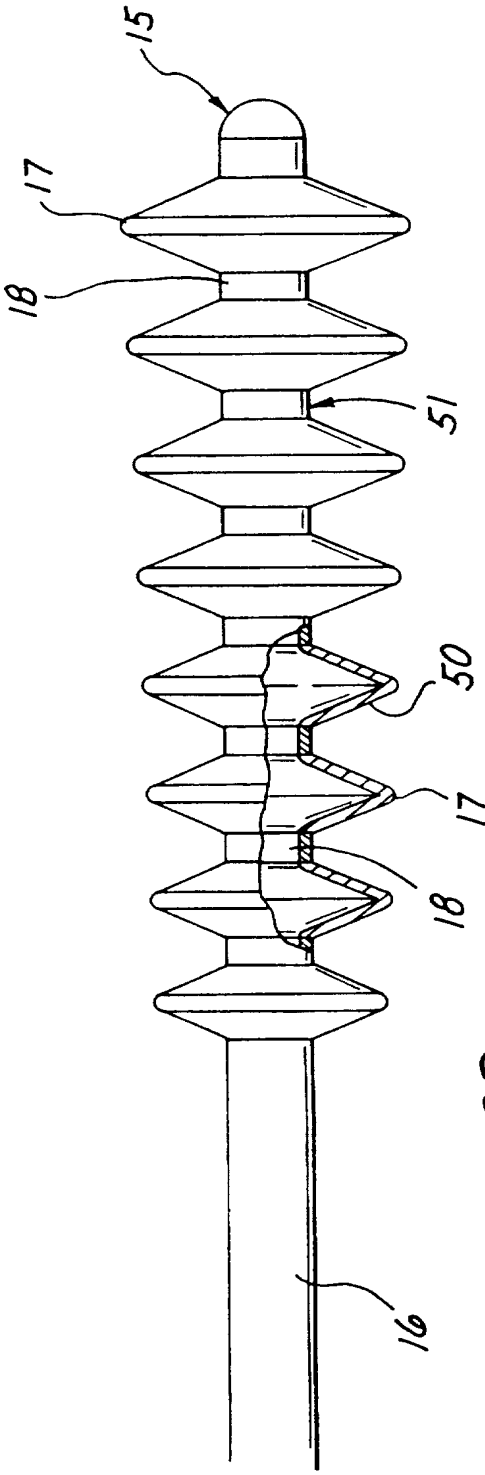


Fig. 2B

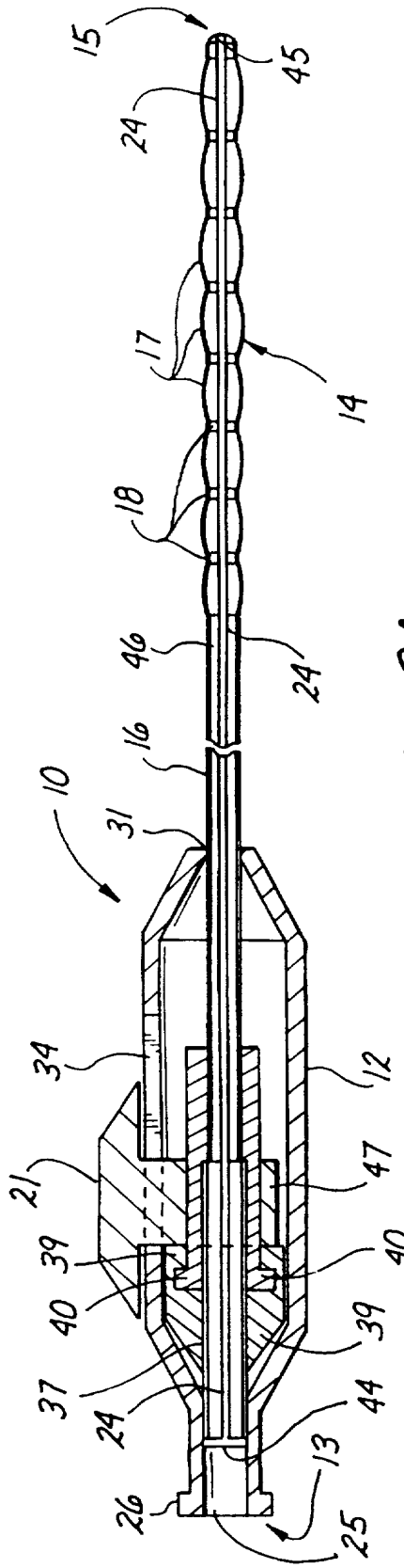

15
45
24
17
14
18
46
24
16
10
31
34
12
21
47
39
40
40
39
37
24
44
13
26
25

Fig. 3A

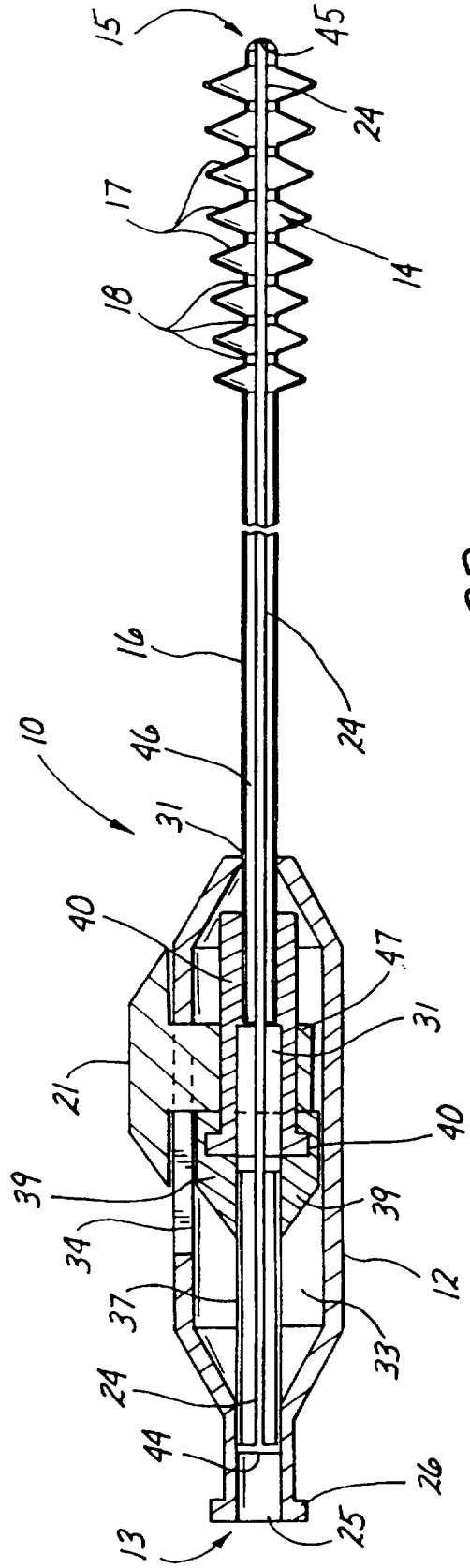

15
45
24
17
14
18
16
24
10
46
31
40
47
31
21
40
39
39
34
12
37
33
24
44
26
13
25

Fig. 3B

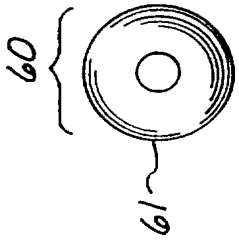


Fig. 4

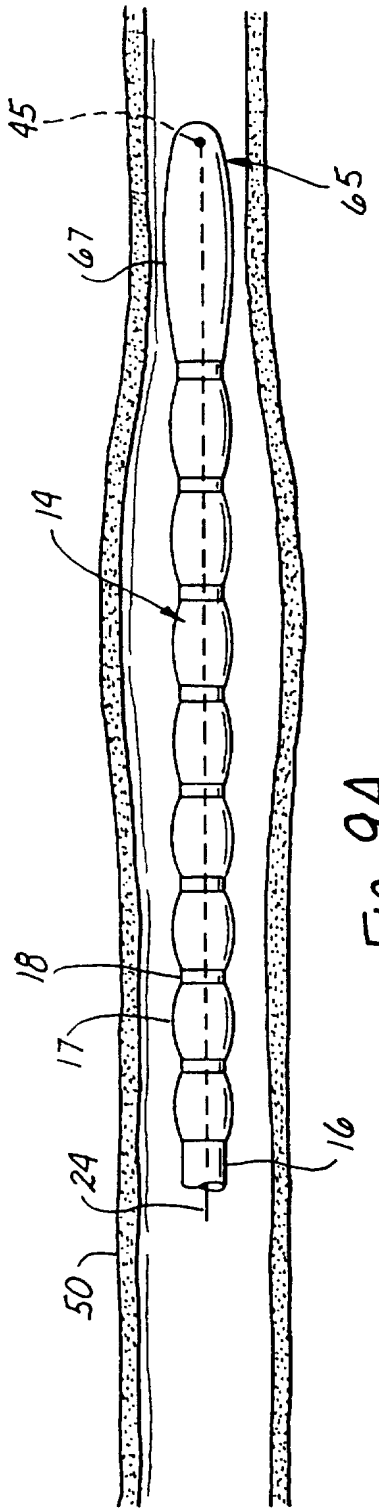


Fig. 9A

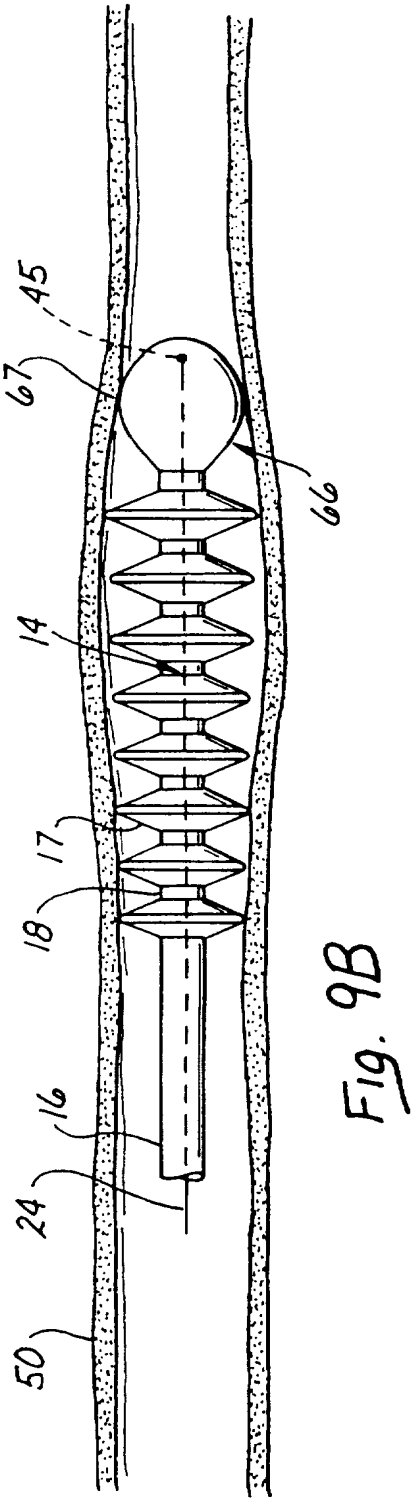


Fig. 9B

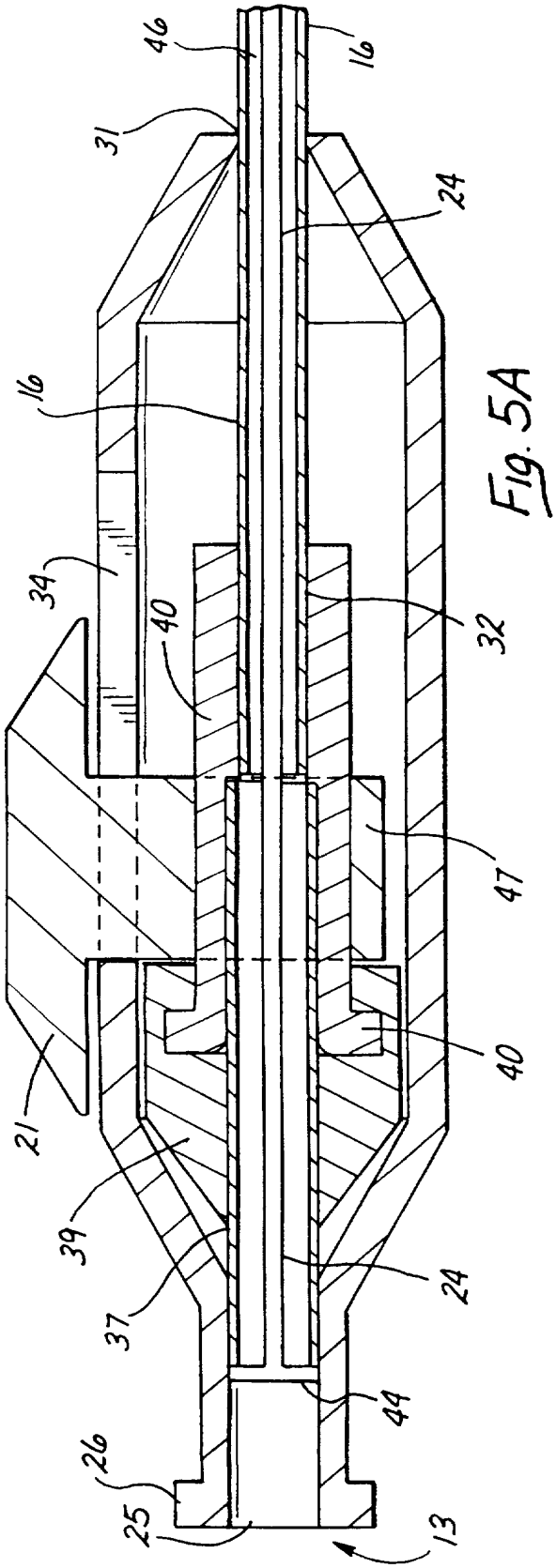

46
16
31
24
16
34
40
32
47
40
21
39
37
24
44
26
25
13

Fig. 5A

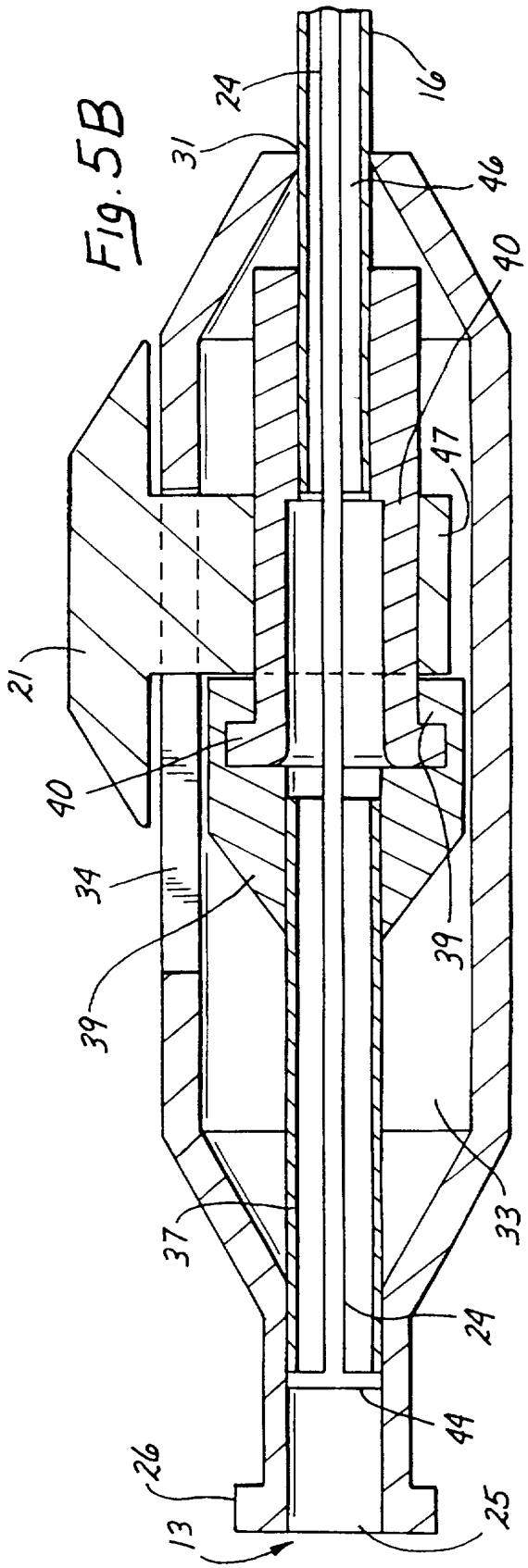

24
16
31
46
40
47
21
40
34
39
39
37
33
24
44
26
13
25

Fig. 5B

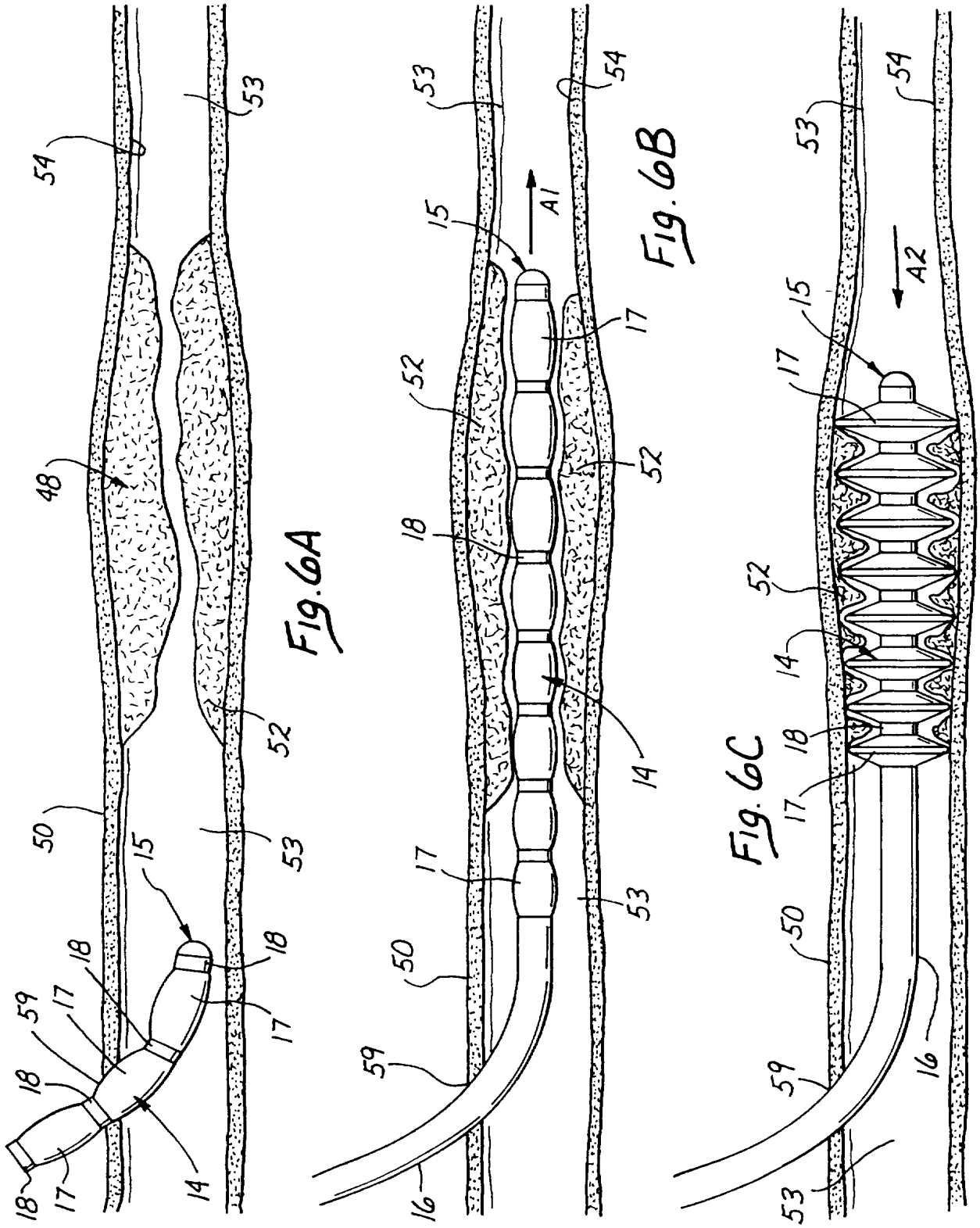


Fig. 6A

Fig. 6B

Fig. 6C

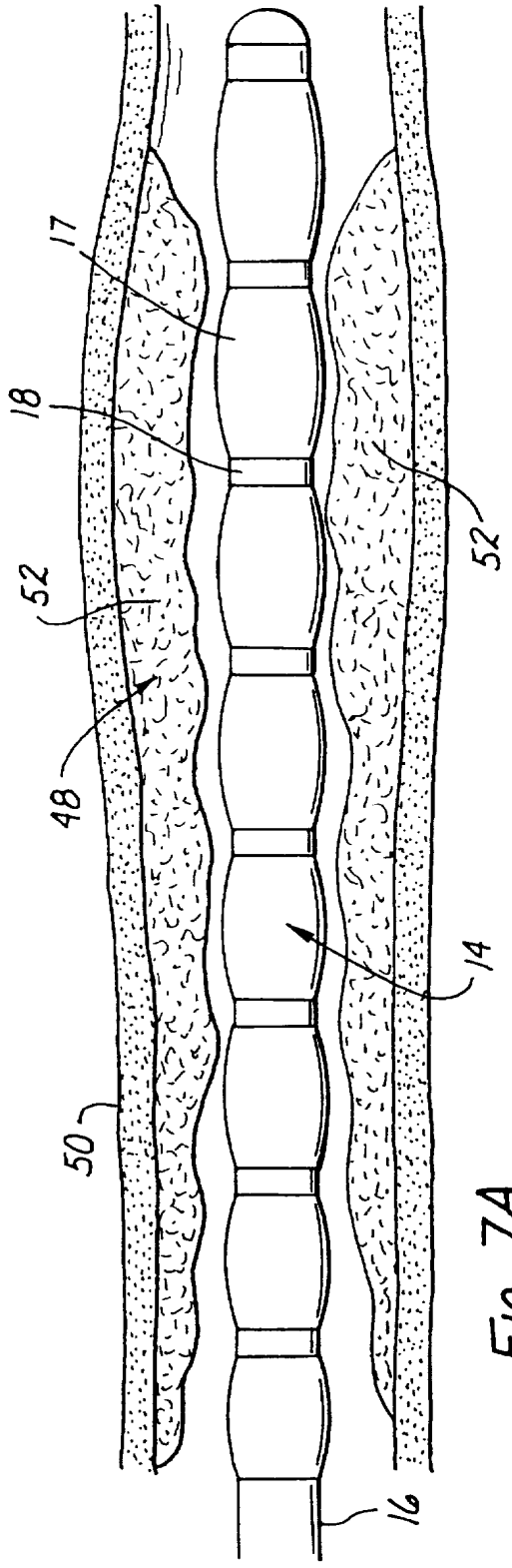


Fig. 7A

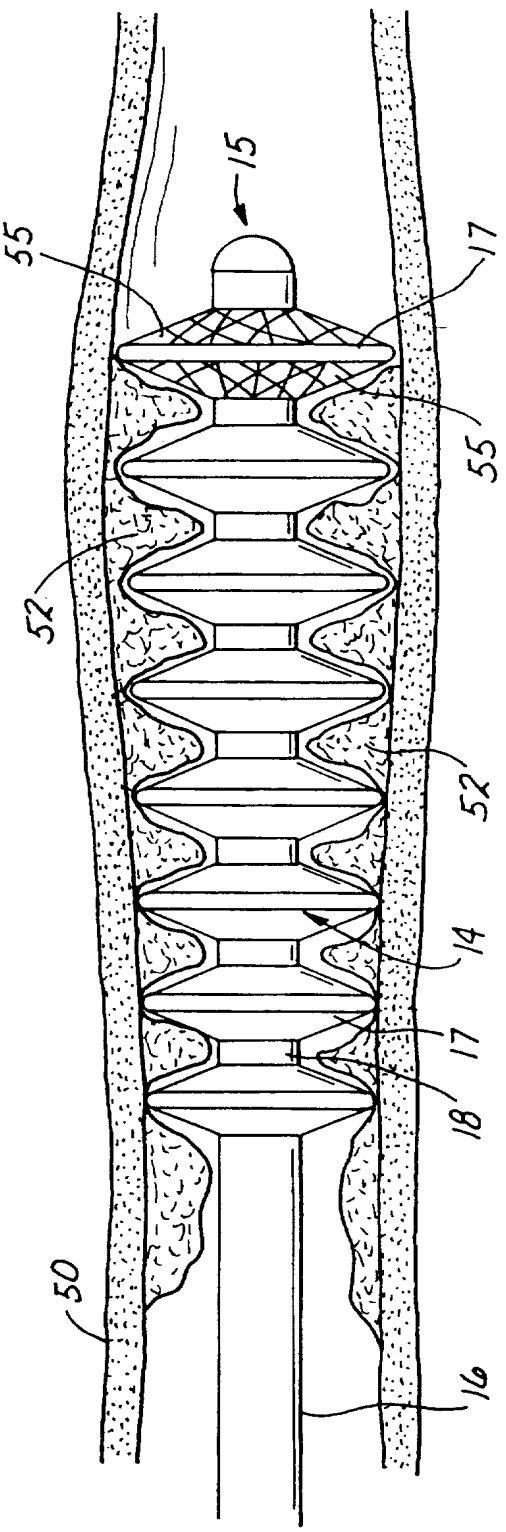


Fig. 7B

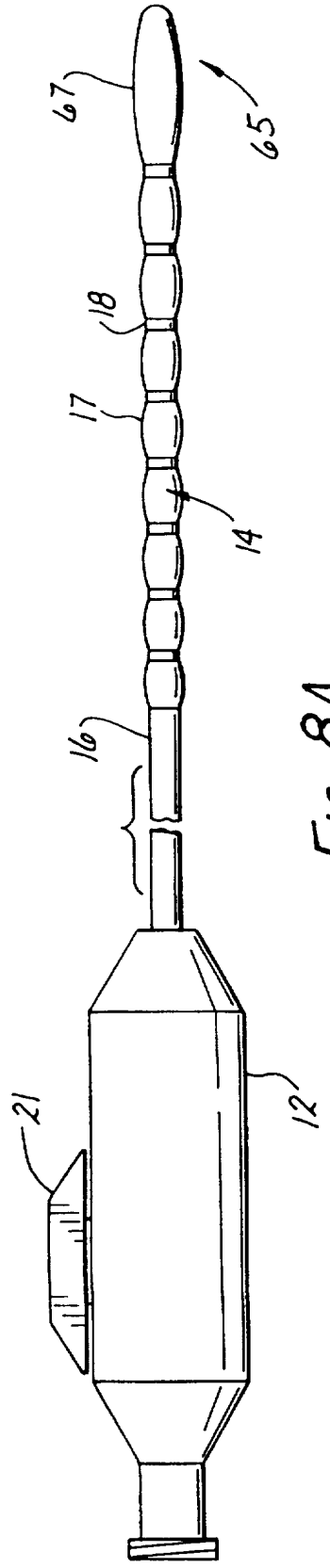


Fig. 8A

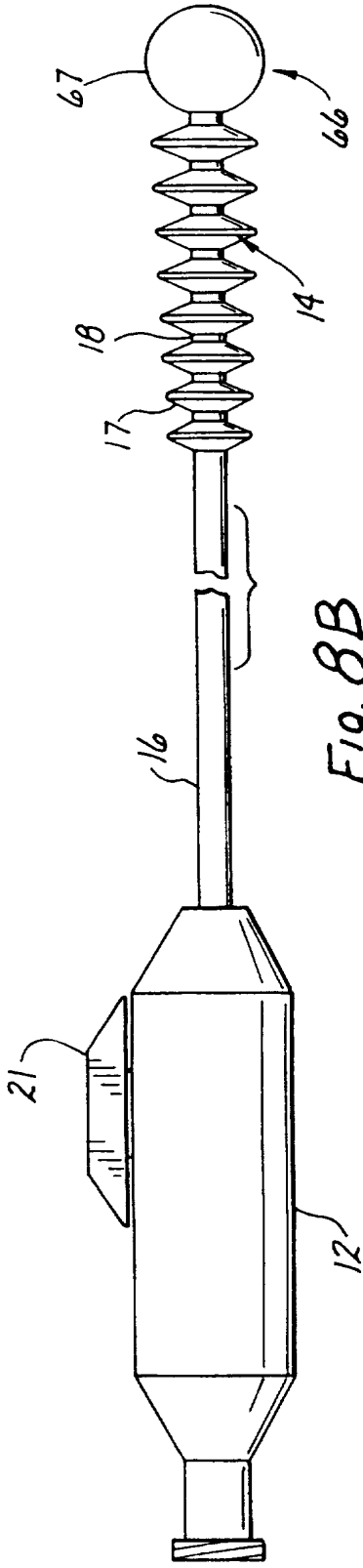


Fig. 8B

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
02 November 2017 (02.11.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/189615 A1

(51) International Patent Classification:
A61B 17/22 (2006.01) *A61B 17/221* (2006.01)

(21) International Application Number:
PCT/US2017/029472

(22) International Filing Date:
25 April 2017 (25.04.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

62/327,024	25 April 2016 (25.04.2016)	US
62/345,152	03 June 2016 (03.06.2016)	US
62/357,677	01 July 2016 (01.07.2016)	US

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

(72) Inventors: **GREENHALGH, E., Skott**; 1426 Rose Glen Road, Gladwyne, Pennsylvania 19035 (US). **WALLACE, Michael, P.**; 5849 Corte Margarita, Pleasanton, California 94566 (US).

(74) Agent: **BURSE, David, T.** et al.; Vista IP Law Group LLP, 21760 Stevens Creek Blvd., Suite 100, Cupertino, California 95014 (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, 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).

Published:
— *with international search report (Art. 21(3))*

(54) Title: CLOT-ENGULFING MECHANICAL THROMBECTOMY APPARATUSES

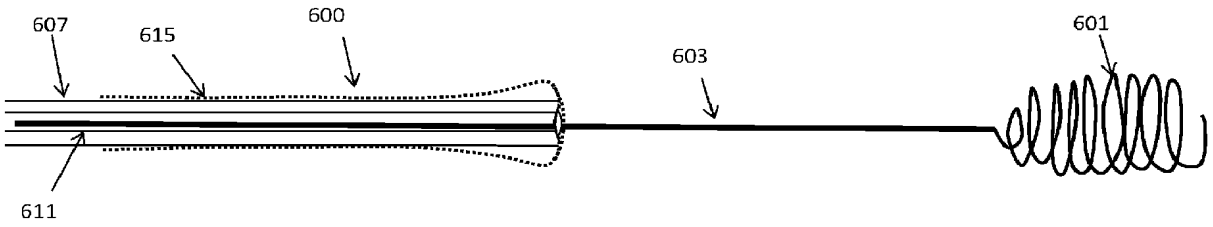


FIG. 6I

(57) Abstract: Mechanical thrombectomy systems including an elongate catheter configured as an elongate inversion support, a flexible tractor configured to roll and invert over the distal end of the elongate inversion support, and a clot engaging member on the distal end of an elongate manipulator are described herein. These systems may capture a clot using the clot engaging member and draw the clot and clot engaging member and roll the flexible tractor into the catheter to remove the clot and clot engaging member from a vessel.

WO 2017/189615 A1

CLOT-ENGULFING MECHANICAL THROMBECTOMY APPARATUSES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to U.S. provisional patent application no. 62/327,024, filed on April 25, 2016 and titled "DOZER THROMBECTOMY SYSTEM"; U.S. provisional patent application no. 62/345,152, filed on June 3, 2016, and titled "DOZER THROMBECTOMY SYSTEM 2"; and U.S. provisional patent application no. 62/357,677, filed on July 1, 2016, and titled "DOZER THROMBECTOMY SYSTEM 3".

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

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

INCORPORATION BY REFERENCE

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

FIELD

[0005] The apparatuses described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods for removing a clot, including removing a clot captured by a clot capture device (e.g., a clot engaging member on the distal end of an elongate manipulator) with a rolling tractor that pulls the clot and clot capture device into a catheter.

BACKGROUND

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

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

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

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

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

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

SUMMARY OF THE DISCLOSURE

[00011] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using them to remove a thrombus, e.g., clot, including safely and easily removing a clot that is captured in a second clot-grabbing (e.g., thrombectomy) apparatus. The mechanical thrombectomy apparatuses described herein may be inverting tractor thrombectomy apparatuses. An inverting tractor apparatus may include a tractor (tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts as it rolls over itself at a distal end. The tractor may be inverted and/or rolled over the end of a catheter. Thus, the flexible tractor may invert and fold back into itself and may be drawn into a catheter portion in a conveyor-like motion as it rolls around to transition from an outward-facing region of the tractor on an outside of the catheter to an inward-facing region within the lumen of the catheter. The rolling motion may draw a clot and/or clot connected to a clot-grabbing apparatus within a vessel into the catheter, which may also compress and/or macerate the clot. The apparatus, including the clot, and in some variations clot and a clot engaging member engaged with the clot, may then be removed from the body.

[00012] Any of these apparatuses may include, or may be used as part of a system with, a clot capture device having a clot engaging member (e.g., a "stentriever") at the distal end of an elongate manipulator.

[00013] The mechanical thrombectomy apparatuses described herein may include pre-loaded inverting tractor thrombectomy apparatuses (e.g., devices, systems, etc.). Described herein are mechanical thrombectomy apparatuses, including inverting tractor thrombectomy apparatuses that may engulf a clot prior to pulling it (e.g., into the apparatus) and may be used in combination with other systems. Such apparatuses may invert over clot first, and may then pull the clot into the catheter. Any of these apparatuses may also incorporate aspiration.

[00014] Described herein are mechanical thrombectomy systems that include an elongate inversion support (typically comprising a catheter), a flexible tractor that inverts over the distal end opening of the elongate inversion support, a puller extending proximally to roll and

invert the tractor into the distal end opening, and a clot engaging member on the distal end of an elongate manipulator. The puller and tractor are configured to pass the elongate manipulator through a lumen extending continuously through the puller and the tractor. As described above, in operation, this may be used to slide the rolling thrombectomy portion (e.g., the elongate inversion support, a flexible tractor and a puller) over the elongate manipulator of the clot capture device (e.g., clot engaging member on the distal end of an elongate manipulator).

[00015] For example, described herein are mechanical thrombectomy systems including: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor 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; a puller connected to the first end of the tractor extending proximally; a clot engaging member on the distal end of an elongate manipulator; and a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator.

[00016] In any of these apparatuses (e.g., systems, devices, etc.), the tractor may be sufficiently soft such that without support from the catheter, it collapses radially under an axial compression of less than a small force (e.g., less than 50g of force, 100g of force, less than 150 g of force, less than 200g of force, less than 250 g of force, less than 300 g of force, etc.) when inverting.

[00017] Further, in any of these apparatuses, the tractor may be biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration.

[00018] The clot engaging member may be expandable. For example, the clot engaging member may be one or more of: a coil, a snare, a basket, or a frame. The elongate manipulator may be a wire, tube (e.g., hypotube), rod, etc.

[00019] Any appropriate flexible tractor may be used. For example, the tractor may be one or more of: a braided material, a knitted material, or a woven material. The tractor is typically a tube of material. The tractor may comprise steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.

[00020] The catheter of the elongate inversion support may extend the full length of the inversion support, or it may be just at the end of the elongate inversion support. The catheter

may be soft (e.g., appropriate for neurovascular use), however the tip may be harder, to resist collapse. For example, the material hardness of catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile.

[00021] The tractor may be lubricious and/or may comprise one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating. The tractor may be any appropriate length (e.g., between about is 3 cm to 100 cm long, between about 10 cm to 200 cm long, between about 3 cm to 50 cm long, between about 200 cm to 500 cm long, etc.).

[00022] Any of these apparatuses may be configured to controllably deploy the tractor, which may be held compressed and/or against the catheter of the elongate inversion support until being deployed. For example, any of these apparatus may include a releasable attachment between the tractor and an outer surface of the catheter (e.g., a tractor hold), wherein the releasable attachment is configured to release when the tractor is pulled (e.g., proximally by the puller) with a force that is greater than a predetermined force threshold. The deployment force threshold may be between 50g and 500g of force (e.g., between 50g and 400g of force, between 100g and 400g of force, etc.).

[00023] Any of these apparatuses may include a sleeve extending over the catheter and tractor. The sleeve may be an outer or intermediate catheter.

[00024] A mechanical thrombectomy system for removing a clot from within a vessel may include: an elongate inversion support comprising a catheter having a distal end and a distal end opening; a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor 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; a puller extending proximally within the catheter and connected to the first end of the tractor; an expandable clot engaging member on the distal end of an elongate manipulator, wherein the expandable clot engaging member comprises one or more of: a coil, a snare, a basket, or a frame; and a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator.

[00025] In operation, these systems may be used to withdraw a thrombus (clot) from within a vessel, including peripheral vessels or neurovascular vessels. For example,

described herein are methods of removing a clot from within a vessel using a mechanical thrombectomy apparatus. These methods generally include rolling the tractor into the catheter by pulling proximally on the tractor (e.g., by pulling on a puller that extends proximally and is attached to the first end of the tractor within the catheter) to roll the tractor into the catheter. The conveyer-belt like tractor motion, either alone or in conjunction with aspiration applied from the proximal end through the mechanical thrombectomy apparatus (e.g., catheter) and/or an outer catheter within which the mechanical thrombectomy apparatus is passed, may be used to pull a clot into the catheter. Typically when drawing the clot into the apparatus (e.g., into the catheter portion of the apparatus), the clot, or a clot and additional clot engaging member coupled to the clot, may be compressed as it is drawn into the apparatus.

[00026] In some cases, the clot may clog or jam in the apparatus. Described herein are methods of removing a clot from within a vessel using a mechanical thrombectomy apparatus, including methods configured to avoid or correct jamming and/or clogging of the apparatus. The method may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to the clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and pull the clot into the catheter with the inverting tractor; withdrawing the catheter proximally away from the tractor and clot when the tractor jams on the distal end of the catheter; pulling the first end of the tractor proximally so that the tractor inverts over the clot within the vessel without rolling over the distal end opening of the catheter; and withdrawing the tractor and clot proximally from the vessel.

[00027] Any of the methods described herein may include releasing the tractor from a locked or secured position on the outside of the catheter of the apparatus. Thus, any of these apparatuses used herein may include a tractor hold that releasably secures the tractor to the outside of the catheter. For example, any of the methods described herein may include disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall, wherein the second end of the tractor is disengaged before pulling the first end of the tractor proximally.

[00028] Once the clot and/or clot engaging member has been engulfed by the tractor, it may then be withdrawn back into the catheter, without requiring the tractor to invert over the catheter. For example, any of the methods described herein may also or alternatively include pulling proximally on the tractor to draw the tractor and clot into the catheter.

[00029] Pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter may comprise advancing the catheter while pulling the first end of the tractor. Alternatively or additionally, pulling the first end of the tractor proximally so that the tractor inverts over the clot may further comprise pulling the catheter proximally with the first end of the tractor. Alternatively or additionally, pulling the first end of the tractor proximally so that the tractor inverts over the clot may comprise pulling a puller at the proximal end of the mechanical thrombectomy apparatus proximally.

[00030] Withdrawing the catheter proximally away from the tractor may comprise pulling the catheter proximally a short distance or a substantial distance. For example, the catheter may be pulled proximally only sufficiently far to disengage the jam of the clot (and/or clot engaging member) from the catheter distal end opening. Alternatively or additionally, withdrawing the catheter proximally away from the tractor (the tractor distal-facing end) may include pulling the catheter beyond a second end of the tractor that is outside of the catheter.

[00031] Alternatively or additionally, the catheter may be pulled proximally with the first end of the tractor (e.g., the tractor puller) as the tractor is pulled proximally so that the tractor inverts over the clot within the vessel without rolling over the distal end opening of the catheter.

[00032] In any of the methods described herein the tractor may be expanded to that all or a portion of the tractor contacts the wall of the vessel. Thus, the tractor may be expanded when released (e.g., from the tractor hold) to contact the wall of the vessel. Any of the tractors described herein may be biased (e.g., heat set, etc.) so that it expands (when over the catheter) to approximately 1x or more (e.g., 1.1x, 1.2x, 1.3x, 1.4x, 1.5x, etc.) the diameter of the vessel. Contact between the vessel wall and the tractor may provide resistance that enhances the ability of the tractor to invert when the first end of the tractor is pulled proximally without inverting over the distal end opening of the catheter. Pulling the first end of the tractor proximally so that the tractor inverts over the clot may comprise pulling the first end of the tractor when the tractor has expanded to contact the vessel wall.

[00033] In any of the methods described herein, a guidewire, catheter or the like may be used to position the apparatus near, adjacent to, or on the clot. For example, positioning the distal end of the mechanical thrombectomy apparatus adjacent to the clot may comprise

sliding the mechanical thrombectomy apparatus over a guidewire or catheter passing through a lumen in the mechanical thrombectomy apparatus.

[00034] A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to the clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall; pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and pull the clot into the catheter with the inverting tractor; withdrawing the catheter proximally away from the tractor and clot when the tractor jams on the distal end of the catheter; pulling the tractor and clot proximally so that the tractor inverts over the clot within the vessel without rolling over the distal end opening of the catheter; pulling proximally on the tractor to draw the tractor and clot into the catheter; and withdrawing the tractor and clot proximally from the vessel.

[00035] Also described herein are methods of removing a clot from within a vessel using a mechanical thrombectomy apparatus in which a secondary clot-grabbing device (e.g., generally referred to herein as a clot engaging member), which may be a secondary device or a part of the mechanical thrombectomy apparatuses described herein, is removed with the clot. Any appropriate clot engaging member may be used. In particular, a clot engaging member may include an expandable/compressible clot engaging member that is configured a frame or wire. For example, a clot engagement member may be an expandable coil or plurality of coils, snare, basket, or frame. Any of these clot engagement members may include an elongate manipulator (e.g., an elongate wire, catheter, shaft, member, etc.) attached to the clot engagement member, such as the proximal end of the clot engagement member.

[00036] Any of the methods described herein may include tracking over the clot engaging member, including sliding over the elongate member attached to the clot engagement member. The mechanical thrombectomy apparatus may be guided to the clot and/or clot engagement member by sliding distally over an elongate member attached to a clot engagement member that has been previously coupled with a clot.

[00037] The clot engagement member may be coupled to the clot by passing into and/or through the clot. For example, the clot engagement member may be passed into the clot where it may engage with the clot material and expanded into the clot. Alternatively or additionally, the clot engagement member may be passed through the clot and expanded distally of the clot so that it may drive the clot proximally when the clot engagement member is pulled proximally, e.g., by pulling proximally on the elongate member coupled to the clot engagement member.

[00038] For example a method of removing a clot from within a vessel using a mechanical thrombectomy apparatus may include: engaging the clot with a clot engaging member on the distal end of an elongate manipulator; sliding the mechanical thrombectomy apparatus over the elongate manipulator to position the distal end of the mechanical thrombectomy apparatus adjacent to the clot, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; pushing the catheter distally while holding the first end of the tractor within the catheter fixed relatively to the elongate manipulator so that the tractor rolls and inverts over the distal end of the catheter and pulls the clot and the clot engaging member into the catheter with the inverting tractor; and withdrawing the mechanical thrombectomy apparatus, clot and clot engaging member proximally from the vessel.

[00039] As mentioned, the clot engaging member may engage with the clot by expanding into the clot and/or beyond the clot. For example, engaging the clot with the clot engaging member on the distal end of the elongate manipulator may comprise expanding the engaging member within the clot. Engaging the clot with the clot engaging member on the distal end of the elongate manipulator may comprise expanding the engaging member on a distal side of the clot. In general, engaging the clot with the clot engaging member on the distal end of the elongate manipulator may comprise expanding the engagement member. For example, the engaging member may comprise an expandable coil(s), snare, basket, or frame.

[00040] In any of these methods in which a clot engaging member is used with the rolling mechanical thrombectomy apparatus, the apparatus may be advanced distally over the apparatus to capture the clot and clot engaging member. For example, in any of these methods pulling the first end of the tractor proximally may comprise advancing the catheter distally as the tractor is pulled proximally. Engulfing the clot and/or clot engaging member by advancing distally over the clot and/or clot engaging member may be particularly

beneficial compared to methods in which the clot and clot engaging member are drawn proximally to be engulfed.

[00041] In any of these apparatuses, pulling the first end of the tractor proximally may comprise pulling a puller proximally wherein the puller is coupled to the first end of the tractor. Alternatively or additionally, pulling the first end of the tractor proximally may comprise pulling the elongate manipulator proximally with the first end of the tractor.

[00042] Any of these methods may also include releasing the tractor from the catheter. For example, any of these methods may include disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall.

[00043] A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus may include: engaging the clot with a clot engaging member on the distal end of an elongate manipulator; sliding the mechanical thrombectomy apparatus over the elongate manipulator to position the distal end of the mechanical thrombectomy apparatus adjacent to the clot, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; sliding the mechanical thrombectomy apparatus over the elongate manipulator to position the distal end of the mechanical thrombectomy apparatus adjacent to the clot, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; and withdrawing the mechanical thrombectomy apparatus, clot and clot engaging member proximally from the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[00044] 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:

[00045] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot form a body region (e.g., a rolling mechanical thrombectomy apparatus). FIG. 1A shows an example of an elongate inversion support portion of an apparatus,

configured as a catheter portion. For example, at least the distal end of the elongate inversion support may be configured as a catheter. FIG. 1B shows an enlarged view of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube) extending from a puller (the puller in this example is configured as a catheter. The tractor is shown in a first (e.g., un-inverted) configuration) and may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus with the elongate inversion support and the flexible tube forming the tractor is shown. The tractor extends through the catheter of the elongate inversion support and doubles back over the distal end opening of the catheter and extends over the outer diameter of the catheter. The outer portion of the tractor (extending along the outer diameter of the catheter) may be held in a collapsed configuration (as shown in FIG. 1E), or it may be expanded, as shown in FIG. 1F. Thus, the tractor may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. FIGS. 1G and 1H illustrate the use of the apparatus of FIGS. 1E and 1F to remove a clot by drawing the flexible tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00046] 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).

[00047] FIGS. 2A-2G illustrate a method of capturing a clot with a rolling mechanical thrombectomy apparatus after it has jammed or clogged the catheter of the rolling mechanical thrombectomy apparatus.

[00048] FIGS. 3A illustrates an example of a rolling mechanical thrombectomy apparatus in which the clot has jammed while rolling the tractor into the distal end opening of the

catheter portion of the rolling mechanical thrombectomy apparatus, similar to that shown in FIG. 2B. FIG. 3B illustrates an example of the clot engulfed by the tractor as illustrated in FIGS. 2C-2F. As shown in FIG. 2F and 2G, the clot and tractor may then be drawn proximally out of the vessel, including by drawing proximally into the catheter first.

[00049] FIGS. 4A-4G illustrate an example of a rolling mechanical thrombectomy apparatus in which the clot has jammed while rolling the tractor into the distal end opening of the catheter portion of the rolling mechanical thrombectomy apparatus.

[00050] FIGS. 5A-5C illustrate examples of clot engaging members coupled to elongate manipulators that may be used with any of the apparatuses described herein.

[00051] FIGS. 6A-6H illustrate a method of capturing a clot engaged with a clot engagement member by advancing a rolling mechanical thrombectomy apparatus over the clot and clot engagement member.

[00052] FIG. 6I illustrates an example of a mechanical thrombectomy system for removing a clot from within a vessel.

[00053] FIGS. 7A-7B illustrate a method of capturing a clot engaged with a clot engagement member as described herein.

DETAILED DESCRIPTION

[00054] In general, described herein are mechanical thrombectomy apparatuses and methods of using them to remove clots. The mechanical thrombectomy apparatuses descried herein may have an inverting tractor region and an elongate inversion support having a distal annulus over which the tractor rolls and inverts over itself. Any of these apparatuses and methods of using them may be configured to prevent premature deployment of the tractor. The elongate inversion support may be a catheter having a distal end opening. The tractor may comprise a flexible tube that may be formed of a sheet having openings, or may be a woven, braided, knitted, etc. material such as a fiber. The tractor may extend longitudinally within the elongate inversion support and may and double back (e.g., invert) over the annulus of the elongate inversion support (e.g., the distal end of a catheter) so that it extends along the midline of the apparatus; when the elongate inversion support is a catheter, the tractor may extend within the catheter lumen. The tractor may connect to an inner puller that is typically coupled to an end of the tractor (which may be referred to as the inner end or the distal end) that can be pulled proximally to pull and invert the tractor over the distal end so that it rolls over the distal end, which may capture a clot. The apparatus may include a guidewire lumen extending through the catheter, tractor and/or tractor puller.

[00055] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support having a distal end and a distal annulus, and a flexible tractor assembly at least partially inverted and configured to roll and invert over the distal annulus of the elongate inversion support.

[00056] In many of the examples described herein, the elongate inversion support is a catheter (or a portion of a catheter at the distal end) and the annulus is formed by the distal end opening of the catheter; the tractor extends within the catheter and doubles back over the distal end of the catheter to extend over the outer diameter of the catheter at the distal end of the catheter, although it may extend proximal for any appropriate distance (including between 1-30 cm, between 2-20 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). The end of the tractor within the catheter may be coupled to a pusher (e.g., at a proximate pusher region connected to the distal or inner end of the tractor). The tubular tractor may include an elongate lumen that is configured to allow passage of a guidewire. The tubular tractor may also be configured to slide along the long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor may be referred to herein as a tractor assembly, tractor portion, tractor tube, or simply a tractor, and is typically positioned and longitudinally slideable within the catheter, and arranged so a portion of the tractor (sometimes referred to as the "distal tractor region" or "distal-facing" tractor region) doubles back over itself.

[00057] 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, 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.

[00058] FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00059] In FIG. 1A, the elongate inversion support is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include a elongate inversion support that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like (as will be described in greater detail below in reference to FIGS. 7A-8D) or may be skived. Thus, any of the apparatuses and methods described herein may be adapted for use with an elongate inversion support that is not limited to catheters, including elongate inversion supports that include a portion of a catheter, or that include a ring or other structure forming the annulus at the distal end. In FIG. 1A the catheter 100 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00060] 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).

[00061] FIG. 1C shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1D. In FIG. 1D, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00062] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor 144 and a less expandable (or non-expandable) proximal portion comprising the puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00063] In FIG. 1E, the flexible tractor of FIG. 1C is shown with the tractor doubled back over itself an over the the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration, as shown in FIG. 1F, the tractor in this second configuration (e.g., the portion that is inverted over the distal end of the catheter)

has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration (shown in FIG. 1F) inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[00064] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter of an elongate inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be "loose" relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[00065] These apparatuses may be highly flexible, both before actuating and during operation. For example, in general, the flexible tractor may not increase the stiffness/flexibility of the catheter, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00066] In any of the apparatuses described herein, in which the tractor is at least partially inverted over the distal end of the catheter so that the tractor extends on the outer surface of the catheter, the tractor may be releasably coupled to the outer diameter of the catheter to allow the apparatus to be inserted through a body, including through tortious vessels in the body, prior to being deployed to remove a clot or other element from the vessel. The tractor may be a braided, woven or knit material tube of material that is inverted over the distal end of the catheter; alternatively the tractor may be formed of a sheet of material that include openings therethrough.

[00067] Any of the apparatuses described herein may be adapted to prevent premature deployment of the tractor, e.g., by including a tractor hold (e.g., a housing, a lock, a clamp, etc.) or the like to secure the outer end of the tractor against and/or relative to the elongate inversion support. For example, a tractor hold may secure the outer end of the tractor against a catheter into which the tractor inverts when pulled proximally by the puller.

[00068] The tractor hold may compress the tractor against the catheter. Typically, the threshold force for the tractor hold is determined by the force required to deploy the tractor within the lumen, which may depend upon the length of the apparatus, the diameter of the tractor and/or catheter, and the materials of the tractor and elongate inversion support (e.g., catheter). For example, the tractor hold may be configured to hold the second end of the tractor until the threshold force is applied, wherein the threshold force is between 100 g force and 2000 g force (e.g., between 50 g of force and 2000 g of force, between 50 g of force and 1500 g of force, between 40 g of force and 1000 g of force, between 50 g of force and 500 g of force, between 100g of force and 500 g of force, between 200 g of force and 500 g of

force, between 250 g of force and 500 g of force, between 50 g of force and 450 g of force, between 100 g of force and 450 g of force, between 100 g of force and 400 g of force, between 200 g of force and 400 g of force, etc.). The range of force appropriate to the threshold force may be important in proper functioning of the apparatus, particularly when the force is applied by pulling proximally on the puller and/or tractor; too little force for the threshold and the tractor will prematurely deploy; too much force and the apparatus will jam (e.g., by kinking the elongate inversion support).

[00069] In any of the variations described herein, the tractor may be biased to collapse and/or expand. For example, the tractor may be biased to collapse over the catheter outer diameter (e.g., the outer diameter of the elongate inversion support, including the distal end of the catheter); such tractors may also be biased to expand after inverting (e.g., within the catheter) over the distal end opening of the elongate inversion support. This arrangement may cause the tractor to form a distal-facing region that flares, trumpet-like, towards a clot distal to the device, which may help in capturing the clot and also may prevent jamming of the tractor. Alternatively or additionally, some or all of the tractor regions may be configured to expand over the outer diameter of the elongate inversion support.

[00070] The proximal end of the tractor hold may be attached to the catheter. The tractor hold may be fixed, fused, or integrally formed with the catheter.

[00071] Any of the apparatuses described herein may be used to withdraw a clot and/or a clot engaging member. For example, FIGS. 2A-2G illustrate removal of a clot using a rolling thrombectomy apparatus. The apparatus may also be referred to as an inverting thrombectomy apparatus. In any of the variations described herein a vacuum may be used to help secure the clot to the tractor.

[00072] In FIG. 2A, the rolling mechanical thrombectomy apparatus 200 is brought near to the clot 220. In this example, a guidewire 205 may be used to help position the apparatus adjacent to the clot. The guidewire may be left in place or removed. Alternatively, as described in variations in which a clot engaging member on the distal end of an elongate manipulator is used, the apparatus 200 may be directed over the elongate manipulator. In FIG. 2A, the rolling thrombectomy apparatus includes a tractor 203 that is configured to roll over the distal end opening of a catheter 207. In FIG. 2A, the tractor is held in tension by holding in a fixed position relative to the catheter at a second (outer) end of the tractor; a tractor hold (not shown in FIG. 2A) may be used to releasably hold an end of the tractor fixed relative to the catheter. When a force sufficient to overcome the deployment force (e.g., 100 g of force or greater, 200 g of force or greater, etc.) is applied by pulling 219 the first end of

the tractor, as shown in FIG. 2B. In FIG. 2B, the puller 209, coupled to the first end of the tractor within the catheter, is pulled to deploy the tractor. When deployed the tractor may expand away from the catheter and towards the wall(s) of the vessel 260.

[00073] As shown in FIG. 2B, the tractor may be rolled and inverted 282 into the catheter by pulling the first end of the tractor from within the catheter (e.g., by pulling 219 the puller proximally). The puller in FIGS. 2A-2G is shows as a hollow member (e.g., catheter, tube, etc.) but it may be a wire, cable, etc.

[00074] Occasionally, if the clot diameter is too large compared to the diameter of the distal end opening of the catheter, and/or if the clot is too stiff and difficult to compress, the clot 220 may jam in the distal end opening of the catheter after at least a portion of the clot has been grabbed by the tractor. This is illustrated in FIG. 2B and 2C. In this example the force required to pull the clot into the catheter may be too high (e.g., greater than the longitudinal compression strength of the catheter, such as greater than 500 g of force, greater than 600 g of force, greater than 700 g of force, greater than 800 g of force, greater than 900 g of force, greater than 1000 g of force, greater than 1100 g of force, greater than 1200 g of force, greater than 1300 g of force, greater than 1400 g of force, greater than 1500 g of force, etc. the threshold may depend on the catheter type and structure.

[00075] When the clot is jammed within the catheter distal end opening, as shown in FIG. 2B (and in FIG. 3A), the method may then proceed to engulf and remove the clot with the tractor by withdrawing the catheter and continuing to pull the first end of the tractor proximally by pulling the puller proximally. In FIG. 2C, the catheter distal end opening 209' is shown withdrawn a substantial distance, e.g., beyond the second (outer) end of the tractor; alternatively the catheter may be withdrawn just slightly relatively to the tractor and/or may be withdrawn with the puller as the puller is withdrawn proximally.

[00076] As shown in FIG. 2D, when the puller is pulled proximally either with the catheter or with the catheter withdrawn proximally (as shown) so that the tractor cannot roll over the distal end opening of the tractor, the interference between the wall of the vessel 260 and the expanded tractor 251 may hold the tractor in place as the clot, which is still secured to the tractor either by the force of interaction between the tractor and the clot, and/or by suction (e.g., through the puller or other lumen connected to the tractor), is pulled proximally with the tractor. Thus, as shown in FIGS. 2D and 2E, the clot may be engulfed by the tractor and pulled proximally into the expanded tractor.

[00077] Ultimately, the tractor, clot and catheter may be removed proximally from the vessel. In some variations, as shown in FIG. 2F and 2G, the the clot may be pulled with the

tractor into the catheter once it has been fully engulfed by the tractor. As illustrated in FIG. 3A, the clot may be jammed so that it is unable to be pulled into catheter by rolling the tractor so that it inverts into the catheter, similar to what was described above for FIG. 2B. In FIG. 3B, the clot has been pulled proximally with the tractor but not rolled over the catheter distal end opening; instead, the catheter has been withdrawn and the clot pulled into the tractor to invert itself round and engulf the clot within the tractor. Thus, pulling back the catheter proximally, even without pulling the tractor proximally or while pulling both the tractor and the catheter proximally, may drag the clot proximally and inert the tractor over the clot, as shown. As mentioned above, it may be helpful to have the tractor expand radially within the vessel to contact the wall of the vessel. This may help lock the tractor in position as the catheter and/or tractor is pulled proximally. The tractor may include at least a portion of its length that has an element that expands to the vessel wall. Inverting the tractor over the clot in this manner may reduce the risk of creating emboli compared to other techniques, including aspiration-only techniques, and also may not require the additional cost and risk of delivering a secondary device, such as a clot engaging member prior to or with the rolling mechanical thrombectomy apparatuses described herein (see below with regard to FIGS. 5A-7B for examples in which a clot engaging member is used in addition to the rolling mechanical thrombectomy apparatuses described herein.

[00078] FIGS. 4A-4G illustrate another example of a method of capturing and/or removing a clot from a vessel using a rolling mechanical thrombectomy apparatus. In this example, rather than pulling the clot proximally into the tractor, the tractor (and catheter) may be advanced distally forward over the clot. For example, in FIG. 4A, a guide wire 405 (or other guide member) may be steered or driven distally to the clot 420. The guidewire may extend just to the clot or may pass at least partially though the clot. In some variations it may be beneficial to stop the guidewire prior to entering the clot, in order to avoid disrupting the clot. Once the guidewire is positioned, a rolling mechanical thrombectomy apparatus 400 may be positioned over the guidewire so that it is adjacent to the clot. The apparatus may include the catheter 401 and a tractor 403 that is coupled at a first end within the catheter to a puller (shown as a puller inner catheter 407). Optionally, the guidewire may be removed (as shown in FIG. 4C), leaving the rolling mechanical thrombectomy apparatus 400 behind.

[00079] The tractor may then be rolled into the catheter and inverted by either pulling proximally on the puller (coupled within the catheter to the first end of the tractor), or alternatively and/or additionally by moving the catheter distally against the tractor, as shown in FIGS. 4C and 4D. In this example, the tractor puller is held in a relatively fixed position

and the catheter is slowly advanced distally, towards the clot. The tractor therefore rolls and inverts 451 into the advancing catheter distal end, which may then travel up and into the clot 420 , as shown in FIG. 4E. As the catheter advances, rolling the tractor so that it grabs and pulls the clot into the catheter distal end with the tractor, the tractor also envelops the clot and compresses it into the catheter inner lumen 460. Once the clot is engulfed and/or completely enveloped by the apparatus, the catheter forward (distal) motion may stop, as shown in FIG. 4F. Thereafter the catheter and tractor may be fixed in relative position (e.g., no motion relative to each other) and the apparatus slowly removed from out of the vessel, as shown in FIG. 4G, with the clot within the tractor and the tractor and clot within the lumen of the catheter.

[00080] As mentioned above, any of the methods and apparatuses described herein may be used with (and/or may integrate into them) a clot engaging member on the distal end of an elongate manipulator. Any type of clot engaging member may be used, and particularly those on on the distal end of an elongate manipulator. For example, FIGS. 5A-5C illustrate different schematic variations of clot engaging member on the distal end of an elongate manipulator. In FIG. 5A the clot engaging member 501 is a coil that is on the distal end of an elongate manipulator 503. The coil may be expandable, e.g., may be compressed so that when released at or near the clot it may expand. The clot engaging member may be secured into the clot or through the clot so that, once expanded, it may help mechanically capture the clot.

[00081] FIG. 5B shows another example of a clot engaging member 501' on the distal end of an elongate manipulator 503'. In FIG. 5B, the clot engaging member includes a plurality of wires that may expand outward within the clot. Similarly, FIG. 5C illustrates another example of a clot engaging member 501'' on the distal end of an elongate manipulator 503''.

[00082] Any of the apparatuses described herein may be used in conjunction with a clot engaging member, and particularly a clot engaging member on the distal end of an elongate manipulator.

[00083] FIG. 6I illustrates an example of a mechanical thrombectomy system for removing a clot from within a vessel. In FIG. 6I, the apparatus (e.g., system) includes an elongate inversion support comprising a catheter 607 having a distal end and a distal end opening, a tractor 615 comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor 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. The system also includes a puller 611 connected to the first end of the tractor that extends proximally within the catheter. The system also includes a clot engaging member 601 on the distal end of an elongate manipulator 603. The elongate member is shown passing through a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator. This system may be used to remove a clot.

[00084] For example, a clot engaging member on the distal end of an elongate manipulator may be advanced through a clot; the expansive/expandable clot engaging member on the distal end of the elongate manipulator may engage with a clot and lock the clot in place in the vessel. The rolling mechanical thrombectomy apparatus may then be delivered, e.g., over the elongate manipulator to the clot and the clot engaging member. Once near the clot, the tractor may be rolled into the distal end of the catheter by pulling the first end of the tractor (e.g., by pulling a puller) proximally and advancing the catheter distally and/or by holding the puller in a relatively fixe position and driving the catheter distally to roll the tractor and invert it into the catheter. Preferably, as illustrated in FIGS. 4A-4G above, the catheter may be advanced forward in the vessel and the proximal end of the tractor may be held and/or fixed (in a fixed longitudinal position). For example, the proximal end of the tractor may be a puller/catheter that is slid over the elongate manipulator and, once positioned adjacent to the clot, held in a fixed position relative to the elongate manipulator. Holding the proximal puller fixed to the elongate manipulator while advancing the catheter forward distally relative to the elongate manipulator may therefore invert the tractor over the clot and clot engaging member similar. This action may force the tractor to roll into the distal end opening of the catheter and grab and engulf the clot along with the clot engaging member. In this example, the clot engaging member may be in the clot and/or distal to the clot, and the elongate manipulator acts as a guide rail for the rolling mechanical thrombectomy apparatus as the catheter is advanced forward. This example is illustrated in FIGS. 6A-6I.

[00085] For example, in FIG. 6A, the clot engaging member 601 on the distal end of an elongate manipulator 603 is advanced distally into and through the clot 620. Thus, the clot engaging member engages the clot from the distal side of the clot, and may pull against the clot when drawn proximally. Altematively, FIG. 6B shows an example in which the engaging member 601 on the distal end of an elongate manipulator 603 is deployed within the clot 620. The engaging member may engage the clot by expanding within the clot.

[00086] Once deployed, the engaging member and clot may be captured by a rolling mechanical thrombectomy apparatus, as shown in FIG. 6C. Once adjacent to the clot, the

apparatus may be advanced distally by driving the catheter 607 distally 609, as shown in FIG. 6D. The elongate manipulator 603 and the puller 611 coupled to the first end of the tractor may be held fixed relative to one another (and/or may be jointly pulled proximally) while the catheter 607 is pushed distally 609, as shown in FIG. 6E. This may therefore roll the tractor over the distal end of the catheter and capture the clot and clot engaging member, pulling it into the catheter 613 as shown in FIG. 6F. This process may be continued until the entire clot and clot engaging member is engulfed and held within the catheter, as shown in FIG. 6G. Once complete, the apparatus, clot and clot engagement member may be withdrawn proximally out of the vessel, as shown in FIG. 6H.

[00087] Alternatively, a clot engagement member may be deployed through a rolling mechanical thrombosis apparatus in order the engage with the clot before removing with the rolling mechanical thrombosis apparatus.

[00088] In any of the variations described herein, the tractor may be actuated by advancing the catheter portion distally over the clot and clot engagement member either with or without pulling the tractor (e.g., puller) proximally within the catheter. The tractor may grab the clot and clot engagement member and may be advanced forward distally over both the clot and the clot engagement mechanism. This technique may avoid dragging the clot engagement apparatus within the vessel and may provide active capturing. This may reduce the risk of any distal emboli on embolization of new territories. As mentioned above, in any of these variations suction/aspiration can be used in combination with any of these steps.

[00089] In any of these variations, the clot engaging mechanism may be pulled proximally into the pre-loaded dozer catheter, rather than advancing the apparatus over the clot engaging mechanism; as the clot engagement mechanism pulls into the pre-loaded tractor and catheter, the tractor may grab and encapsulate the clot as the clot and clot engagement mechanism is pulled proximally.

[00090] FIGS. 7A and 7B illustrate an example in which the clot engagement apparatus 703 is linked to the puller 705, so that the two may be moved or held motionless together, relative to the catheter 707, and/or the vessel. For example, in FIG. 7B, the apparatus is inserted into the vessel and adjacent to clot engagement mechanism and held motionless while the catheter is driven forward, allowing the tractor 713 to roll distally and into the catheter and and capture the clot without requiring the clot and/or clot engagement mechanism to move within the vessel. This may reduce the risk for further embolization.

[00091] As mentioned above, any of the apparatuses and methods described herein may be used with aspiration (e.g., vacuum). For example, any of these methods described herein

may be may use a combination of aspiration and a tractor pull mechanism. For example, to initiate the grabbing of the clot by the tractor, the tractor may be rolled around a catheter wall and may make physical (e.g., direct) contact with the clot. A user may apply vacuum through the catheter (e.g., via a syringe or pump, etc.) prior to or at the same time as pulling tractor into the catheter. Alternatively or additionally, vacuum may be applied through the puller (e.g., a pulling catheter). If vacuum is applied prior to pulling the tractor the vacuum may be applied 1sec to 5min prior ensure the clot is in good contact with the distal end of the catheter. Preferred range of 5-60sec vacuum prior to activating/pulling dozer. The application of vacuum prior to pulling the braid will ensure the proximal most end of the clot is in contact with the catheter tip and some amount of the clot ($\geq$ 0.5mm) is extruded into the lumen of the catheter tip. Next when the dozer is pulled there will be clot at the tip of the catheter for the braid/dozer to grab and pull in. Also, when the dozer is pulled there are resultant forces from the braid/dozer that put compression forces on the catheter tip encouraging the catheter tip to buckle and/or move proximally away from the proximal edge of the clot. The application of vacuum ensures that even if the catheter tip wants to move proximally when pulling the tractor that the clot will stay in contact with the clot and/or prevent the catheter tip from pulling back away from the clot. Once the tractor engages a grabs a few mm of clot the vacuum may be kept on or turned off.

[00092] Any of the methods (including user interfaces) described herein may be implemented as software, hardware or firmware, and may be described as a non-transitory computer-readable storage medium storing a set of instructions capable of being executed by a processor (e.g., computer, tablet, smartphone, etc.), that when executed by the processor causes the processor to control perform any of the steps, including but not limited to: displaying, communicating with the user, analyzing, modifying parameters (including timing, frequency, intensity, etc.), determining, alerting, or the like.

[00093] 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.

[00094] 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 "/".

[00095] 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.

[00096] 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.

[00097] 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.

[00098] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[00099] 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.

[000100] 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.

[000101] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A mechanical thrombectomy system for removing a clot from within a vessel, the apparatus comprising:
    an elongate inversion support comprising a catheter having a distal end and a distal end opening;
    a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor 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;
    a puller connected to the first end of the tractor extending proximally;
    a clot engaging member on the distal end of an elongate manipulator; and
    a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator.

2. The system of claim 1, wherein the clot engaging member is an expandable clot engaging member.

3. The system of claim 1, wherein the clot engaging member comprises one or more of: a coil, a snare, a basket, or a frame.

4. The system of claim 1, wherein the tractor is sufficiently soft such that without support from the catheter, it collapses radially under an axial compression of less than 200g of force when inverting.

5. The system of claim 1, wherein the tractor is biased to expand to greater than the outer diameter of the catheter in the inverted configuration and is biased to expand to greater than the inner diameter of the catheter in the un-inverted configuration.

6. The system of claim 1, wherein the elongate manipulator comprise a hypotube.

7. The system of claim 1, wherein the tractor comprises one or more of: a braided material, a knitted material, or a woven material.

8. The system of claim 1, wherein the tractor comprises steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.

9. The system of claim 1, wherein the material hardness of catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile.

10. The system of claim 1, wherein the tractor comprises one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating.

11. The system of claim 1, further comprising a releasable attachment between the tractor and an outer surface of the catheter, wherein the releasable attachment is configured to release when the tractor is pulled with a force that is greater than a predetermined force threshold.

12. The system of claim 1, further comprising a sleeve extending over the catheter and tractor.

13. The system of claim 1, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with a lumen though the tractor.

14. The system of claim 1, wherein the tractor is 3 cm to 50 cm long.

15. A mechanical thrombectomy system for removing a clot from within a vessel, the apparatus comprising:

an elongate inversion support comprising a catheter having a distal end and a distal end opening;

a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor 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;

a puller extending proximally within the catheter and connected to the first end of the tractor;

an expandable clot engaging member on the distal end of an elongate manipulator, wherein the expandable clot engaging member comprises one or more of: a coil, a snare, a basket, or a frame; and

a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator.

16. A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus, the method comprising:

positioning a distal end of the mechanical thrombectomy apparatus adjacent to the clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;

pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and pull the clot into the catheter with the inverting tractor;

withdrawing the catheter proximally away from the tractor and clot when the tractor jams on the distal end of the catheter;

pulling the first end of the tractor proximally so that the tractor inverts over the clot within the vessel without rolling over the distal end opening of the catheter; and

withdrawing the tractor and clot proximally from the vessel.

17. The method of claim 16, further comprising disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall, wherein the second end of the tractor is disengaged before pulling the first end of the tractor proximally.

18. The method of claim 16, further comprising pulling proximally on the tractor to draw the tractor and clot into the catheter.

19. The method of claim 16, wherein pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter comprises advancing the catheter while pulling the first end of the tractor.

20. The method of claim 16, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot further comprises pulling the catheter proximally with the first end of the tractor.

21. The method of claim 16, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot comprises pulling a puller at the proximal end of the mechanical thrombectomy apparatus proximally.

22. The method of claim 16, wherein pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter comprises engaging the clot with the tractor.

23. The method of claim 16, wherein withdrawing the catheter proximally away from the tractor comprises pulling the catheter proximally beyond a second end of the tractor that is outside of the catheter.

24. The method of claim 16, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot comprises pulling the first end of the tractor when the tractor has expanded to contact the vessel wall.

25. The method of claim 16, further wherein positioning the distal end of the mechanical thrombectomy apparatus adjacent to the clot comprises sliding the mechanical thrombectomy apparatus over a guidewire or catheter passing through a lumen in the mechanical thrombectomy apparatus.

26. A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus, the method comprising:

positioning a distal end of the mechanical thrombectomy apparatus adjacent to the clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;

disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall;

pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter and pull the clot into the catheter with the inverting tractor;

withdrawing the catheter proximally away from the tractor and clot when the tractor jams on the distal end of the catheter;

pulling the tractor and clot proximally so that the tractor inverts over the clot within the vessel without rolling over the distal end opening of the catheter;

pulling proximally on the tractor to draw the tractor and clot into the catheter; and

withdrawing the tractor and clot proximally from the vessel.

27. The method of claim 26, wherein pulling the first end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter comprises advancing the catheter while pulling the first end of the tractor.

28. The method of claim 26, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot further comprises pulling the catheter proximally with the first end of the tractor.

29. The method of claim 26, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot comprises pulling a puller at the proximal end of the mechanical thrombectomy apparatus proximally.

30. The method of claim 26, wherein withdrawing the catheter proximally away from the tractor comprises pulling the catheter proximally beyond a second end of the tractor that is outside of the catheter.

31. The method of claim 26, wherein pulling the first end of the tractor proximally so that the tractor inverts over the clot comprises pulling the first end of the tractor when the tractor has expanded to contact the vessel wall.

32. The method of claim 26, further wherein positioning the distal end of the mechanical thrombectomy apparatus adjacent to the clot comprises sliding the mechanical thrombectomy apparatus over a guidewire or catheter passing through a lumen in the mechanical thrombectomy apparatus.

33. A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus, the method comprising:

engaging the clot with a clot engaging member on the distal end of an elongate manipulator;

sliding the mechanical thrombectomy apparatus over the elongate manipulator to position the distal end of the mechanical thrombectomy apparatus adjacent to the clot, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;

pushing the catheter distally while holding the first end of the tractor within the catheter fixed relatively to the elongate manipulator so that the tractor rolls and inverts over the distal end of the catheter and pulls the clot and the clot engaging member into the catheter with the inverting tractor; and

withdrawing the mechanical thrombectomy apparatus, clot and clot engaging member proximally from the vessel.

34. The method of claim 33, wherein engaging the clot with the clot engaging member on the distal end of the elongate manipulator comprises expanding the engaging member within the clot.

35. The method of claim 33, wherein engaging the clot with the clot engaging member on the distal end of the elongate manipulator comprises expanding the engaging member on a distal side of the clot.

36. The method of claim 33, wherein engaging the clot with the clot engaging member on the distal end of the elongate manipulator comprises expanding the engagement member, further wherein the engaging member comprises an expandable coil, snare, basket, or frame.

37. The method of claim 33, further comprising pulling the first end of the tractor proximally as the catheter is pushed distally.

38. The method of claim 33, further comprising holding the first end of the tractor and the elongate manipulator fixed relative to the vessel while pushing the catheter distally.

39. The method of claim 33, further comprising pulling the first end of the tractor proximately and pulling the elongate manipulator proximately relative to the vessel while pushing the catheter distally.

40. The method of claim 33, further comprising disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer surface of the catheter by pulling the tractor proximally with a force greater than a deployment force and expanding the tractor against the vessel wall.

41. A method of removing a clot from within a vessel using a mechanical thrombectomy apparatus, the method comprising:

engaging the clot with a clot engaging member on the distal end of an elongate manipulator;

sliding the mechanical thrombectomy apparatus over the elongate manipulator to position the distal end of the mechanical thrombectomy apparatus adjacent to the clot, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter;

pushing the catheter distally while pulling the first end of the tractor and the elongate manipulator proximally within the catheter to roll and invert the tractor over the distal end of the catheter and advancing the catheter distally, to pull the clot and the clot engaging member into the catheter with the inverting tractor; and

withdrawing the mechanical thrombectomy apparatus, clot and clot engaging member proximally from the vessel.

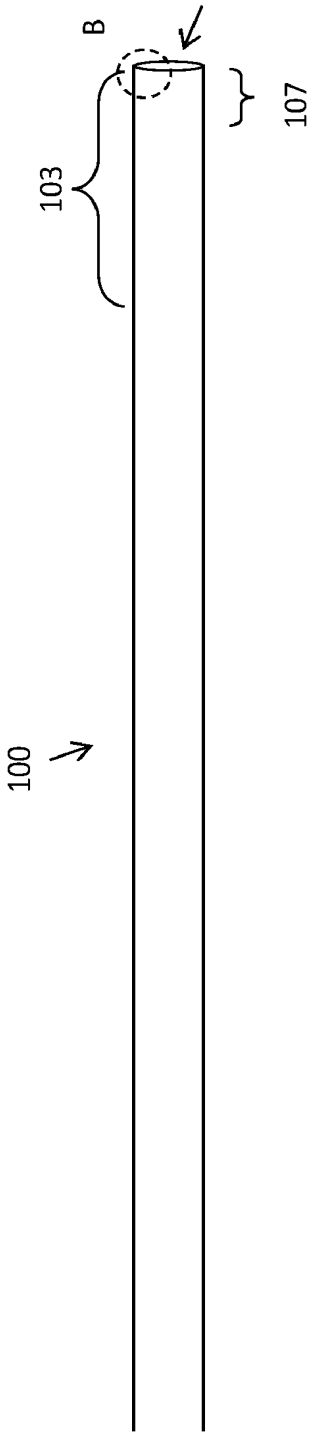


FIG. 1A

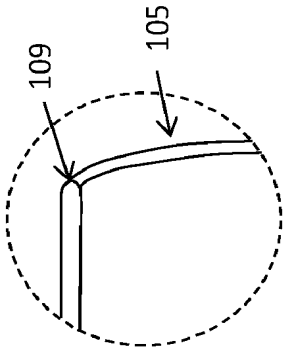


FIG. 1B

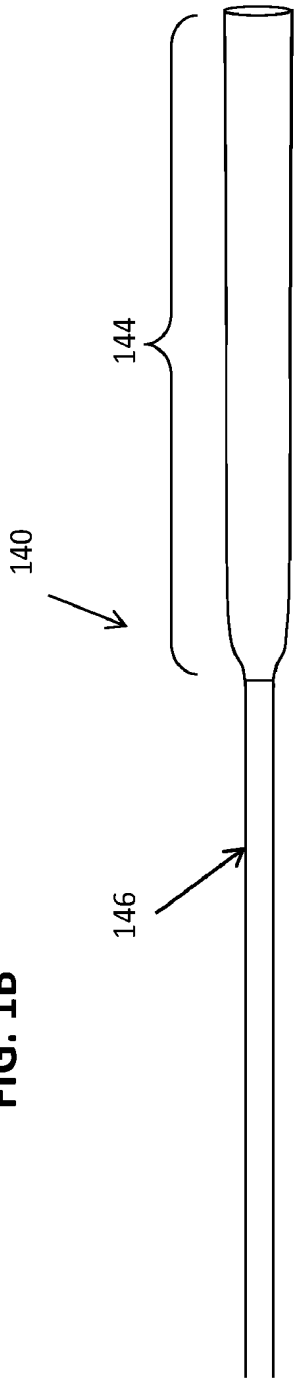


FIG. 1C

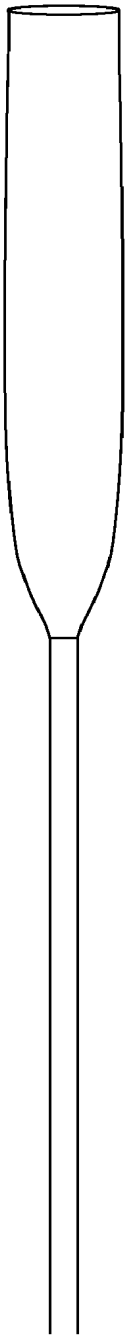


FIG. 1D

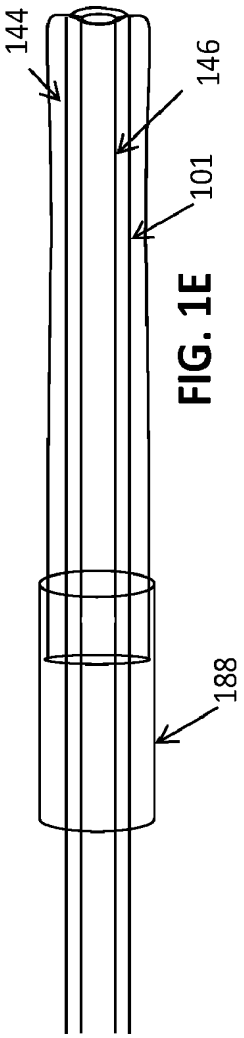


FIG. 1E

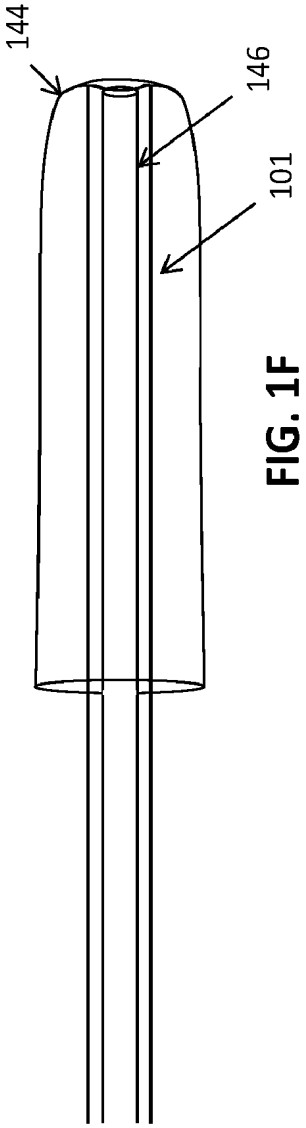


FIG. 1F

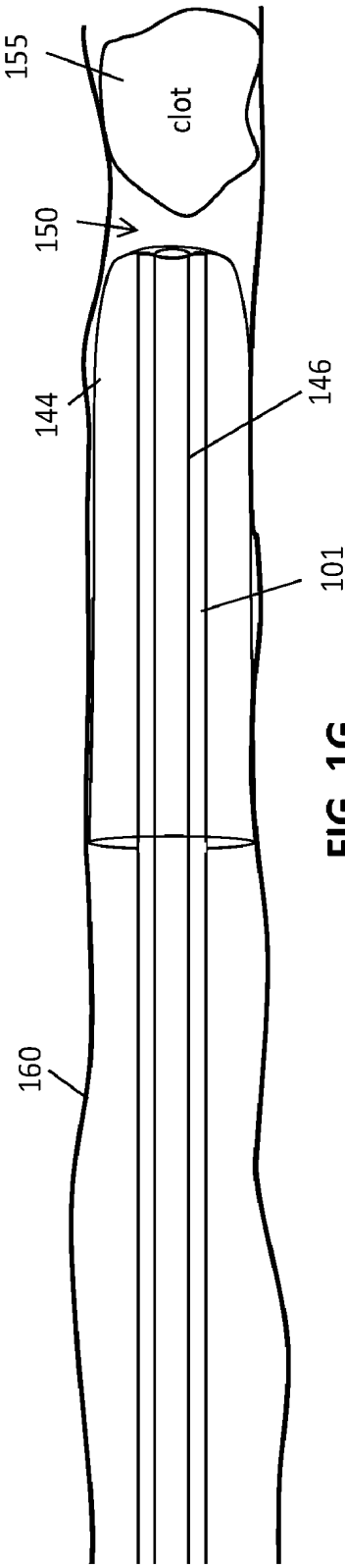


FIG. 1G

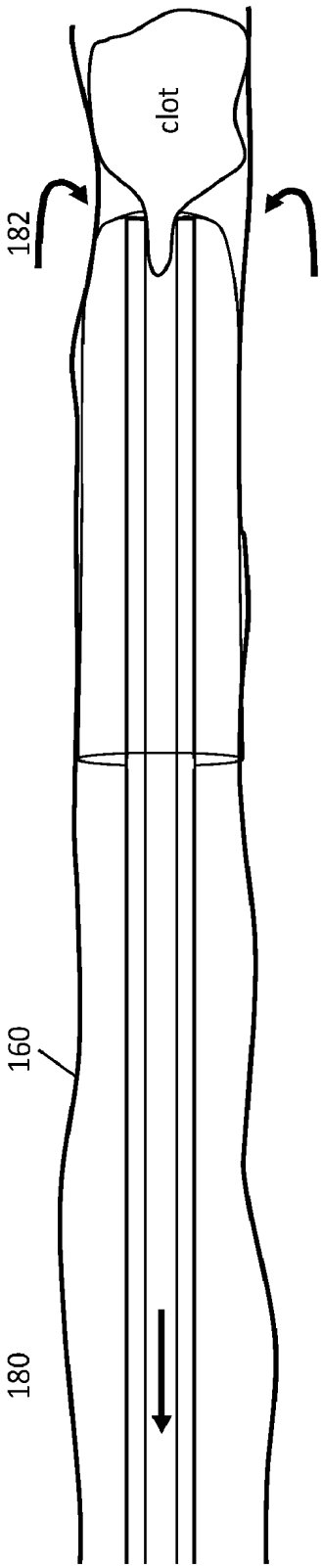


FIG. 1H

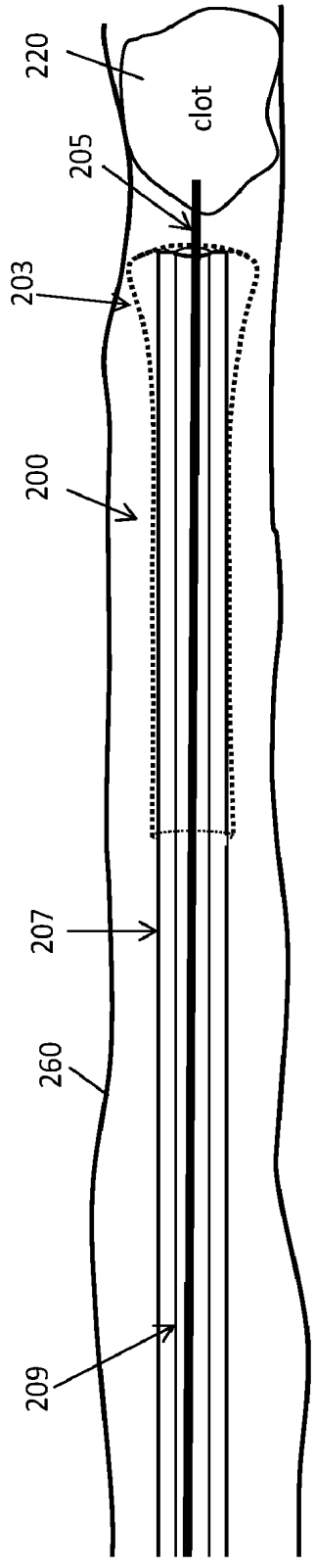


FIG. 2A

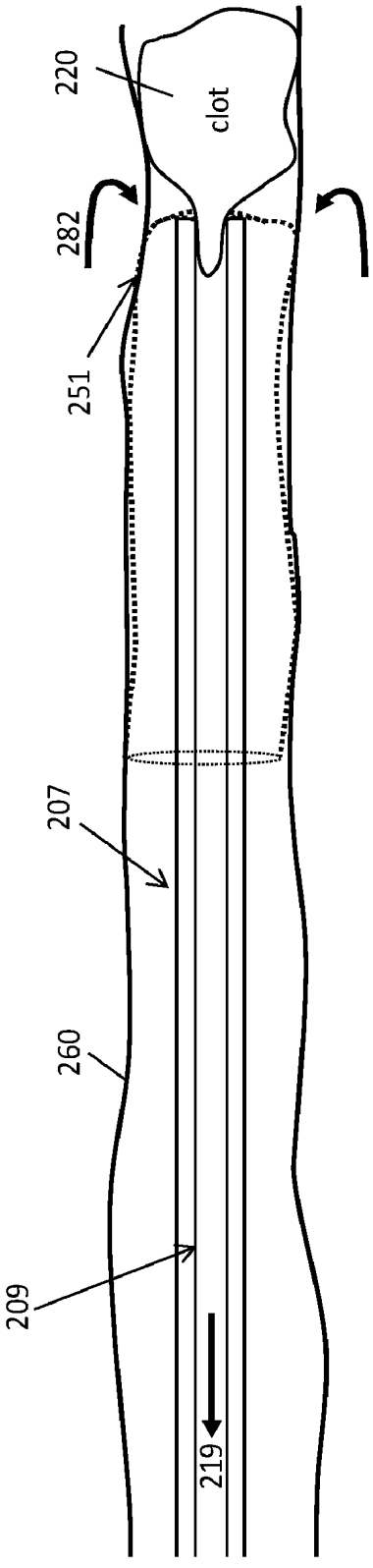


FIG. 2B

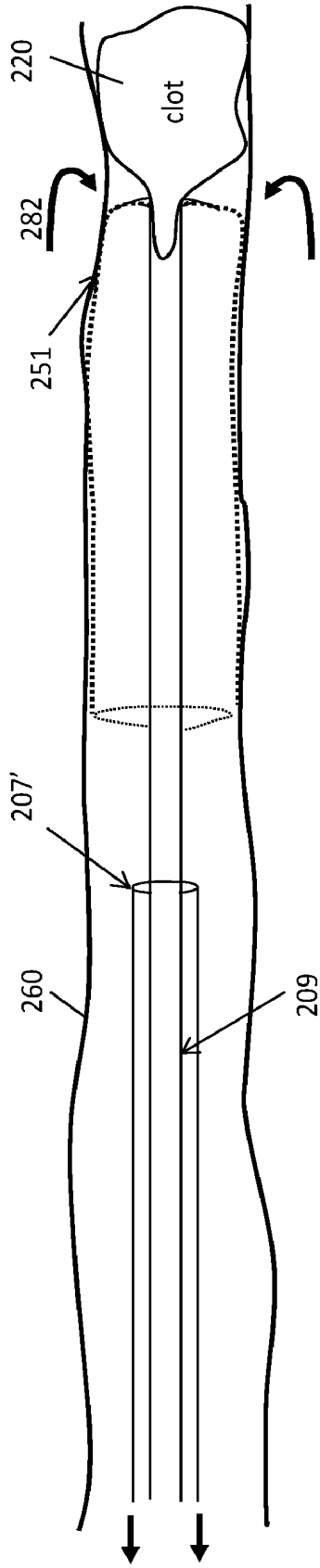


FIG. 2C

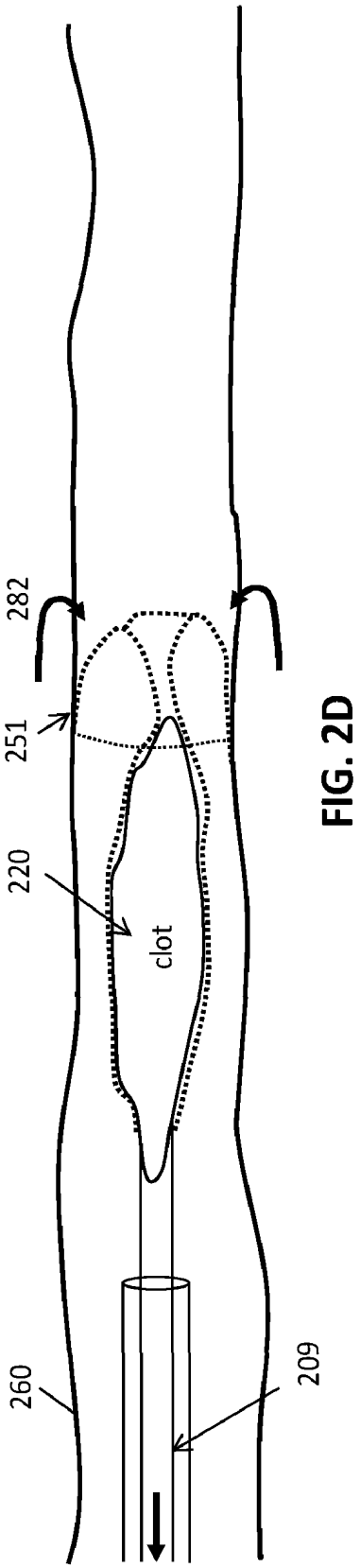


FIG. 2D

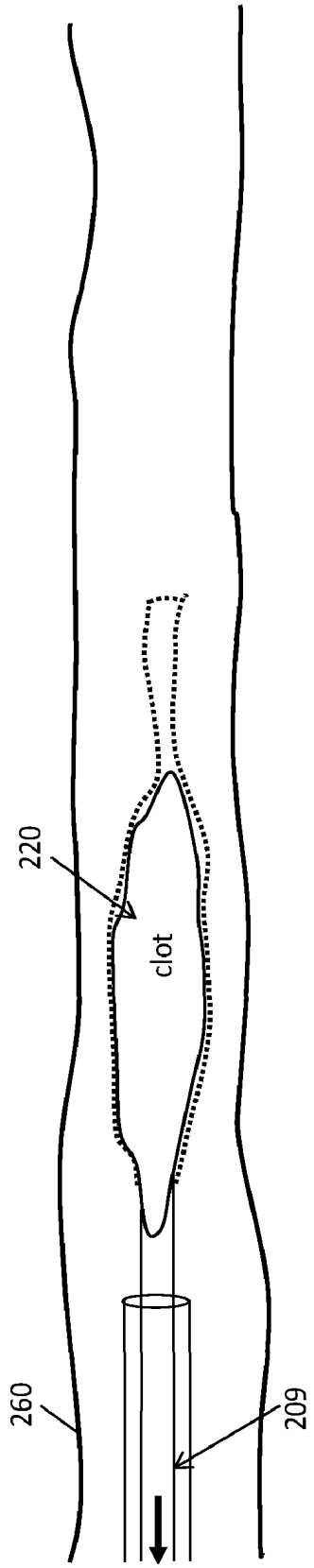


FIG. 2E

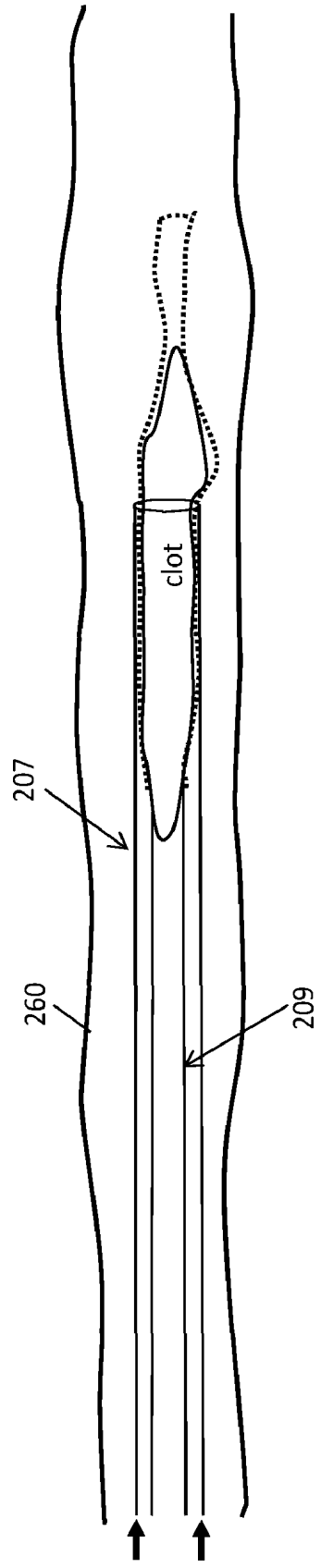


FIG. 2F

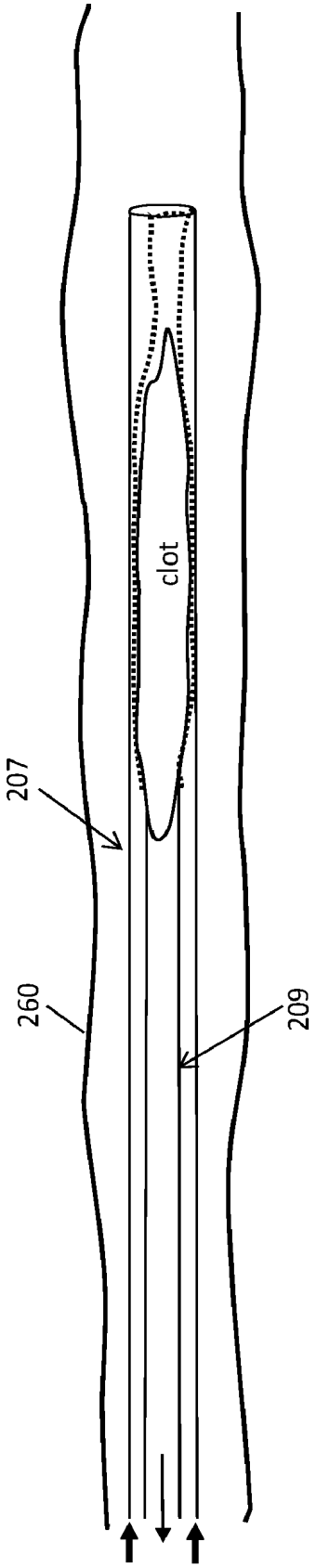


FIG. 2G

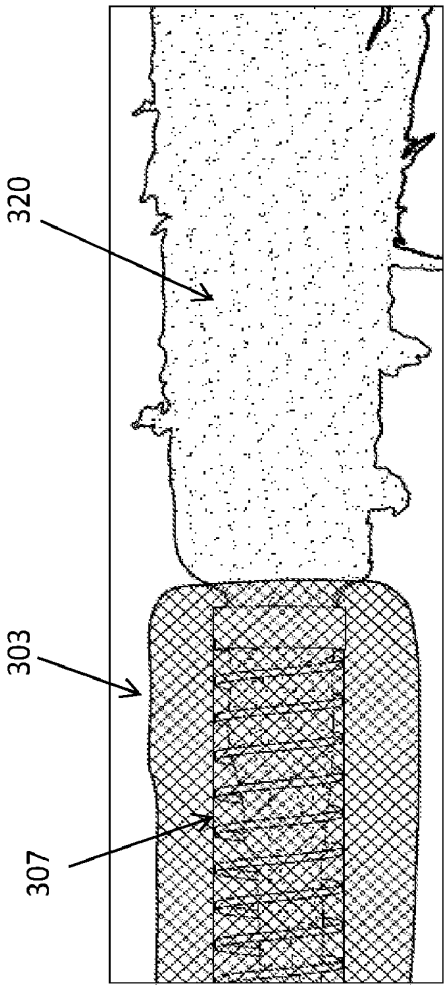


FIG. 3A

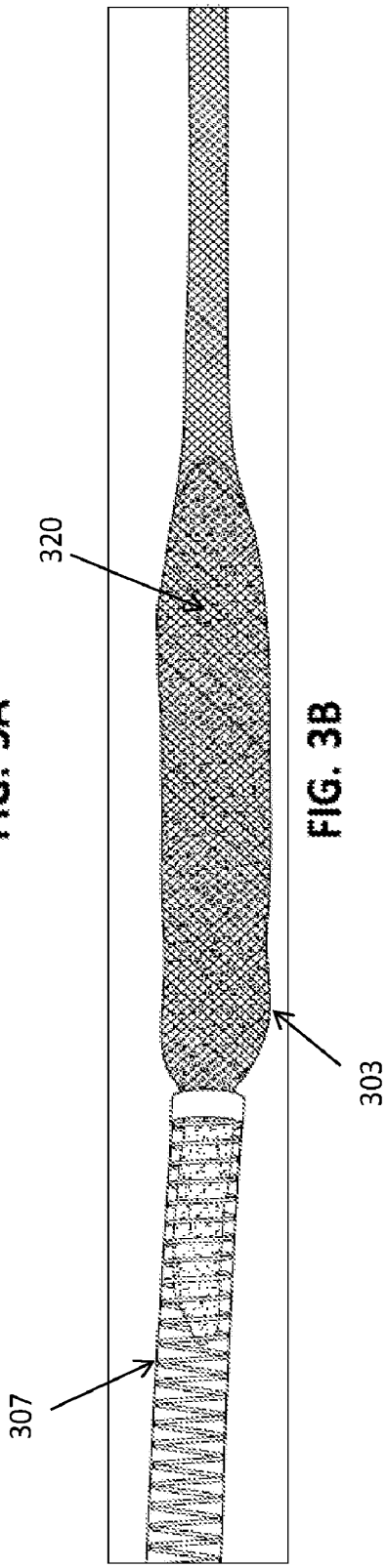


FIG. 3B

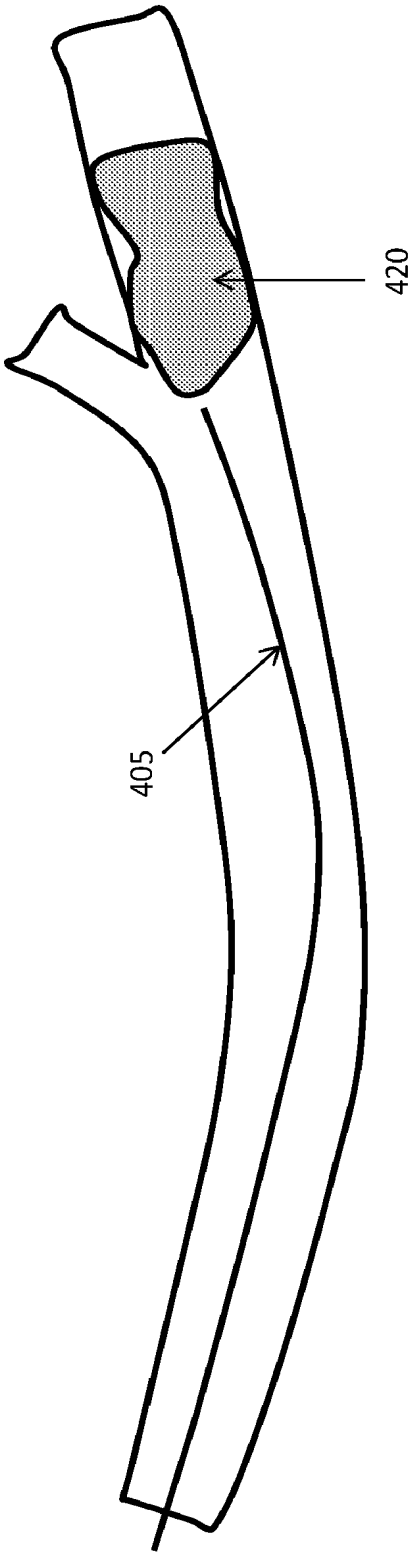


FIG. 4A

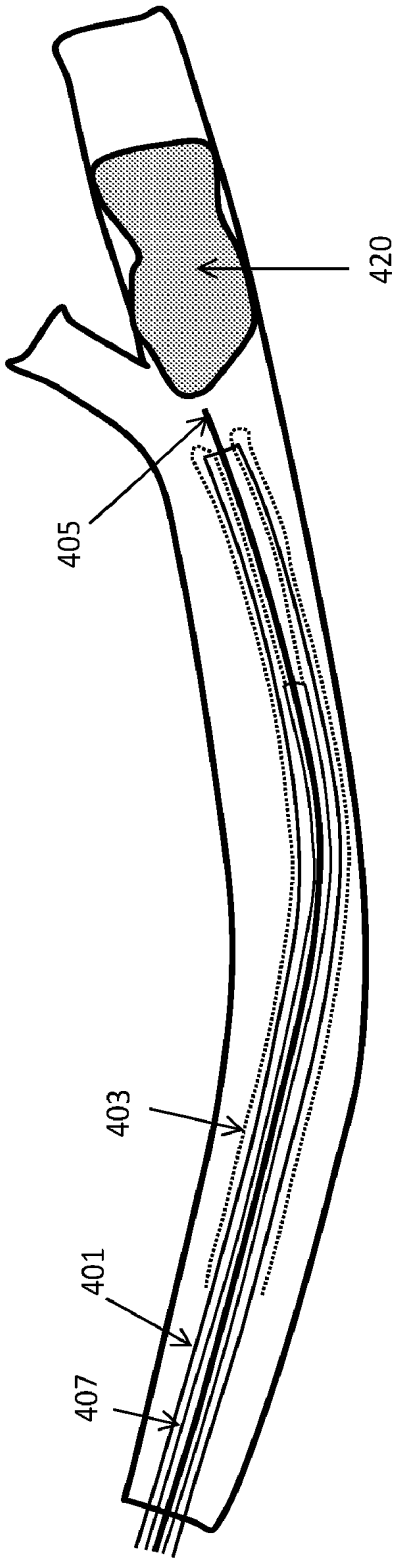


FIG. 4B

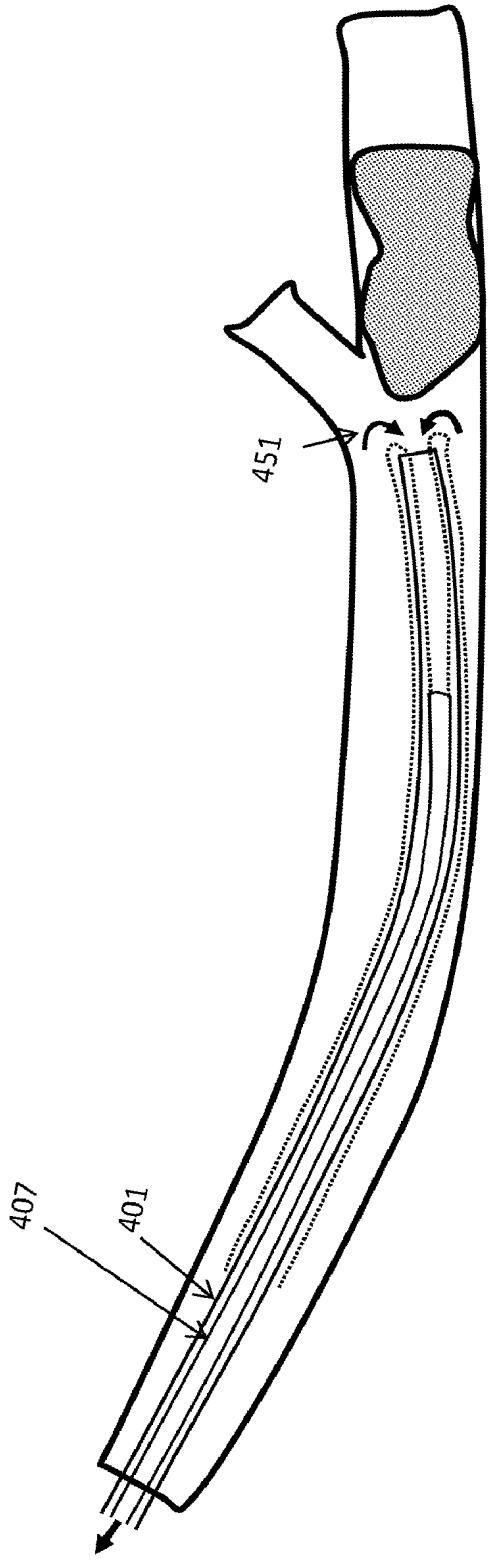


FIG. 4C

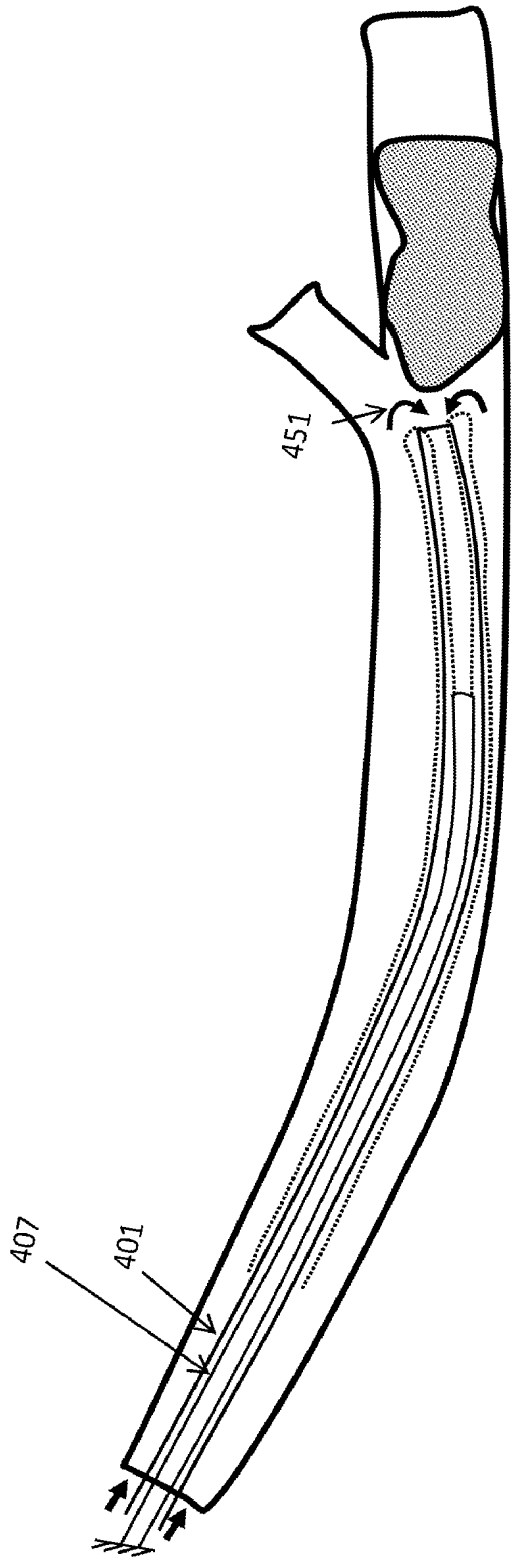


FIG. 4D

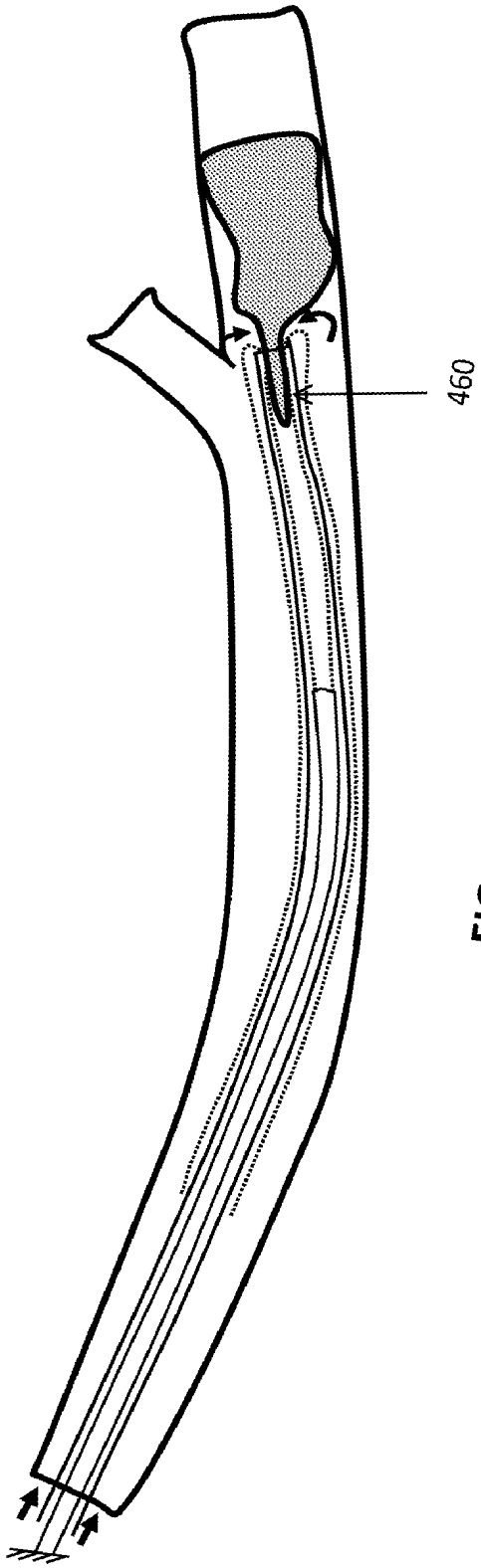


FIG. 4E

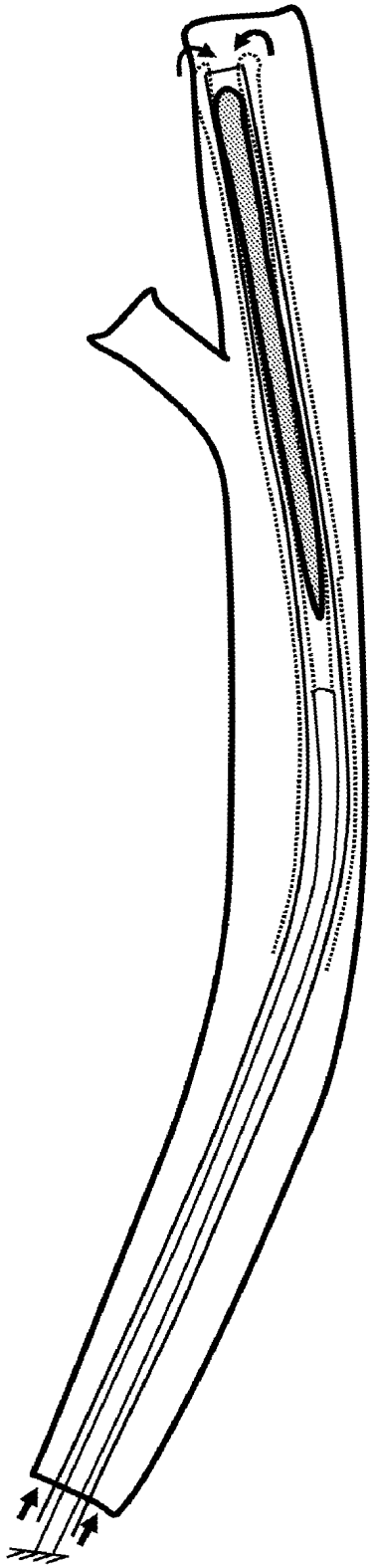


FIG. 4F

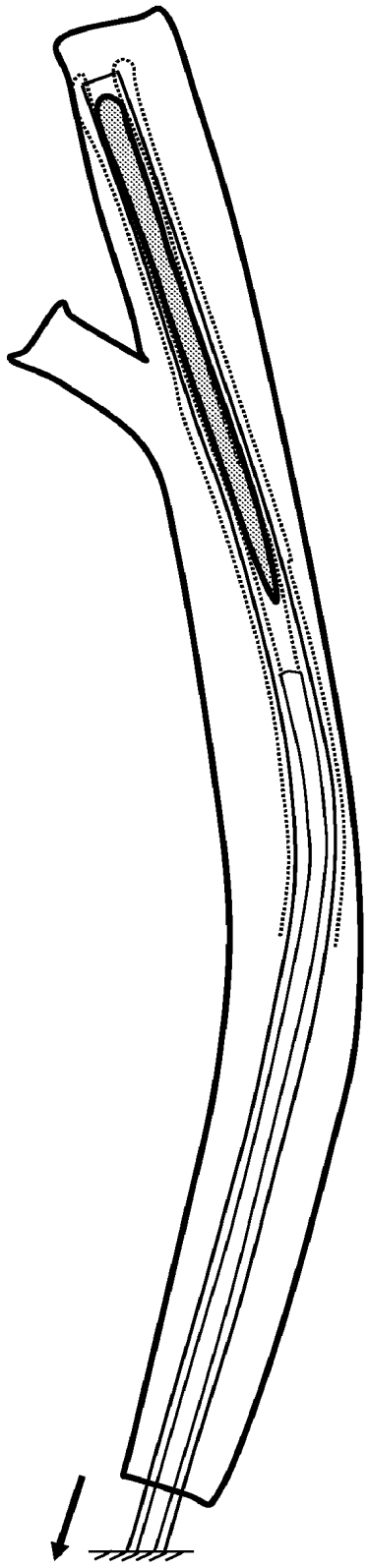


FIG. 4G

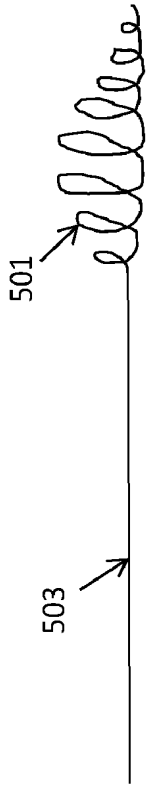


FIG. 5A

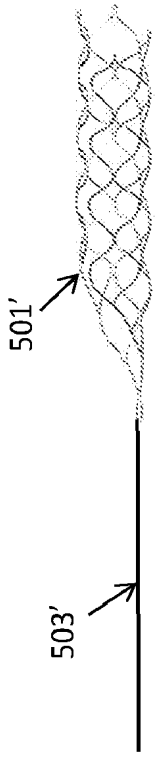


FIG. 5B

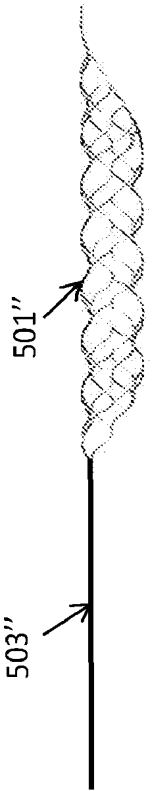


FIG. 5C

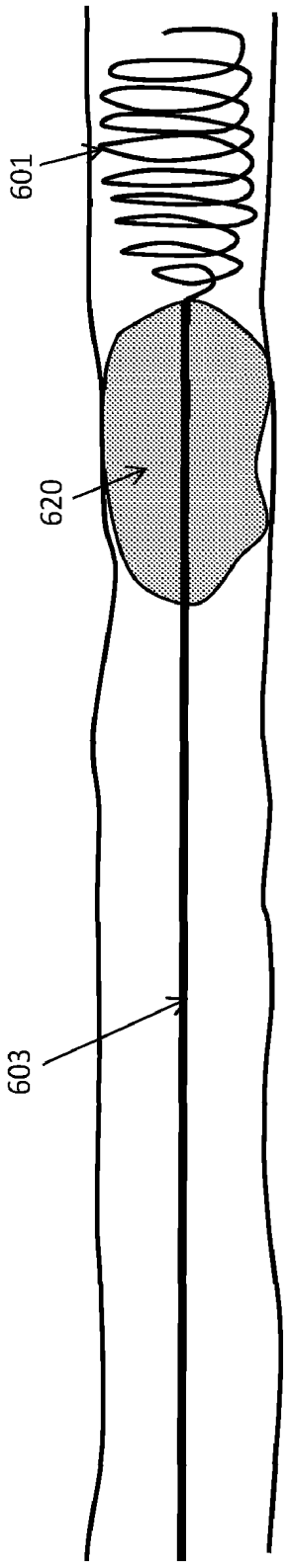


FIG. 6A

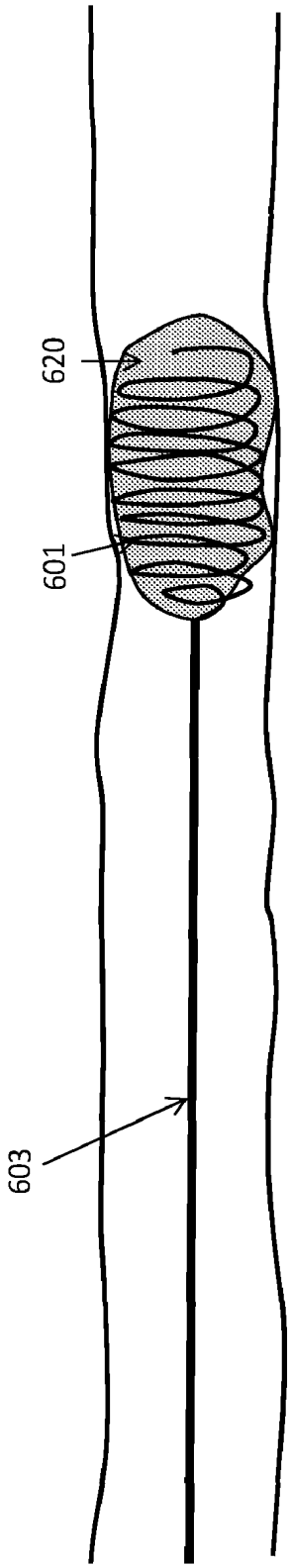


FIG. 6B

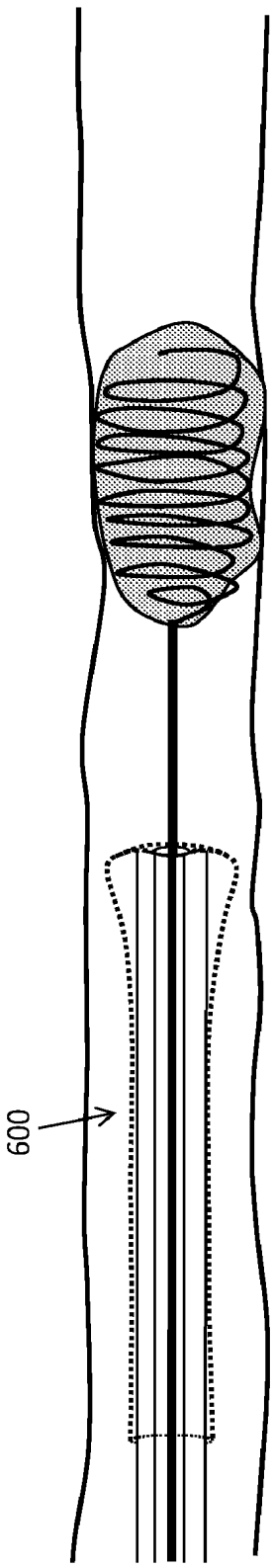


FIG. 6C

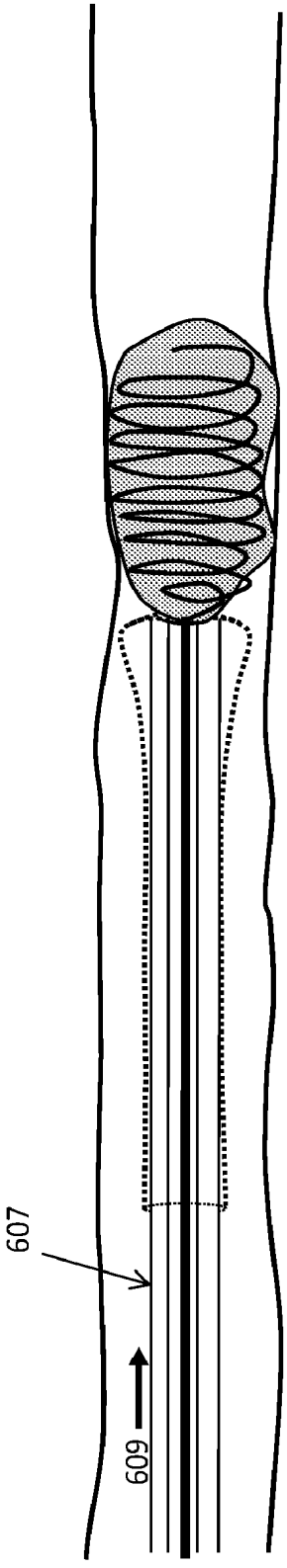


FIG. 6D

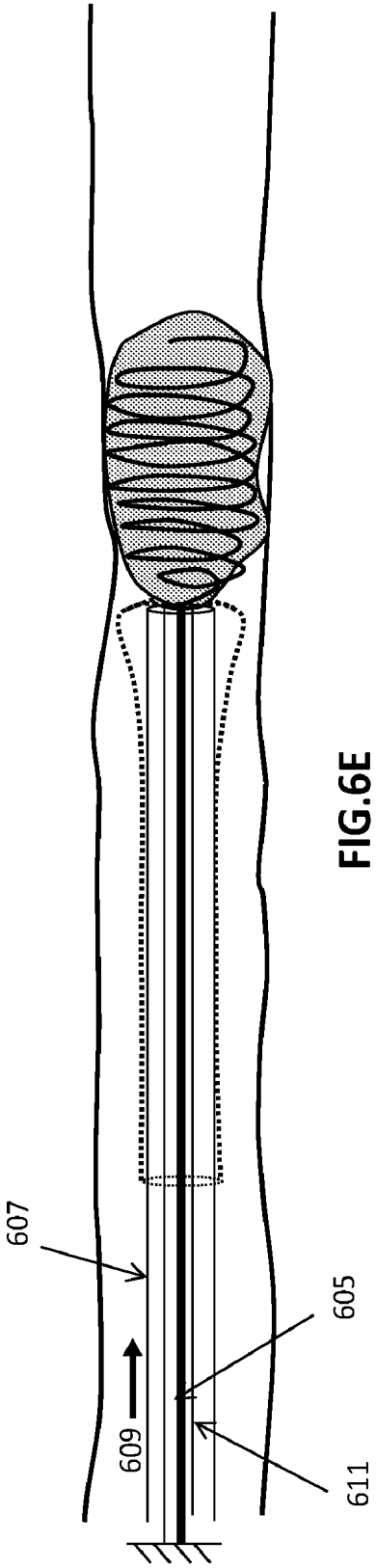


FIG.6E

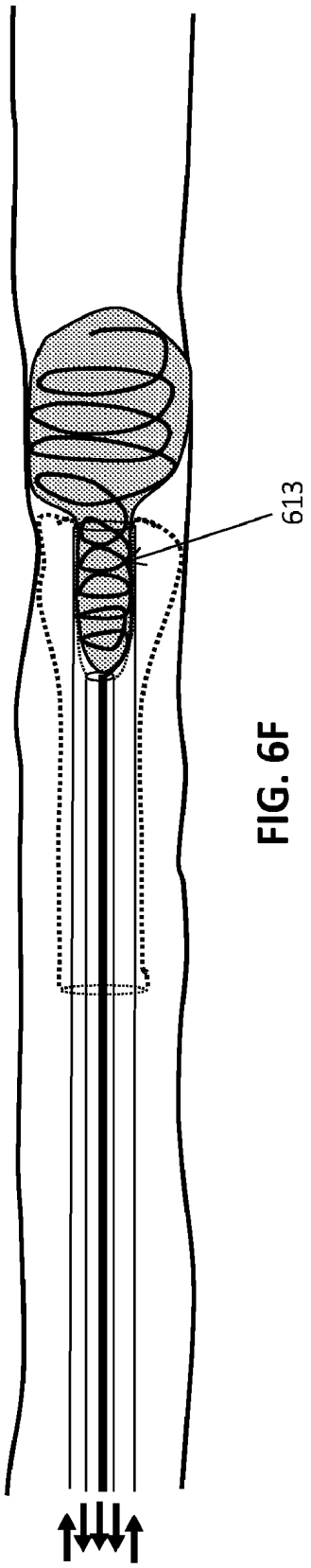


FIG. 6F

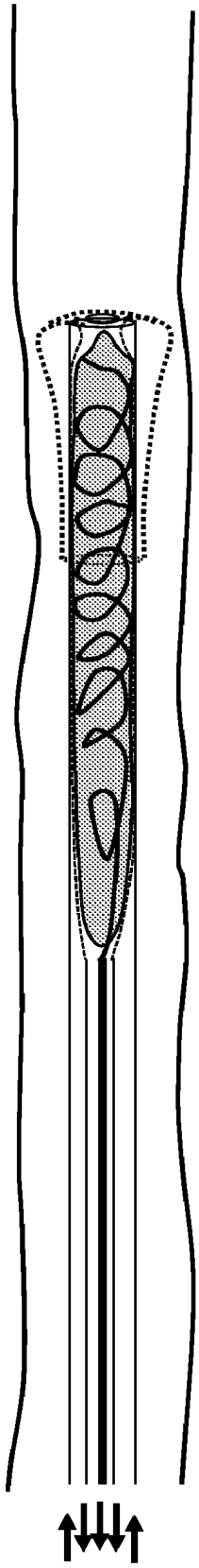


FIG. 6G

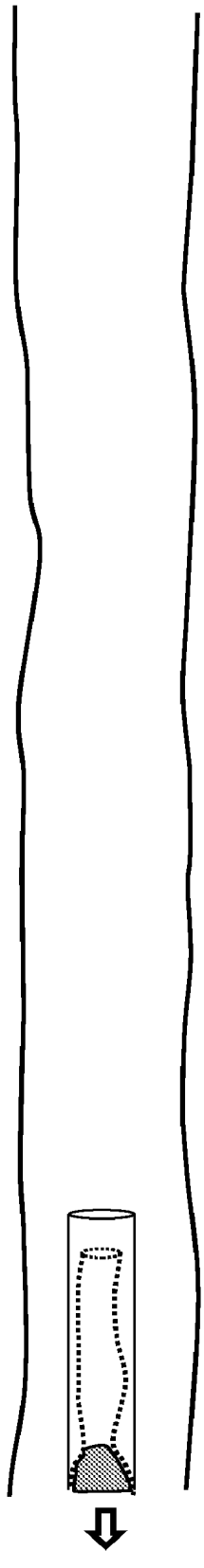


FIG. 6H

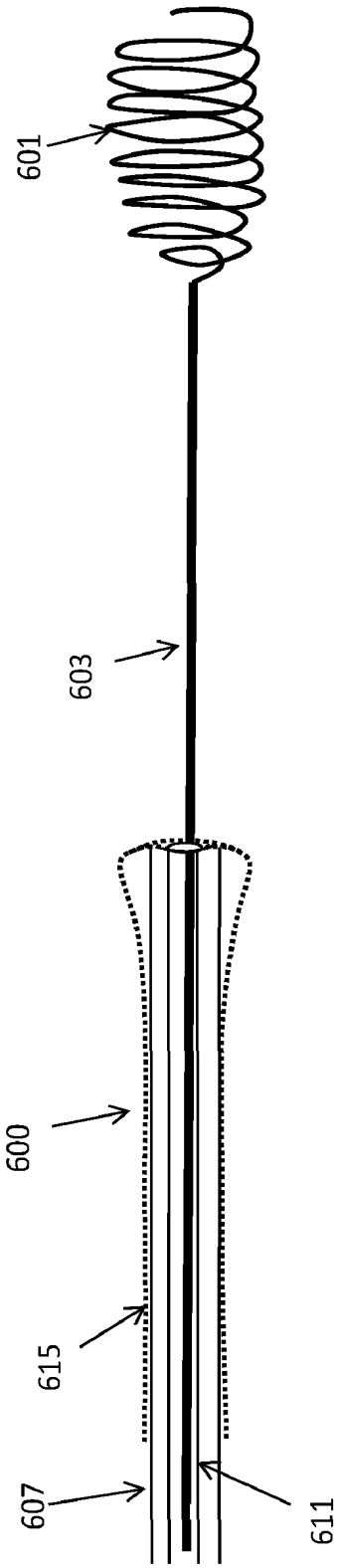


FIG. 6I

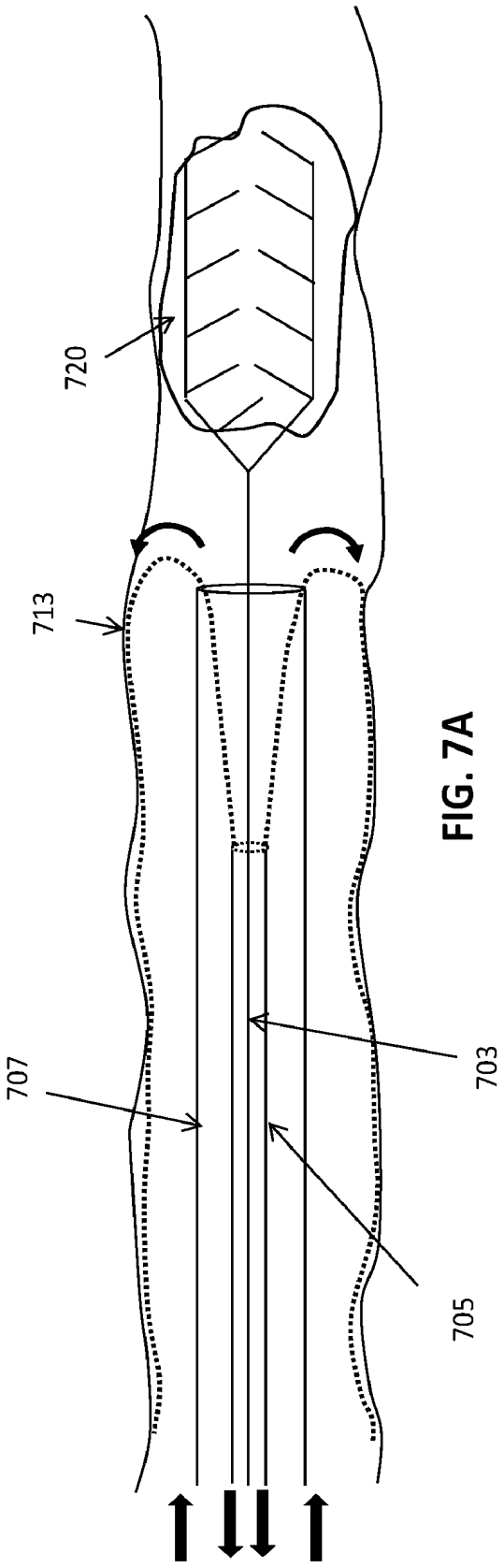


FIG. 7A

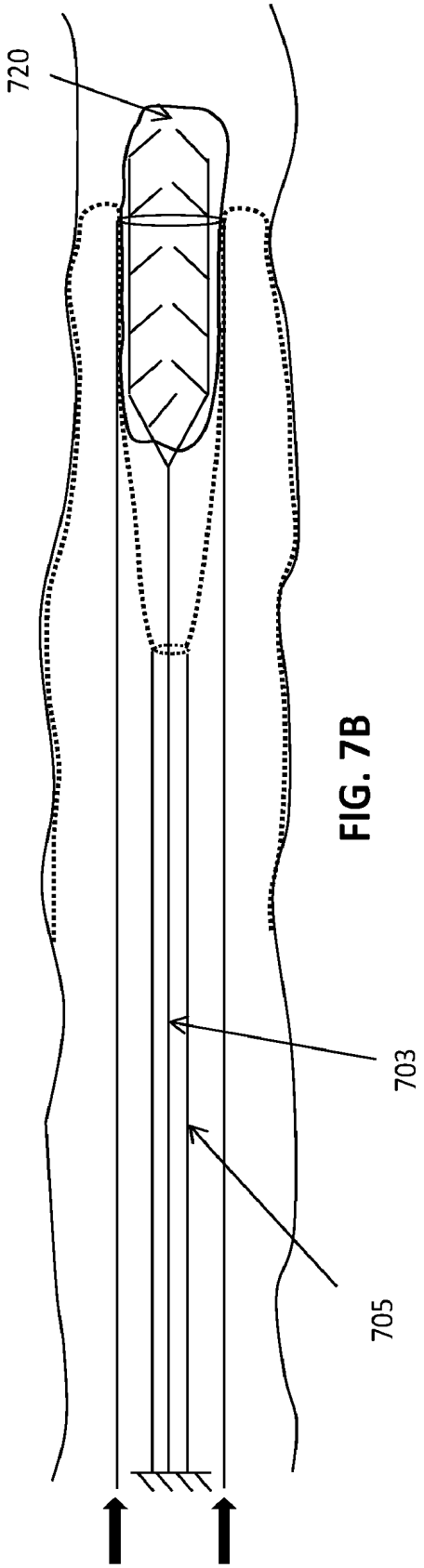


FIG. 7B

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1-15
Y	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 5	1-15
A	US 2006/195137 A1 (SEPETKA ET AL.) 31 August 2006 (2006-08-31) abstract; figures	1,15
A	US 2005/085826 A1 (NAIR ET AL.) 21 April 2005 (2005-04-21) figures	1,15

-/--

[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
29 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 2012/049652 A1 (ENDOGROWTH (PROPRIETARY) LIMITED) 19 April 2012 (2012-04-19) figures	1,15
A	US 4 243 040 A (BEECHER) 6 January 1981 (1981-01-06) figures	1,15
X,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document	1-15

1

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.: 16-41
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.

Continuation of Box II.2

Claims Nos.: 16-41

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 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 2006195137 A1	31-08-2006	US 2006195137 A1	31-08-2006
		US 2014135814 A1	15-05-2014
		US 2016310152 A1	27-10-2016
		WO 2007044995 A2	19-04-2007
US 2005085826 A1	21-04-2005	AT 428358 T	15-05-2009
		CA 2543211 A1	12-05-2005
		EP 1684647 A1	02-08-2006
		ES 2324915 T3	19-08-2009
		JP 2007508903 A	12-04-2007
		US 2005085826 A1	21-04-2005
		US 2007249998 A1	25-10-2007
		WO 2005041788 A1	12-05-2005
WO 2012049652 A1	19-04-2012	US 2013226196 A1	29-08-2013
		WO 2012049652 A1	19-04-2012
		ZA 201302264 B	30-04-2014
US 4243040 A	06-01-1981	NONE	
WO 2017058280 A1	06-04-2017	US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		WO 2017058280 A1	06-04-2017

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 March 2018 (15.03.2018)

WIPO | PCT

(10) International Publication Number
WO 2018/049317 A1

(51) International Patent Classification:
A61B 17/22 (2006.01) *A61B 17/221* (2006.01)

(21) International Application Number:
PCT/US2017/050933

(22) International Filing Date:
11 September 2017 (11.09.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/393,460 12 September 2016 (12.09.2016) 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). **GREENHALGH, Skott, E.**; 1426 Rose Glen Road, Gladwyne, Pennsylvania 19035 (US).

(74) Agent: **BURSE, David, T.** et al.; Vista IP Law Group LLP, 21760 Stevens Creek Blvd., Suite 100, Cupertino, California 95014 (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).

Published:
— *with international search report (Art. 21(3))*

(54) Title: SELF-ROLLING THROMBECTOMY APPARATUSES AND METHODS

(57) Abstract: Self-rolling mechanical atherectomy aka thrombectomy apparatuses for removing a clot from a vessel include a tractor tube portion that rolls and inverts over itself in a continuous motion, tractor-like, to draw material into the tractor tube, wherein the tractor tube rolls over itself without requiring any additional internal support at the distal-facing region of the tractor tube.

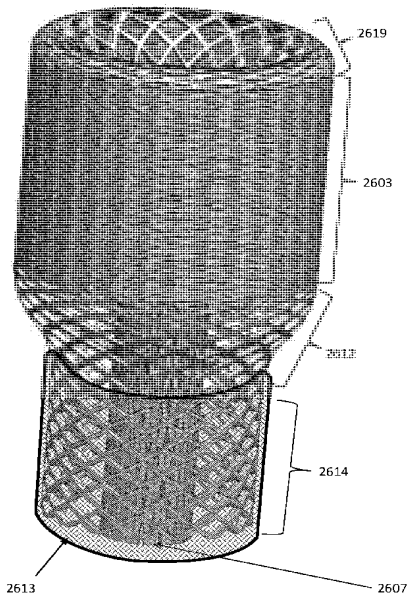


FIG.26A

WO 2018/049317 A1

SELF-ROLLING THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims the benefit of priority to U.S. Provisional Patent Application No. 62/393,460, filed September 12, 2016.

[0002] The subject matter of this patent application is related to the subject matter disclosed and described in each of U.S. Patent Application No 15/291,015, filed October 11, 2016; U.S. Patent Application No. 15/043,996, filed February 15, 2016, now U.S. 9,463,035, U.S. Patent Application No. 15/496,570, filed April 25, 2017; U.S. Patent Application No. 15/496,668, filed April 25, 2017; U.S. Patent Application No. 15/496,786, filed April 25, 2017; U.S. Patent Application No. 15/497,092, filed April 25, 2017; and U.S. Patent Application No. 15/611,546, filed June 1, 2017. Each of the foregoing patents and patent applications is incorporated by reference herein in its entirety.

INCORPORATION BY REFERENCE

[0003] 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

[0004] 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

[0005] It is often desirable to remove tissue from the body in as minimally invasive a manner as possible, so as not to damage other tissues. For example, removal of tissue from within a patient's vasculature, such as removal of blood clots from veins and arteries, may improve patient conditions and quality of life.

[0006] Many vascular problems stem from insufficient blood flow through blood vessels. One cause 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. 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.

[0007] 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 a coronary artery 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 can be 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 the brain. 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. If myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's needs.

[0008] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes in such cases. 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.

[0009] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to mechanical retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are systems and apparatuses, and methods of using such systems and apparatuses, that address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[00010] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them.

[00011] In general, described herein are self-rolling mechanical atherectomy apparatuses for removing a clot from a vessel. These atherectomy apparatuses, which may also be referred to as thrombectomy apparatuses, typically include a tractor tube portion that rolls and inverts over itself in a continuous motion, tractor-like, to draw material into the tractor tube.

The apparatuses described herein may be similar to the mechanical atherectomy apparatuses, systems and methos disclosed and described in the above-list of related U.S. patents and applications, which have been incorporated by reference herein in their entirety. However, the self-rolling mechanical atherectomy apparatuses described herein are configured such that the tractor tube (also referred to as a tractor region) rolls and inverts over itself unsupported at the distal-facing end when the inner tractor tube portion is pulled proximally. Specifically, the apparatuses described herein are configured so that the tractor tube rolls and inverts over itself, unsupported, without the need for an internal catheter extending within the inverting tractor tube providing a support or distal end opening to roll over.

[00012] Thus, the tractor tube is inverted over itself to form a distal-facing region at the distal end of the self-rolling mechanical atherectomy apparatus where, in a deployed configuration, the outer tractor tube portion rolls over and into itself, unsupported to become the inner tractor tube portion as the proximal end of the inner tractor tube portion is pulled proximally. At least the distal-most region of the tractor tube (e.g., the region at or near the distal-facing, inverting region of the tractor tube) is unsupported over at least the distal-most 1 or more cm of the apparatus. The tractor tube may be actuated to roll over itself by pulling proximally on the inner tractor tube portion (or an inner tractor puller coupled to the inner tractor tube portion) and/or by pushing distally on a proximal end of the outer tractor tube portion that is braced against an outer tractor pusher. In general, in an expanded configuration, the proximal end of the outer tractor tube portion is braced against a tapered portion of the tractor tube proximal to the outer tractor tube portion.

[00013] The tractor tube may be adapted to allow unsupported rolling over itself having a column strength of the outer tractor tube portion that resists buckling and/or collapse when compressed by pulling proximally on the inner tractor tube portion. As described in greater detail herein, this may be accomplished by one or more of forming the tractor tube from a braided material having a compressed braid angle relative to the proximal-to-distal axis that is greater than 80 degrees (e.g., greater than 85 degrees, greater than 90 degrees, greater than 95 degrees, greater than 100 degrees, between 80-170 degrees, between 90-170 degrees, between 95-170 degrees, etc.); the braid angle of the inner tractor tube portion under tension in the proximal-to-distal axis is typically much less than the compressed braid angle of the outer tractor tube portion in compression, and may be, e.g., less than 90 degrees (e.g., less than 85 degrees, less than 80 degrees, less than 75 degrees, less than 70 degrees, less than 65 degrees, less than 60 degrees, less than 50 degrees, less than 45 degrees, less than 40 degrees, between 90-5 degrees, between 80-5 degrees, between 70-5 degrees, between 65-5 degrees,

between 60-5 degrees, etc.). The compressed outer tractor tube braid angle refers to the braid angle of the outer tractor tube in the deployed (e.g., radially expanded) configuration; pulling the inner tractor tube portion proximally, e.g., by pulling the inner tractor puller, results in a compressive load on the outer tractor tube portion that is continuous but inverted relative to the inner tractor tube portion.

[00014] For example, described herein are self-rolling mechanical atherectomy apparatuses that include: an outer tractor pusher comprising a catheter having a distal end and a distal end opening; a tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured so that pulling the inner tractor tube portion proximally compresses the outer tractor tube portion so that it has a column strength that resists collapsing, further wherein pulling the inner tractor tube proximally causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

[00015] In general, the outer tractor pusher may be a catheter, tube, cannula, or the like. During delivery or positioning of the apparatus, the tractor tube, and an inner tractor puller, if included, may be held within the outer tractor pusher in an un-deployed configuration. Prior to clot removal, the tractor tube may be deployed out of the outer tractor pusher portion and the outer tractor pusher portion maybe expanded into a deployed configuration that has an outer radial diameter that is greater than the inner radial diameter of the outer tractor pusher. The outer tractor pusher may then be positioned to support or brace the outer tractor tube portion to allow it to roll over and into itself distally when the inner tractor puller is pulled proximally. Alternatively, a separate distal access catheter may be included, and the outer tractor pusher may be held within the distal access catheter along with the tractor tube prior to deployment within the blood vessel.

[00016] In any of these apparatuses, the outer tractor pusher may be coupled to a proximal end of the outer tractor tube portion of the tractor tube. Alternatively, the proximal end of the outer tractor tube portion may be unconnected to the outer tractor pusher.

[00017] As mentioned, the apparatus may include a distal access catheter. The outer tractor pusher, the tractor tube and inner tractor puller may be held within the distal access catheter in an un-deployed configuration, further wherein the tractor tube may be configured to be pushed distally out of the distal access catheter so that the outer tractor tube portion may

expand to a diameter that is greater than an outer diameter of the distal access catheter in a deployed configuration. Alternatively, the outer tractor pusher may be configured as a distal access catheter wherein the tractor tube and inner tractor puller may be held within the outer tractor pusher in an un-deployed configuration, further wherein the tractor tube may be configured to be deployed by being pushed distally out of the outer tractor pusher so that the outer tractor tube portion expands to an outer diameter that is greater than an outer diameter of the outer tractor pusher.

[00018] In any of the self-rolling mechanical atherectomy apparatuses described herein, the tractor tube may be configured so that pulling the inner tractor tube proximally compresses the outer tractor tube portion and the column strength of the outer tractor tube portion resists collapsing up to at least 300g of compression (e.g., at least about 350 g of compression, at least about 400 g of compression, at least about 450 g of compression, at least about 500 g of compression, at least about 550 g of compression, at least about 600 g of compression, at least about 650 g of compression, at least about 700g of compression, etc.).

[00019] In general, the tractor tube comprises a braided or woven material. For example, the tractor tube may be a woven or braided tube, e.g., formed of one or a plurality of filament. The filaments may be monofilaments or bundles of filaments, and may be a polymeric material, a metal material, a natural fiber material, etc. For example, the tractor tube may be formed of between 24-48 filaments. The tractor tube may be formed of a plurality of filaments having a diameter of greater than about 0.003 inches (e.g., greater than 0.0020 inches, greater than 0.0025 inches, greater than 0.0035 inches, greater than 0.0040 inches, greater than 0.0045 inches, greater than 0.0050 inches, etc.).

[00020] In particular, the tractor tube may be configured to resist buckling when rolling over itself based in part on the arrangement of the filaments. For example, the outer tractor tube portion may have a braid angle in a proximal to distal axis (in a compressed configuration) that is between 80 and 170 degrees, and the inner tractor tube portion may have a braid angle in the proximal to distal axis (e.g., under tension) of less than 80 degrees.

[00021] In any of the apparatuses described herein, the proximal end of the outer tractor tube portion may be configured to have a tapered shape when the outer tractor tube portion is expanded radially outward. This tapered region may be shape set into the tractor tube (e.g., when the tractor tube is formed of a shape-settable material, for example, such as a nickel titanium alloy) and/or it may be formed by attaching a retaining structure to the proximal end of the outer tractor tube portion, such as a retaining band, retaining ring, etc., or by attachment to the outer tractor pusher.

[00022] As mentioned, the distal-facing region of the tractor tube may be unsupported, including unsupported over at least 1 cm proximally from the distal-facing region of the tractor tube (e.g., at least 1.5 cm, at least 2 cm, at least 2.5 cm, etc.). Thus, the tractor tube does not roll over a support (such as a catheter) at the distal-facing tractor portion at the distal end of the device.

[00023] In general, the tractor tube may be porous. For example, the tractor tube may have a porosity of 50% or greater (e.g., 55% or greater, 60% or greater, 65% or greater, 70% or greater, 75% or greater, etc.).

[00024] Any of the apparatuses described herein may be used with a guidewire, for placing the apparatus. For example, the inner tractor puller may include an inner lumen configured to pass a guidewire out of a distal end of the apparatus. In general a guidewire may be included as part of the apparatus.

[00025] Any of these apparatuses may include a vacuum source coupled to the tractor tube and configured to apply a vacuum (e.g., aspiration) therethrough. The vacuum source may include a pump.

[00026] For example, a self-rolling mechanical atherectomy apparatus for removing a clot from a vessel may include: an outer tractor pusher comprising a catheter having a distal end and a distal end opening; a tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured so that pulling the inner tractor tube portion proximally compresses the outer tractor tube portion so that it has a column strength that resists collapsing up to at least 500g of compression and extends inner tractor tube portion, further wherein pulling the inner tractor tube proximally causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

[00027] Also described herein are methods of removing a clot from a blood vessel using any of the apparatuses described herein. Generally, these methods may include actuating a self-rolling mechanical atherectomy apparatus so that the distal-facing region of the tractor tube is unsupported as the outer tractor tube portion rolls over and into itself and inverts, pulling in any clot or other target material into the tractor tube. The tractor tube is typically configured to roll over itself without support (e.g., be "self-rolling") from any other structure, e.g., by having a sufficient column strength in the outer tractor tube portion in compression to resist or prevent buckling, bending or collapse, yet be sufficiently flexible that it may bend

and navigate through the often tortious anatomy of the vasculature (and particularly the neurovasculature), and to roll over itself. Various configurations are described herein to achieve this combination of flexibility and column strength, including forming the apparatus with a braided (or woven) tractor tube having a large braid angle in the outer tractor tube portion (under compression) and a relatively smaller braid angle in the inner tractor tube portion (e.g., under tension).

[00028] For example, a method of removing a clot from a blood vessel may include: advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller; pulling an inner tractor puller of the tractor tube proximally to compresses an outer tractor tube portion of the tractor tube, wherein pulling the inner tractor puller proximally causes the outer tractor tube portion at a distal-facing region of the tractor tube to roll over itself, unsupported, and invert into the inner tractor tube portion; and engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled into the tractor tube.

[00029] Any of these methods may include deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that the outer tractor tube portion of the tractor tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher. Pulling the inner tractor puller may include bracing a distal-facing end of the outer tractor pusher against a tapered face of the tractor tube that is proximal to the outer tractor tube portion. Thus, the tapered face or region of the tractor tube may be pushed against the outer tractor pusher when the tractor tube is attached or un-attached to the outer tractor pusher. When attached to the outer tractor pusher, the tapered face region of the tractor tube may still be driven against the opening of the outer tractor pusher.

[00030] Any of the methods described herein may include advancing a guidewire within the blood vessel to the clot, wherein advancing the self-rolling mechanical atherectomy apparatus comprises advancing the self-rolling mechanical atherectomy apparatus over the guidewire through the blood vessel until the self-rolling mechanical atherectomy apparatus is proximate to the clot.

[00031] Engaging (or "grabbing") the clot may include advancing the outer tractor pusher distally while pulling the inner tractor puller proximally. Alternatively or additionally, engaging the clot may include advancing the outer tractor pusher distally at a first rate while pulling the inner tractor puller proximally at a second rate that is different (e.g., faster) than the first rate.

[00032] In general, advancing may include advancing the self-rolling mechanical atherectomy apparatus distally with the tractor tube and inner tractor puller within the outer tractor pusher, wherein the tractor tube is in an un-deployed configuration. Once near (e.g., adjacent) the clot or other target, the tractor tube may be deployed from the inner tractor puller and/or distal access catheter.

[00033] Any of these methods may include applying aspiration through the tractor tube.

[00034] Advancing the self-rolling mechanical atherectomy apparatus may include advancing a distal access catheter enclosing the tractor tube, outer tractor pusher and inner tractor puller, wherein the outer tractor tube portion is inverted over the inner tractor puller in an un-deployed configuration within the distal access catheter.

[00035] Pulling the inner tractor puller may include applying up to 500 g of compressive force on the outer tractor tube portion without collapsing the outer tractor tube portion.

[00036] For example, a method of removing a clot from a blood vessel may include: advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller; deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that an outer tractor tube portion of the tractor tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher, wherein a distal-facing end of the outer is braced against a tapered face of the tractor tube proximal to the outer tractor tube portion, and wherein the outer tractor tube portion inverts over itself at a distal-facing region of the tractor tube and extends proximally within the outer tractor tube portion as an inner tractor tube portion that is coupled to the inner tractor puller; pulling the inner tractor puller proximally to compresses the outer tractor tube portion of the tractor tube, and to cause the outer tractor tube portion of the tractor tube to roll over itself, unsupported, at the distal-facing region and to invert into the inner tractor tube portion; engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled into the tractor tube; and withdrawing the self-rolling mechanical atherectomy holding the clot from the blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[00037] 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:

[00038] FIGS. 1A-1C illustrate an example of an apparatus for mechanically removing an object such as a clot form a body region that include an inverted tube (e.g., "tractor" tube) of material that rolls and inverts over the distal end of an inner catheter. FIG. 1A shows the device, including the tractor tube portion connected to a puller that is within the catheter. The tractor tube may be deployed in a vessel near a clot, as shown in FIG. 1B. To activate this type of mechanical thrombectomy device the end of the tractor tube in the catheter, which is shown connected to a puller also within the catheter, is pulled proximally away from the clot, rolling the tractor tube over the distal end of the catheter and inverting it, as shown in FIG. 1C. The clot may then be drawn into the catheter by the rolling and inverting action of the tractor tube.

[00039] FIG. 2A illustrates one example of a self-rolling mechanical atherectomy apparatus that is configured so that the distal-facing portion of the tractor tube inverts over itself, unsupported, when the internal tube portion of the tractor tube is pulled proximally. In FIG. 2A, the apparatus includes an outer tractor pusher (e.g., catheter, cannula, tube, etc.), a tractor tube that is inverted over itself at a distal-facing portion of the apparatus, and an inner tractor puller (e.g., rod, catheter, cannula, tube, etc.) connected to an inner tractor tube portion of the tractor tube that is inverted relative to the outer tractor tube portion and extends inside of the outer tractor tube portion.

[00040] FIG. 2B shows the apparatus of FIG. 2A within a delivery catheter (e.g., a distal access catheter).

[00041] FIG. 2C is another example of a self-rolling mechanical atherectomy apparatus similar to the one shown in FIG. 2A, in which the end of the outer tractor tube portion of the tractor tube that is on the outside of the inverted tractor tube is attached to the outer tractor pusher.

[00042] FIG. 2D is another example of a self-rolling mechanical atherectomy apparatus similar to the apparatus shown in FIG. 2D, in which the end of the outer tractor tube portion of the tractor tube that is on the outside of the inverted tractor tube is attached to an outer tractor pusher that is internal to an outer (e.g., distal access) catheter, and may be used to push or pull the tractor tube from the proximal end. The outer catheter may be slid distally to protect the tractor portion, or it may be held proximally relative to the outer tractor pusher to help support the proximal end of the outer tractor tube portion of the tractor tube.

[00043] FIGS. 3A and 3B show examples of self-rolling mechanical atherectomy apparatuses. In FIG. 3A, the tractor tube is formed of as a woven structure that is configured to compress with a large braid angle under tension, e.g., when pushing the outer tractor tube portion distally and/or pulling the inner tractor tube portion proximally, and is further configured to have a small braid angle in the inner tractor tube portion. Thus, the tractor tube supports itself so that it may roll over itself and invert at a distal-facing region when either the inner tractor tube portion of the tractor tube is pulled proximally (and the outer tractor tube portion of the tractor tube is held in position or pushed distally), or when the outer tractor tube portion of the tractor tube is pushed distally (and when the inner tractor tube portion is pulled proximally or held in position). The tractor tube rolls over itself at the distal-facing region of the tractor tube and this rolling action may draw material into the inner tractor tube portion. FIG. 3B is similar to FIG. 3A, except that one end of the tractor tube (the region adjacent to the outer tractor tube portion) is constrained within the outer tractor pusher, and the outer tractor pusher pushes or braces against the tapered surface between the constrained region and the outer tractor tube portion.

[00044] FIGS. 4A-4D illustrates the operation of a self-rolling mechanical atherectomy apparatus such as those shown in FIGS. 2A-3. In FIG. 4A, the self-rolling mechanical atherectomy apparatus has a tractor tube is inverted over itself at a distal-facing region, and includes an inner tractor rube portion that is connected to an inner tractor puller. The inner tractor puller shown may be a rod, catheter, or cannula (e.g., hypotube). In this example, the end of the outer tractor tube portion of the tractor tube is connected to an outer tractor pusher (catheter). FIG. 4B illustrates the self-rolling mechanical atherectomy apparatus being actuated to roll and invert the tractor tube over itself, unsupported, at its distal-facing region. In FIG. 4B, the outer tractor tube region has sufficient column strength to prevent buckling, or collapse of the tractor tube under the applied tension. The apparatus is actuated in FIG. 4B by pushing the outer tractor pusher distally (to the right) while holding the inner tractor puller fixed relative to the patient's body (e.g., the vessel). FIG. 4C shows actuation of the self-rolling mechanical atherectomy apparatus of FIG. 4A so that the tractor tube rolls and inverts from the outer tractor tube portion to the inner tractor tube portion at the distal-facing region by holding the outer tractor pusher and pulling proximally on the inner tractor puller. FIG. 4D illustrates actuation of the self-rolling mechanical atherectomy apparatus of FIG. 4A by both pulling the inner tractor tube portion proximally (e.g., by pulling the inner tractor puller proximally) and by pushing the outer tractor tube portion distally (e.g., by pushing the outer tractor pusher distally).

[00045] FIGS. 5A-5D illustrate the use of a self-rolling mechanical atherectomy apparatus such as those shown schematically above, to remove a clot (thrombus) from within a vessel. In FIG. 5A, the apparatus includes an outer catheter (e.g., distal access catheter), a tractor tube having an outer tractor tube portion that inverts at a distal-facing region into an inner tractor tube portion, an inner tractor puller connected at the proximal end of the inner tractor tube portion of the tractor tube, and an outer tractor pusher connected at the proximal end of the outer tractor tube portion of the tractor tube. The apparatus is in a vessel and is maneuvered so that the distal-facing end region of the tractor tube is adjacent to the clot. Once positioned, the outer catheter may be withdrawn, and tension may be applied (e.g., by pushing distally on the outer tractor pusher), expanding the tractor tube within the vessel, as shown in FIG. 5B. The tractor tube may be positioned at or against the clot. Thereafter, the tractor tube may be rolled on itself, unsupported by any internal catheter at the distal-facing end region, as shown in FIG. 5C, by pulling the inner tractor puller proximally and/or pushing the outer tractor pusher distally, drawing the clot into the inner tractor tube portion. This process may be continued until the entire clot is pulled into the inner tractor tube portion, as shown in FIG. 5D. Thereafter the tractor tube, outer tractor pusher and inner tractor puller may be withdrawn back into the distal access catheter and withdrawn from the vessel.

[00046] FIGS. 6A-6D illustrate a method of removing of a clot using a self-rolling mechanical atherectomy apparatus. In FIG. 6A, the apparatus includes a tractor tube having an outer tractor tube portion, distal-facing region where the outer tractor tube portion inverts into an inner tractor tube portion, and an inner tractor puller that is connected to the inner tractor tube portion. The tractor tube and the inner tractor puller are held within a distal access catheter, and the outer tractor tube portion is unattached. The self-rolling mechanical atherectomy apparatus is positioned within a vessel near a clot. In FIG. 6B the outer distal access catheter is withdrawn proximaly and/or the inner tractor puller is advanced distally, so that the tractor tube is partially extended from the distal end of the outer distal access catheter and adjacent to the clot. The outer tractor tube portion is placed under tension, e.g., by pulling the inner tractor puller proximally, as shown in FIG. 6B, expanding the outer tractor tube portion so that it is jammed against the distal opening of the outer distal access catheter. As the inner tractor puller is pulled proximally, the tractor tube rolls and inverts at the distal-facing region, drawing the inner tractor tube portion proximally and engaging the clot, as shown in FIG. 6C. The inner tractor tube portion is withdrawn proximally by pulling the

inner tractor puller until the clot is engulfed, as shown in FIG. 6D. The self-rolling mechanical atherectomy apparatus, holding the clot, may then be withdrawn.

[00047] FIG. 7A-7B illustrate possible failure modes for the operation of a self-rolling mechanical atherectomy apparatus. In FIG. 7A, the tractor tube (e.g., the outer tractor tube portion) is shown collapsed when applying tension by pulling the inner tractor puller proximally. In FIG. 7B, the tractor tube (e.g., the outer tractor tube portion) is shown collapsed when applying tension by pushing the outer tractor pusher (e.g., an outer catheter) distally. The configuration of the tractor tube may be configured to avoid this failure mode, including adjusting the braid angle of the outer and/or inner tractor tube portions, the amount of expansion of the tractor in the outer tractor tube portion, the number of strands (or strand equivalents) forming the tractor tube, the minimum length of expanded tractor tube, the material used for the tractor tube, the thickness of the strands or strand equivalents of the tractor tube, the porosity of mesh forming the tractor tube, or combinations of these.

[00048] FIGS. 8A and 8B illustrate another example of a possible failure mode of a self-rolling mechanical atherectomy apparatus. FIG. 8A shows an example of a self-rolling mechanical atherectomy apparatus. FIG. 8B show the apparatus of FIG. 8A when the outer tractor tube portion is placed under tension by advancing the outer catheter (e.g., outer tractor pusher) relative to the inner tractor puller, collapsing the proximal end of the outer tractor pusher portion

[00049] FIG. 9 schematically illustrates a self-rolling mechanical atherectomy apparatus showing examples of internal and external braid angles for the outer tractor tube portion and the inner tractor tube portion, respectively.

[00050] FIG. 10 is an example of the distal-facing region of a self-rolling mechanical atherectomy apparatus.

[00051] FIG. 11 is an example of a self-rolling mechanical atherectomy apparatus including a tractor tube that is inverted over itself, and an inner tractor puller.

[00052] FIG. 12 shows an example of the attachment of an outer tractor tube portion of a tractor tube connected to an outer tractor pusher, showing the braid angle of the outer tractor tube portion.

[00053] FIG. 13 is another example of a distal-facing region of a self-rolling mechanical atherectomy apparatus, similar to that shown in FIG. 10.

[00054] FIGS. 14A-14D show examples of a method of using a self-rolling mechanical atherectomy apparatus having a pre-shaped tractor tube. In FIG. 14A the self-rolling mechanical atherectomy apparatus, which is held within a distal access catheter, is positioned

adjacent to a clot within a blood vessel. Once positioned, distal access catheter is withdrawn, allowing the outer tractor tube portion of the tractor tube to expand, as shown in FIG. 14B. The proximal end of the outer tractor tube portion is tapered, as shown, and may present a face that the distal access catheter, acting as an outer tractor pusher, may push against, as shown in FIG. 14C. The proximal end may be shape-set into this tapered shape, or it may be formed in this shape. Thereafter, the proximal end of the inner tractor tube portion may be pulled proximally to roll the outer tractor tube portion over itself (unsupported) so that it inverts into the inner tractor tube portion, capturing and drawing the clot with it, as shown in FIG. 14D. The inner tractor tube may be pulled fully back into the outer tractor pusher (in this example, the distal access catheter) and withdrawn from the body.

[00055] FIG. 15A illustrates an example of a tractor tube including an outer tractor tube portion that is tapered forming a face that me braced against an outer tractor pusher. The distal end of an exemplary outer tractor pusher is shown for reference. FIG. 15B is an example of another example of an outer tractor tube portion including a collar (shown as a ring) that forms a tapered shape at the proximal end of the outer tractor tube portion or a tractor tube.

[00056] FIGS. 16A-16C illustrate another example of a self-rolling mechanical atherectomy apparatus in which the proximal end of the outer tractor tube portion of the tractor tube of the apparatus is releasably attached to an outer tractor pusher, e.g., by bonding with a frangible material, mechanical connection, dissolvable connection, etc. In contrast, the proximal end of the inner tractor tube portion of the tractor tube may be permanently bonded to an inner tractor puller, as shown in FIG. 16A. FIG. 16B illustrates the use of the self-rolling mechanical atherectomy apparatus of FIG. 16A to grab and withdraw a clot from a vessel by pulling the inner tractor tube portion of the tractor tube proximally, so that the outer tractor tube portion rolls over itself, unsupported, at the distal-facing region of the tractor tube, and inverts to become more inner tractor tube portion. FIG. 16C illustrates the fully withdrawing the tractor tube into the outer tractor pusher, releasing the end of the tractor tube that is attached to the outer tractor pusher and allowing the entire (now inverted) tractor tube to be withdrawn into the apparatus.

[00057] FIGS. 17A-17D illustrate exemplary tractor tubes formed by cutting (e.g., laser cutting) a tubular material.

[00058] FIGS. 18A-18C illustrate different slotted patterns that may be cut into a tube (or sheet) to form a tractor tube or portion of a tractor tube.

[00059] FIG. 19 is another example of a pattern that may be use to form a tractor tube.

[00060] FIGS. 20A-20B show an example of a pattern that may be use to form a tractor tube. FIG. 20B is an enlarged view of the pattern of FIG. 20A.

[00061] FIGS. 21A-21B show an example of a pattern that may be use to form a tractor tube. FIG. 21B is an enlarged view of the pattern of FIG. 21A.

[00062] FIGS. 22A-22B show an example of a pattern that may be use to form a tractor tube. FIG. 22B is an enlarged view of the pattern of FIG. 22A.

[00063] FIGS. 23A-23B show an example of a pattern that may be use to form a tractor tube. FIG. 23B is an enlarged view of the pattern of FIG. 23A.

[00064] FIGS. 24A-24B show an example of a pattern that may be use to form a tractor tube. FIG. 24B is an enlarged view of the pattern of FIG. 24A.

[00065] FIGS. 25A-25B illustrate tractor regions having different patterns of slots and openings.

[00066] FIG. 26A illustrates another example of a tractor portion of a self-rolling mechanical atherectomy apparatus, showing properties of different regions ("zones") of the tractor tube in different configurations, including an inner tractor tube portion that stretches in tension, a distal-facing region between the inner tractor tube portion and the outer tractor tube portion, a high column strength outer tractor tube portion, a constrained region at the proximal end of the outer tractor tube portion, and a transition zone between the high column strength outer tractor tube portion and the constrained region.

[00067] FIGS. 26B and 26C illustrate the functional operation of the different regions ("zones") of the self-rolling mechanical atherectomy apparatus shown in FIG. 26A. Pulling on the inner tractor tube portion (e.g., by pulling on the inner tractor tube portion itself or on an inner tractor puller to which it is attached) causes the outer tractor tube portion closest to the distal-facing region of the tractor tube to roll over itself and invert into the inner tractor tube portion; at least in part because of the high column strength of the outer tractor tube portion and the strength of the transition zone preventing the tractor tube from collapsing (as shown in FIGS. 7A-7B and 8B). FIG. 26B shows a side perspective view, while FIG. 26C shows a sectional view though the self-rolling mechanical atherectomy apparatus of FIG. 26B during operation of the apparatus.

[00068] FIG. 27A shows a top view looking proximally on the distal-facing region of the tractor puller of FIGS. 26A-26C, showing the change in the braid angle from the high column strength (large braid angle) outer tractor tube portion in compression, to the elongated (small braid angle) inner tractor tube portion in extension, when pulling the inner tractor tube portion proximally.

[00069] FIG. 27B shows a bottom view looking distally from the constrained region at the proximal end of the outer tractor tube portion, showing the inside of the distal-facing region of the tractor tube.

[00070] FIG. 28 illustrates a shape outline of a tractor tube of a self-rolling mechanical atherectomy apparatus, showing a funnel shape that may be formed as the tractor tube is rolled over itself, unsupported, at the distal-facing region. The tractor tube may be configured to form this funnel shape; the tractor tube may be a braided, woven, knit, solid, or some combination of these.

DETAILED DESCRIPTION

[00071] In general, described herein are self-rolling mechanical thrombectomy apparatuses having an inverting tractor tube that is configured to roll over and into itself at an unsupported distal-facing region that is at the very distal end of the apparatus, which may be used to capture and remove a blood clot from a blood vessel. These apparatuses may include a tractor tube that comprises a flexible tube that doubles back over (e.g., inverts) over itself so that an outer portion (e.g., an outer tractor tube portion) rolls and inverts, becoming an inner portion (e.g., an inner tractor tube portion) as this inner portion is pulled proximally. The apparatus typically includes an outer tractor pusher that supports and/or pushes the tractor tube just proximal to the proximal end of the outer tractor tube portion. The tractor tube may taper from the outer tractor tube diameter (which is typically larger than the diameter of the outer tractor pusher) to a dimeter that is smaller than the inner diameter of the outer tractor pusher. The end of the tractor tube may be attached to the outer tractor pusher or it may be unattached to the outer tractor pusher. Any of these apparatuses may also include an inner tractor puller that is coupled to the other end of the tractor tube (e.g., the end that become the proximal end of the inner tractor tube portion when operating as described herein). Thus, the apparatus may be actuated to cause the tractor tube to roll and invert over itself, unsupported at the distal-most end, by pulling directly on the inner tractor tube portion or by pulling on an inner tractor puller that is coupled to the proximal end of the inner tractor tube portion.

[00072] Thus, in general, the inner tractor tube portion may therefore be pulled proximally to roll and invert the tractor tube over itself, without the need to roll over an annulus at the distal end of an elongate inverting support, since the apparatus may be configured to have a sufficient column strength on the outer portion of the tractor tube (the radially-expanded and longitudinally compressed outer tractor tube portion) to prevent buckling, bending or failure of the tractor tube when compression force (e.g., up to 300 g or more, 350 g or more, 400 g or

more, 500 g, etc.) is applied to the outer tractor tube region by pulling the inner tractor tube region proximally. This is an improvement compared to other mechanical atherectomy apparatuses, including those described and shown in FIGS. 1A-1C, which typically include an elongate support that includes an annulus over which the tractor inverts at the distal end. The support (e.g., catheter) is typically positioned in the distal end region (e.g., the distal-facing tractor tube region) of the apparatus and the tractor tube inverts over it, rather than over itself; such embodiments may therefore require that the support be maneuvered with the tractor, any outer catheter and any inner puller.

[00073] For example, FIGS. 1A-1C shows an example of a mechanical thrombectomy apparatus that is not self-rolling. In this variation, an elongate inversion support is included (shown here as catheter 101) as a part of the mechanical thrombectomy apparatus. In this example, the elongate inversion support catheter 101 has a distal end region 103 that includes a distal end opening. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region may be substantially less soft than the region immediately proximate to it.

[00074] In FIG. 1A, the elongate inversion support (e.g., catheter 101) 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 more 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 a higher force (e.g., at least 1500 g of compressive force, at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). The elongate inversion support may not be 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 or may be skived. However, in each of these example, the support extends to the distal end region of the apparatus to provide a supporting surface over which the tractor tube can roll.

[00075] In FIG. 1A the support catheter 101 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00076] FIG. 1B shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly, however the support catheter 101 extends between the outer

tractor tube portion and the inner tractor tube portion all the way to the distal-facing tractor portion at the distal-most end of the apparatus. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. In general, it may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1C. In FIG. 1C, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00077] In FIG. 1C, the flexible tractor of FIG. 1B is shown with the tractor doubled back over itself and over the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration the tractor (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[00078] FIG. 1C illustrates the removal of a clot using this supported tractor apparatus shown in FIGS. 1A and 1B. In this example the apparatus is configured as a thrombectomy

apparatus including a catheter of an elongate inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor.

[00079] However, described herein are self-rolling atherectomy (thrombectomy) apparatuses that do not need to roll over a support such as an elongate inversion support catheter. Instead, these apparatuses are configured to roll over just themselves, unsupported at their distal end. FIGS. 2A-2D illustrate examples of self-rolling thrombectomy apparatuses 200. Any of these apparatuses may include a tractor tube 206 (e.g., having, in a deployed configuration, an outer tractor tube portion 204, an inner tractor tube portion 208, and a distal-facing region 206 at which they invert) that may be configured to prevent collapse when under compression. In FIG. 2A, the apparatus also includes an inner tractor puller 205 coupled to the proximal end of the inner tractor tube portion 208, and an outer tractor pusher 207 which is shown (in this example) unconnected to the tractor tube.

[00080] FIGS. 2B-2D illustrate other variations of the self-rolling atherectomy apparatuses. In FIG. 2B, the apparatus of FIG. 2A is shown in a separate distal access catheter 211. The tractor tube is in an un-deployed configuration, within the distal access catheter; once deployed, the outer tractor tube portion may expand as shown in FIG. 2A. The self-rolling atherectomy apparatus shown in FIG. 2C is similar to that shown in FIG. 2A, however the proximal end of the outer tractor tube 204 is attached 213 to the outer tractor pusher 207. In FIG. 2D, the apparatus of FIG. 2C is shown including both an outer tractor pusher 207 as well as a distal access catheter 211.

[00081] Any of these apparatuses may include a guidewire lumen extending through the tractor tube and/or inner tractor puller that is configured to pass a guidewire.

[00082] Any of these apparatuses may include one or more projections that are configured to enhance engaging and/or maceration of a clot. Engaging the clot may be particularly, but not exclusively, helpful when the tractor is lubricious. It may also be particularly helpful to include projections that are retracted along the length of the tractor adjacent to the outer diameter of the elongate inverting support (e.g., catheter), for example, when positioning the apparatus within a vessel, but extend the projections outward from the tractor when rolling and inverting to grab a clot.

[00083] In many of the examples described herein, the tractor tube and/or inner tractor puller may extend for any appropriate distance (including between 1-100 cm, between 2-100 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). Similarly, the outer tractor pusher may extend to the same length or longer. The tractor tube may form an elongate lumen that is configured to allow passage of a guidewire, as mentioned. The tractor tube may also be configured to slide along the long axis within a distal access catheter (and/or an outer tractor pusher) lumen, e.g., during initial placement in the vessel. The tractor tube may therefore be longitudinally slideable within the distal access catheter, and may be arranged so a portion of the tractor tube (the distal –facing tractor region) doubles back over itself within the distal access catheter/outer tractor pusher or after being deployed from the distal access catheter or outer tractor pusher.

[00084] In general the self-rolling mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation.

[00085] The self-rolling mechanical thrombectomy apparatuses described herein typically create a rolling cylinder (tractor or tractor tube) that may be used to entrap or ensnare foreign objects from the human body.

[00086] The structure of the tractor tube may be formed from wires, threads, filaments, laser slotted tubing, or the like. The tractor tube may be braided, or may have a braided appearance. See, e.g., FIG. 3. When activated to roll and invert over itself, the tractor tube may produce a center-grabbing effect, similar to conveyor belt. The self-rolling mechanical thrombectomy apparatus may be delivered via a catheter (e.g., distal access catheter and/or outer tractor pusher) to a site of interest (peripheral vessel, neuro vascular, MIS surgical procedure, etc.). When the apparatus is in place, the device may be pushed and/or pulled, as described and illustrated below to activate the tractor tube so that it acts like a grabbing conveyor belt.

[00087] For example, FIG. 3A illustrates an apparatus including a tractor tube 303, outer tractor pusher 305 and inner tractor puller 307. The tractor tube is shown in a deployed configuration. In this example, the tractor tube 303 includes an outer tractor tube portion 309 that is shown in a compressed configuration having a large braid angle (e.g., greater than 150 degrees in this example). The tractor tube 303 also includes an inner tractor tube portion 311 that has a much smaller braid angle (e.g., less than 45 degrees in this example). The portion of the tractor tube proximal to the outer tractor tube portion 309 is a constrained region 313 that may be held (e.g., by shape setting, by a mechanical or structural constraint, such as a ring or catheter, etc.) in an intermediate configuration that is not as radially expanded as the

outer tractor tube portion 309. A tapered region 315 is formed between the constrained region 313 of the tractor tube and the outer tractor tube portion 309 and may act as a bracing surface for an outer tractor pusher 305' (as shown in FIG. 3B). In FIG. 3A, the outer tractor pusher is shown pushing against 317 the end of the constrained region 313 of the tractor tube 303.

[00088] In FIG. 3A and 3B, the tractor tube includes a distal-facing region 319 where the tractor tube rolls and inverts over itself. As will be illustrated below (e.g., in FIGS. 26A-26C), when the outer tractor pusher pushes against the end of the tractor tube closest to the outer tractor tube portion and the inner tractor tube portion is pulled proximally, the resulting compressive force compresses the outer tractor tube region 309, resulting in a column strength that prevents buckling and failure of the tractor tube while driving rolling of the outer portion of the tractor tube over and into itself at the distal-facing region 319 of the tractor tube.

[00089] Thus, any of these apparatuses may include a patterned (e.g., braided) tractor tube that may be shape set (e.g., heat set). The inner tractor tube region may be configured to have a lower column strength that allows it to expand to adjust to the clot diameter as it is drawn into the tractor tube.

[00090] FIGS. 4A-4D illustrate examples actuating a self-rolling mechanical atherectomy apparatus. For example, in FIG. 4A, similar to that shown in FIG. 2A-2D, the self-rolling mechanical atherectomy apparatus includes a tractor region (having an expanded/deployed outer tractor region 404 that is continuous with an inner tractor region 408 after rolling and inverting over itself at the distal-facing region. In FIG. 4D the apparatus is shown deployed, with the outer tractor tube portion 404 expanded radially, having an outer diameter that is greater than the inner diameter of the outer tractor pusher 405. The outer tractor pusher is braced against the tapered region 415 proximal to the outer tractor tube region.

[00091] FIGS. 4B-4D illustrate alternative methods of actuating the tractor tube so that it rolls over itself and inverts, unsupported, only at the distal end. For example, in FIG. 4B, the outer tractor pusher 405 is pushed distally while the inner tractor puller is held, causing the outer tractor tube portion to roll over itself 431and invert into the inner tractor tube portion, as shown. Similarly, in FIG. 4C, the tractor tube is actuated by pulling proximally on the inner tractor tube portion while holding the outer tractor pusher in place. FIG. 4D illustrates a combined method including both pushing the outer tractor pusher distally while pulling the inner tractor puller proximally; the two may be operated at different rates or distances. For example, the inner tractor puller may be pulled more proximately than the outer tractor pusher is pushed. In some variations, the entire apparatus may be advanced distally by

pushing the outer tractor pusher distally, while still pulling the inner tractor puller proximally to roll the tractor tube into itself, as shown.

[00092] FIGS. 5A-5D illustrate removal of a clot using a self-rolling mechanical atherectomy apparatus as described herein. In this example, the self-rolling mechanical atherectomy apparatus is a co-axial system including both a distal access catheter 509 and an outer tractor pusher 511, as well as an inner tractor puller 513. The apparatus is deployed in a blood vessel 503. In FIG. 5A, the self-rolling mechanical atherectomy apparatus is shown in an un-deployed configuration in which the tractor tube 505, which is connected at one end 523 to the outer tractor pusher, and at the other (inner) end to the inner tractor puller 513, is in a collapsed configuration within the lumen of the distal access catheter 509. The apparatus is initially positioned adjacent to the clot 519 (FIG. 5A). The distal-facing end 516 of the tractor tube is shown initially inside the distal end of the distal access catheter 509. The tractor tube 505 can either be preloaded in the distal access catheter 509 during access or delivered through the distal access catheter after the distal access catheter is positioned adjacent to the clot. The inner tractor puller can be cannulated (like a catheter) to allow delivery of a guidewire through its self to aid in delivery of the system to the clot. In FIG. 5A, the distal-facing region 516 of the tractor tube is the distal-most end of the assembly. Alternatively the distal-facing region 516 of the tractor tube can be inverted on itself (not shown) prior to delivering the system up to the clot.

[00093] The tractor tube may be made of a braid structure as described above. In this example, when constrained, it may have low braid angles (e.g., between 5 - 90 degrees, between 5-45 degrees, between 5-30 degrees, etc.). After it is released from the distal access catheter and deployed, the braid angle would may be much larger; once compression is applied to the outer tractor tube portion, e.g., by pulling on the inner tractor puller, the braid angle will be much larger (e.g., between 80-170 degrees), while the braid angle in the portion under tension (e.g., the inner tractor tube portion) may be much lower (e.g., less than 90 degrees, less than 80 degrees, less than 70 degrees, etc.). In this context, the braid angle referred to herein may refer to the braid angle relative to the proximal-to-distal axis, and the angle formed between intersecting strands of the mesh forming the tractor tube. This is illustrated below, in FIG. 9.

[00094] In FIG. 5B, the apparatus is shown deployed from the distal access catheter by pulling back on the distal access catheter to release the tractor tube, allowing it to expand radially to an outer diameter that is larger than the inner diameter of both the distal access catheter and the outer tractor pusher. Alternatively or additionally, the tractor tube can be

driven forward out of the distal access catheter, (e.g. and into or towards the clot) rather than pulling back the distal access catheter.

[00095] In FIG. 5C, the inner tractor puller 513 is retracted proximally to cause the tractor tube to invert over and into itself, unsupported at the distal-facing region of the tractor tube, so that it can grab clot and pull the clot into the tractor tube, as shown. The distal facing region of the of tractor tube forms a conical shape as it inverts on its self. By continuing to pull the inner tractor puller or fix the inner tractor puller and push the outer tractor pusher (or some combination of both movements), the conical shape formed on the tractor tube behaves like a conveyor, engaging (i.e., "grabbing") the clot 519 and pulling it into the tractor tube, engulfing the clot and capturing it, as shown in FIG.5D.

[00096] Pushing the outer tractor pusher and/or pulling the inner tractor puller may be continued until the clot is fully captured. The clot can be removed from the vessel by either withdrawing the entire system, or by pulling the tractor tube into the distal access catheter and then pulling out the tractor tube while leaving the distal access catheter in place. The distal access catheter and or other components (e.g., the inner tractor puller and/or tractor tube) can have vacuum applied during, before and/or after clot engagement by the tractor tube. Alternatively, while pulling the inner tractor puller and pushing the outer tractor pusher, the tractor tube may be withdrawn inside the distal end of the outer tractor pusher with the clot.

[00097] FIGS.6A-6D illustrate the operation of an alternative variation of a self-rolling mechanical atherectomy apparatus, in which the same catheter acts as both the distal access catheter (e.g., delivering the apparatus to the clot) and the outer tractor pusher, e.g., pushing or bracing the tractor tube from the proximal end to allow it to rollover itself distally.

[00098] In FIG. 6A, the apparatus includes a tractor tube 605 that is connected at one end to an inner tractor puller 613; both the tractor tube and the inner tractor puller are held within the outer tractor pusher 611 (acting as a distal access catheter). This configuration may be referred to as a single axial system. The tractor tube is not attached 623 to the outer tractor pusher in this example. In FIG. 6B, the tractor tube may be deployed by pulling back the outer tractor tube (distal access catheter) 611 and allowing the outer tractor tube portion of the tractor tube to expand radially, as shown. The tractor tube 605 can be fully deployed into vessel or the proximal end of the tractor tube can remain in the outer tractor pusher, as shown. The outer tractor pusher braces against the tractor tube at a tapered end before (e.g., just proximal to) the outer tractor tube portion. Alternatively, the tractor tube can be driven

forward into the clot and out of the outer tractor pusher rather than pulled back to deploy the tractor tube in the vessel.

[00099] In FIG. 6C, the inner tractor tube portion is retracted proximally so as to invert the tractor tube over and into itself, thereby engaging the clot 619. The distal-facing region of the tractor tube forms a conical shape as it inverts on itself when pulling the inner tractor puller and/or pushing the outer tractor pusher. By continuing to pull inner tractor puller or holding the inner tractor puller fixed and pushing the outer tractor pusher (or some combination of both movements), the conical shape formed on the tractor tube may act like a conveyor, engaging and pulling the clot into tractor tube (i.e., engulfing and capturing the clot). As shown in FIG. 6D, the clot may be engaged/grabbed and enclosed at least partially, within the tractor tube and removed from patient.

[000100] The self-rolling mechanical atherectomy apparatuses described herein may provide improved clot engagement with lower grabbing forces, and without jamming. As will be described in greater detail below, these apparatuses may be tuned to provide sufficient column strength so that they do not fail during operation, and the forces required to invert the tractor tube are relatively small. The high column stiffness of the expanded tractor tube acts like a catheter-tube, enabling it to be easily advanced forward in a vessel. Finally, these apparatuses can be used with or without aspiration.

[000101] As mentioned above, the self-rolling mechanical atherectomy apparatuses described herein are specifically configured so that the tractor tube portion rolls over itself, unsupported, at its distal end when pulling the inner tractor tube portion proximally and/or pushing the outer tractor tube portion distally. Generally, when pushing and/or pulling a flexible tube that is woven, braided, knitted, or even solid, the tractor tube will bend, buckle or collapse. This is particularly true of flexible tractor tubes that inverted over themselves and biased to expand radially outward in either or both the outer tractor tube configuration and the inner tractor tube configuration). Buckling and collapsing are therefore failure modes for such tractor tube which must be avoided if operating a self-rolling mechanical atherectomy apparatus.

[000102] FIGS. 7A-7B and 8A-8B illustrate these common failure modes. In FIG. 7A, self-rolling mechanical atherectomy apparatus 701 similar to those shown in FIGS. 2A-2D, 3A-3D, 4A-4D, 5A-5D, and 6A-6D are shown buckling or collapsing when either or both the inner tractor tube portion is pulled proximally (e.g., by pulling an inner tractor puller) or the outer tractor tube portion is pushed proximally (e.g., by pushing an outer tractor pusher). In FIG. 7A, a distal access catheter 709 is configured as an outer tractor pusher because a

tapered portion 712 of the tractor tube that is proximal to the outer tractor tube portion 703 of the tractor tube 705 is pushed against the distal opening face 710 of the distal access catheter when the outer tractor pusher (distal access catheter 709) is pushed distally while holding the inner tractor puller 711 fixed relative to the vessel wall as indicated (or alternatively pulling it proximally). In this example, although the outer tractor tube portion 703 may being rolling over itself, unsupported, at its distal end (distal facing end 719), the outer tractor tube portion 803 in the expanded configuration (e.g., not constrained within the distal access catheter) does not have sufficient column strength to prevent the outer tractor tube portion from compressing and buckling. One or more outer tractor tube regions buckle 721, 721', collapsing under the compressive force on the outer tractor tube portion. In some variations, the tractor tube will roll slightly, as shown in FIG. 7A; alternatively, the tractor tube will not roll at all, but will immediately collapse or buckle.

[000103] In FIG. 7A, the force required to roll and invert at the distal end is greater than the force that will causes the expanded outer tractor tube region to buckle; as a result, the outer tractor tube buckles. Once the tractor tube 705 begins to buckle or collapse, it will no longer roll over the distal end region, may lead to further collapse. In addition, the force required to advance the increasingly collapsed tractor tube distally by pushing the outer tractor pusher/distal access catheter may increase substantially.

[000104] A similar failure may occur when pulling the inner tractor tube region proximally, as illustrated in FIG. 7B. In FIG. 7B, a distal access catheter 709 is braced against the distal opening face of the distal access catheter and the inner tractor tube portion 707 is pulled proximally, by pulling on the inner tractor puller 711. The outer tractor tube portion 703 is in the expanded configuration (e.g., not constrained within the distal access catheter). Because the tractor tube 705 is unsupported at the distal-facing end 719, pulling on the inner tractor tube portion 707 compresses the outer tractor portion 705. In this case, as in FIG. 7A, the compressive force is greater than column strength of the outer tractor tube portion. Typically, the force applied to actuated the devices described herein may be up to a maximum of about 400 g of force, (e.g., 300 g of force, 350 g of force, 400 g of force, 450 g of force, 500 g of force, 550 g of force, 600 g of force, etc.), particularly in neurovascular applications. When the applied actuating force, which becomes the applied compressive force, is greater than the column strength of the outer tractor tube portion, the outer tractor tube portion buckles 731, 731' as shown in FIG. 7B.

[000105] Thus, in general, for any of the apparatuses described herein to operate, they must be configured so that the column strength of the expended outer tractor tube portion, which

may be a braided or woven material, is greater than at least the maximum force in the range of forces used to actuate the apparatus so that the tractor tube rolls and inverts over itself, unsupported, at its distal-facing end region. For example, the apparatuses described herein may be configured so that the outer tractor tube portion has a column strength that is sufficient to resist buckling or collapse under a compressive force of least about 500 g.

[000106] In addition to the column strength of the outer tractor tube under compression, which may lead to buckling or collapse around the longitudinal length of the apparatus, as shown in FIGS. 7A-7B, FIGS. 8A-8B illustrate another failure mode causing collapse at the proximal end of the outer tractor tube portion, which may occur when the proximal tapered portion of the expanded tractor tube buckles against the outer tractor pusher/distal access catheter.

[000107] For example, in FIG. 8A, a self-rolling mechanical atherectomy apparatus 801 is shown in an expanded or deployed configuration. The tractor tube 805 includes an outer tractor tube region 803 that is expanded out of the distal end of the distal access catheter. The tractor tube includes a proximal tapered region 812 that is braced against the distal end opening 810 of the distal access catheter 809. The apparatus also includes an inner tractor puller 811 that is connected to an end of the tractor tube 805; when the tractor tube rolls and inverts over itself at the distal-facing end 819, the inner tractor puller 811 will be attached to the proximal end of the inner tractor tube region. FIG. 8A shows the apparatus prior to actuating by either or both pulling the inner tractor puller and/or pushing the outer tractor pusher (in this configuration, the distal access catheter).

[000108] In FIG. 8B, upon actuating the apparatus, e.g., by either or both pulling or pushing, the tapered region 812 at the proximal end of the outer tractor tube portion 803, against which the distal end opening 810 of the outer tractor pusher 809 pushes or braces collapses, folding the proximal end of the outer tractor tube portion over the distal access catheter. In this example, the relative weakness of the proximal tapered region between the expanded outer tractor tube portion and the distal end opening of the outer tractor pusher/distal access catheter causes this tapered region to fail, so that the tractor tube rolls over 841 the open end 810 of the distal access catheter (and therefore over itself proximally), rather than rolling over itself distally at the distal-facing opening 819.

[000109] As illustrated by FIGS. 7A-7B and 8B-8B, the apparatus, and particularly the tractor tube, should preferably be configured so that the column strength of the expanded outer tractor tube portion is greater than the maximum applied compressive force (e.g.,

actuating force), and the strength of the tapered region should resist the force applied by the outer tractor pusher.

[000110] Thus, a functional self-rolling mechanical atherectomy apparatus for removing a clot from a vessel should be configured to avoid at least these failure modes. Specifically a self-rolling mechanical atherectomy apparatus should have a tractor tube with a sufficient column strength in an expanded outer tractor tube portion so as to resist a compressive force of greater than at least some minimum threshold (e.g., 400 g of force, 500 g of force, 600 g of force, etc.). Alternatively or additionally, the tractor tube should have a tapered region proximal to the expanded outer tractor tube portion that is configured to resist the distally directed force applied by the outer tractor pusher.

[000111] Described herein are configurations and parameters for forming a tractor tube meeting these criterion. For example, the tractor tube may be formed of a material (and particularly a mesh, e.g., braided or woven material) having a braid angle in the expanded tractor tube, when compressed by pushing and/or pulling, in a proximal-to-distal axis that is between about 80 and about 170 degrees. The inner tractor tube portion may have a braid angle in the proximal to distal axis under tension of less than 80 degrees (e.g., less than 75 degrees, less than 70 degrees, less than 65 degrees, less than 60 degrees, less than 50 degrees, less than 45 degrees, less than 40 degrees, less than 35 degrees, etc.). In addition, the amount of expansion f the outer tractor tube portion may be between +/- about 30% of the outer diameter of the outer tractor pusher. In addition, for woven or braided configurations, the number of strands (or strand equivalents) may be at least 12 (e.g., 12 or more, 16 or more, 18 or more, 24 or more, 36 or more, 40 or more, 50 or more, 60 or more, 72 or more, etc.). The expanded tractor tube may also be configured to have a minimum length (e.g., of 0.7 cm or greater, e.g., 0.8 cm or greater, 0.9 cm or greater, 1 cm or greater, 1.2 cm or greater, etc.). For example, the unsupported tractor tube length may be $\geq$ 1 cm. When the tractor tube is formed of a woven or braided material, the material used for the tractor tube may be a monofilament or a collection of filaments. The tractor tube may also include a number of pores (e.g., cells) formed by the strands; the porosity of the mesh may be, for example, 70% or less (e.g., 65% or less, 60% or less, 55% or less, 50% or less, 45% or less, etc.) and in particular, 60% or less.

[000112] In general, the applicants have found that, for braided or woven tractor tubes having the following ranges of parameters, a self-rolling (e.g., unsupported) tractor tube apparatus will not kink or collapse or otherwise fail as described in FIGS. 7A and 7B and 8A-8B: the tractor tube may be formed of a least 10 strands and have a distal-to-proximal facing

braid angle for the expanded configuration of the outer tractor tube portion of between about 80 and about 170 degrees, a distal-to-proximal facing braid angle of the tensioned inner tractor tube portion that is always less than the braid angle of the expanded outer tractor tube portion and is about 80 degrees or less, further wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of the outer diameter of the outer tractor pusher. Such tractor tubes may have sufficient column strength to resists collapsing when actuated (e.g., with at least 500 g of force) and under compression so as to roll over the distal-facing end of the tractor tube, unsupported.

[000113] For example, it may be preferable that, for braided or woven tractor tubes, the tractor tube is formed of a least 10 strands of materials (more preferably at least 12 strands of material, still more preferably at least 16 strands of material), where the strands have a thickness of about 0.003 inches or greater. The fibers forming the tractor tube may have a distal-to-proximal facing braid angle of between about 80 and about 170 degrees in the expanded outer tractor tube portion under compression and a braid angle in a distal-to-proximal direction of the tensioned inner tractor tube portion that is less than the braid angle of the expanded outer tractor tube portion and is 80 degrees or less. The outer tractor tube portion of the tractor tube may be configured to expand to within +/- about 30% of the outer diameter of the outer tractor pusher. The length of the tractor tube may be at least 1 cm or more.

[000114] Thus, in any of the apparatuses described herein, the tractor tube may be flexible enough to be pushed through a catheter located in the tortuous neuro vasculature anatomy. The tractor may be delivered partially inverted (e.g., rolled on itself) to the clot face through a catheter. The distal-facing end of the tractor tube is generally unsupported (e.g., the tractor tube does not roll over and against the distal opening of a catheter or other support). The unsupported outer tubular length of the tractor tube may be of adequate length when in its axial compressed form to grab typical clot lengths seen in stroke patients (e.g., 1 cm or greater) in a single pass/pull. Typically, the outer tractor tube portion rolls around the distal-facing end of the tractor tube when the distal-facing end of the tractor tube is adjacent and may be in contract (e.g., jammed up against) a clot. The user may then drive the outer tube distally by (or while) pulling the inner tractor puller, and therefore the inner tractor tube portion, proximally, and either supporting or pushing the outer tractor pusher distally. The axial pushing forces on the tractor tube generate an axial compressive load on the expanded outer tractor tube portion and, as long as the column strength is greater than the compressive load, and as long as the strength of the tapered region against the outer tractor pusher is

sufficient, the tractor tube will roll over itself, unsupported, without kinking, collapsing or otherwise failing. Thus, the flexible tractor tubes described herein are configured to have sufficient axially columnar stiffness that when axially compressive forces are applied, the outer tractor tube portion rolls and inverts rather than bunch, buckle, accordion or collapse.

[000115] In general, the outer tractor tube portion may be configured so that the maximum expansion relative to the outer diameter of the outer tractor pusher that it is supported against is sized appropriately so device doesn't jam in vessel when pushed & axially compressed, or collapse as shown in FIG. 8B. If the expanded outer diameter (OD) of the outer tractor tube portion is too big, the tractor tube may lock in the vessel when being pushed, rather than advancing in the vessel or driving the rolling/inverting action. Similarly, if the tractor tube OD is too small, the tractor tube may not be large enough to grab the clot sufficiently (e.g., it may core out center of clot only, leaving some of the clot behind or requiring additional removal steps. Thus, in general, the tractor tube may be configured so that it does not over-expand, e.g., due to compressive forces are applied by user to the tractor tube.

[000116] In any of the apparatuses described herein, the tractor tube may have sufficient coarseness at its rolling tip to engage and grab a clot. For example, when the tractor tube rolls over the distal end of the apparatus, the inner tractor tube portion may maintain an adequate inner diameter (ID) to leave room for clot. Thus, the inner tractor tube portion may also be configured to expand radially outwards somewhat, rather than collapse onto itself when pulled and tensioned proximally. For example, the inner tractor tube portion may be biased radially outwards to have an inner diameter that is 30% or more of the inner diameter of the expanded outer tractor tube portion (e.g., 35% or more, 45% or more, 50% or more, 55% or more, 60% or more, etc.). The tractor tube may generally be porous, which may provide additional coarseness. For example, it may be beneficial to have a porous structure that has relatively small pores (e.g., small enough to capture all the clot when inverting/rolling), and a sufficient number of pores (e.g., less than 70%, less than 65%, less than 60%, less than 55%, less than 50%, etc. porosity).

[000117] Any of the apparatuses described herein can be used in combination with vacuum/aspiration. For example a vacuum may be applied through the inner tractor puller and/or the tractor tube. Further, any of the apparatuses described herein may be configured so that they are visible under fluoroscopy; in particular, the tractor tube or a portion of the tractor tube may be configured so that it is visible under fluoroscopy.

[000118] FIG. 9 shows one example of a self-rolling thrombectomy apparatus with a braided tractor tube that is configured to provide sufficient column strength in the outer

tractor tube portion when compressed to as to prevent failure by kinking, bending, collapsing or otherwise failing. In FIG.9, the apparatus includes a distal access catheter 909, an outer tractor pusher 913, and a braided tractor tube 905. The braided tractor tube has an expanded, outer tractor tube portion 903, a tapered portion 912 proximal to the outer tractor tube portion, and an inner tractor tube portion 907 that is connected to an inner tractor puller 911. The tractor tube 905 inverts over itself so that the outer tractor tube portion rolls and inverts to become the inner tractor tube portion at the distal-facing end region 919.

[000119] In FIG. 9, an exemplary distal-to-proximal facing braid angle 909 (Φ_1) for the outer tractor tube portion is illustrated. This Φ_1 angle may be between 80 degrees and 170 degrees, but is more preferably > 90 degrees. In the example shown in FIG. 9, it is between 110 degrees and 160 degrees. FIG. 10 shows an example of a distal-facing end region 1019 of a prototype tractor tube that is configured as described above, including having a distal-to-proximal facing angle (Φ_1) 1015 of between 80 degrees and 70 degrees; in this example, the Φ_1 angle is approximately 130 degrees. Returning to FIG. 9, the outer tractor tube portion in the expanded state has a high braid angle, jammed braid state, and max diameter that provide a high resistance to axial compressive force (e.g., column strength in compression), which makes it easy to advance/push braid structure forward, as well as resisting kinking and failure of the tractor tube. In FIG. 9, the distal-to-proximal braid angle of the inverted, inner tractor tube region 911 (shown as Φ_2) is typically much smaller than Φ_1, and may be, e.g., less than 90 degrees (e.g., less than 80 degrees, less than 70 degrees, less than 60 degrees, etc.). In FIG. 10, the distal-to-proximal facing braid angle of the inner tractor tube portion 1007 (Φ_2) is also shown, and in this example is about 35 degrees. The low braid angle of the inner tube region is formed as the braid collapses to a small diameter when the tractor tube rolls around distal-facing end, and inverts inside the larger outer tractor tube portion. In FIG. 10, the braided tractor tube is formed of 24 strands ("24 end") of 0.0005" x 0.0010" NiTi ribbon that is braided to have a maximum OD (when axially compressed of 2.5mm.

[000120] FIGS. 11, 12 and 13 illustrate other examples of tractor tubes that may be used as part of a rolling mechanical atherectomy apparatus as described. In FIG. 11, the tractor tube 1105 is shown inverted over itself. The outer tractor tube portion is expanded to a large braid angle. As described and shown above, the braid angle is the distal-to-proximal facing angle formed between intersecting strands of the braid. In FIG. 11 and FIG. 12, the braid angle is greater than 120 degrees for the fully expanded outer tractor tube portion 1103. The inner tractor tube portion is not easily visible in FIG. 11. The proximal end of the outer tractor tube portion is tapered, and has a smaller braid angle as it tapers down (e.g., the tapering braid

angle goes from the expanded outer tractor tube portion braid angle of >120 degrees to approximately 90 degrees where it is attached to the outer surface of the outer tractor pusher 1113. The tractor tube in FIG. 11 is formed of a braided Nickle titanium (NiTi) material. In FIG. 12 a similar tractor tube is shown, including a braid angle (distal-to-proximal facing) of the expanded outer tractor tube portion 1203 that is approximately 150 degrees. The tapered region 1212 proximal to the outer tractor tube portion transitions to a smaller braid angle (e.g., between about 100 and 70 degrees), where it is attached to the outer tractor pusher 1213. FIG. 13 shows a distal-facing end of a tractor tube of a self-rolling apparatus that is unsupported. The distal-facing end 1319 of the tractor tube shown illustrates the inverted, rolling end of the tractor tube. The tractor tube does not enclose or surround a support element (e.g., catheter, loop, etc.) at or near the distal-facing end that is rolling.

[000121] FIGS. 14A-14D illustrate and alternative to the "clot grabbing" tractor tube in which the region of the tractor tube that is proximal to the expanded outer tractor tube portion is shape set into a taper in the relaxed, otherwise expanded, configuration. For example, in FIG. 14A, the apparatus is configured as a single-axis system within a vessel 1402. In operation, the apparatus is delivered within the vessel 1402 through a distal access catheter 1409. A guidewire may also be used to position the apparatus. In FIG. 14A, the apparatus is compressed within the distal access catheter and slid or otherwise driven through the vessel to the clot 1455. The tractor tube 1405 is compressed, but is pre-rolled around itself with a distal-facing end region at the distal end of the device that may be positioned in proximity to the clot 1455 in the vessel. The inner tractor tube portion is attached to an inner tractor puller 1411. In this single axial system shown, the distal access catheter 1409 also acts as the outer tractor pusher once the tractor is pushed out of the catheter and expanded, as shown in FIG. 14B.

[000122] In FIG. 14B, the distal access catheter may be withdrawn proximally and/or the rest of the apparatus may be pushed distally, allowing the distal access catheter to release and deploy the apparatus so that the outer tractor tube portion 1403 can expand to a diameter that is within +/- 30% of the outer diameter of the distal access catheter/outer tractor pusher 1409. In this example, the distal access catheter is withdrawn proximally past the outer, proximal end of the tractor tube portion, showing that this end of the tractor tube is pre-set to a tapered shape 1412. Thus, in FIG. 13C, the distal access catheter (outer tractor pusher) may be advanced distally back over this tapered region, to either drive the outer tractor tube portion distally or to brace against the tapered portion and hold the outer tractor tube portion in position while pulling the inner tractor tube portion proximally, as shown. Thus, in FIG. 14C,

the distal-facing region of the tractor tube forms a conical shape as it inverts on itself when the inner tractor puller is pulled proximally and/or the outer tractor pusher (distal access catheter) is pushed distally. By continuing to pull inner tractor puller and/or hold the inner tractor puller and push the outer tractor pusher (or some combination of both movements), the conical shape formed on the tractor tube behaves like a conveyor, thereby "grabbing" the clot and pulling the clot into tractor tube (e.g., engulfing the clot/capturing the clot). Once the tractor tube is inverted, it (along with the captured clot) can be pulled into the distal access catheter, as shown in FIG. 14D. In FIG. 14D, the inner tractor puller can be fully retracted and the tractor tube can be removed from the patient out of the distal access catheter.

[000123] FIGS. 15A and 15B illustrate variations for forming the pre-set tapered regions of the tractor tube proximal to the expanded outer tractor tube portions. In FIG. 15A, the tapered proximal region 1512 is shown with a rolled distal-facing end region 1532. In this example, the maximum outer diameter is within a predefined range of the outer diameter of the outer tractor pusher catheter 1513 is within a predefined percentage (e.g., between about +/- 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, etc. of the outer diameter of the distal access catheter 1513). The tapered distal region 1512 may be formed by shape setting to the tapered shape. Alternatively, as shown in FIG. 15B, the apparatus may include a limiter, such as a ring, neck, band, etc. 1552 that limits the expansion of the tractor tube portion.

[000124] For example, in FIG. 15B, the proximal end of the tractor tube 1505 on the outside of the tractor tube includes a polymer and/or metal ring 1552 or bulking agent to increase the effective wall thickness of the proximal end of the tractor tube, making it easier for the distal end opening of the distal access catheter to engage with this proximal end of the tractor tube, and may also support and allow for easier pushing of the construct, and/or prevent the failure mode shown in FIG. 8B, above. This can be achieved by bonding, fusing or integrating a separate element into the proximal end of the tractor tube (e.g., stent, O ring, beading of glue/adhesive, fusing or melting a polymer ring or by inverting the braid so the braid is doubled up on the proximal end, making the wall thickness thicker). Alternatively or additionally, the ends of the braid at this proximal end may be left open and even purposely frayed to provide filaments that would easily catch on the distal end of the distal access catheter when trying to push the tractor tube distally.

[000125] In general, the self-rolling apparatuses described herein may have a jammed braid angle on the outside of the tractor tube (e.g., a maximum diameter of the braid). The braid's maximum diameter during axially compression may be slightly smaller and/or larger than the vessel ID (e.g., it may have the same OD, > 5% bigger, >10% bigger, <5 % smaller, <10%

smaller, < 20% smaller, < 30% smaller, etc.). This may facilitate the structure advancing when pushed forward. Examples of high braid angles range from 80-170deg, or by an increment within that range by 10 deg or more. For example, a tractor tube for an M1 vessel (e.g., 2-2.5mmID) may have 36 braid ends of 0.001" NiTi wire formed onto a 2mm mandrel at max braid angle. This tractor tube may be annealed to this shape on the 2mm mandrel. In another example, a tractor tube may be formed for an M1 vessel (e.g., 2-2.5mmID), from 48 braid ends of 0.0005" by 0.001" of flat wire onto a 2.5 mm mandrel, at max angle. In another example, a tractor tube for an M1 vessel (e.g., 2-2.5mmID) may have a braid of 48 ends of 0.0005" by 0.001" flat NiTi wire onto a 2.5 mm mandrel, near max angle, that is removed from mandrel, and slid over a larger mandrel of 2.75mm (e.g., to increase braid angle to a jammed braid angle). In another example, for a larger vessel (e.g., 3-3.5 mm ID), a braid having 72 ends of 0.0005" by 0.001" of flat NiTi wire may be formed onto a 3 mm mandrel, near max angle, removed from the mandrel, and slid over a larger mandrel of 3.5 mm (to increase braid angle to a jammed braid angle). For much larger vessels (e.g., 5 -8mm) a 72 ends 0.002"-0.003" NiTi wire, having a max braid angle on 5-8 mm mandrel may be formed.

[000126] In general, the tractor tube may be formed of flat wires; this may help create a grabbing edge when the braid rolls. In addition, radiopaque wires can be mixed into the pattern for visibility under flouro (e.g., platinum, platinum iridium, DFT wire, gold, marker bands or beads, etc.). Any of these apparatuses can be delivered pre-loaded inside the distal access catheter and/or separately (e.g., using a secondary catheter after the distal access catheter is in position) delivered.

[000127] Any of the tractor tubes may be coated with a flexible material like urethane, silicone or other elastic element. A coating can be throughout the entire tractor tube length and/or thickness or partially on the length, e.g., just on one surface (such as inside or outside of the structure). In one embodiment, the tractor tube surface that touches ID of the distal access catheter wall when rolled around the catheter tip may not have a coating (as this surface touches the clot), while the other surfaces may have a coating or lamination. These coatings may cover all the interstices of the structure so aspiration/vacuum could be applied through the inner tractor puller and/or the distal access catheter to get a vacuum force to the clot. The coating could also include a hydrophilic coating to help make the CGS more lubricous for rolling on itself.

[000128] In any of the apparatuses described herein, the proximal end of tractor tube may be temporarily attached to the distal end of the outer tractor pusher (in some variations, the distal access catheter). For example, a temporary bond or connection between the end of the

tractor tube and the outer tractor pusher may allow the tractor tube to push and maybe pull the tractor tube distally and proximally; however, when the tractor tube is fully inverted, the tractor tube may be released from the distal end of the outer tractor pusher, allowing the user to pull out both elements separately (e.g., the outer tractor pusher and the tractor tube). FIGS. 16A-16C illustrate one example of this. In FIG. 16A, the apparatus includes a distal access catheter 1609 that has been withdrawn over a separate outer tractor pusher 1613 within the blood vessel 1602. The outer tractor pusher is temporarily attached 1633 (e.g., by a frangible bond or connection that is fused, adhesive and/or a mechanical connection) to and end of the tractor tube 1605, and particularly the end that is proximal to the outer tractor tube portion, which is shown expanded in this example. The opposite end of the tractor tube is permanently attached 1631 to the distal end of an inner tractor puller 1611. The apparatus is shown deployed within the vessel adjacent to a clot 1619.

[000129] In FIG. 16B, the inner tractor puller may be withdrawn proximally as describe above to grab the clot and withdraw it into the tractor tube as it is rolled from the outer tractor tube portion into the inner tractor tube portion. Once the entire outer tractor tube portion has been rolled and inverted into itself, the connection to the outer tractor pusher may be broken, as shown in FIG. 16C, so that the entire tractor tube may be withdrawn into the outer tractor pusher and distal access catheter, as shown.

[000130] FIGS. 26A-26C and 27A-27B illustrate examples tractor tubes that are formed from slotted tubes (e.g. tubes formed with slot or openings cut through them). The same general properties described above for woven/braided tractor tubes may be applied to rolled/cut or otherwise formed tractor tubes. For example, in FIG. 26A, the tractor tube may be formed of a tube of material into which slots and pores (windows) through the tube have been laser cut. The material may initial be a sheet of solid (e.g., nickel titanium) material. In FIG. 26A, the tractor tube includes a distal-facing region 2619 is the rolling zone of the tractor tube, the region where the outer tractor tube portion 2603 rolls and inverts to become the inner tractor tube portion 2607. The cuts in the sheet of material form quadrilaterals arranged with a "braid angle" (in this variation, a cut angle) that converts from the very large braid angle in the compressed outer tractor tube portion 2603 to a much smaller braid angle in the inner tractor tube region.

[000131] The expanded outer tractor tube region 2603 shows that the angles of the pores (the braid angle) arranged in the proximal-to-distal axis have an angle of between 80-170 degrees, as described above. In This example, the angle is approximately 165 degrees. The cut-out pores are approximately diamond shapes and the entire circumference is cut with

these shapes, forming a larger diameter, flexible cylindrical column structure that has a very high column strength. Just proximal to the expanded outer tractor tube region 2603 is a tapered region 2612 that is a transition zone between a smaller diameter region that is constrained to have a smaller diameter (e.g., by the outer tractor pusher and/or the distal access catheter). The length (along the distal-to-proximal axis) of this tapering transition region 2612 may be approximately 0.25x to 2x the diameter (outer diameter) of the outer tractor tube region 2603.

[000132] As mentioned, the constrained region 2614 may be constrained so that it cannot expand radially (unlike the expanded outer tractor tube region), and may also be held to the outer tractor pusher by a releasable bond, as described above in FIGS. 16A-16D. This region may be held within the outer tractor pusher 2613.

[000133] FIG. 26B illustrates the rolling movement of the variation shown in FIG. 26A when the inner tractor tube portion 2607 is pulled proximally 2651. In this example, pulling the inner tractor tube portion proximally results in the elongation and tension on the inner tractor tube portion, putting compression (by the forced pulling down 2653 from the inner tractor tube portion, and the opposing force 2655 from the outer tractor pusher 2613) on the outer tractor tube portion 2603. The compressive force as well as the biasing force from the tractor tube maintains the expansion 2657 of the outer tractor tube portion. Pulling the inner tractor tube proximally and holding the outer tractor pusher (or pushing it distally) results in rolling 2659 of the distal-facing region of the tractor tube, causing it to collapse and fold back onto itself, as shown. The outer diameter of the outer tractor tube portion is therefore compressed to a minimum axial (distal-to-proximal) length, and a jammed maximum diameter, as shown. The constrained region 2614 is held within the outer tractor pusher 2613 by the constraining force 2661 against the inner diameter of the outer tractor pusher. The outer tractor pusher also applies a force 2665 against the tapered region 2612.

[000134] The sectional view of FIG. 26C provides additional detail, showing the transition between the outer tractor tube portion 2603 and the inner tractor tube portion 2607. As shown, the outer regions of the tractor tube (e.g., the constrained region, the tapered region and the outer tractor tube portion 2603) are all in compression while the inner regions (e.g., the inverting region and the inner tractor tube portion 2607) are in tension, causing rolling of the tractor tube.

[000135] FIGS. 27A-27B show views looking down the long axis of the tractor tube form the distal end and the proximal ends, respectively. In FIG., 26C, the transition in the cut angles ("braid angles") between the outer tractor tube portion and the inner tractor tube

portion at the distal-facing region of the tractor is apparent. FIG. 28 is a transparent view of a tractor tube showing the regions discussed above. In FIG. 28, the tractor tube includes the distal-facing region 2819 which forms a funnel-shape 2841 as it transitions from the expanded outer tractor tube portion 2803 to the inner tractor tube portion 2807. The inner funnel region could be formed/shaped and/or laser cut to be more similar in diameter to the ID of the outer tube, as described above. Thus, the inner tractor tube diameter could be biased to expand to a particular diameter (e.g., a fraction of the constrained tractor tube region, such as 30%, 40%, 45%, 50%, 60%, 65%, 70%, 80%, etc., or a fraction of the unconstrained outer tractor tube portion, etc.). In FIG. 28, the shape outline also shows the constrained region 2814, and a tapered region 2812 that is proximal to the expanded outer tractor tube region 2803. As already mentioned above, the tractor tubes may be formed from braid, knit, fabric tube, polymer extrusion, etc.

[000136] For example, any of the tractor tubes described herein may be formed from a laser-cut tube material. Examples of slotted laser cut tubes forming a tractor are provided herein, including those shown in FIGS. 17A-25B. The starting tubes may be flexible or rigid. For example, a soft flexible tube, strip, or roll of material such as ePTFE or a dense fabric (e.g., knit or weave or braid) may be used. Flexible tubes may provide tractors and/or combinations of tractors and catheters that allow tracking of the apparatus to the treatment site even in tortious vessels. Tracking allows pushing of the apparatus through tortuous vessels of small caliber over long distances from their introduction site to the human body, over length that can exceed 1 meter in some uses. A flexible tube (pre-laser cutting to form the tractor) may have a softness resulting in a low radial crush force, such as a micro-porous, polymer based tube. The tube may be processed (e.g., by cutting or any of the other techniques mentioned herein) to provide flexibility (e.g., the ability to pull the tractor into catheter, invert, and expand over catheter outer diameter) and/or to create a textured/porous surface that may aid in engaging/grabbing a clot (e.g., emboli) and may provide free spaces (voids) that may help store and/or masticate emboli, making them easier to store within the apparatus and transport. Prior to forming into the tractors the sheets or tubes (e.g., films, rolls, etc.) may have a smooth surface. Patterns may be formed into the sheet or tube to form the tractor. For example, laser slot patterns may be formed in the material to increase macro-surface roughness. Holes, slots, edges, divots, and bumps may be formed on the material. In addition to helping grab and hold emboli, such holes or slots may create free space in the tube wall to cut the clot and/or carry it away. The patterns used to form any of the tractors described herein may have a shorter strut length to strut width ratios. Short, wider struts may

create tractors that are stiffer and may grab clot better. In combination with strut length to width, in some variations, thicker walls may be preferred. Thicker slotted walls may create stiffer struts and more aggressive surface texture to grab clots. Furthermore, thicker walls may enhance clot storage capacity within the slot gaps.

[000137] In some variations, it may be beneficial to provide slot designs which do not foreshorten. For example, if the slotted tube design is pulled axial (e.g., down its length), the tube diameter may not decrease. A decreasing diameter slotted tube may grab the outside of the catheter and cleat, increasing drag force when the tube is pulled.

[000138] In variations in which the initial tube or sheet of material used to form the tractor tube is relatively rigid (e.g., formed of a material such as Steel, Nitinol, Polyester, PTFE, Nylon, etc.), the initial tube stiffness/hardness may enhance the clot-grabbing ability when the tractor is slotted properly, to allow both increased flexibility, expansion and rolling. For example, a rigid tube may include slot designs that focuses in catheter tracking and creates a flexibly bending tractor with minimal foreshortening, that is able to be pulled into a catheter (inverting) structure. As with the more flexible starting tubes discussed above, tractors formed of more rigid starting materials may grab and transfer a clot, and the number of slots and/or voids may be increased to increase clot grabbing and/or carrying capacity. A slotted tube forming a tractor may include surface grabbing features, such as channels/corrugations (e.g. any of the microstructures such as those shown in FIGS. 12A-12I above. More rigid tubes may create harder or stiffer slotted tractors. For example, when struts are formed into the tractor (e.g., by cutting, etc.), the slot strut length to strut width may be greater than with less rigid starting materials, and may be a function of the rigid tubes elastic modulus. Higher elasticity materials (e.g., Niti, PET, PTFE) may have strut length to width ratios from 10 to 100. Stiffer materials (e.g., steel, MP35N) may have a length to width ratio greater than 50. The wall thickness to strut width ratio for elastic materials may be, for example, between 0.5 to 10. For stiffer materials, the wall thickness to strut width ratio may be, for example, between 0.25 to 5.

[000139] As mentioned, any of the apparatuses described herein may include a tractor region that is non-foreshortening. The foreshortening of the tractor may depend at least in part on the slot designs for non-woven, non-braided, non-knitted designs (e.g., tractors that are not formed of a strand or strands of material). FIGS. 17A-17D illustrate an example of non-foreshortening design. Also, for both flexible and rigid starting tubes forming a non-woven tractor, the tube inner diameter can be slightly bigger then catheter tube outer diameter pre-slotting. Slotted tube designs which foreshorten may reach their smallest diameter limit

when tensioned axially. If the tube is sized to be slightly larger than the catheter outer diameter, then it may jam (preventing any foreshortening) before it cleats to the catheter outer diameter. Tractor regions formed of an initially rigid material may grab clot more efficiently than tractors having an equivalent thickness but formed of a more flexible material, although more flexible materials may deform as a function of stiffness.

[000140] FIGS. 17A-17D illustrate an example of tractors that are formed by cutting slots and/or windows into tubes of material. In FIGS. 17A-17D, an initially soft material (e.g., ePTFE) was formed by a subtractive manufacturing technique to from, slots, pores and textures in the soft flexible tube. In FIGS. 17A-17D, a 3mm ID ePTFE tube (configured to be used with a 2.9mm OD catheter) was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall to create textures and bend zones which impart clot grabbing and rolling. The ePTFE itself is highly lubricous. Addition of a lubricant (e.g., hydrophilic coating) may improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately. FIG. 17A shows a first pattern 1701, having minimal cuts to create a smooth rolling of the tractor around the catheter 1703 portion of the apparatus.

[000141] A second exemplary pattern is shown in FIG. 17B. In this example, the apparatus slightly larger cut-out regions 1709 (removed by laser cutting in this example), which may create better clot grabbing properties and more clot holding capacity. In FIG. 17B, the ePTFE tube forming the tractor region is slotted on the outside of the catheter. Note that the porosity (14 holes around the circumference) may help grab and hold colt. In both FIG. 17A and 17B, the laser pattern may foreshorten, but may jam before it grips/cleats the catheter outer surface.

[000142] Another example of a tractor was made from a 2.9 mm OD ePTFE tube (configured for use with a 3 mm ID catheter). This example was made to be highly flexible and have some level of column stiffness and radial/hoop stiffness by laser-cutting slot patterns into the tube wall in a pattern to create textures and configured to include bend zones which impart clot grabbing and rolling. Similarly, a tractor may be made of, e.g., a 2.9mm OD PET woven fabric tube (for use with a 3mm ID catheter). The tractor may be formed of 30 Denier PET multi-filaments, 0.003" thickness. The resulting tractor may be configured to be soft and have some level of column stiffness and radial/hoop stiffness by laser cutting slot patterns into the tube wall in a patterns providing texture and bend zones which may impart clot grabbing and rolling. As with ePTFE, the PET material may itself be lubricous although

additional lubricant may be added to improve tracking and rolling. Lubricant can be applied to ID and OD or to either separately.

[000143] An example of a tractor made from a somewhat rigid starting material was formed from a nickel titanium (NiTi) tube having a 3mm OD (which may be used with, e.g., a 2.9 mm ID catheter). The wall thickness in these examples was between 0.001" and 0.002". Laser slot patterns were cut into the tube wall in various patterns to create textures and purpose-designed bend zones which may help impart clot grabbing and rolling. A lubricant may be applied, e.g., as a coating, to the ID and OD or to either separately. A first pattern similar to that shown in FIG. 17A was made by minimal laser cutting to create a smooth rolling tractor, with a strut length to width ratio between 25-50. A second pattern having larger slots/openings (similar to that shown in FIG. 17B) was formed by laser cutting. These patterns may foreshorten, but typically minimize or stop foreshortening before the tractor grips/cleats the catheter outer surface (which may result in jamming). The Niti design has the additional benefits of radiopacity, thermal shaping and super elasticity.

[000144] Any of these designs or patterns may for projections that may extend from the rolling distal-facing and inverting portion of the tractor, as discussed above. Such projection may be cut out as "teeth" or elongate members. The regions forming the projections may be sharp, e.g., pointy and/or cutting. Sharp projections may be chew and cut a mature clot. These projections regions may be short or long, may extend in one or more directions (e.g., forward or backward or bidirectional), and may be scoop-shaped (e.g., paddle-shaped). The number of projections may be selected based on the desired coarseness, e.g., the number of projections, the size (length/width/thickness), etc. The projections may change density down their length. For example, the laser pattern can be designed to allow tractor rolling (e.g., long struts) more easily initially, then have grabbing teeth at higher density; alternatively the tractor may be configured for greater initially grabbing, having a pattern with more and/or larger projections initially (distally) then transitioning to more slits (and flexibility) toward the proximal end, which may make it easier to pull. Further, the distribution of projections can be uniform around the tube perimeter and/or non-uniform (e.g., forming a spiral pattern, distributed in patches, having open areas, etc.).

[000145] Any of the tractors described herein may include a marker or makers (e.g., radiopaque markers, such as gold, Pt, etc.). When forming the tractor from a tube or sheet, the tubes may be be cut, then shaped to have any profile, such as straight, rolled over the tip, flaring at the proximal end, etc. Any of the microstructure described herein may be included or formed, as mentioned above, e.g., wells on the struts may help carry and grab clot.

Tractors formed of tubes from which material was removed (or sheets formed into tubes) may be configured to have less cleating of the tractor onto the outer diameter of the clot, preventing jamming, particularly compared to woven or braided or knitted materials. However any of the slotted tube tractor configurations described herein may be used with, e.g., in combination with, a braid or knit or polymer sleeve, including either in parallel or in series. In general, any of these tractors may be formed as multi-layers, particular these slotted tube tractors.

[000146] For example, a tractor portion of an apparatus may be formed by removing material from a Niti tube that is slightly smaller than the inner diameter of the catheter that it will be used with, or it may be made from a tube that is slightly larger than the outer diameter of the catheters. The tube may be cut with a pattern that increase the coarseness of the outer surface (e.g., to include projections such as struts/scoops/teeth). For example a 0.001" tube wall thickness or smaller may be used.

[000147] FIGS. 17C and 17D illustrate an example of a tractor region cut from paper. In FIG. 17C a rigid paper tube was cut to include slots and the distal end expanded, a shown. It may be inverted over itself and used as a tractor region. This paper prototype was prepared to illustrate the effectiveness of this pattern. Similarly, FIG. 17D is an example of a prototype tractor region.

[000148] FIGS. 18A-18C illustrate examples of patterns that may be formed into a flat sheet or tubular member to form a tractor (e.g., slotted tractor). Similar to those shown in FIGS. 17A-17D. In FIG. 18A, the pattern may be cut to form the tractor. White regions 1801 may represent or form struts, while the lines indicate slots 1803 from which material is removed. This pattern is one of many resulting in a flexible tube having stout struts. FIG. 18B shows a similar example having a higher density of slots forming thinner struts and potentially higher porosity, which may result in a larger clot-carrying capacity. FIG. 18C illustrates an example of a pattern having curves that may produce a slightly more bendable (flexible in bending stiffness) slotted tractor. In FIGS. 18A-18C, the pattern is oriented so that the distal direction of the tractor formed by the pattern is at the right or left of the pattern shown (e.g., the tube is oriented right and left, relative to the figures, so that the tube is formed by rolling up from the bottom of the figure).

[000149] FIG. 19 is an example of a pattern that may be formed into a tube as part of a tractor having a plurality of both slots 1903 and cut-out regions 1901 (holes). Another example of a pattern having a plurality of cut-out holes 2001 formed into it is shown in FIGS. 20A and 20B. FIG. 20B shows an enlarged view.

[000150] An example of a pattern having a plurality of projections is shown in FIGS. 21A-24B. For example in FIGS. 21A and 21B, the pattern includes a plurality of slots 2101 and cut-out regions that leave a projecting strut or tooth 2105 behind. In these examples, the tooth 2105 is pointed and oriented to the left of the page, which may be the distal end direction of the tractor. (e.g., the left side of the image may correspond to the distal end of the tractor); thus when the pattern is formed into a tubular body to form the tractor, and the tractor is inverted over itself (e.g., rolling over the distal end opening of a catheter) the plurality of pointed projections 2105 may extend out of the tractor, and may help grab and draw clot into the catheter.

[000151] Similarly, the pattern shown in FIGS. 22A-22B illustrate another example include a slot 2201, a projection 2203 and a cut-out portion 2205. As in FIGS. 21A and 21B, the projection may extend out of the plane of the tubular tractor (shown here as the plane of the paper, even when rolled up to form the tractor region). FIG. 23A, and enlarged view of FIG. 24B, shows another example of a pattern for a tractor that is similar to that shown in FIG. 21A-21B, but with smaller projecting regions. In this example, the projections 2305 are sharp, and open into an opening 2303 connected to a slot 2301. The pattern shown in FIGS. 24A-24B is similar to that shown in FIG. 23A-23B but with additional openings (cut out regions 2407) which may increase the carrying capacity (e.g., clot carrying capacity) of the tractor region.

[000152] FIGS. 25A-25B are examples of laser-cut tube prototypes of tractor regions. In FIG. 25B the tractor region is inverted over the distal end opening of the catheter.

[000153] 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 elernent 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.

[000154] 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 "/".

[000155] 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.

[000156] 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.

[000157] 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.

[000158] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[000159] 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.

[000160] 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.

[000161] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

1. A self-rolling mechanical atherectomy apparatus for removing a clot from a vessel, comprising:

an outer tractor pusher comprising a catheter having a distal end and a distal end opening;

a tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured such that pulling the inner tractor tube portion proximally (i) compresses the outer tractor tube portion into a configuration having a column strength that resists collapsing, and (ii) causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and

an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

2. The apparatus of claim 1, wherein the outer tractor pusher is coupled to a proximal end of the outer tractor tube portion of the tractor tube.

3. The apparatus of claim 1, further comprising a distal access catheter, wherein the outer tractor pusher, the tractor tube, and inner tractor puller are held within the distal access catheter in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the distal access catheter so that the outer tractor tube portion expands to a diameter that is greater than an outer diameter of the distal access catheter in a deployed configuration.

4. The apparatus of claim 1, wherein the outer tractor pusher is configured as a distal access catheter in which the tractor tube and inner tractor puller are held within the outer tractor pusher in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the outer tractor pusher so that the outer tractor tube portion expands to an outer diameter that is greater than an outer diameter of the outer tractor pusher.

5. The apparatus of claim 1, wherein the tractor tube is configured so that pulling the inner tractor tube proximally compresses the outer tractor tube portion into a configuration in which the column strength of the outer tractor tube portion resists collapsing up to at least 500g of compression.

6. The apparatus of claim 1, wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of an outer diameter of the outer tractor pusher.

7. The apparatus of claim 1, wherein the tractor tube comprises a braided material.

8. The apparatus of claim 7, wherein the outer tractor tube portion has a braid angle in a proximal to distal axis in a compressed configuration that is between 80 and 170 degrees, and the inner tractor tube portion has a braid angle in the proximal to distal axis under tension of less than 80 degrees.

9. The apparatus of claim 1, wherein the tractor tube is formed of between 24-48 filaments.

10. The apparatus of claim 1, wherein the tractor tube is formed of a plurality of filaments, each having a diameter of greater than 0.003 inches.

11. The apparatus of claim 1, wherein the proximal end of the outer tractor tube portion is configured to have a tapered shape when the outer tractor tube portion is expanded radially outward.

12. The apparatus of claim 1, wherein the distal-facing region of the tractor tube is unsupported over at least 1 cm proximally from the distal-facing region of the tractor tube.

13. The apparatus of claim 1, wherein the tractor tube has a porosity of 60% or greater.

14. The apparatus of claim 1, wherein the inner tractor puller comprises an inner lumen configured to pass a guidewire out of a distal end of the apparatus.

15. The apparatus of claim 1, further comprising a vacuum source coupled to the tractor tube and configured to apply a vacuum therethrough.

16. A self-rolling mechanical atherectomy apparatus for removing a clot from a vessel, comprising:

an outer tractor pusher comprising a catheter having a distal end and a distal end opening;

a tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured so that pulling the inner tractor tube portion proximally (i) compresses the outer tractor tube portion into a configuration having a column strength that resists collapsing up to at least 500g of compression and extends inner tractor tube portion, and (ii) causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion; and

an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

17. The apparatus of claim 16, wherein the outer tractor pusher is coupled to a proximal end of the outer tractor tube portion of the tractor tube.

18. The apparatus of claim 16, further comprising a distal access catheter, wherein the outer tractor pusher, the tractor tube, and inner tractor puller are held within the distal access catheter in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the distal access catheter so that the outer tractor tube portion expands to a diameter that is greater than an outer diameter of the distal access catheter in a deployed configuration.

19. The apparatus of claim 16, wherein the outer tractor pusher is configured as a distal access catheter in which the tractor tube and inner tractor puller are held within the outer tractor pusher in an un-deployed configuration, and wherein the tractor tube is configured to be deployed by being pushed distally out of the outer tractor pusher so that the

outer tractor tube portion expands to an outer diameter that is greater than an outer diameter of the outer tractor pusher.

20. The apparatus of claim 16, wherein the tractor tube comprises a braided material.

21. The apparatus of claim 20, wherein the outer tractor tube portion has a braid angle in a proximal to distal axis in a compressed configuration that is between 80 and 170 degrees, and the inner tractor tube portion has a braid angle in the proximal to distal axis under tension of less than 80 degrees.

22. The apparatus of claim 16, wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of an outer diameter of the outer tractor pusher.

23. The apparatus of claim 16, wherein the tractor tube is formed of between 24-48 filaments.

24. The apparatus of claim 16, wherein the tractor tube is formed of a plurality of filaments, each having a diameter of greater than 0.003 inches.

25. The apparatus of claim 16, wherein the proximal end of the outer tractor tube portion is configured to have a tapered shape when the outer tractor tube portion is expanded radially outward.

26. The apparatus of claim 16, wherein the distal-facing region of the tractor tube is unsupported over at least 1 cm proximally from the distal-facing region of the tractor tube.

27. The apparatus of claim 16, wherein the tractor tube has a porosity of 60% or greater.

28. The apparatus of claim 16, wherein the inner tractor puller comprises an inner lumen configured to pass a guidewire out of a distal end of the apparatus.

29. The apparatus of claim 16, further comprising a vacuum source coupled to the tractor tube and configured to apply a vacuum therethrough.

30. A self-rolling mechanical atherectomy apparatus for removing a clot from a vessel, comprising:

an outer tractor pusher comprising a catheter having a distal end and a distal end opening;

a tractor tube formed from 10 or more strands, the tractor tube comprising an outer tractor tube portion that extends distally in an un-inverted configuration and inverts into itself at a distal-facing region to form an inner tractor tube portion, wherein the tractor tube is configured such that pulling the inner tractor tube portion proximally (i) compresses the outer tractor tube portion into a configuration having a column strength that resists collapsing, and (ii) causes a region of the outer tractor tube portion at the distal-facing region to roll over itself, unsupported, and invert into the inner tractor tube portion,

wherein the outer tractor tube portion has an expanded configuration with a distal-to-proximal facing braid angle for the expanded configuration of between about 80 and about 170 degrees; and wherein the outer tractor tube portion of the tractor tube is configured to expand to between about +/- 30% of an outer diameter of the outer tractor pusher; and

an inner tractor puller coupled to the inner tractor tube portion and extending proximally within the outer tractor pusher.

31. A method of removing a clot from a blood vessel, comprising:

advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller;

pulling an inner tractor puller of the tractor tube proximally to compresses an outer tractor tube portion of the tractor tube, wherein pulling the inner tractor puller proximally causes the outer tractor tube portion at a distal-facing region of the tractor tube to roll over itself, unsupported, and invert into the inner tractor tube portion; and

engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled into the tractor tube.

32. The method of claim 31, further comprising deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that the outer tractor tube portion of the tractor

tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher.

33. The method of claim 31, wherein pulling the inner tractor puller comprises bracing a distal-facing end of the outer tractor pusher against a tapered face of the tractor tube that is proximal to the outer tractor tube portion.

34. The method of claim 31, further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the self-rolling mechanical atherectomy apparatus comprises advancing the self-rolling mechanical atherectomy apparatus over the guidewire through the blood vessel until the self-rolling mechanical atherectomy apparatus is proximate to the clot.

35. The method of claim 31, wherein engaging the clot comprises advancing the outer tractor pusher distally while pulling the inner tractor puller proximally.

36. The method of claim 31, wherein engaging the clot comprises advancing the outer tractor pusher distally at a first rate while pulling the inner tractor puller proximally at a second rate that is faster than the first rate.

37. The method of claim 31, wherein advancing the distal end of the self-rolling mechanical atherectomy apparatus comprises advancing the self-rolling mechanical atherectomy apparatus distally with the tractor tube and inner tractor puller within the outer tractor pusher, wherein the tractor tube is in an un-deployed configuration.

38. The method of claim 31, further comprising applying aspiration through the tractor tube.

39. The method of claim 31, further wherein advancing the distal end of the self-rolling mechanical atherectomy apparatus comprises advancing a distal access catheter enclosing the tractor tube, outer tractor pusher and inner tractor puller, wherein the outer tractor tube portion is inverted over the inner tractor puller in an un-deployed configuration within the distal access catheter.

40. The method of claim 31, wherein pulling the inner tractor puller comprises applying up to 500 g of compressive force on the outer tractor tube portion without collapsing the outer tractor tube portion.

41. A method of removing a clot from a blood vessel, comprising:

advancing a distal end of a self-rolling mechanical atherectomy apparatus through the blood vessel to the clot, wherein the self-rolling mechanical atherectomy apparatus comprises a tractor tube, an outer tractor pusher, and an inner tractor puller;

deploying the tractor tube of the self-rolling mechanical atherectomy apparatus so that an outer tractor tube portion of the tractor tube expands to have an outer diameter that is greater than an outer diameter of the outer tractor pusher, wherein a distal-facing end of the outer is braced against a tapered face of the tractor tube proximal to the outer tractor tube portion, and wherein the outer tractor tube portion inverts over itself at a distal-facing region of the tractor tube and extends proximally within the outer tractor tube portion as an inner tractor tube portion that is coupled to the inner tractor puller;

pulling the inner tractor puller proximally to compresses the outer tractor tube portion of the tractor tube, and to cause the outer tractor tube portion of the tractor tube to roll over itself, unsupported, at the distal-facing region and to invert into the inner tractor tube portion;

engaging the clot with the tractor tube as it rolls over itself so that the clot is pulled into the tractor tube; and

withdrawing the self-rolling mechanical atherectomy holding the clot from the blood vessel.

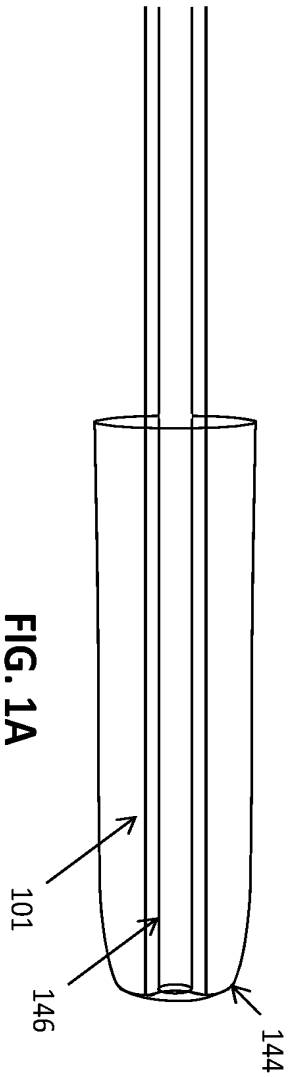


FIG. 1A

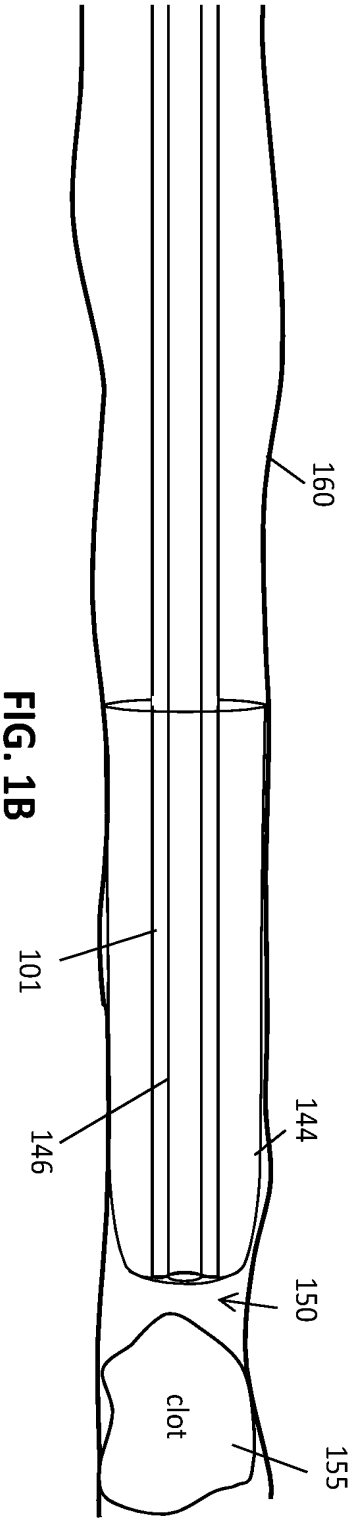


FIG. 1B

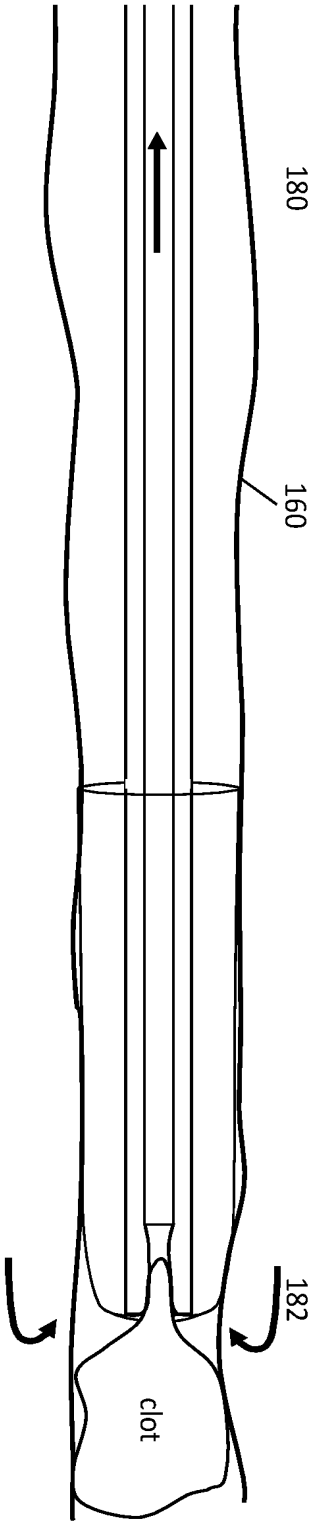


FIG. 1C

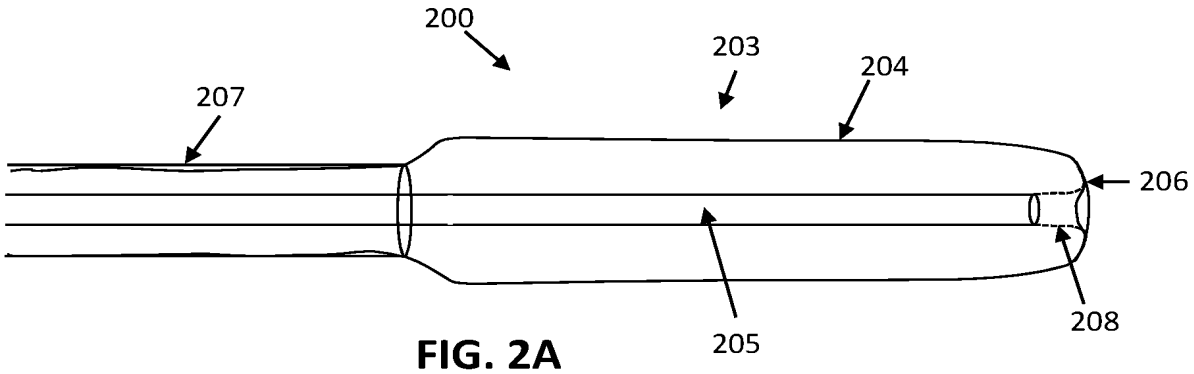


FIG. 2A

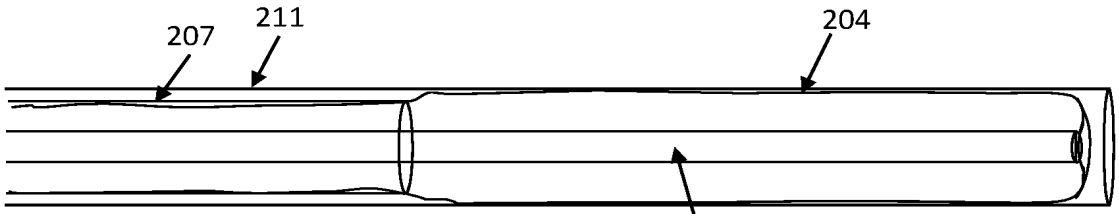


FIG. 2B

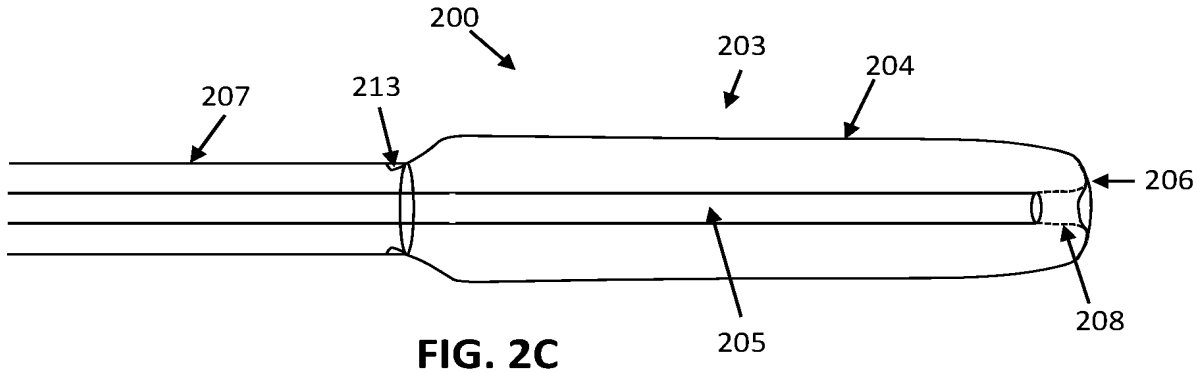


FIG. 2C

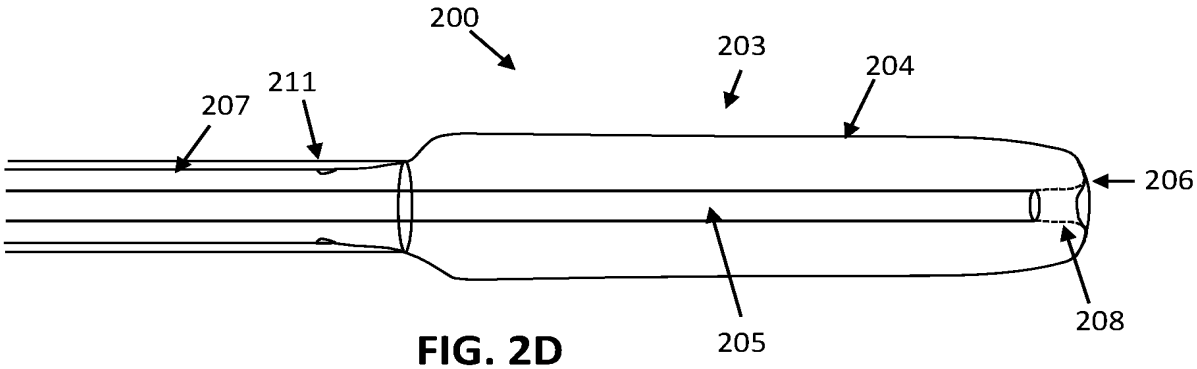


FIG. 2D

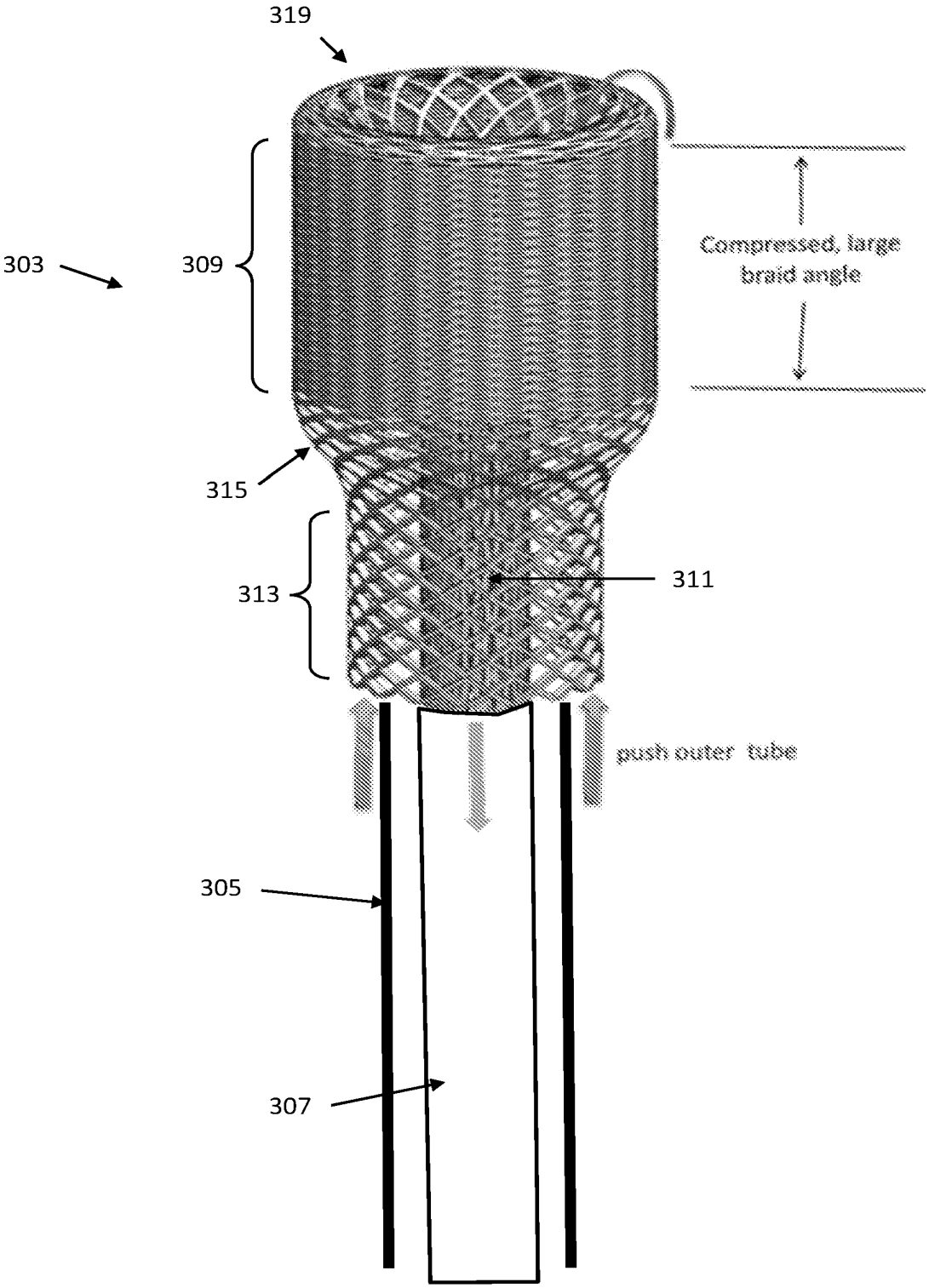

319
303
309
Compressed, large braid angle
315
313
311
push outer tube
305
307

FIG. 3A

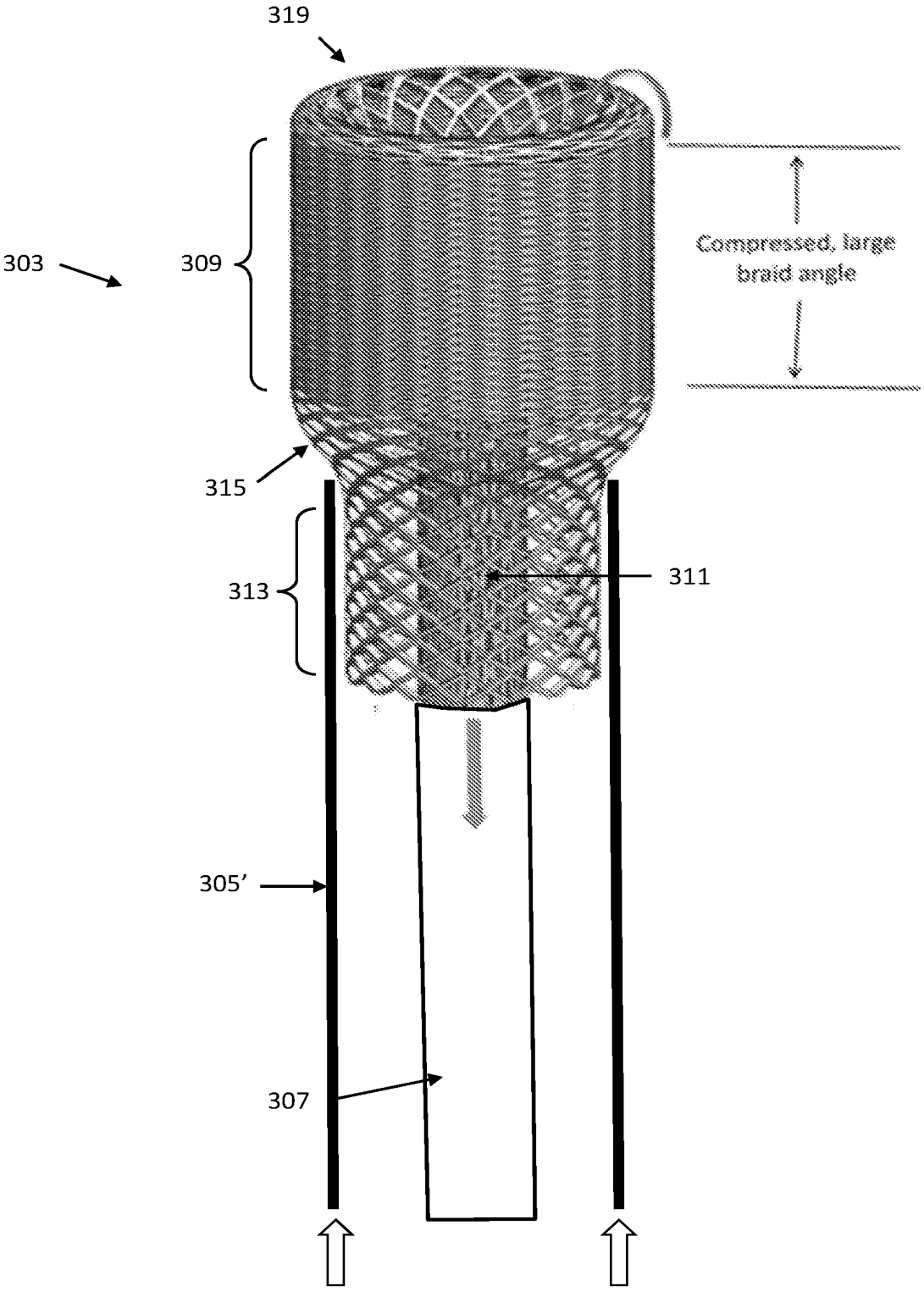


FIG. 3B

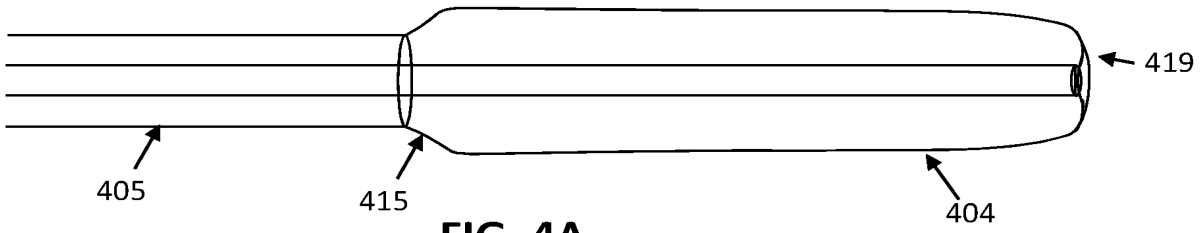


FIG. 4A

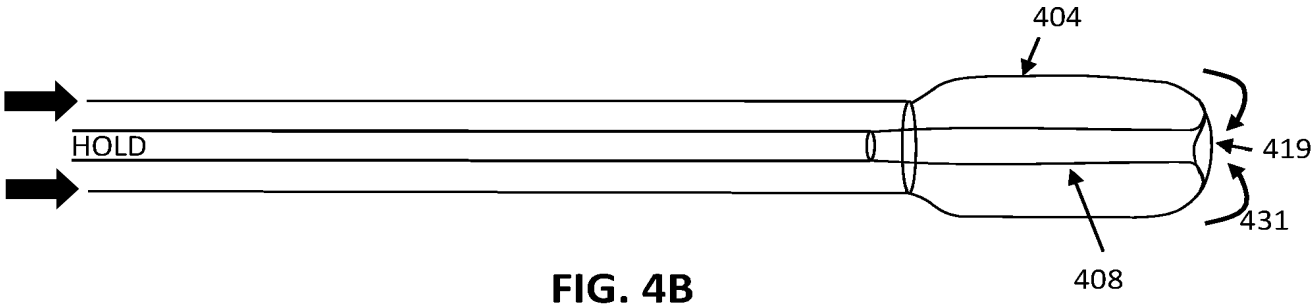


FIG. 4B

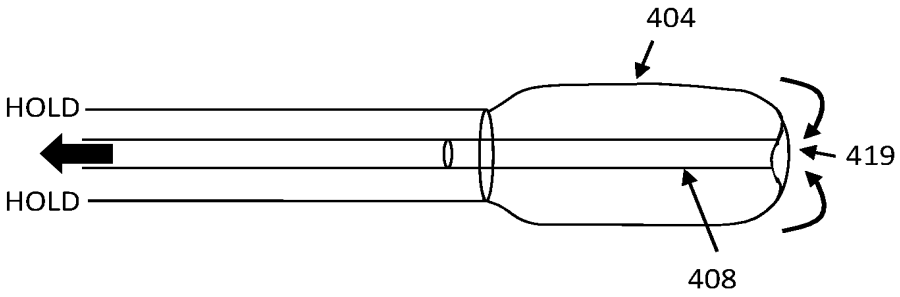


FIG. 4C

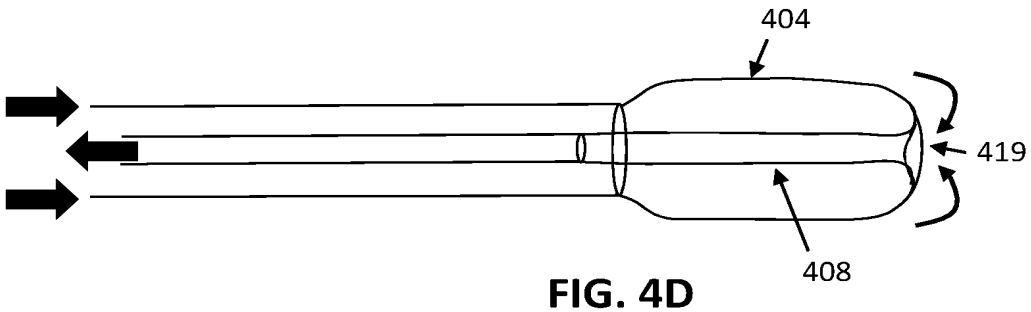


FIG. 4D

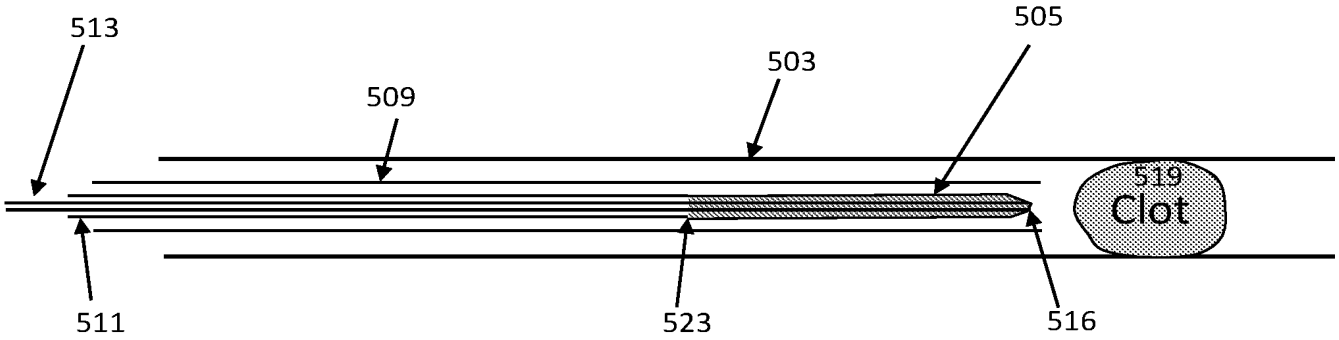


FIG. 5A

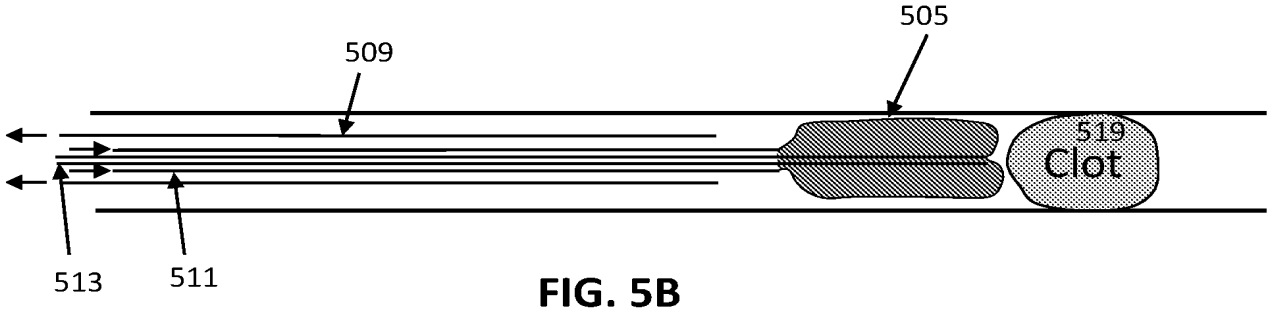


FIG. 5B

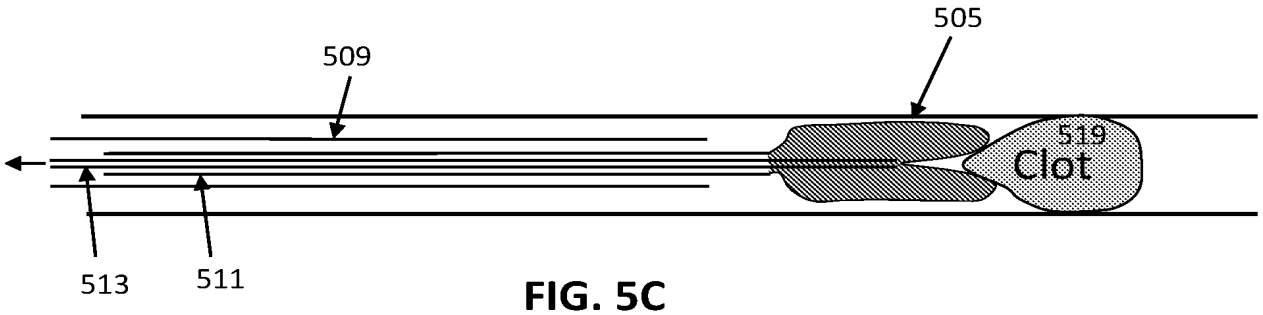


FIG. 5C

FIG. 5D

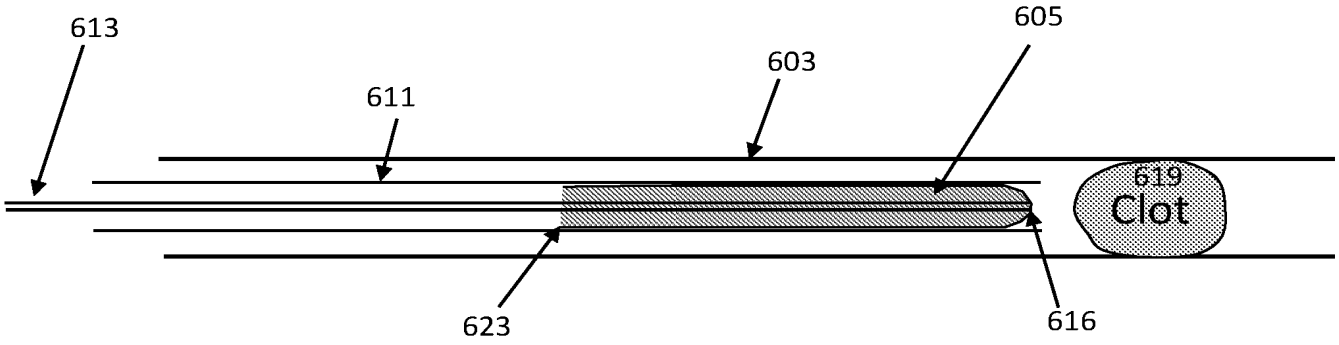


FIG. 6A

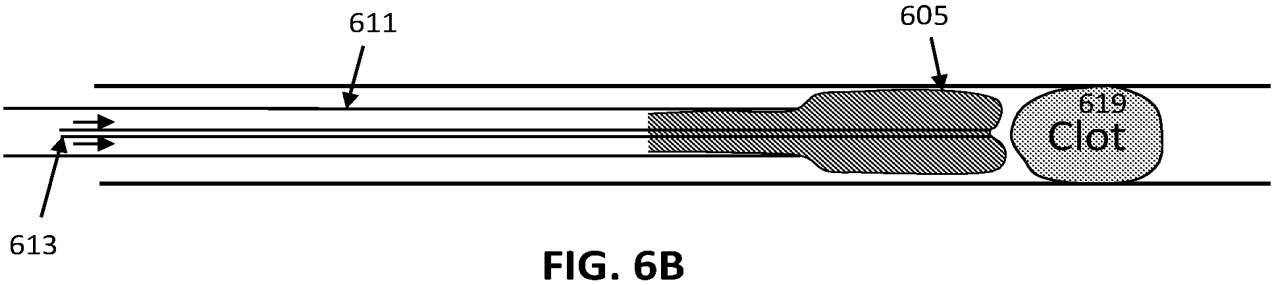


FIG. 6B

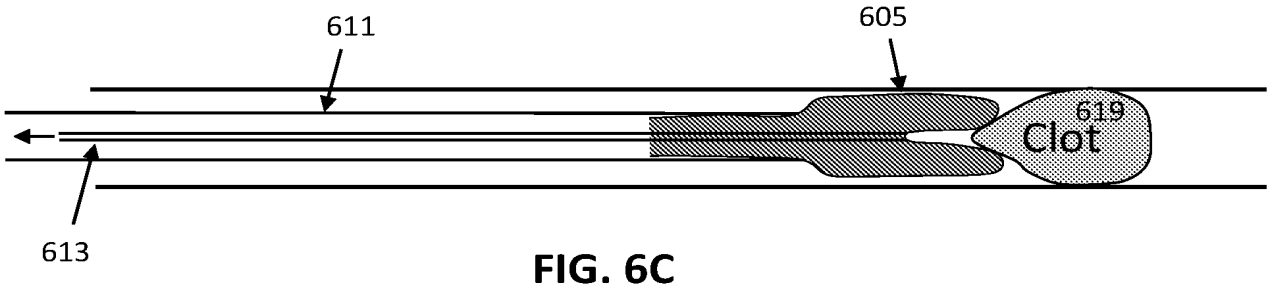


FIG. 6C

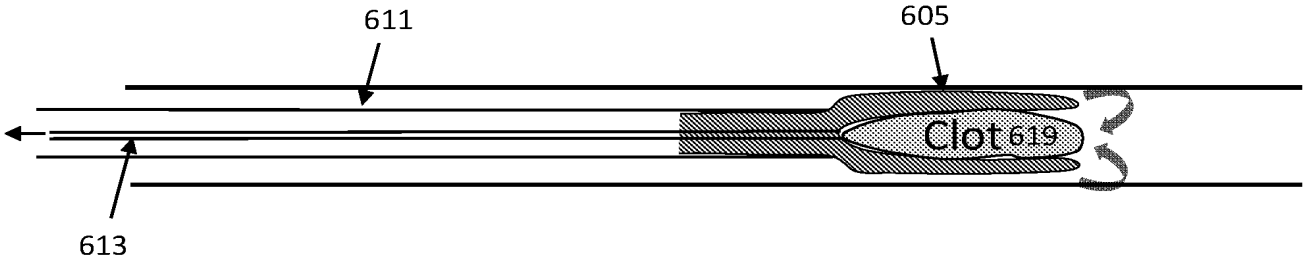


FIG. 6D

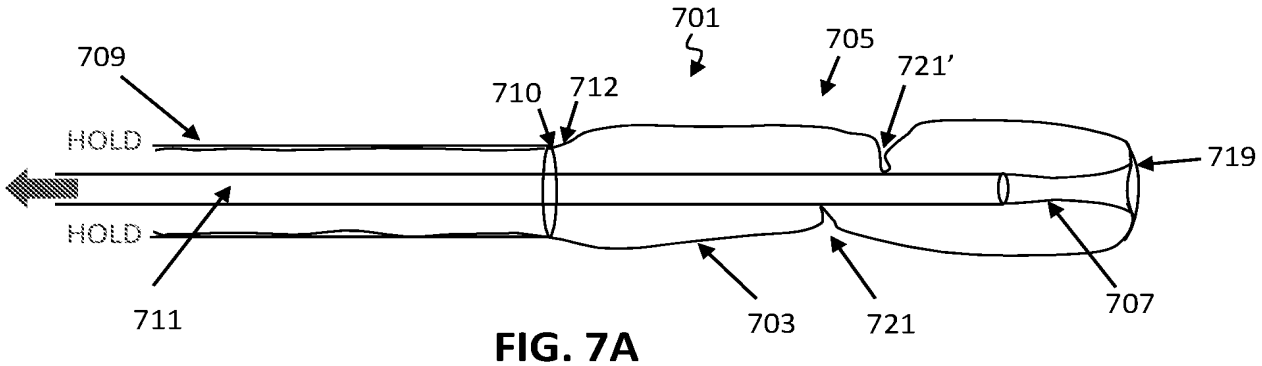


FIG. 7A

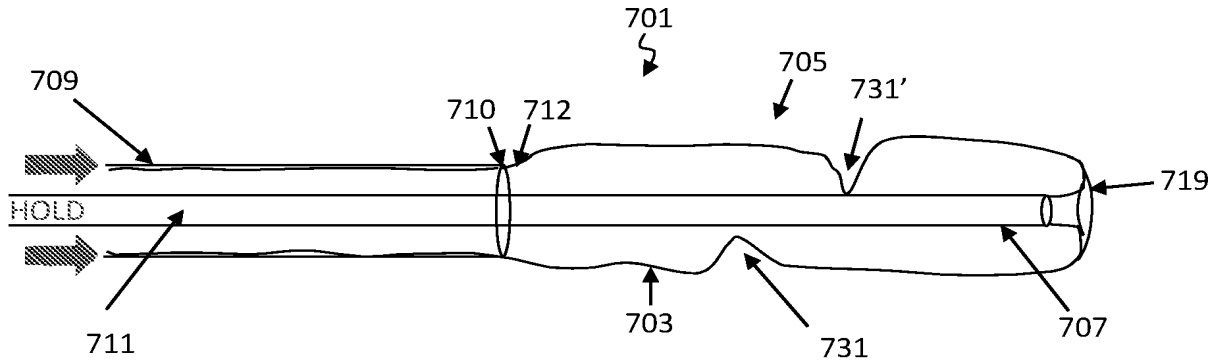


FIG. 7B

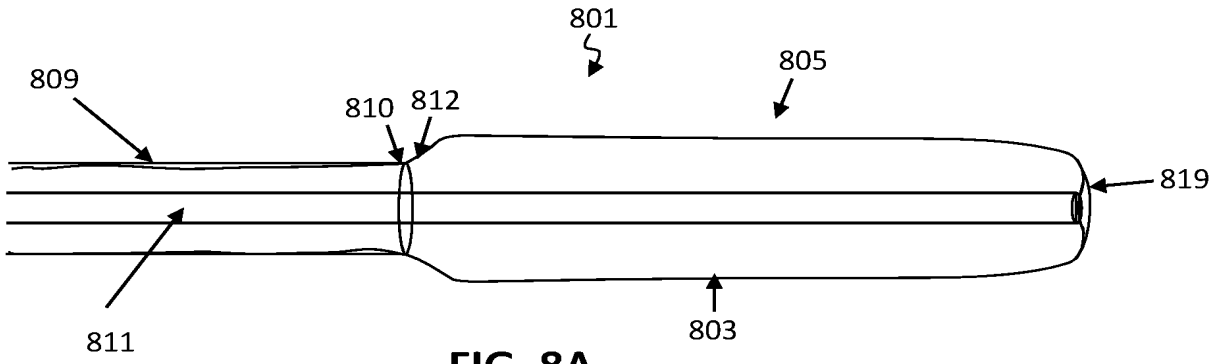


FIG. 8A

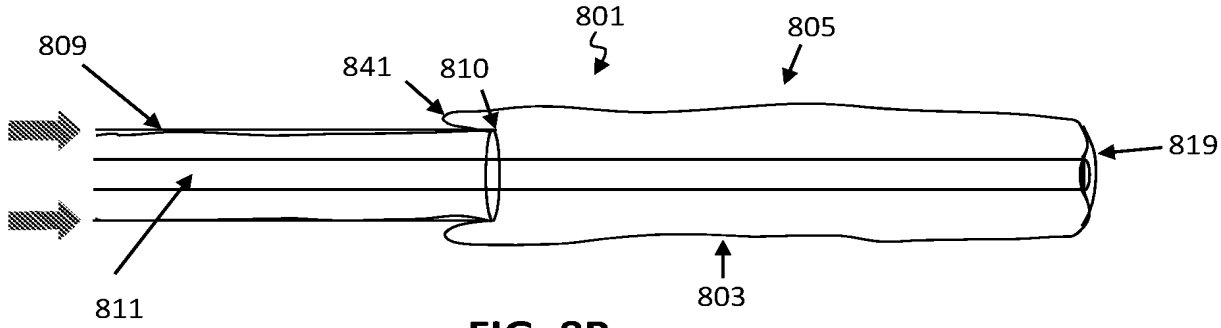


FIG. 8B

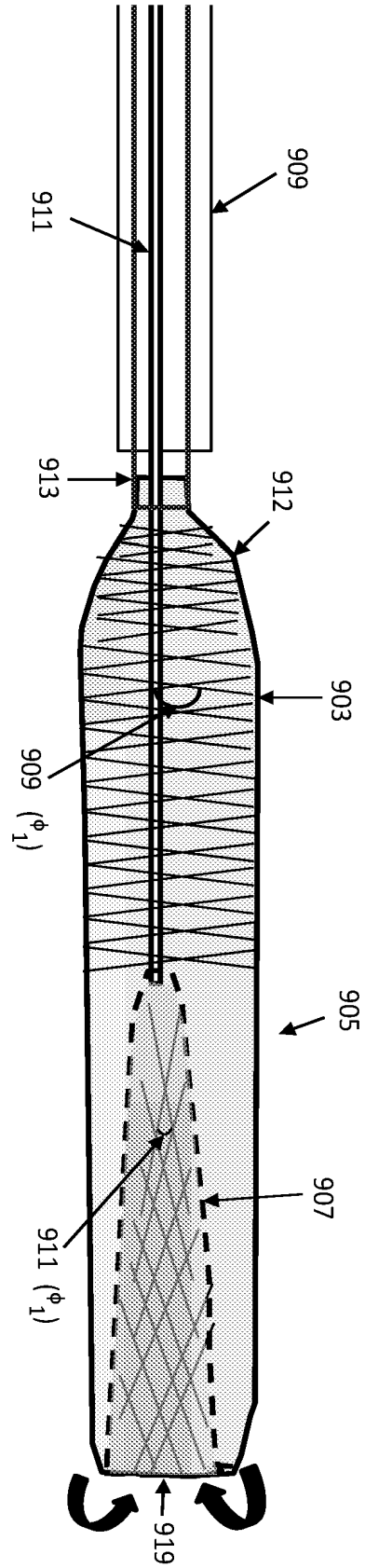

909
911
913
912
903
909 (ϕ_1)
905
907
911 (ϕ_1)
919

FIG. 9

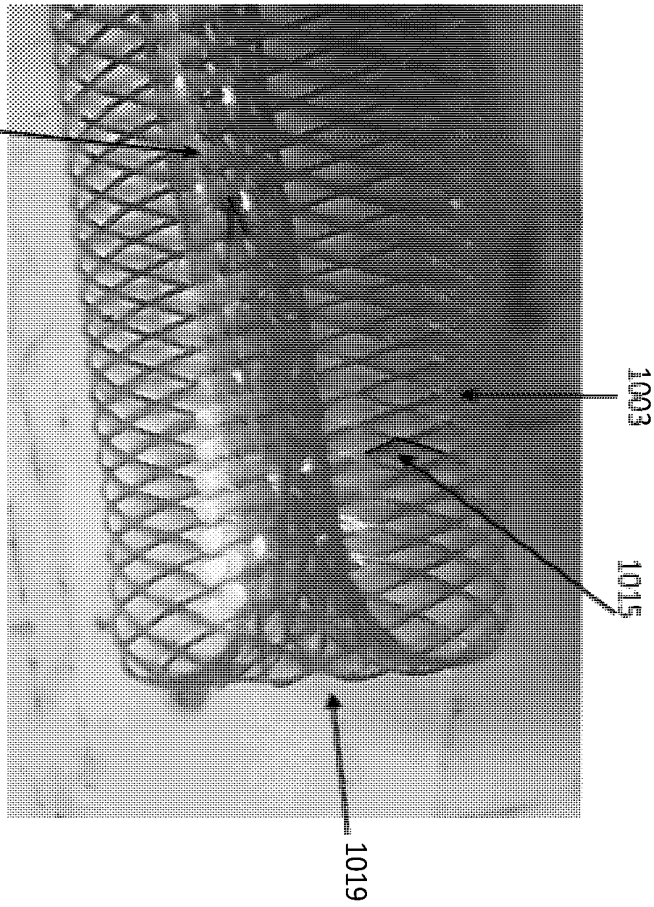

1007
1003
1015
1019

FIG. 10

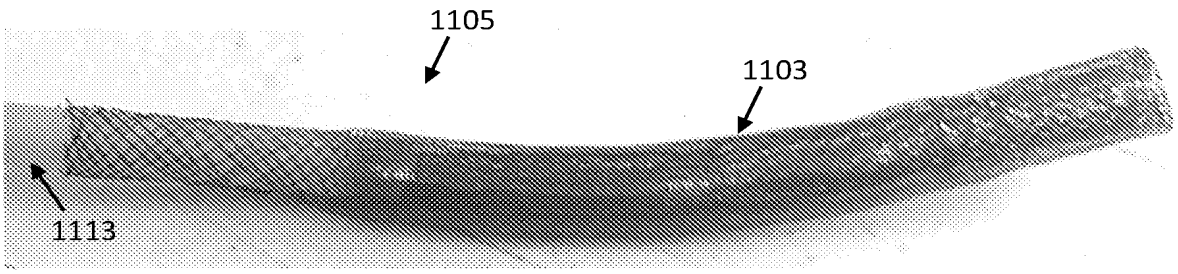


FIG. 11

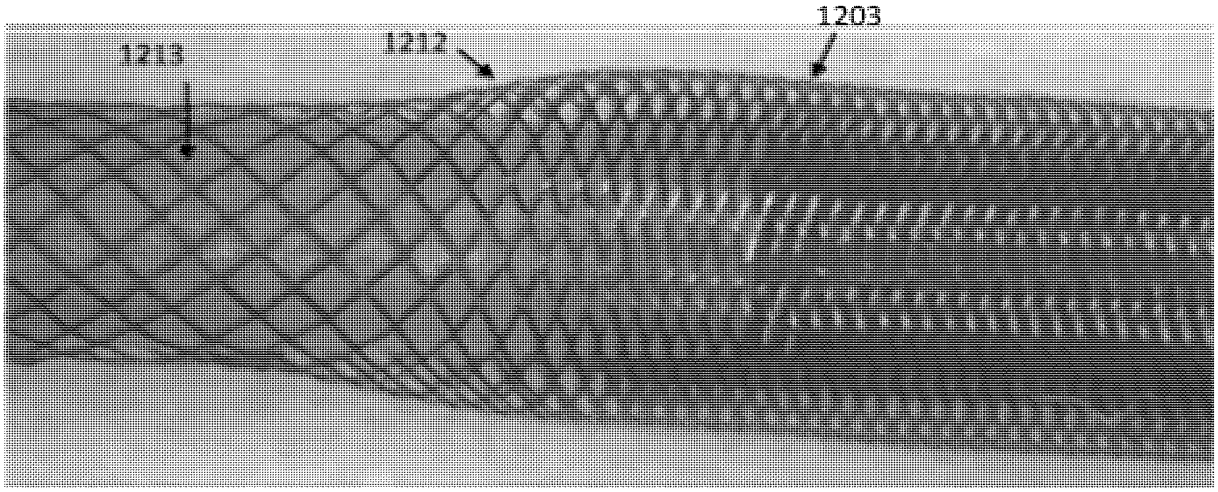


FIG. 12

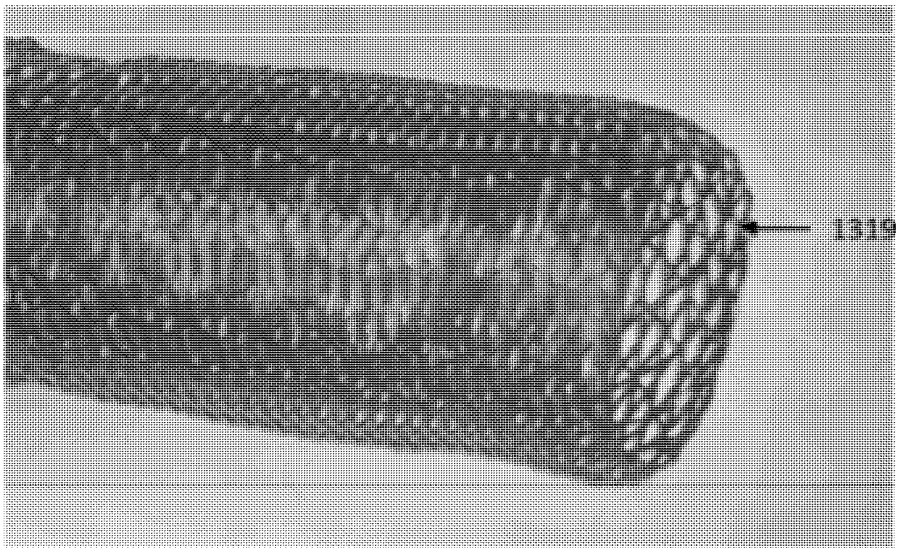


FIG. 13

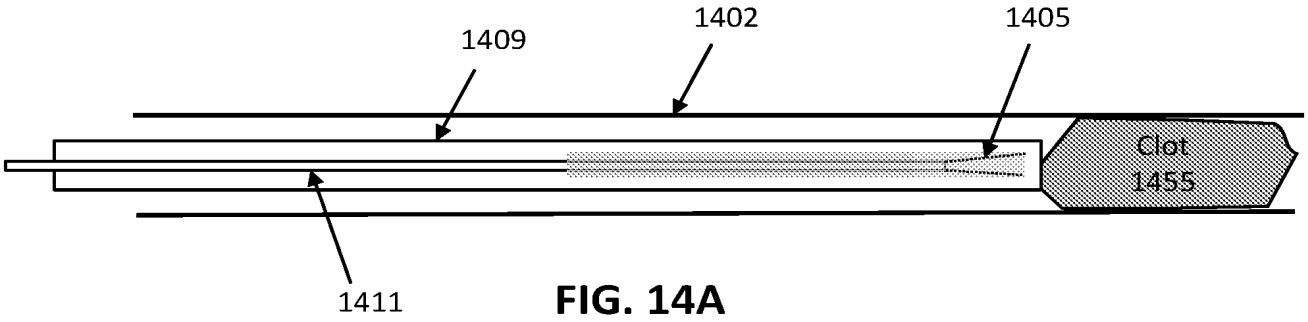


FIG. 14A

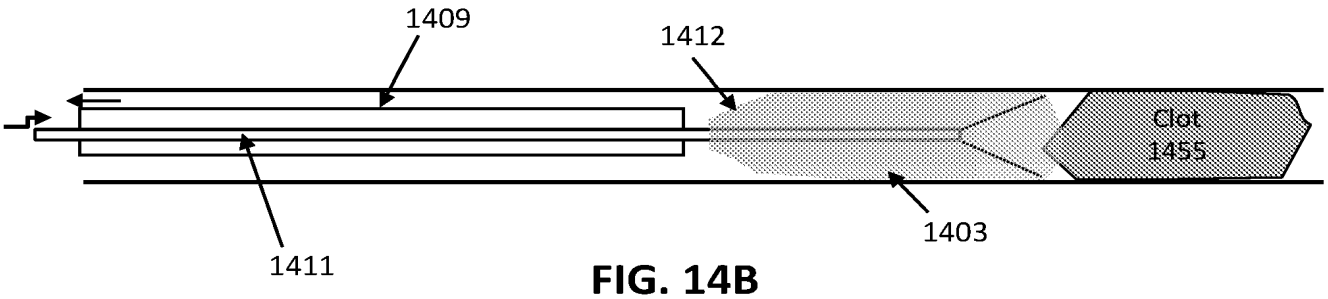


FIG. 14B

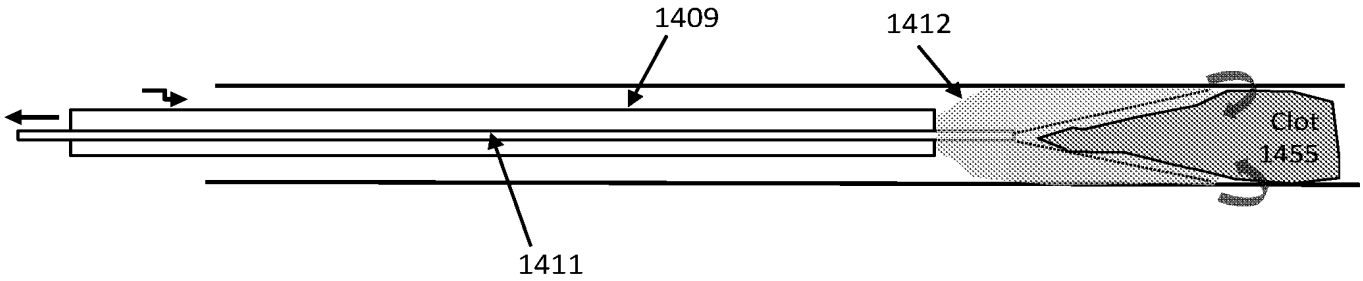


FIG. 14C

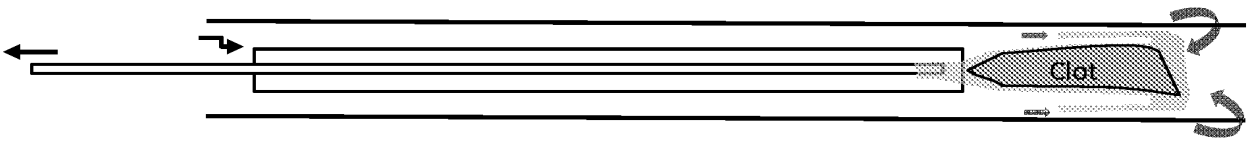


FIG. 14D

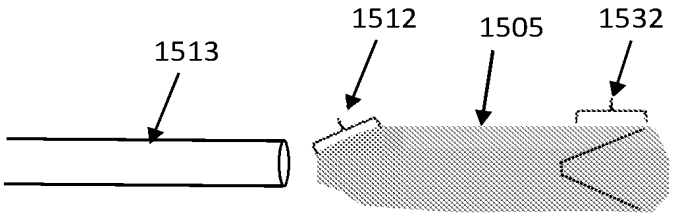


FIG. 15A

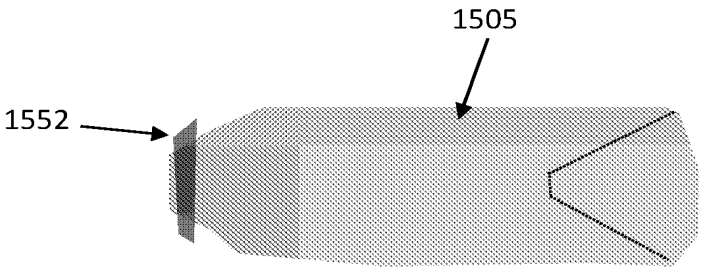


FIG. 15B

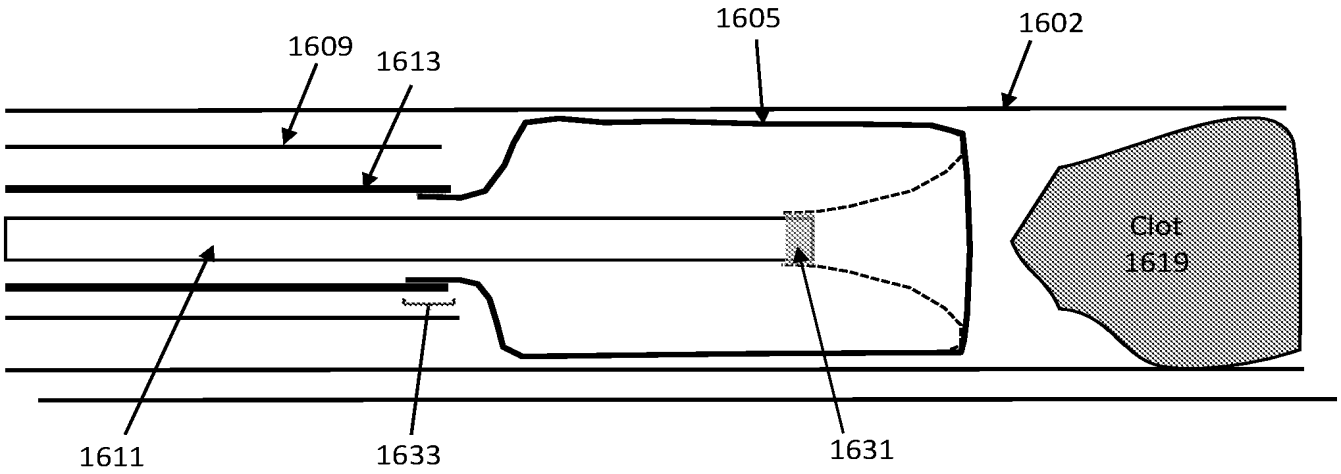


FIG. 16A

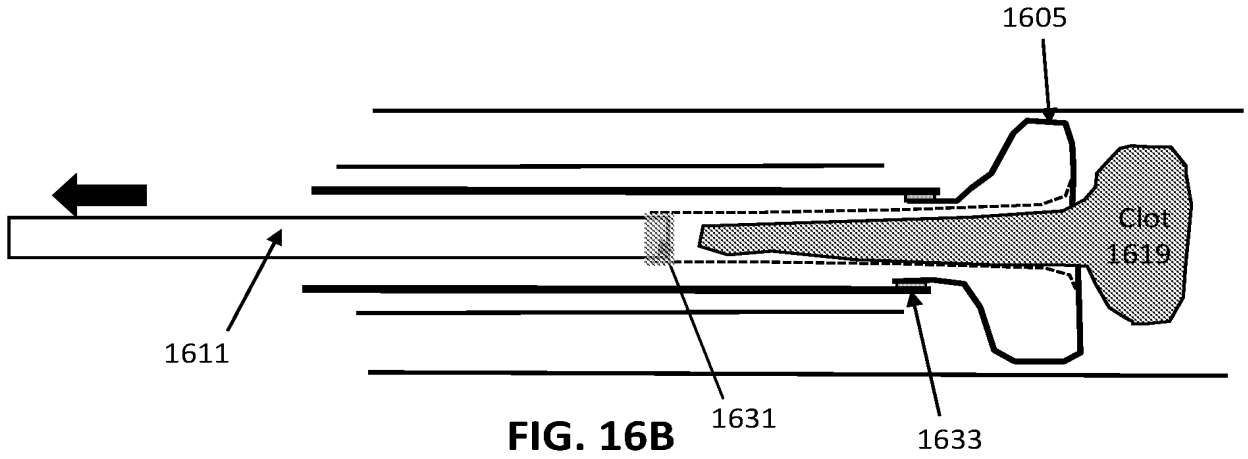


FIG. 16B

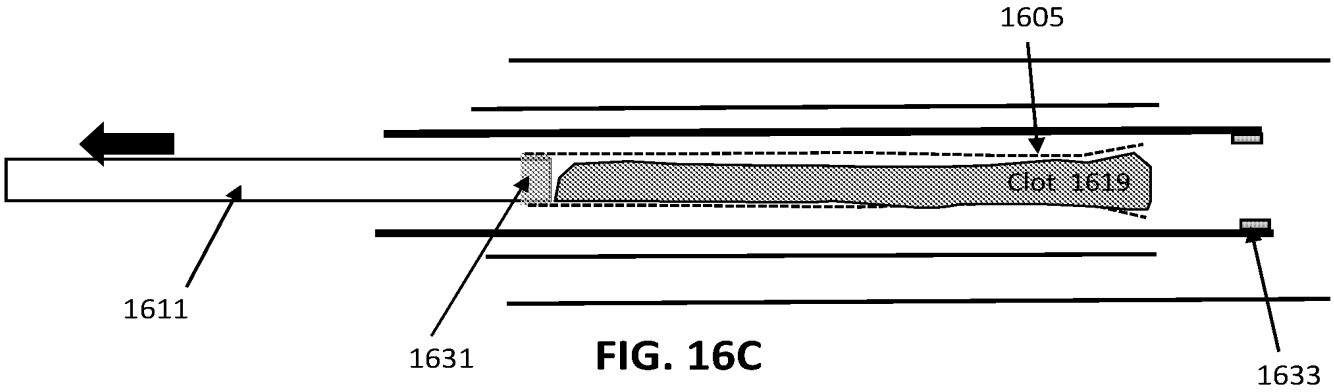


FIG. 16C

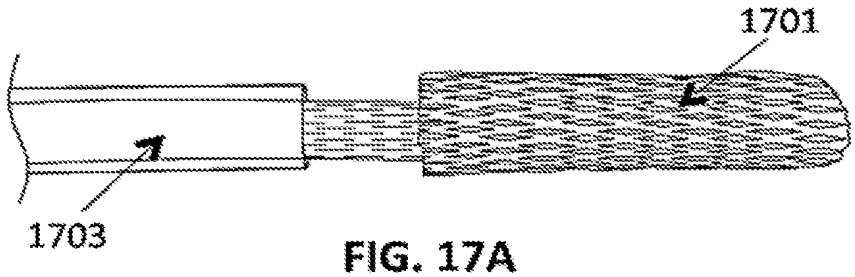


FIG. 17A

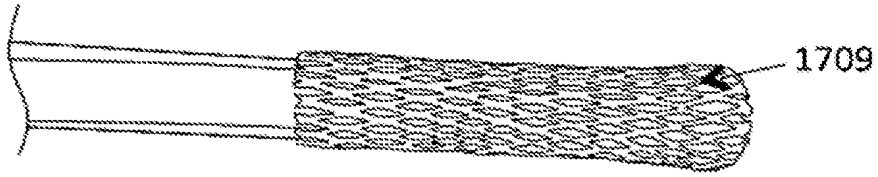


FIG. 17B

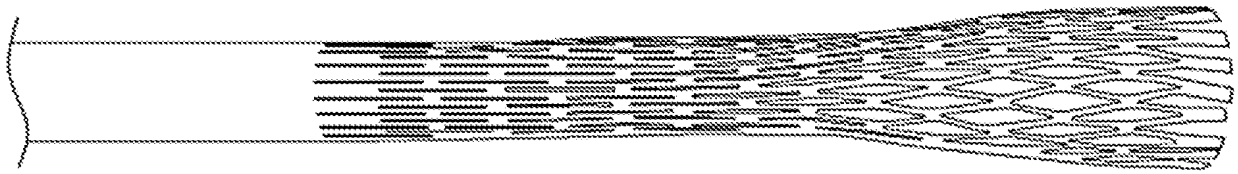


FIG. 17C

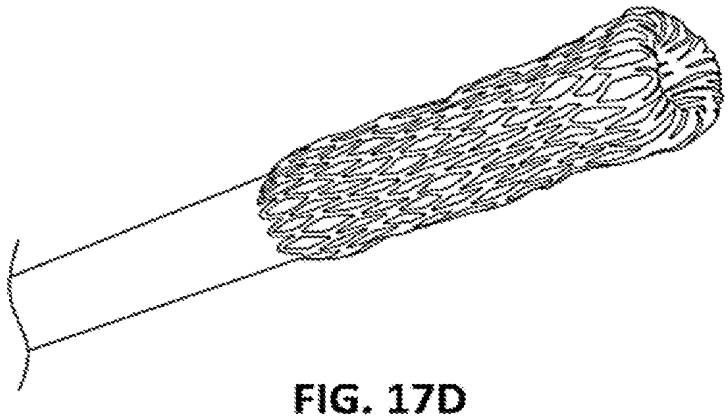


FIG. 17D

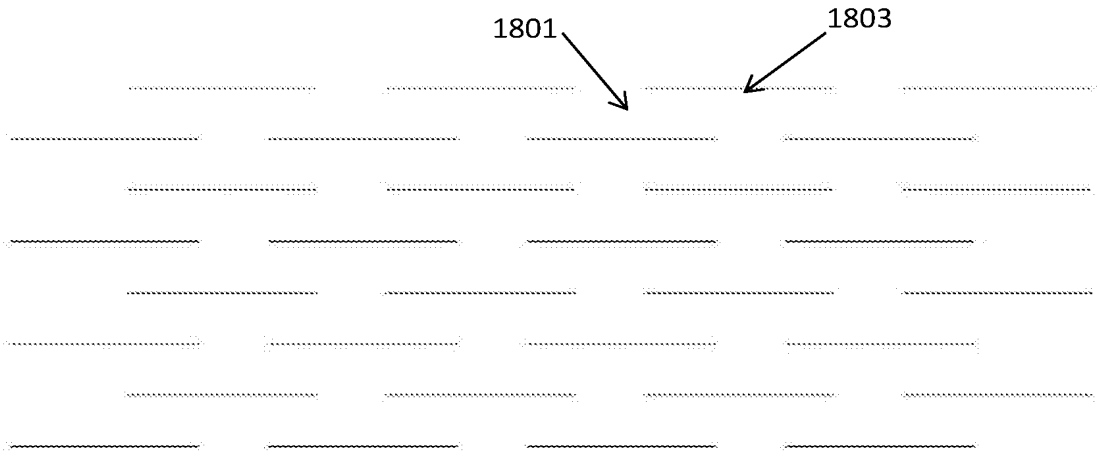


FIG. 18A

FIG. 18B

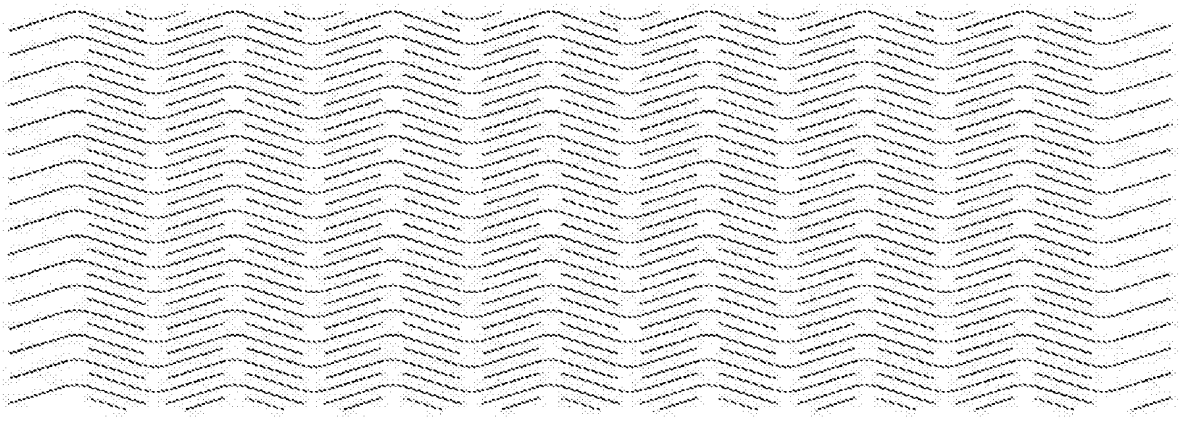


FIG. 18C

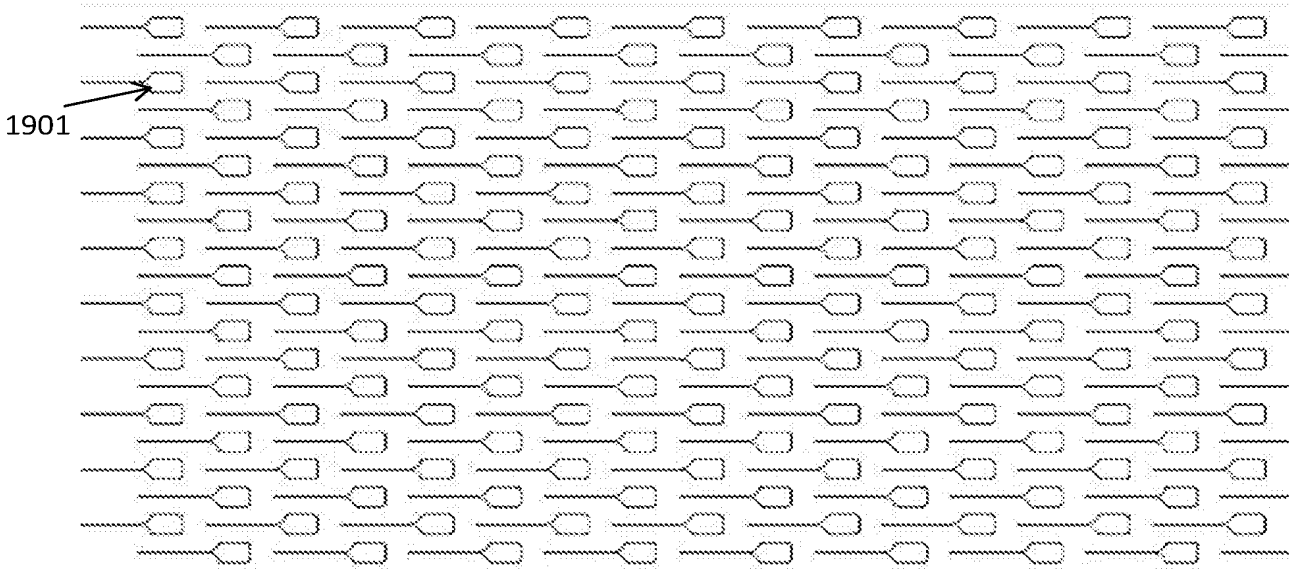


FIG. 19

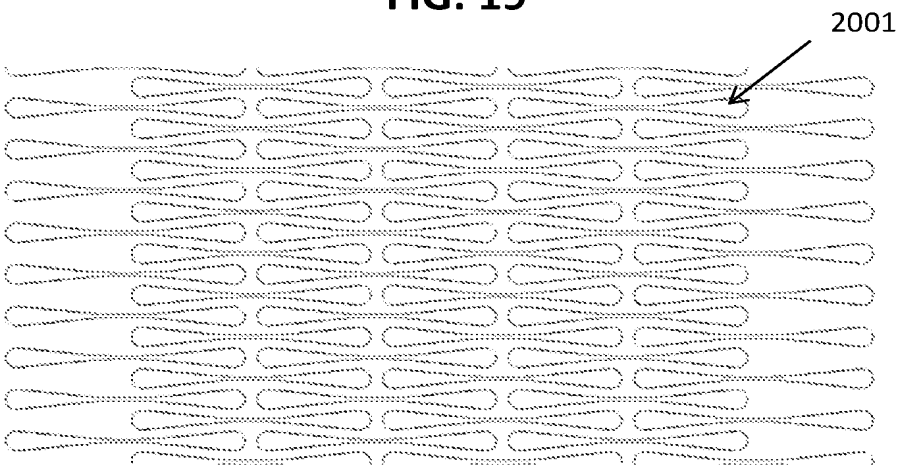


FIG. 20A

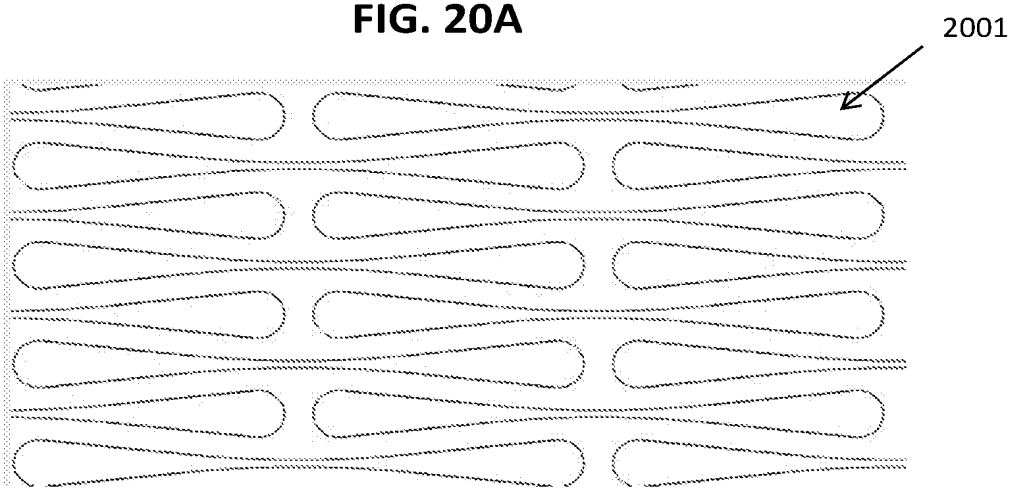


FIG. 20B

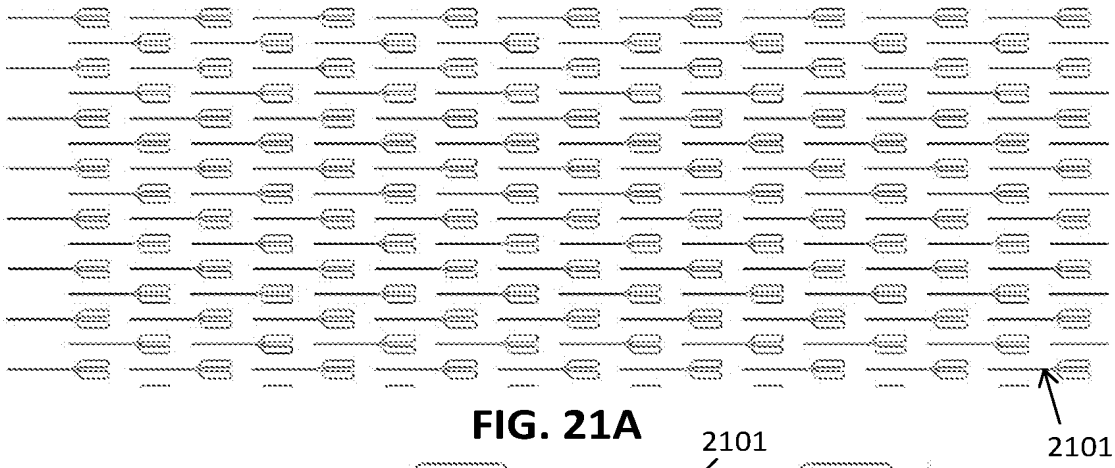


FIG. 21A

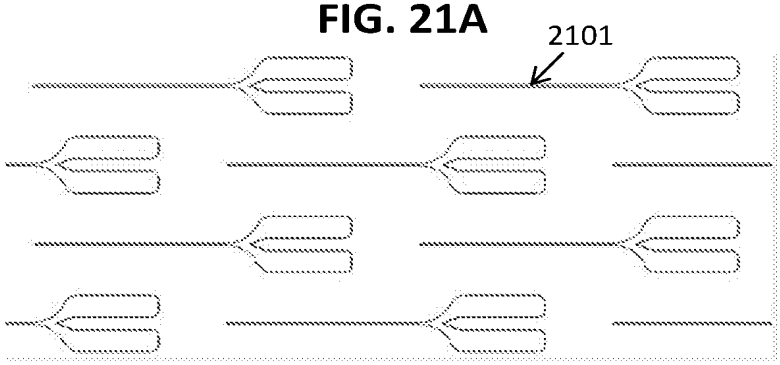


FIG. 21B

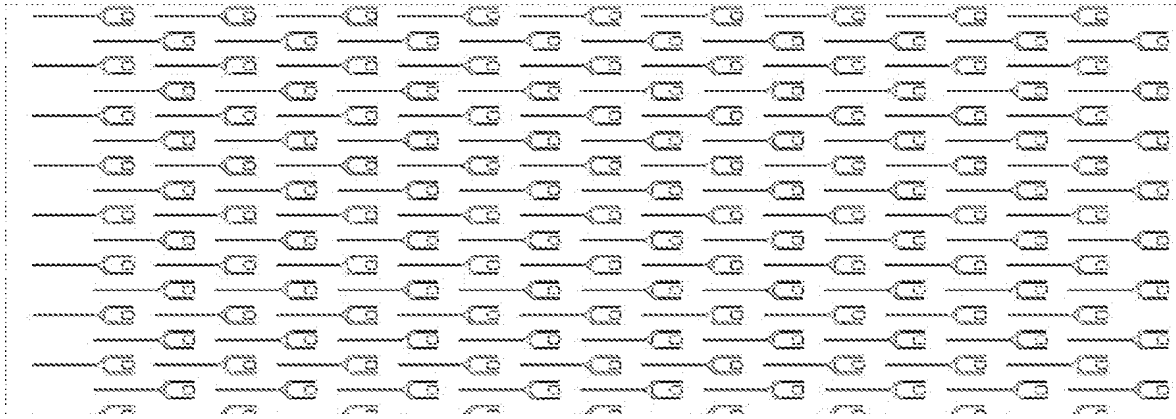


FIG. 22A

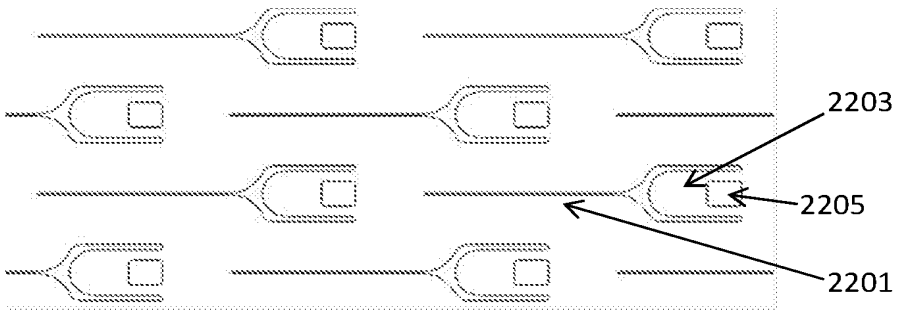


FIG. 22B

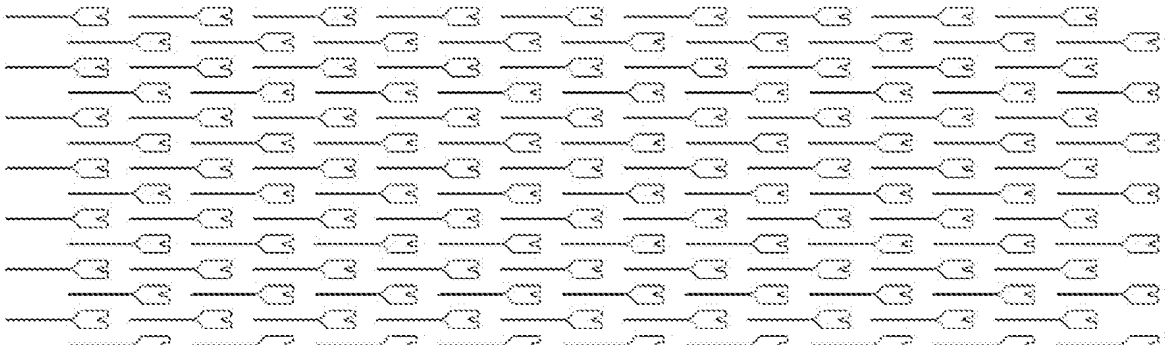


FIG. 23A

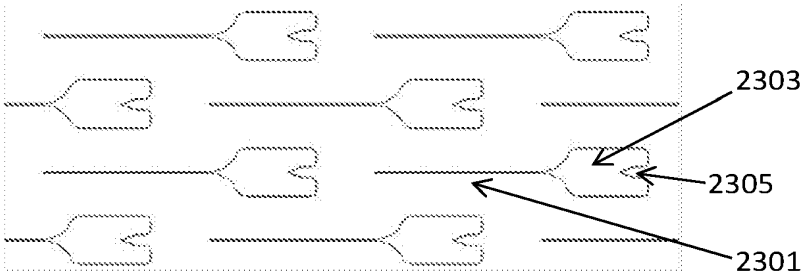


FIG. 23B

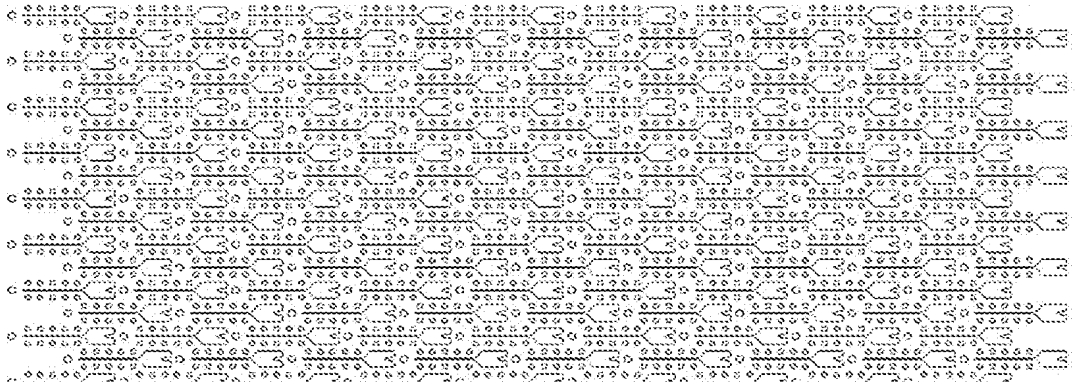


FIG. 24A

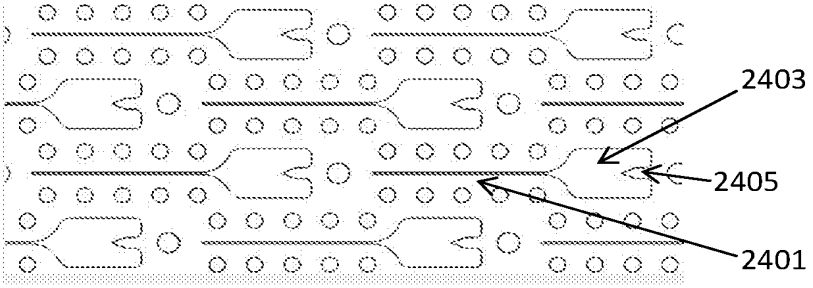


FIG. 24B

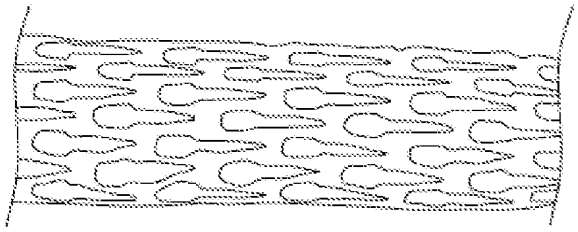


FIG. 25A

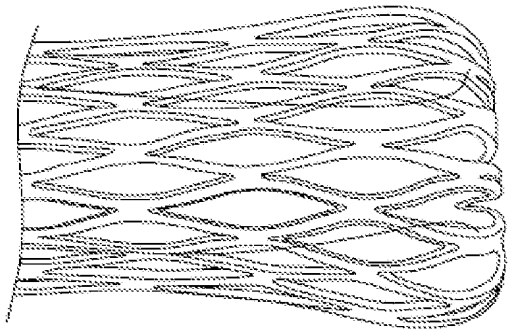


FIG. 25B

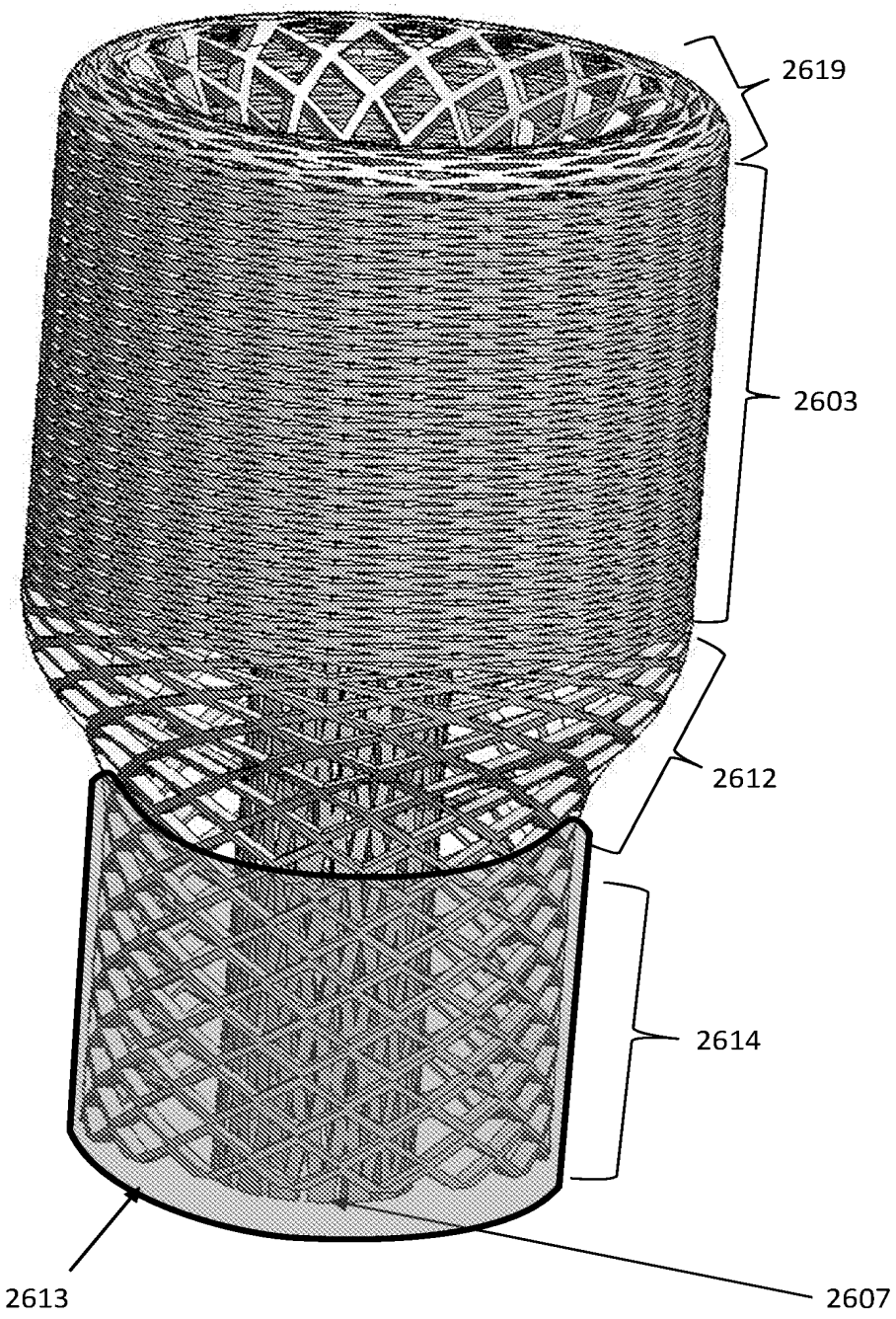


FIG.26A

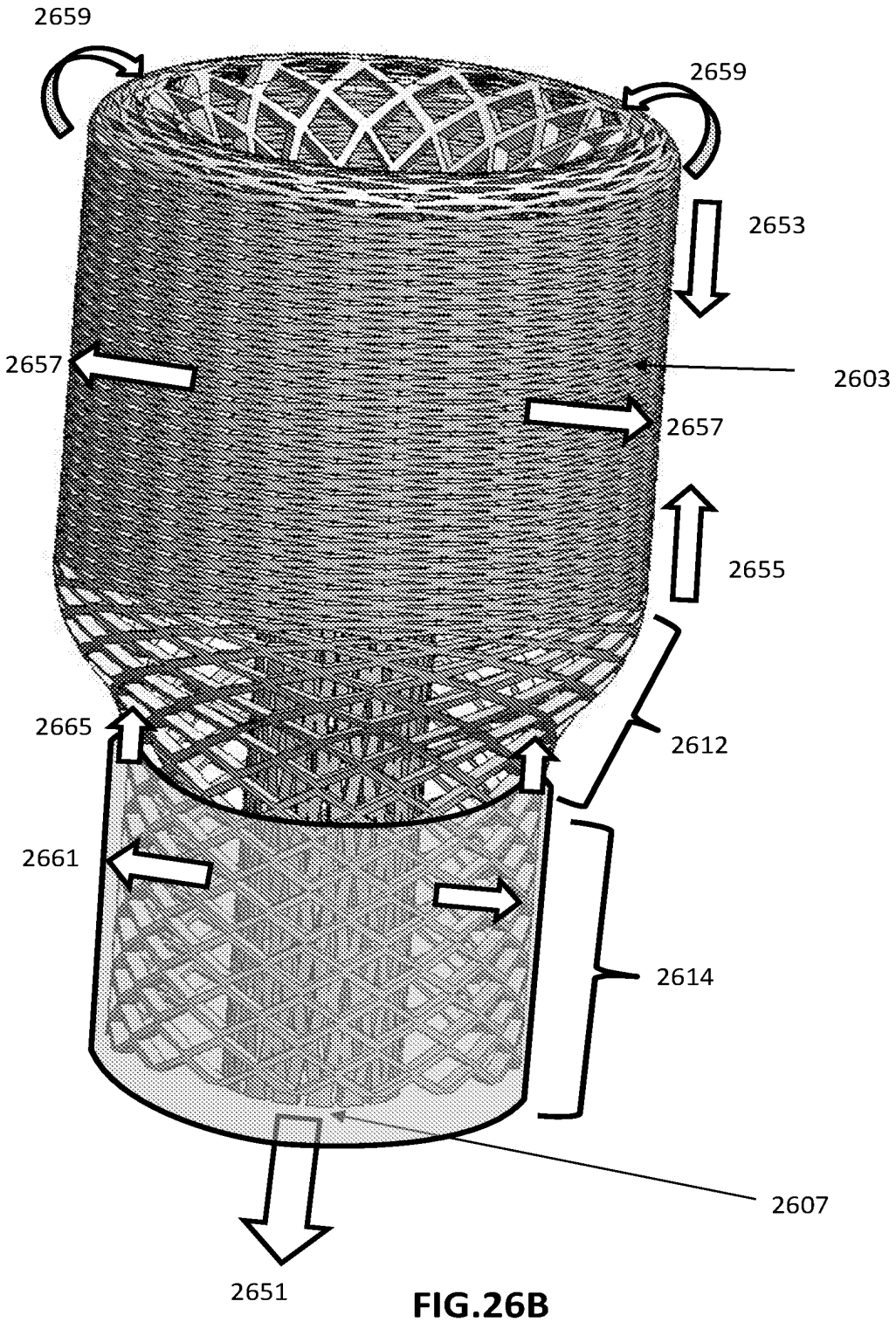

2659
2659
2653
2657
2603
2657
2655
2665
2612
2661
2614
2607
2651

FIG.26B

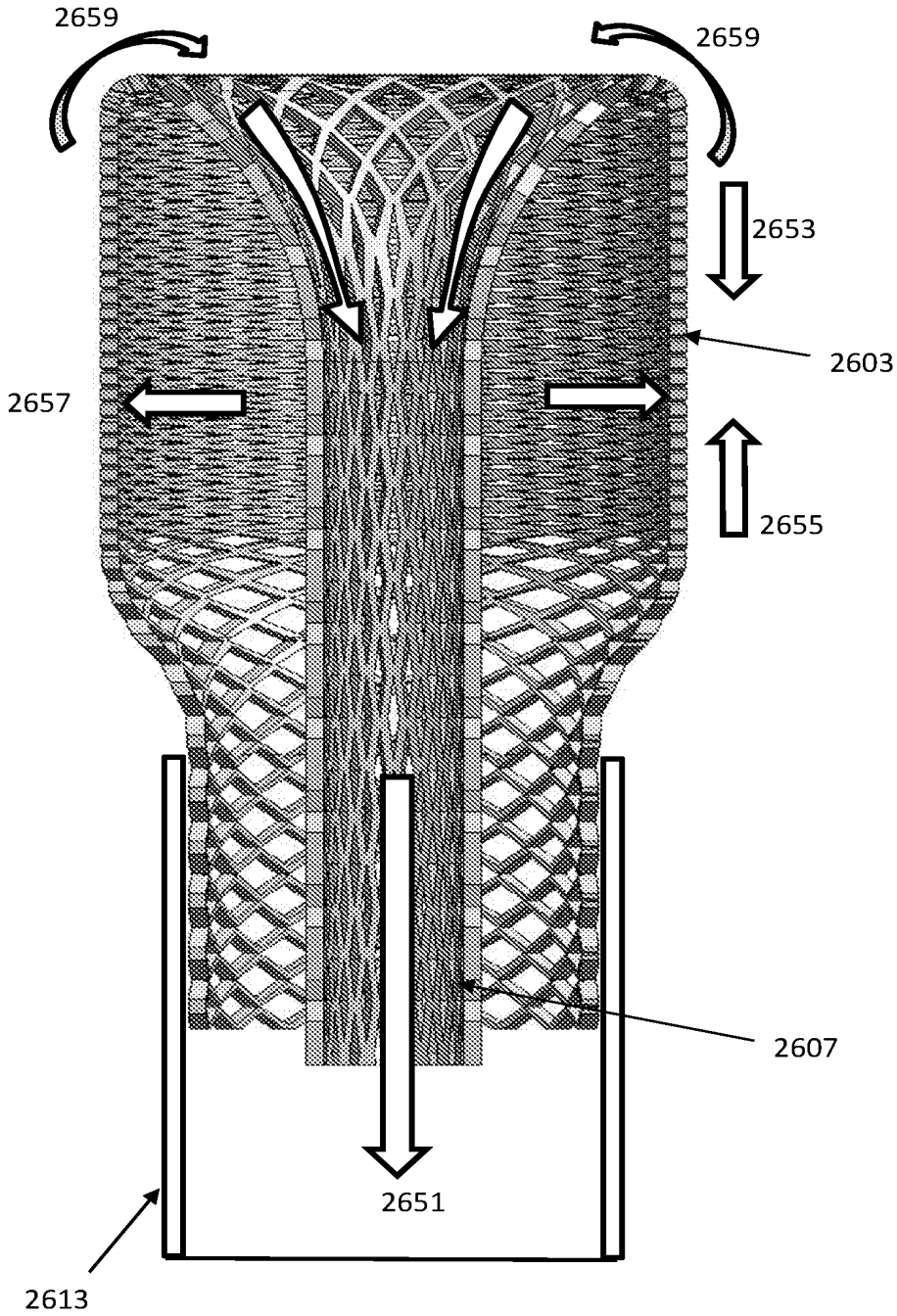


FIG.26C

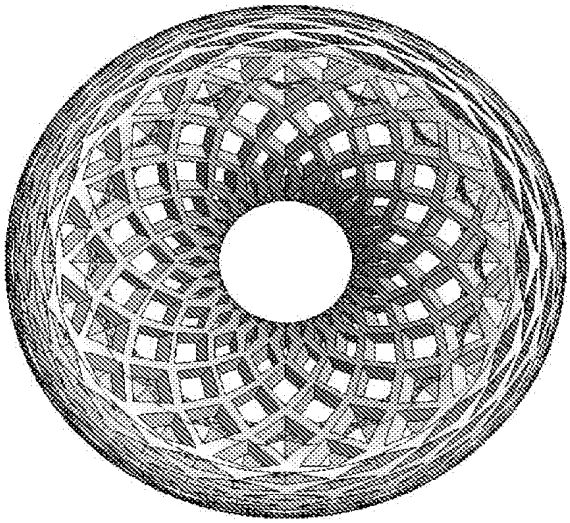


FIG.27A

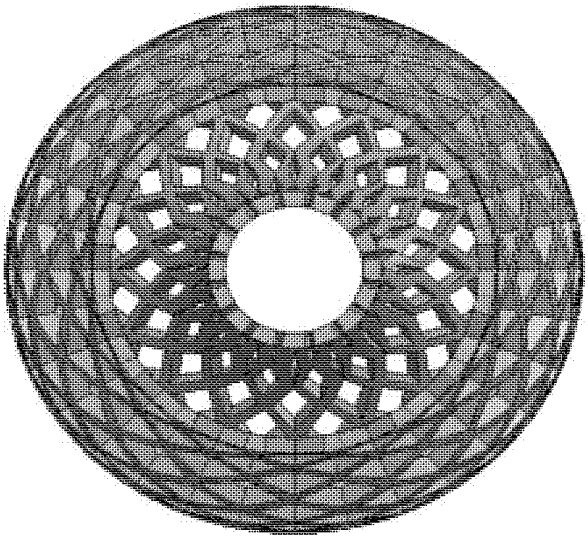


FIG.27B

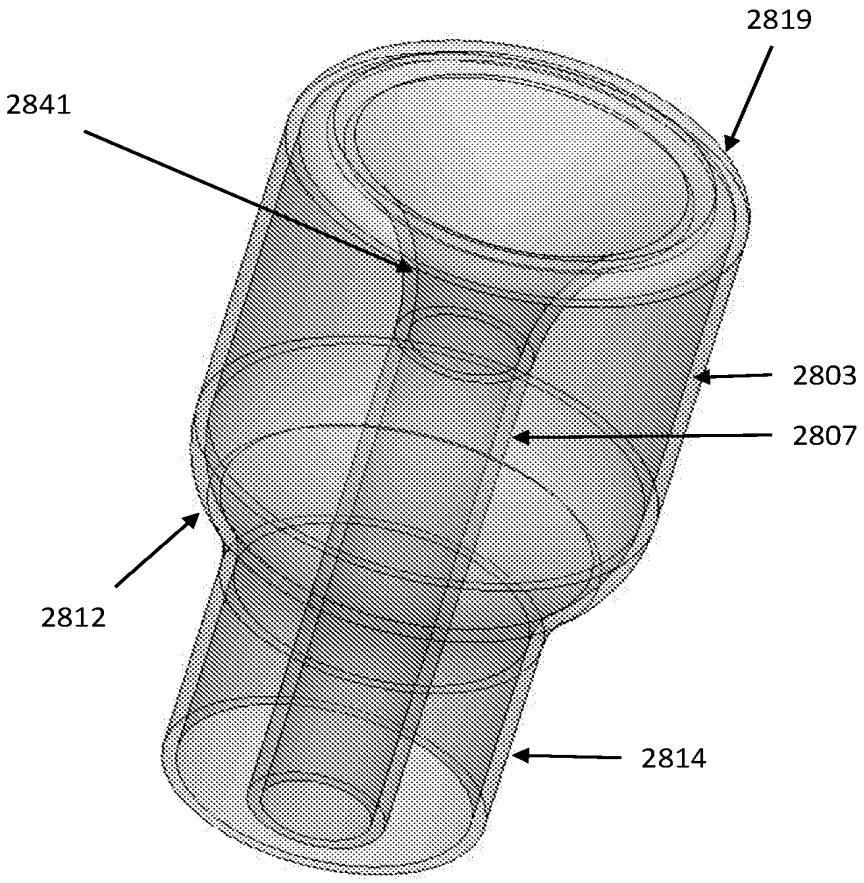


FIG.28

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/050933

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.
X Y	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0008], [0077], [0161], [0167] - [0170], [0172]; figures 10, 13B	1-14, 16-28,30 15,29
Y	US 2010/249815 A1 (JANTZEN ET AL.) 30 September 2010 (2010-09-30) paragraphs [0026], [0027], [0030]; figures 1,2	15,29
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; claims; figures page 8, line 12 - page 11, line 16	1,16,30

-/--

[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
26 October 2017	10/11/2017

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

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 2012/049652 A1 (ENDOGROWTH (PROPRIETARY) LTD) 19 April 2012 (2012-04-19) page 8, line 32 - page 15, line 26; figures 4-10 -----	1,16,30
A	US 4 863 440 A (CHIN) 5 September 1989 (1989-09-05) abstract; figures -----	1,16,30

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/050933

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. [X] Claims Nos.: 31-41
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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:

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

Information on patent family members

International application No
PCT/US2017/050933

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
US 2010249815 A1	30-09-2010	NONE	
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 2012049652 A1	19-04-2012	US 2013226196 A1	29-08-2013
		WO 2012049652 A1	19-04-2012
		ZA 201302264 B	30-04-2014
US 4863440 A	05-09-1989	CA 1326198 C	18-01-1994
		DE 3686408 D1	17-09-1992
		DE 3686408 T2	21-01-1993
		EP 0227583 A2	01-07-1987
		JP 2529838 B2	04-09-1996
		JP S62170260 A	27-07-1987
		US 4863440 A	05-09-1989

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

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 254 634 B1

(12) # EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
23.07.2003 Bulletin 2003/30

(51) Int Cl.[7]: **A61B 17/00**

(21) Application number: **01850081.9**

(22) Date of filing: **03.05.2001**

(54) **Guiding tool for wound closure element**

Führungswerkzeug für Wundverschluss

Outil de guidage pour fermeture de plaie

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR

(43) Date of publication of application:
06.11.2002 Bulletin 2002/45

(73) Proprietor: **RADI MEDICAL SYSTEMS AB**
754 50 Uppsala (SE)

(72) Inventors:
- **Akerfeldt, Dan**
  755 92 Uppsala (SE)
- **Egnelöv, Per**
  754 40 Uppsala (SE)
- **Preinitz, Fredrik**
  753 50 Uppsala (SE)

(74) Representative: **Lindgren, Anders**
Dr. Ludwig Brann Patentbyra AB,
P.O. Box 1344,
Drottninggatan 7
751 43 Uppsala (SE)

(56) References cited:
WO-A-01/13800
US-A- 5 620 461
US-A- 5 649 950
US-A- 5 725 519

Printed by Jouve, 75001 PARIS (FR)

EP 1 254 634 B1

Description

[0001] The present invention relates generally to sealing of a percutaneous incision or puncture in the wall of a vessel, duct, lumen or hollow organ in the body of a living being, by positioning a sealing device in said incision or puncture, where the incision or puncture is smaller than said sealing device. In particular the invention relates to a guiding tool for enabling the correct positioning of such a sealing device, ensuring a leak-proof sealing.

Background of the Invention

[0002] In recent years a number of devices and apparatuses have been developed enabling the closure or occlusion of e.g. punctures in the femoral artery following catheterization. Instead of applying a pressure to the puncture site for a period of time sufficient for blood clot formation to occur, the new methods are e.g. based on providing a plug, commonly referred to as an "artery plug", in the puncture. The plug is made of a resorbable material, such that it can be left in place until the tissue has recovered properly and the wound or puncture is healed. The plug can be made of collagen, and applied to the outside of a vessel against a counteracting element, also made of a resorbable material, introduced into the interior of the vessel. A locking means secures the collagen plug in place. A device of this kind is disclosed in US-5,935,147 (Kensey et al). The sealing action is thus performed by the externally applied collagen plug. However, a certain percentage of applied plugs will not be leak-proof and often further compression by other devices or manually must be applied.

[0003] Alternatively, a plug can be made of two members such that a first member is positioned within a vessel and acts as the occluding member, and a second member is positioned outside the vessel and locked to the first member by a locking means. In order to ensure leak-proof action, the first member is larger than the puncture in all directions, i.e. it will cover a surface larger than the area of the puncture. In order to make this possible, the first member is foldable. A device of this kind is disclosed in our own EP-application EP-00850184.3 (corresponding to US patent application serial No. 09/704,726).

[0004] US-A-5 649 950 discloses a loading device for a collapsible occluder. This device has a conical lumen. US-A-5 649 950 corresponds to the preamble of claim 1.

[0005] The problem facing all systems wherein a folding or deformation of an element is needed in order to introduce the element into a vessel or through any tissue wherein the hole is smaller than the element itself, is that it can be difficult to achieve a reproducible unfolding, that accurately seals the hole from the inside. Also, in many cases the closure element is provided inside an introducer member such as a tube, in a folded state, already at the time of manufacture of the kit comprising all components. If the kit is stored for extended periods of time, and even for shorter times, the folded closure element most likely does not unfold properly at the time of use. To avoid the risk of permanent deformation, the closure element could be inserted into the introducer device by the physician, but this would require an extra manipulation, and it might be very difficult to maintain the sterility of the devices in such a case.

Summary of the Invention

[0006] Thus, in view of the problem with the prior art devices, it is the object of the present invention to improve the rate of successful sealing operations using wound closure devices, when foldable or deformable closure elements are introduced into a vessel through a hole, smaller than the element itself, and to enable the folding and unfolding operation to take place during the sealing operation, and to avoid manipulation of the closure element by the physician at the time of performing the sealing operation.

[0007] This object is achieved by the provision of a guiding tool which in a controlled manner deforms or folds a wound closure element such that it after having been introduced through a puncture, unfolds and regains its original shape in a reproducible and controllable manner, and thereby provides adequate sealing at an excellent rate of success, this procedure taking place at the time of performing the sealing operation. The guiding tool according to the invention is defined in claim 1.

Brief Description of the Drawings

[0008]

Fig. 1 a-c is a schematic illustration of a system for wound closure during operation thereof;

Fig. 2a illustrates an embodiment of the guiding tool not belonging to the invention in cross section;

Fig. 2b is a view in longitudinal cross section of a second embodiment of the inventive guiding tool;

Fig. 2c illustrates cross sections at A-E in Fig. 2b;

Fig. 2d is a perspective cut view in two different directions of a third preferred embodiment of the inventive guiding tool;

Fig. 3a is a cross section view of a closure element; and

Fig. 3b is a top view of a closure element.

Detailed Description of the Invention

[0009] Fig. 1a-c illustrates the procedure of inserting a wound closure (occlusion) element 2 in a blood vessel 4 and clamping it by means of a locking member 6. Thereby, an incision 8 is made in the blood vessel 4 in question, and an introducer tube 10 is inserted into the vessel 4, see Fig. 1a. Then, a folded, or in some other manner deformed closure element 2 is passed through said introducer tube 10 and into the vessel 4. The closure element 2 is secured to e.g. a suture 12, and some rigid elongated element 14 such as a steel pin or pusher rod (not shown) can be used to guide the closure element 2 through the tube 10 and into the vessel 4, where it unfolds. Once the closure element 2 has unfolded inside the vessel 4, the pusher rod and the introducer tube 10 are withdrawn from the vessel but maintained close to the exterior of the vessel 4. Then, the closure element 2 is pulled back using the suture 12, so as to be located in a position where it is held against the interior vessel wall 16, Fig. 1b. An essentially disk shaped locking element 18, having a central hole, is provided on the suture 12, the suture running through said hole, such that the locking member can be moved along the suture 12 to be brought into contact with the exterior vessel wall 20. By the provision of suitable friction enhancing means 19 on the very distal end of the suture, the locking element can be pushed against the wall of the vessel while engaging the portion of the suture having higher friction, and thereby cause a locking of the closure element, Fig. 1c. This principle is used in e.g. US-5,916,236.

[0010] It is important that the closure element unfolds in a reproducible way, such that it will contact the inner vessel wall around the circumference of the incision. If the closure element is delivered to the user in a folded state, in position inside the introducer, as a "kit" ready for use by a physician, and the kit has been stored on a shelf for some time, it may happen that the closure element has become permanently deformed, and will not assume the desired shape (which may be to regain its original shape) inside the vessel. Such an event would of course dramatically increase the risk that the closure element will not fulfill its function, and cause a leakage.

[0011] Therefore, in accordance with the present invention, there is provided a guiding tool that is connectable to an introducer of the type discussed above, the closure element being provided in said guiding tool in an unfolded state. Thereby the actual deformation or folding of the closure element, necessary to enable insertion through the incision (which is smaller than the closure element) and into the blood vessel, is not performed until the time of performing the operation of inserting the closure element. In this way, the closure element will not be subjected to a prolonged deformation during storage.

[0012] An embodiment not falling under the invention is illustrated in Fig. 2a. It comprises a body in the shown embodiment in the form of an elongated tube like member 20 (although cylindrical outer symmetry is no requirement), having an inner lumen 22 that has a first diameter in the proximal end portion 24 and over a fraction of its length (up to the dotted line X), forming a space 26 in which an closure element (not shown) can be housed without being deformed. Over a second fraction of the length, from the dotted line X and up to the distal end 26 portion, the lumen becomes narrower, rendering the 22 lumen cone shaped over this portion. Finally there is a connection portion 28, connectable to an introducer tube (such as the tube 10 in Fig. 1a). The exit diameter is equal to or slightly smaller than the inner diameter of the introducerbe, i.e. small enough to enable passing the closure element into the blood vessel.

[0013] In Fig. 2b a second embodiment of the guiding tool according to the present invention is illustrated. It is adapted for a closure element 30 having the general shape shown in Figs. 3a and 3b. The closure element suitable for use with the illustrated embodiment of the guiding tool, has a thick mid portion 32, that is generally elongated, and has peripheral wings 34 or edges, which are substantially thinner, and thus more flexible than the mid portion 32. The peripheral shape is like a slightly distorted ellipse, but could in principle be circular, the wings 34 thereby forming rather a collar or a brim surrounding the mid portion. Other shapes are also possible. A suitable kind of closure element is disclosed and claimed in our copending EP-00850184.3. In view of its flexibility, the wings 34 or brim are foldable such that the entire element will have a smallest dimension in a folded state that fits well within an incision or puncture in a blood vessel, thereby enabling insertion into said vessel.

[0014] Thus, the embodiment of the guiding tool according to the present invention shown in Fig. 2b, comprises an essentially tubular element 42 having a proximal end 44 and a distal end 46 and a lumen 48 extending between said distal 46 end and said proximal end 44. There is further a wound closure element introduction opening 50 in the proximal end 44, and a wound closure element exit opening 52 in the distal end 46. The distal end is shaped so as to be connectable to an introducer tube, like the one described above in connection with Fig. 1.

[0015] The lumen 48 has inner walls 54 provided with wound closure element deformation surfaces 56, adapted to deform a wound closure element during passage thereof, past said surfaces 56, through the guiding tool, from an essentially undeformed or unfolded state to a deformed or folded state. The effect of this deformation/folding should be such that the overall dimension of the wound closure element is changed to render it capable of passing through the puncture in the blood vessel. Also, after passage through said incision or puncture it must regain a shape that is capable of providing a sealing action against the inner wall of the vessel.

[0016] In Fig. 2b there is also shown a pusher rod 51, having a fork like configuration, that is used to push the

closure element 30 through the introducer and into the blood vessel. This pusher rod is retracted once the element is properly located inside the vessel.

[0017] In the embodiment shown in Fig. 2b the deformation surfaces 56 have a specific design, illustrated by a sequence in Fig. 2c, which are cross section views through the lumen at the positions indicated with corresponding letters A, B, C, D, E in Fig. 2b. Thus, there is one guiding surface 56 for each wing on the closure element 30, and a guiding recess 60 in which the thicker mid portion 32 of the closure element 30 will run during its passage through the guiding tool. The guiding surfaces will initially have an orientation such that the wings 34 of the unfolded or undeformed closure element 30, when inserted into the guiding tool in the introduction opening, will rest thereon in a position and orientation causing no deformation (referred to as a "horizontal" orientation: position A in Fig. 2c). Thereby the nominal shape of the closure element 30 is preserved also during extended storage. In a direction towards the exit opening, the guiding surfaces will gradually become elevated (A-B-C-D-E in Fig 2c) from the initial, essentially horizontal orientation, and also curved such that they form what could be referred to as a "quasi-conical" lumen inside the tool. At the end of the lumen, near the exit opening, the guiding surfaces will have reached a state where the cross section of the lumen is essentially circular, and where the diameter corresponds to the inner diameter of the introducer tube.

[0018] Preferably, there are guiding rails 62 provided above the guiding surfaces 56, such that the wings or brims 34 of the closure element 30 will be kept down during the process of pushing it with the pusher rod through the guiding tool, thereby preventing inadvertent tilting or incorrect behavior of the closure element during the movement through said guiding tool. The rails are preferably integrated in the "roof" of the lumen. However, they can also be provided as an insert and attached by suitable means inside the lumen.

[0019] In a further variation of the above described embodiment, the interior lumen of the guiding tool essentially has a cross section that exactly corresponds to the cross section of the closure element. This lumen would then form a guiding slot inside the tool, whereby the slot would be shaped so as to gradually change from a cross section corresponding to the above mentioned "horizontal orientation" to an essentially circular cross section, the diameter of which would be smaller than the incision through which the closure element is to be inserted. There must however be a space above the closure element for the access by the pushing rod needed for advancing the closure element through the tool and the introducer.

[0020] The sequence A-E in Fig. 2c illustrates the folding process, and it is clearly seen that the closure element reaches a folded state where it conforms to the circular cross section of the introducer tube, which is connected to the guiding tool at the exit end thereof.

[0021] Another embodiment of the guiding tool is shown in Fig. 2d, showing perspective cuts through the device at two orientations perpendicular to each other. Like reference numerals are used for like elements in Figs. 2c and 2d. Like in the above described embodiment, this embodiment of the guiding tool comprises an essentially tubular element 42 having a proximal end 44 and a distal end 46 and a lumen 48 extending between said distal 46 end and said proximal end 44. There is further a wound closure element introduction opening 50 in the proximal end 44, and a wound closure element exit opening 52 in the distal end 46. The distal end is shaped so as to be connectable to an introducer tube.

[0022] Also in this embodiment, the lumen 48 has inner walls 54 also provided with wound closure element deformation surfaces 56, adapted to deform a wound closure element during passage thereof, past said surfaces 56, through the guiding tool, from an essentially undeformed state to a deformed state.

[0023] However, the deformation surfaces have a different design in this embodiment. Namely, one wall of the inner lumen is flat such that the closure element can be placed essentially flat thereon, in an unfolded state, e.g. during shelf storage, corresponding to the "horizontal orientation" discussed above in connection with Fig. 2b, but with the thicker mid portion facing upwards. Towards the exit opening the lumen is shaped as cone, much like in the first embodiment of Fig. 2a, whereby the final diameter of the inner lumen corresponds to a diameter smaller than the diameter of the opening in the blood vessel through which the closure element is to be introduced. About half-way along the conical portion of the lumen, there are provided a pair of deflection surfaces 64, having a "steeper" angle than the over-all cone angle of the lumen. These surfaces will engage the peripheral brim or collar portions of the closure element, such that they are deflected or bent downwards from the essentially flat initial position. Also, the pusher rod discussed above will cause the closure element not to lie completely flat, but slightly angled with the trailing edge at a slightly elevated position compared to the leading edge. Furthermore, said pusher rod will assist in keeping the leading edge forced against the flat surface.

[0024] In order to facilitate correct positioning of the closure element during insertion, also in this case there may be provided guiding rails like those described above.

[0025] The invention having been described with reference to preferred embodiments thereof can be subject to alterations and modifications by the man skilled in the art, and the scope of the invention is limited only by the appended claims.

Claims

1. A guiding tool for controllable and reversible folding or deformation of a wound closure element (2) be-

fore insertion of said wound closure element into a percutaneous incision or puncture in the wall (4) of a vessel, duct, lumen or hollow organ in the body of a living being, said incision or puncture being smaller than said wound closure element in an unfolded or undeformed state, said tool comprising a body (20) having a distal end (26) and a proximal end (24) and a lumen (22) extending between said distal end and said proximal end; a wound closure element introduction opening (50) in the proximal end, and a wound closure element exit opening (52) in the distal end;

characterized in that

said lumen has inner walls (54) provided with wound closure element guiding surfaces (56, 64) in the form of separate deflection elements protruding from the inner wall of said lumen, for reversibly reducing the spatial extension of a wound closure element during its passage through the guiding tool, by engaging a peripheral brim or collar portions of the closure element, such that they are deflected or bent downwards from an essentially flat initial position, whereby said wound closure element is capable of passing through said incision or puncture, and whereby it after passage through said incision or puncture assumes a shape that is capable of providing a sealing action against said incision or puncture.

2. The tool as claimed in claim 1, wherein said guiding surfaces (56) in the proximal end of said tool are essentially flat, and in a direction towards the distal end, gradually becomes elevated and also curved such that they form a quasi-conical lumen inside the tool, and wherein the guiding surfaces, at the distal end of the lumen, near the exit opening, will have reached a state where the cross section of the lumen is essentially circular.

3. The tool as claimed in claim 1 or 2, wherein there are guiding rails (62) provided above the guiding surfaces (56), such that wings or rims (34) of a closure element (30) will be kept down during the process of pushing through the guiding tool, said guiding rails (62) being arranged to prevent the closure element from inadvertent tilting or other incorrect behavior during its movement through the guiding tool.

4. The tool as claimed in claim 1, wherein said introduction opening is larger than said exit opening, and optionally is provided with a sealing plug (53) to prevent leakage of body fluid.

5. The tool as claimed in claim 1, wherein said guiding surfaces (56) gradually change from the proximal end, where they do not affect the nominal shape of the wound closure element (30), towards the distal end where they force the wound closure element (30) to assume a shape that conforms to the inner lumen of an introducer tube, connectable to the distal end of said guiding tool.

6. The tool as claimed in claim 1, wherein said lumen is cone shaped at least in the distal region of said guiding tool, and has a large enough diameter in the proximal region of the guiding tool, that the nominal shape of the wound closure element (30) is not affected, and a small enough diameter in the distal end that the wound closure element conforms to the inner lumen of an introducer tube, connectable to the distal end of said guiding tool.

7. The tool as claimed in claim 1, wherein the proximal region of the tool is essentially cylindrical, forming a storage compartment for said closure element (30), in which the nominal shape of the wound closure element is not affected.

8. A system for the introduction and securing of a wound closure element into a percutaneous incision or puncture in the wall of a vessel, duct, lumen or hollow organ in the body of a living being, said incision or puncture being smaller than said wound closure element in an unfolded or undeformed state, said system comprising

a wound closure element (30);

an introducer tube (10) for introducing said wound closure element into said incision;

a pusher device for enabling the passage of said wound closure element through said introducer; and

a tool as claimed in claim 1, connectable to said introducer.

Patentansprüche

1. Führungswerkzeug zum gesteuerten und reversiblen Falten oder Verformen eines Wundverschlusselements (2) vor der Einführung dieses Wundverschlusselements in einen perkutanen Schnitt oder eine perkutane Punktur in der Wand (4) eines Gefäßes, eines Kanals, eines Lumens oder eines hohlen Organs im Körper eines Lebewesens, wobei der Schnitt oder die Punktur kleiner ist als das Wundverschlusselement in einem ungefalteten oder nichtverformten Zustand, wobei das Werkzeug einen Körper (20) mit einem distalen Ende (26) und einem proximalen Ende (24) sowie einem Lumen (22) aufweist, das sich zwischen dem distalen und dem proximalen Ende erstreckt, eine Einführöffnung (50) für das Wundverschlusselement in dem proximalen Ende und eine Ausgangsöffnung (52) für das Wundverschlusselement in dem distalen Ende;

dadurch gekennzeichnet, dass

das Lumen Innenwände (54) hat, die mit Führungsflächen (56, 64) für das Wundverschlusselement in Form von separaten Ablenkelementen versehen sind, die von der Innenwand des Lumens hervorstehen, um die räumliche Ausdehnung eines Wundverschlusselements während seines Durchgangs durch das Führungswerkzeug durch Ineingriffbringen eines Außenrands oder Kragenbereichs des Verschlusselements reversibel zu reduzieren, so dass diese aus einer im Wesentlichen flachen anfänglichen Position abgelenkt oder nach unten gebogen werden, wobei das Wundverschlusselement durch den Schnitt oder die Punktur hindurchtreten kann und wobei es nach dem Durchtritt durch den Schnitt oder die Punktur eine Gestalt annimmt, die eine Dichtungswirkung gegen den Schnitt oder die Punktur bieten kann.

2. Werkzeug nach Anspruch 1, wobei die Führungsflächen (56) am proximalen Ende des Werkzeugs im Wesentlichen flach sind und in Richtung des distalen Endes nach und nach erhaben und auch gekrümmt werden, so dass sie ein quasi konisches Lumen innerhalb des Werkzeugs bilden, und wobei die Führungsflächen am distalen Ende des Lumens in der Nähe der Ausgangsöffnung einen Zustand erreicht haben werden, wo der Querschnitt des Lumens im Wesentlichen kreisförmig ist.

3. Werkzeug nach Anspruch 1 oder 2, wobei Führungsschienen (62) oberhalb der Führungsflächen (56) vorgesehen sind, so dass Flügel oder Kanten (34) eines Verschlusselements (30) während des Vorgangs des Hindurchdrückens durch das Führungswerkzeug unten gehalten werden, wobei die Führungsschienen (62) so angeordnet sind, dass ein unbeabsichtigtes Kippen oder anderweitiges unkorrektes Verhalten des Verschlusselements während seiner Bewegung durch das Führungswerkzeug hindurch verhindert wird.

4. Werkzeug nach Anspruch 1, wobei die Einführöffnung größer ist als die Ausgangsöffnung und optional mit einem Dichtungsverschluss (53) versehen ist, um ein Auslaufen von Körperflüssigkeit zu verhindern.

5. Werkzeug nach Anspruch 1, wobei die Führungsflächen (56) sich von dem proximalen Ende, wo sie die Nenngestalt des Wundverschlusselements (30) nicht beeinflussen, in Richtung des distalen Endes, wo sie das Wundverschlusselement (30) dazu zwingen, eine Gestalt einzunehmen, die sich dem inneren Lumen einer Einführröhre anpasst, verbindbar mit dem distalen Ende des Führungswerkzeugs, nach und nach verändern.

6. Werkzeug nach Anspruch 1, wobei das Lumen zumindest im distalen Bereich des Führungswerkzeugs kegelförmig ist und im proximalen Bereich des Führungswerkzeugs einen Durchmesser hat, der groß genug ist, um die Nenngestalt des Wundverschlusselements (30) nicht zu beeinflussen, und im distalen Ende einen Durchmesser hat, der klein genug ist, damit sich das Wundverschlusselement an das innere Lumen einer Einführröhre, verbindbar mit dem distalen Ende des Führungswerkzeugs, anpasst.

7. Werkzeug nach Anspruch 1, wobei der proximale Bereich des Werkzeugs im Wesentlichen zylindrisch ist und ein Aufbewahrungsabteil für das Verschlusselement (30) bildet, wobei die Nenngestalt des Wundverschlusselements nicht beeinträchtigt wird.

8. System zum Einführen und Sichern eines Wundverschlusselements in einen perkutanen Schnitt oder eine perkutane Punktur in der Wand eines Gefäßes, eines Kanals, eines Lumens oder eines hohlen Organs im Körper eines Lebewesens, wobei der Schnitt oder die Punktur kleiner ist als das Wundverschlusselement in einem ungefalteten oder nicht-deformierten Zustand, wobei das System Folgendes aufweist:

ein Wundverschlusselement (30) ;

eine Einführröhre (10) zum Einführen des Wundverschlusselements in den Schnitt;

eine Druckeinrichtung zum Ermöglichen des Durchgangs des Wundverschlusselements durch die Einführröhre hindurch; und

ein Werkzeug nach Anspruch 1, das mit der Einführröhre verbindbar ist.

Revendications

1. Outil de guidage pour le repliement ou la déformation contrôlables et réversibles d'un élément de fermeture de plaie (2) avant l'insertion dudit élément de fermeture de plaie dans une incision percutanée ou un orifice dans la paroi (4) d'un vaisseau, d'un canal, d'une ouverture ou d'un organe creux dans le corps d'un être vivant, où ladite incision ou ledit orifice est plus petit que ledit élément de fermeture de plaie à l'état non replié ou non déformé, ledit outil comprenant un corps (20) avec une extrémité distale (26) et une extrémité proximale (24) et une ouverture (22) entre lesdites extrémités distale et proximale, une ouverture d'introduction (50) de l'élément de fermeture de plaie à l'extrémité proximale et une ouverture de sortie (52) de l'élément de

fermeture de plaie à l'extrémité distale, **caractérisé en ce que** ledit passage présente des parois internes (54) offrant des surfaces de guidage (56, 64) de l'élément de fermeture de plaie sous la forme d'éléments déflecteurs distincts disposés en saillie sur la paroi interne dudit passage et destinés à réduire de manière réversible l'extension dans l'espace d'un élément de fermeture de plaie pendant son passage dans l'outil de guidage en agissant sur un bord ou collet périphérique de l'élément de fermeture de manière à ce qu'il soit fléchi où replié vers le bas à partir d'une position initiale essentiellement plane, si bien que ledit élément de fermeture de plaie peut passer au travers de ladite incision ou dudit orifice et, après son passage dans ladite incision ou ledit orifice, reprendre une forme telle qu'il soit en mesure d'exercer une action de fermeture sur ladite incision ou ledit orifice.

2. Outil selon la revendication 1, où lesdites surfaces de guidage (56) dans l'extrémité proximale dudit outil sont essentiellement planes et, en direction de l'extrémité distale, remontent et se courbent progressivement de manière à former une ouverture pratiquement conique à l'intérieur de l'outil et où les surfaces de guidage, à l'extrémité distale de l'ouverture, près de l'ouverture de sortie, atteignent une position telle que la section de l'ouverture est essentiellement circulaire.

3. Outil selon la revendication 1 ou 2, où il existe au-dessus des surfaces de guidage (56) des rails de guidage (62) tels que les ailes ou bords (34) de l'élément de fermeture (30) sont maintenus en position basse pendant l'opération de poussée au travers de l'outil de guidage, lesdits rails de guidage (62) étant disposés de manière à éviter que l'élément de fermeture ne puisse inopinément basculer ou mal se positionner pendant son mouvement au travers de l'outil de guidage.

4. Outil selon la revendication 1, où ladite ouverture d'introduction est plus grande que ladite ouverture de sortie et peut en option être dotée d'un bouchon étanche (53) destiné à éviter l'épanchement des fluides corporels.

5. Outil selon la revendication 1, où lesdites surfaces de guidage (56) changent progressivement, entre l'extrémité proximale, où elles n'affectent pas la forme nominale de l'élément de fermeture de plaie (30), et l'extrémité distale, où elles forcent l'élément de fermeture de plaie (30) à prendre une forme correspondant à l'ouverture interne d'un tube d'introduction pouvant être connecté à l'extrémité distale dudit outil de guidage.

6. Outil selon la revendication 1, où ledit passage est de forme conique, au moins dans la région distale dudit outil de guidage, et possède un diamètre suffisamment grand dans la région proximale de l'outil de guidage pour que la forme nominale de l'élément de fermeture de plaie (30) ne soit pas affectée et un diamètre suffisamment petit dans la région distale pour que l'élément de fermeture de plaie corresponde à l'ouverture interne d'un tube d'introduction pouvant être connecté à l'extrémité distale dudit outil de guidage.

7. Outil selon la revendication 1, où la région proximale de l'outil est essentiellement cylindrique, formant un compartiment de stockage pour ledit élément de fermeture de plaie (30), où la forme nominale de celui-ci n'est pas affectée.

8. Système pour l'introduction et la fixation d'un élément de fermeture de plaie dans une incision percutanée ou un orifice dans la paroi d'un vaisseau, d'un canal, d'une ouverture ou d'un organe creux du corps d'un être vivant, ladite incision ou ledit orifice étant plus petit que ledit élément de fermeture de plaie à l'état non replié ou non déformé, ledit système comprenant

un élément de fermeture de plaie (30),

un tube d'introduction (10) pour introduire ledit élément de fermeture de plaie dans ladite incision,

un dispositif de poussage permettant de faire passer ledit élément de fermeture de plaie dans ledit tube d'introduction, et

un outil selon la revendication 1, pouvant être connecté audit tube d'introduction.

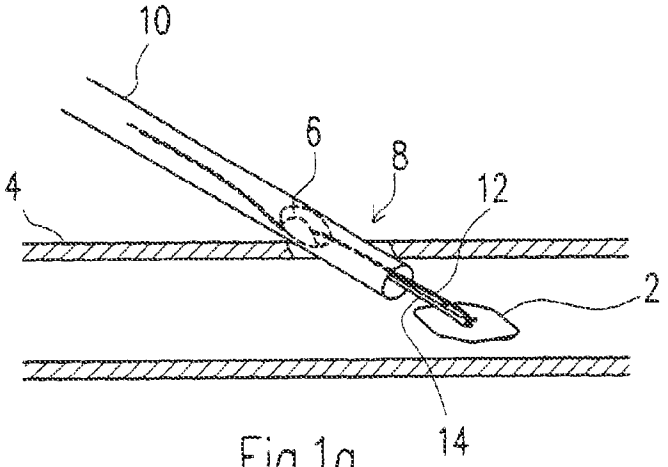


Fig.1a

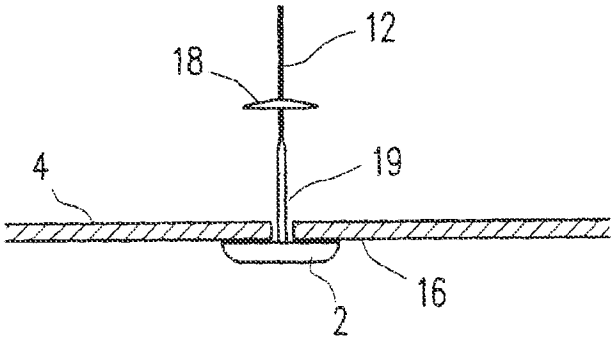


Fig.1b

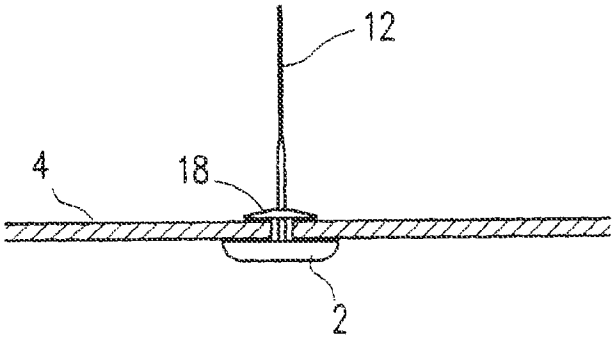


Fig.1c

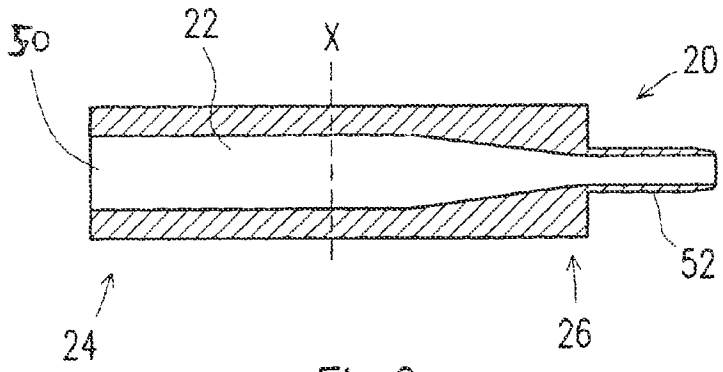


Fig.2a

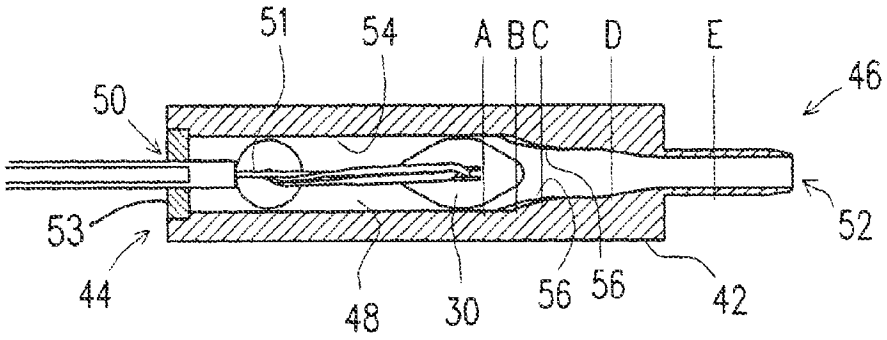


Fig.2b

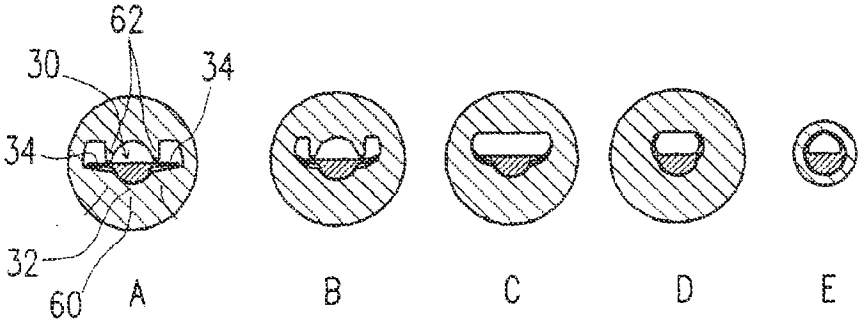


Fig.2c

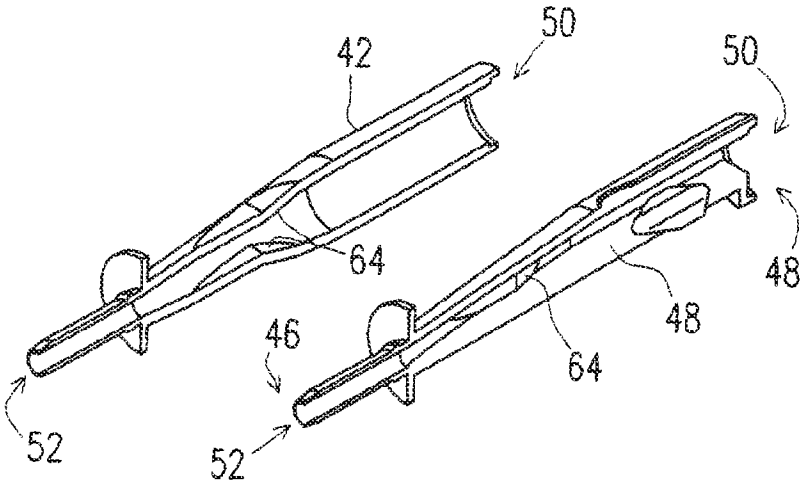


Fig.2d

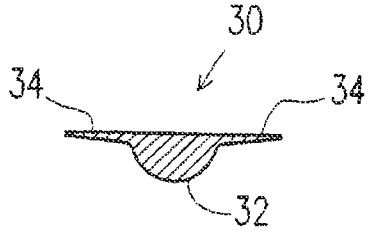


Fig.3a

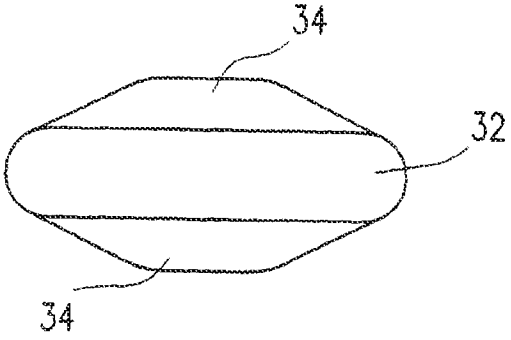


Fig.3b

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-09-PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2020/014854	23 January 2020 (23-01-2020)	
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 4 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. 3C
      [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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/014854

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. [X] Claims Nos.: 21-27
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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:

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/US2020/014854

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 A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 9 463 035 B1 (GREENHALGH E SKOTT [US] ET AL) 11 October 2016 (2016-10-11) cited in the application column 36, line 40 - column 37, line 3 figures 38A, 38B	1-20
A	US 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26) paragraph [0218]; figures 38A, 38B, 39A-39C	1-20
A	US 2003/168068 A1 (POOLE ANTHONY GEORGE [GB] ET AL) 11 September 2003 (2003-09-11) paragraphs [0004], [0108] - [0113], [0119] - [0132], [0144]; figures 7, 10	1-20

☐ 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
25 September 2020	05/10/2020

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	Chabus, Hervé

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/014854

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 9463035 B1	11-10-2016	CN 108348319 A	31-07-2018
		CN 111281482 A	16-06-2020
		EP 3355829 A1	08-08-2018
		EP 3406208 A1	28-11-2018
		JP 2018529495 A	11-10-2018
		JP 2020146487 A	17-09-2020
		US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		US 2019336148 A1	07-11-2019
		WO 2017058280 A1	06-04-2017
US 2017303948 A1	26-10-2017	CN 109890304 A	14-06-2019
		EP 3448280 A2	06-03-2019
		EP 3590446 A1	08-01-2020
		JP 2019519341 A	11-07-2019
		US 2017303948 A1	26-10-2017
		US 2019117244 A1	25-04-2019
		US 2019133622 A1	09-05-2019
		WO 2017189535 A2	02-11-2017
US 2003168068 A1	11-09-2003	AT 324827 T	15-06-2006
		AU 8428601 A	22-03-2002
		CA 2421370 A1	14-03-2002
		DE 60119343 T2	07-09-2006
		EP 1315444 A2	04-06-2003
		ES 2260275 T3	01-11-2006
		JP 2004508084 A	18-03-2004
		US 2003168068 A1	11-09-2003
		WO 0219899 A2	14-03-2002

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/US2020/014854	23.01.2020	

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	Chabus, Hervé 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. 21-27

because:

☒ the said international application, or the said claims Nos. 21-27 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. 21-27

☐ 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	1-20
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-20
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-20
	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

1 **Re Item III**

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Method claims 21-27 refer to a method of removing a clot from a blood vessel which is a method for treatment of the human or animal body. No opinion is required for such a method (see Rule 67.1(iv) PCT).

2 **Re Item V**

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2.1 Reference is made to the following documents:

D1	US 9 463 035 B1 (GREENHALGH E SKOTT [US] ET AL) 11 October 2016 (2016-10-11)cited in the application
D2	US 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26)
D3	US 2003/168068 A1 (POOLE ANTHONY GEORGE [GB] ET AL) 11 September 2003 (2003-09-11)

2.2 D1 (column 36, line 40 - column 37, line 3; figures 38A, 38B) is regarded as being the prior art closest to the subject-matter of claim 1, and discloses an apparatus for removing a material (3805) from a body lumen, the apparatus comprising:
an elongate inversion support catheter (3811) having a proximal end region, a distal end region, and a distal end opening;
an elongate puller (3807) extending within the inversion support catheter;
a flexible tube having a distal first end attached to the puller, wherein the flexible tube extends over an outer surface of the inversion support catheter and is configured to invert into the distal end opening of the inversion support catheter when the puller is pulled proximally; and
a depot (3813) ~~movably~~ coupled to the proximal end region of the inversion support catheter, the depot comprising an inner storage region~~, wherein a~~

~~proximal portion of the flexible tube is held compressed within the inner storage region in a folded configuration that is configured to unfurl out of a distal end opening of the depot when the puller is pulled proximally~~.

The subject-matter of claim 1 therefore differs from this known apparatus in that the depot is movably coupled to the proximal end region of the inversion support catheter, and wherein a proximal portion of the flexible tube is held compressed within the inner storage region in a folded configuration that is configured to unfurl out of a distal end opening of the depot when the puller is pulled proximally.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as to provide an apparatus which can be easily adapted to different lengths of use.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

Document D3 (see paragraphs [0004], [0108] - [0113], [0119] - [0132], [0144]; figures 7, 10) discloses an assembly comprising an endoscope and a body cavity liner which is stored in a compressed state in a housing and which is everted when deployed from the housing. While D3 appears to disclose part of the solution, the skilled person would not consider D3 for solving the above stated problem because it relates to a completely different device.

D2 (see paragraph [0218]; figures 38A, 38B, 39A-39C) does not disclose any depot comprising an inner storage region for the flexible tube.

Therefore, the skilled person does not find, in the prior art, any hint towards the proposed solution when trying to solve the problem mentioned above.

2.3 Claim 20 contains all the features of claim 1. For the same reason, the subject matter of claim 20 involves an inventive step.

2.4 Claims 2-19 are dependent on one or more independent claims whose subject-matter is considered as being new and inventive, as discussed above, and as such said dependent claims also meet the requirements of the PCT with respect to novelty and inventive step.

3 **Re Item VII**

Certain defects in the international application

3.1 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).

3.2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

4 **Re Item VIII**

Certain observations on the international application

4.1 The application does not meet the requirements of Article 6 PCT, because claim 13 is not clear as it misses a final punctuation point.

4.2 Although claims 1 and 20 have been drafted as separate independent claims, claim 20 consists essentially of the combination of features of claims 1, 2 and 17. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

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-011-PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2020/018655	18 February 2020 (18-02-2020)	
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. [X] **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. 3b

[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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/018655

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. [X] Claims Nos.: 26-32
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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. [X] 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.

[X] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/018655

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221 A61M25/01
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2019/046219 A1 (MARCHAND PHIL [US] ET AL) 14 February 2019 (2019-02-14) paragraphs [0098], [0099], [0200], [0201]; figures 1, 29, 30	1-16
A	US 2014/005717 A1 (MARTIN BRIAN B [US] ET AL) 2 January 2014 (2014-01-02) paragraph [0158]; figures 11A, 13A	1-16
A	US 2018/236205 A1 (KRAUTKREMER DANIEL LEE [US] ET AL) 23 August 2018 (2018-08-23) paragraphs [0063], [0064]; figures 13, 14	1-8
A	US 2016/022293 A1 (DUBRUL WILLIAM R [US] ET AL) 28 January 2016 (2016-01-28) paragraphs [0099] - [0102]; figures 9-16	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
7 December 2020	16/12/2020

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	Chabus, Hervé

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.
A	EP 1 254 634 A1 (RADI MEDICAL SYSTEMS [SE]) 6 November 2002 (2002-11-06) paragraph [0022]; figure 2d	1
X	US 2019/133623 A1 (WALLACE MICHAEL P [US] ET AL) 9 May 2019 (2019-05-09)	17-22,24
Y	paragraphs [0138], [0139], [0153]	33-39
A	figures 7A-8C, 14A-14D	23,25
Y	US 2009/076417 A1 (JONES GREGORY ALLEN [US]) 19 March 2009 (2009-03-19) paragraphs [0040], [0041]; claim 1 figures 5, 6	33-39
Y	US 2017/042571 A1 (LEVI TAMIR S [IL]) 16 February 2017 (2017-02-16) paragraph [0037]; figures	33-39
Y	US 3 515 137 A (SANTOMIERI LOUIS S) 2 June 1970 (1970-06-02) figures 6-10	33-39
A	WO 2019/010318 A1 (STRYKER CORP [US]) 10 January 2019 (2019-01-10) paragraphs [0041], [0105], [0106] figures 9A-9C	17-25, 33-39
A	US 2016/228134 A1 (MARTIN BRIAN [US] ET AL) 11 August 2016 (2016-08-11) paragraph [0170] figure 10	33-39

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/018655

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2019046219 A1	14-02-2019	CN 110312481 A	08-10-2019
		EP 3528717 A1	28-08-2019
		US 2018193043 A1	12-07-2018
		US 2019046219 A1	14-02-2019
		WO 2018080590 A1	03-05-2018
US 2014005717 A1	02-01-2014	CN 102036611 A	27-04-2011
		EP 2231037 A1	29-09-2010
		JP 5385302 B2	08-01-2014
		JP 5914432 B2	11-05-2016
		JP 2011508635 A	17-03-2011
		JP 2013233454 A	21-11-2013
		JP 2016041275 A	31-03-2016
		US 2009299393 A1	03-12-2009
		US 2014005717 A1	02-01-2014
		US 2017325830 A1	16-11-2017
		WO 2009086482 A1	09-07-2009
US 2018236205 A1	23-08-2018	CN 110536713 A	03-12-2019
		EP 3585468 A1	01-01-2020
		JP 2020508153 A	19-03-2020
		US 2018236205 A1	23-08-2018
		WO 2018156819 A1	30-08-2018
US 2016022293 A1	28-01-2016	NONE	
EP 1254634 A1	06-11-2002	AT 245389 T	15-08-2003
		DE 60100507 T2	09-06-2004
		EP 1254634 A1	06-11-2002
		ES 2202269 T3	01-04-2004
US 2019133623 A1	09-05-2019	CN 111343932 A	26-06-2020
		EP 3706650 A1	16-09-2020
		US 2019133623 A1	09-05-2019
		US 2019133624 A1	09-05-2019
		US 2019133625 A1	09-05-2019
		US 2019133626 A1	09-05-2019
		US 2019133627 A1	09-05-2019
		WO 2019094456 A1	16-05-2019
US 2009076417 A1	19-03-2009	NONE	
US 2017042571 A1	16-02-2017	EP 3334487 A1	20-06-2018
		US 2017042571 A1	16-02-2017
		US 2019117395 A1	25-04-2019
		WO 2017030897 A1	23-02-2017
US 3515137 A	02-06-1970	AT 291427 B	12-07-1971
		SE 351128 B	20-11-1972
		US 3515137 A	02-06-1970
WO 2019010318 A1	10-01-2019	CN 110913778 A	24-03-2020
		EP 3648686 A1	13-05-2020
		JP 2020526255 A	31-08-2020
		WO 2019010318 A1	10-01-2019
US 2016228134 A1	11-08-2016	EP 2403583 A1	11-01-2012
		US 2012197285 A1	02-08-2012

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		US 2016228134 A1	11-08-2016
		WO 2010102307 A1	10-09-2010

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

Device and associated method for introducing an inversion support catheter into a delivery sheath

---

2. claims: 17-25

System for removing a material from a body vessel and system for reloading an inverting tube apparatus

---

3. claims: 33-39

System for removing a material from a body vessel comprising a compressible grip

---

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/US2020/018655	18.02.2020	

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/22 A61B17/221 A61M25/01

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	Chabus, Hervé 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. 26-32

because:

☒ the said international application, or the said claims Nos. 26-32 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. 26-32

☐ 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. 1-39

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, 23, 25, 33-39
	No:	Claims	17-22, 24
Inventive step (IS)	Yes:	Claims	1-16, 23, 25
	No:	Claims	17-22, 24, 33-39
Industrial applicability (IA)	Yes:	Claims	1-25, 33-39
	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

1 **Re Item III**

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Method claims 26-32 are directed to methods of removing material from a body vessel. These methods are methods for treatment of the human body by surgery for which no search and no opinion are required (Rules 39.1(iv) and 67.1(iv) PCT).

2 **Re Item IV**

Lack of unity of invention

2.1 This Authority considers that the application does not meet the requirements of unity of invention and that there are three inventions covered by the claims indicated as follows:

Invention 1: claims: 1-16

Device and associated method for introducing an inversion support catheter into a delivery sheath

Invention 2: claims: 17-25

System for removing a material from a body vessel and system for reloading an inverting tube apparatus

Invention 3: claims: 33-39

System for removing a material from a body vessel comprising a compressible grip

2.2 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 matter linking together the independent claims is the following:

an inversion support comprising a catheter and an expandable funnel disposed on a distal end of the catheter, the catheter having an open distal end in communication with an interior region of the funnel.

This common matter does not comprise a single general inventive concept, based on same or corresponding special technical features within the meaning of Rule 13.2 PCT, because it is already known from document D1 (see (paragraphs [0200], [0201]; figures 29, 30).

The technical features, representing the difference over the non-inventive common matter, of independent claims 1, 9 and 11 are a device for introducing an inversion support catheter into a delivery sheath, the device comprising: an elongate body with a lumen, said body being configured to tear along a defined tear line, said lumen having a first diameter at the proximal end region of the body and a second diameter at the distal end region of the body, wherein the second diameter is greater than the first diameter, wherein a sidewall of the body defining the lumen comprises a first flat region and a second flat region spaced apart from the first flat region along a distal to proximal axis of the body.

These features solve the objective technical problem of facilitating the loading of the inversion support catheter into a delivery sheath.

The technical features, representing the difference over the non-inventive common matter, of independent claims 17, 24 and 25 are a system for removing a material from a body vessel comprising a tractor comprising a flexible tube having an un-inverted portion that extends distally along an outer surface of the catheter and a stop on the outer surface of the catheter, wherein the stop prevents the tractor from moving proximally along the outer surface of the catheter without inhibiting the tractor from moving distally along the outer surface of the catheter, wherein the stop maintains the un-inverted portion of the tractor on the outer surface of the catheter in a packed configuration as the tractor is pulled proximally within the catheter lumen.

These features solve the objective technical problem of preventing the tractor from unstacking in the proximal direction.

The technical features, representing the difference over the non-inventive common matter, of independent claim 33 are a system for removing a material from a body vessel comprising a compressible grip slideably coupled to the outer surface of the inversion support catheter.

These features solve the objective technical problem of facilitating the manipulation of the inversion support catheter.

Hence, the independent claims comprise neither the same, nor corresponding special technical features, so the technical relationship between the subject matter of the claims required by Rule 13.2 PCT is lacking and the claims are not so linked as to form a single general inventive concept as required by Rule 13.1 PCT.

Consequently the application does not meet the requirement for unity of invention.

3 Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3.1 Reference is made to the following documents:

D1 US 2019/046219 A1 (MARCHAND PHIL [US] ET AL) 14 February 2019 (2019-02-14)

D2 US 2014/005717 A1 (MARTIN BRIAN B [US] ET AL) 2 January 2014 (2014-01-02)

D3 US 2018/236205 A1 (KRAUTKREMER DANIEL LEE [US] ET AL) 23 August 2018 (2018-08-23)

D4 US 2016/022293 A1 (DUBRUL WILLIAM R [US] ET AL) 28 January 2016 (2016-01-28)

D5 EP 1 254 634 A1 (RADI MEDICAL SYSTEMS [SE]) 6 November 2002 (2002-11-06)

D6 US 2019/133623 A1 (WALLACE MICHAEL P [US] ET AL) 9 May 2019 (2019-05-09)

D7 US 2009/076417 A1 (JONES GREGORY ALLEN [US]) 19 March 2009 (2009-03-19)

D8 US 2017/042571 A1 (LEVI TAMIR S [IL]) 16 February 2017 (2017-02-16)

D9 US 3 515 137 A (SANTOMIERI LOUIS S) 2 June 1970 (1970-06-02)

D10 WO 2019/010318 A1 (STRYKER CORP [US]) 10 January 2019 (2019-01-10)

D11 US 2016/228134 A1 (MARTIN BRIAN [US] ET AL) 11 August 2016 (2016-08-11)

Invention 1 (claims 1-16)

3.2 D1 (see paragraphs [0098], [0099]; figure 1) is regarded as being the prior art closest to the subject-matter of claim 1, and discloses a device (158) for introducing an inversion support catheter into a delivery sheath, the device comprising:
an elongate body having a lumen extending from a distal end region to a proximal end region, ~~the body configured to tear along a defined tear line extending proximally to distally~~, the lumen having a first diameter at the proximal end region of the body and a second diameter at the distal end region of the body, wherein the second diameter is greater than the first diameter,
~~wherein a sidewall of the body defining the lumen comprises a first flat region and a second flat region spaced apart from the first flat region along a distal to proximal axis of the body~~.

The subject-matter of claim 1 therefore differs from this known device in that the body is configured to tear along a defined tear line extending proximally to distally and in that a sidewall of the body defining the lumen comprises a first flat region and a second flat region spaced apart from the first flat region along a distal to proximal axis of the body .

The subject matter of claim 1 is therefore new (Article 33(2) PCT).

The problems to be solved by the present invention may be regarded as to facilitate the removal of the device and the loading of the inversion support catheter into a delivery sheath.

The solutions to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

Although part of the solution are known from documents D4 (see paragraphs [0099] - [0102]; figures 9-16) and D5 (see paragraph [0022]; figure 2d), the skilled person would have no incentive to consider them because they solve different problems than the ones mentioned above. In D4, the weakened region (76) allows removal of a stopper sleeve (72) during use of the device and not for facilitating the removal of an inversion support catheter introducer. In D5, the pair of flat angled surfaces (64) engage the peripheral rim or collar portions of the closure element, such that they are deflected or bent downwards from the essentially flat initial position.

The rest of the prior art does not hint either at the proposed solutions. Therefore, the subject matter of claim 1 is inventive in view of the prior art at hand.

3.3 For similar reasons, the subject matter of independent claims 9 and 11 involves an inventive step.

3.4 Claims 2-8, 10, 12-16 are dependent on one or more independent claims whose subject-matter is considered as being new and inventive, as discussed above, and as such said dependent claims also meet the requirements of the PCT with respect to novelty and inventive step.

Invention 2 (claims 17-25)

3.5 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claims 17 and 24 is not new in the sense of Article 33(2) PCT.

3.5.1 Document D6 (see paragraphs [0138], [0139], [0153]; figures 7A-8C, 14A-14D) discloses a system for removing a material from a body vessel, the system comprising:
an inversion support comprising a catheter (707), the catheter having a lumen and a distal end opening in communication with the lumen;
a tractor (715) comprising a flexible tube having an un-inverted portion that extends distally along an outer surface of the catheter, and wherein the flexible

tube inverts over the distal end opening of the catheter, wherein an inverted portion of the flexible tube extends proximally within the catheter lumen in an inverted configuration, wherein the flexible tube is configured to invert by rolling over the distal end opening when a first end of the tractor is pulled proximally within the catheter lumen; and
a stop (1401) on the outer surface of the catheter, wherein the stop prevents the tractor from moving proximally along the outer surface of the catheter without inhibiting the tractor from moving distally along the outer surface of the catheter, wherein the stop maintains the un-inverted portion of the tractor on the outer surface of the catheter in a packed configuration as the tractor is pulled proximally within the catheter lumen.

The subject matter of independent claim 17 is therefore not new over D6.

3.5.2 D6 (see figure 14A and paragraph [0153]) takes also the subject matter of independent claim 24.

3.6 Dependent claims 18-22 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 novelty. Document D6 (paragraph [0153]; figures 14A-14D) discloses a knitted tractor (715) and a stop comprising an annular ring.

3.7 Independent claim 25 and dependent claim 23 (positive opinion)

The prior art does not hint at providing an introducer covering the tractor (715) wherein the introducer comprises an introducer stop within a lumen of the introducer that prevents the tractor from extending proximally beyond the stop without inhibiting the tractor from moving distally, the introducer further comprising a defined tear line extending proximally to distally and configured to tear away to remove the introducer.

The subject matter of independent claim 25 and also of dependent claim 23 is therefore new and inventive in view of D6 and the rest of the found prior art.

Invention 3 (claims 33-39)

3.8 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 33 does not involve an inventive step in the sense of Article 33(3) PCT.

Document D6 (see [0138], [0139], [0153]; figures 7A-8C, 14A-14D) is regarded as being the prior art closest to the subject-matter of claim 33, and discloses a system for removing a material from a body vessel, the system comprising:
an inversion support catheter having a lumen, a distal end region, a proximal end region, and a distal end opening in communication with the lumen;
a puller with the lumen of the inversion support catheter;
a tractor comprising a flexible tube having a first end attached to the puller, wherein the flexible tube extends distally in an un-inverted configuration along an outer surface of the inversion support catheter and is configured to invert by rolling over the distal end opening of the inversion support catheter when the first end of the flexible tube is pulled proximally within the catheter lumen; and
~~a compressible grip slideably coupled to the outer surface of the inversion support catheter~~.

The subject-matter of claim 33 therefore differs from this known system in that it comprises a compressible grip slideably coupled to the outer surface of the inversion support catheter

The problem to be solved by the present invention may therefore be regarded as to facilitate the manipulation of the system.

The solution proposed in claim 33 of the present application cannot be considered to involve an inventive step (Article 33(3) PCT).

The skilled person is already acquainted with the use of compressible grips coupled to the outer surface of a catheter to provide an assistance in its manipulation (see for example D7, paragraphs [0040], [0041]; claim 1; figures 5, 6; D8, paragraph [0037]; figures and D9, figures 6-10).

It would have been obvious at the date of filing of the application to use one the known compressible grips as disclosed in D7 to D9 to facilitate the manipulation of the inversion support catheter known from D6.

No inventive step is therefore present in independent claim 33 (Art. 33(3) PCT).

3.9 Dependent claims 34-39 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.

The features of claims 34 to 39 are known from D7 to D9 (see their corresponding passages cited in the search report).

4 **Re Item VII**

Certain defects in the international application

4.1 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

4.2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1 to D11 is not mentioned in the description, nor are these documents identified therein.

5 **Re Item VIII**

Certain observations on the international application

5.1 The application does not meet the requirements of Article 6 PCT, because claim 10 is not clear as it makes reference to "the" tractor whereas no tractor is defined in any of the preceding claims.

5.2 Although claims 1 and 9 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.

Independent claim 9 contains essentially all the features of claim 1 and should have been drafted as a dependent claim referring to claim 1.

5.3 The independent claims 17, 24 and 25 of the second invention also lacks conciseness and do not meet therefore the requirements of Article 6 PCT.

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-10-PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2020/017684	11 February 2020 (11-02-2020)	
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. 8b

☒ 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/US2020/017684

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. [X] Claims Nos.: 22-24, 41, 42
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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. [X] 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.:

1-21

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/US2020/017684

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/221 A61B17/22
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2019/336148 A1 (GREENHALGH E SKOTT [US] ET AL) 7 November 2019 (2019-11-07) cited in the application paragraphs [0049], [0057], [0058], [0150], [0158], [0165], [0171], [0176] - [0177]; claim 2; figures 2, 13, 15A-15D, 19A-21D	1-21
A	WO 2019/010318 A1 (STRYKER CORP [US]) 10 January 2019 (2019-01-10) paragraphs [0011], [0038] - [0040], [0101] - [0105]; figures 5, 7A-8B	1-21
A	US 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26) paragraphs [0148], [0182] - [0189]; figures 10A-10E, 31A-37C	1-21

-/--

[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
29 September 2020	30/11/2020

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	Chabus, Hervé

1

Form PCT/ISA/210 (second sheet) (April 2005)

International application No
PCT/US2020/017684

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2019/133624 A1 (WALLACE MICHAEL P [US] ET AL) 9 May 2019 (2019-05-09) paragraphs [0009], [0018], [0034] - [0046]; figures 6, 13A-13C	1-21

1

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2019336148 A1	07-11-2019	CN 108348319 A	31-07-2018
		CN 111281482 A	16-06-2020
		EP 3355829 A1	08-08-2018
		EP 3406208 A1	28-11-2018
		EP 3741315 A1	25-11-2020
		ES 2784779 T3	30-09-2020
		JP 2018529495 A	11-10-2018
		JP 2020146487 A	17-09-2020
		US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		US 2019336148 A1	07-11-2019
		US 2020315642 A1	08-10-2020
		WO 2017058280 A1	06-04-2017
WO 2019010318 A1	10-01-2019	CN 110913778 A	24-03-2020
		EP 3648686 A1	13-05-2020
		JP 2020526255 A	31-08-2020
		WO 2019010318 A1	10-01-2019
US 2017303948 A1	26-10-2017	CN 109890304 A	14-06-2019
		EP 3448280 A2	06-03-2019
		EP 3590446 A1	08-01-2020
		JP 2019519341 A	11-07-2019
		US 2017303948 A1	26-10-2017
		US 2019117244 A1	25-04-2019
		US 2019133622 A1	09-05-2019
		WO 2017189535 A2	02-11-2017
US 2019133624 A1	09-05-2019	CN 111343932 A	26-06-2020
		EP 3706650 A1	16-09-2020
		US 2019133623 A1	09-05-2019
		US 2019133624 A1	09-05-2019
		US 2019133625 A1	09-05-2019
		US 2019133626 A1	09-05-2019
		US 2019133627 A1	09-05-2019
		WO 2019094456 A1	16-05-2019

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-21

Apparatus for removing a material from a body lumen with a knitted tube configured to prevent any locking at the distal end of the catheter when pulled

---

2. claims: 25-40

Apparatus for removing a material from a body lumen with a funnel configured to facilitate removal of harder material

---

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/US2020/017684	11.02.2020	

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/221 A61B17/22

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	Chabus, Hervé 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. 22-42

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ 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. 22-42

☐ 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. 1-21

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	4, 5, 8, 9, 15-21
	No:	Claims	1-3, 6, 7, 10-14
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-21
Industrial applicability (IA)	Yes:	Claims	1-21
	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

1 **Re Item III**

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Method claims 22-24, 41 and 42 relate to methods of removing material from within a body lumen. These methods are methods for treatment of the human body by surgery for which no opinion is required (Rule 67.1(iv) PCT).

2 **Re Item IV**

Lack of unity of invention

2.1 This Authority considers that the application does not meet the requirements of unity of invention and that there are 2 inventions covered by the claims indicated as follows:

Invention 1: claims: 1-21

Apparatus for removing a material from a body lumen with a knitted tube configured to prevent any locking at the distal end of the catheter when pulled

Invention 2: claims: 25-40

Apparatus for removing a material from a body lumen with a funnel configured to facilitate removal of harder material

2.2 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 matter linking together the independent claims 1, 15, 25 and 40 is the following:

an apparatus for removing a material from a body lumen, the apparatus comprising:

an elongate inversion support comprising a catheter having a circumference, a distal end, and a distal end opening; and

a knitted tube that extends distally in an un-inverted configuration along an outer surface of the catheter, inverts into the distal end opening of the catheter, and extends proximally within the catheter in an inverted configuration, wherein the

knitted tube is configured to invert by rolling into the distal end opening of the catheter when a first end of the knitted tube is pulled proximally within the catheter.

This common matter does not comprise a single general inventive concept, based on same or corresponding special technical features within the meaning of Rule 13.2 PCT, because it is known from document D1 (see paragraphs [0049], [0057], [0058], [0150], [0158], [0165], [0171], [0176] - [0177]; claim 2; figures 2, 13, 15A-15D, 19A-21D and item V point 3.2 below).

The differentiating features of the independent claims over the above identified common matter are as follows:

Claim 1: the knitted tube is configured to stretch less than 3 percent when pulled in tension with a force of 2 Newtons so that the knitted tube does not lock onto the outer surface of the catheter.

Claim 15: the knitted tube has a length of 20 cm or greater and has a choke ratio greater than 2.9.

Claim 25: the inversion support further comprises an expandable funnel disposed at a distal end of the catheter body and extending in a proximal to distal axis, wherein a distal end of the funnel defines a distal end opening in communication with an interior of the funnel and the catheter lumen, respectively, and wherein, in an open configuration, an interior wall of the funnel has a wall angle of less than 14 degrees relative to the proximal to distal axis for a majority of a length of the funnel, and includes a first region in which the wall angle is between 14 and 50 degrees with respect to the proximal to distal axis.

Claim 40: an expandable funnel is disposed at a distal end of the catheter body and extending in a proximal to distal axis, wherein a distal end of the funnel defines a distal end opening in communication with an interior of the funnel and the catheter lumen, respectively, and wherein, in an open configuration, an interior wall of the funnel comprises one or more constricted regions in which the interior wall of the funnel constricts from the proximal to distal direction.

The features of claims 1 and 15 are corresponding as they solve the same problem of preventing locking of the knitted tube at the distal end of the catheter.

The features of claims 25 and 40 are also corresponding since they solve the same problem of facilitating the removal of harder material.

However the features of claims 1 and 15 on the one hand and the features of claims 25 and 40 on the other hand are neither the same nor corresponding since they solve different problems.

Therefore, invention 1 and invention 2 as defined above are not so linked by a single general inventive concept (Rule 13.1 PCT) involving same and corresponding special technical features (Rule 13.2 PCT).

Consequently the application does not meet the requirement for unity of invention.

3 Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3.1 Reference is made to the following documents:

D1	US 2019/336148 A1 (GREENHALGH E SKOTT [US] ET AL) 7 November 2019 (2019-11-07)cited in the application
D2	WO 2019/010318 A1 (STRYKER CORP [US]) 10 January 2019 (2019-01-10)
D3	US 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26)
D4	US 2019/133624 A1 (WALLACE MICHAEL P [US] ET AL) 9 May 2019 (2019-05-09)

3.2 The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 is not new, as far as it can be understood (see clarity objection in item VIII).

D1 (see paragraphs [0049], [0057], [0058], [0150], [0158], [0165], [0171], [0176] - [0177]; claim 2; figures 2, 13, 15A-15D, 19A-21D) discloses an apparatus for removing a material from a body lumen, the apparatus comprising:
an elongate inversion support comprising a catheter having a circumference, a distal end, and a distal end opening; and
a knitted tube that extends distally in an uninverted configuration along an outer surface of the catheter, inverts into the distal end opening of the catheter, and extends proximally within the catheter in an inverted configuration, wherein the knitted tube is configured to invert by rolling into the distal end opening of the catheter when a first end of the knitted tube is pulled proximally within the catheter.
It is further considered that the knitted tube as disclosed in D1, due to the diameter of the catheter, the diameter of the filament and the number of loops, is configured to stretch less than 3 percent when pulled in tension with a force of 2 Newtons so that the knitted tube does not lock onto the outer surface of the catheter (see paragraphs [0159], [0165], [0171], [0177]).

The subject matter of claim 1 is therefore not new in view of D1.

3.3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 15 does not involve an inventive step in the sense of Article 33(3) PCT.

Document D1 discloses all the features of claim 15 except the specific ratio linking the number of loops, the diameter of the filament and the circumference of the catheter as defined in the claim. However, the skilled person, starting from D1 and choosing a filament having a diameter of 0.003 inch and a catheter diameter of 0.035 inch as taught in D1 (see paragraph [0165]), he would have no difficulty to choose a number of loops of 10 or greater (see figure 21C) and would arrive at a choke ratio of at least 8.57 which is greater than 2.9.

Therefore, the subject matter of independent claim 15 does not involve an inventive step in view of D1 and the common general knowledge.

3.4 Dependent claims 2-14, 16-21 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.

The additional features of claims 2-14, 16-21 are either known from D1 (see paragraphs [0049], [0057], [0058], [0150], [0158], [0165], [0171], [0176] - [0177]; claim 2; figures 2, 13, 15A-15D, 19A-21D) or relate to obvious modifications of the known apparatus.

4 **Re Item VII**

Certain defects in the international application

4.1 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).

4.2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D2 to D4 is not mentioned in the description, nor are these documents identified therein.

5 **Re Item VIII**

Certain observations on the international application

5.1 The application does not meet the requirements of Article 6 PCT, because claims 1-3 are not clear.

5.1.1 Claim 1 is not clear (Art. 6 PCT) as its subject matter is defined by a result to be achieved and not by clear structural features. The expression "configured to stretch less than 3 percent when pulled in tension with a force of 2 Newtons so that the knitted tube does not lock onto the outer surface of the catheter" merely refers to a result. It is an undue burden for the skilled person to determine the features necessary for achieving the intended result.

According to the description (see paragraphs [00102]-[00108]), this result is achieved by choosing a knitted tube of a 20 cm long and with design parameters such that the choke ratio, as defined in paragraph [00105] is greater than 2.9. This definition should have been introduced into claim 1.

5.1.2 The same remark applies *mutatis mutandis* to claims 2 and 3 which refer also to results to be achieved. Moreover in claim 3, the number loops N and the diameter of the filament are not defined.

5.2 Although claims 1, 15 for the first invention and claims 25 and 40 for the second invention 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.

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-07-PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2019/050467	10 September 2019 (10-09-2019)	10 September 2018 (10-09-2018)
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.

☐ 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. 24B

☒ 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/US2019/050467

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. [X] Claims Nos.: 20-30
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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. [X] 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, 2, 5-12, 17

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/US2019/050467

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221 A61B17/3207
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.
X	WO 2017/189535 A2 (STRYKER CORP [US]) 2 November 2017 (2017-11-02) abstract paragraphs [00055], [000122], [000132], [000154] - [000195], [000221] - [000222]; figures 1-44	1,2, 5-12,17
X	US 5 971 938 A (HART CHARLES C [US] ET AL) 26 October 1999 (1999-10-26) abstract column 6, line 66 - column 15, line 61; figures 1-34	1,5-12, 17
A	WO 2012/162437 A1 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]; DIECK MARTIN S [US]) 29 November 2012 (2012-11-29) paragraphs [0062], [0077] - [0093]; figures 2-11	1,2, 5-12,17

-/--

[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
21 October 2019	18/12/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Ioanovici, T

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.
A	US 2017/112513 A1 (MARCHAND PHIL [US] ET AL) 27 April 2017 (2017-04-27) abstract paragraphs [0142] - [0183]; figures 15-28	1,2, 5-12,17
A	WO 2009/086482 A1 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US] ET AL.) 9 July 2009 (2009-07-09) abstract paragraphs [0158] - [0164]; figures 12-13	1,2, 5-12,17

2

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2017189535 A2	02-11-2017	CN 109890304 A	14-06-2019
		EP 3448280 A2	06-03-2019
		EP 3590446 A1	08-01-2020
		JP 2019519341 A	11-07-2019
		US 2017303948 A1	26-10-2017
		US 2019117244 A1	25-04-2019
		US 2019133622 A1	09-05-2019
		WO 2017189535 A2	02-11-2017
US 5971938 A	26-10-1999	NONE	
WO 2012162437 A1	29-11-2012	BR 112013030183 A2	05-12-2017
		CA 2874586 A1	29-11-2012
		CN 103841905 A	04-06-2014
		CN 107126244 A	05-09-2017
		EP 2713909 A1	09-04-2014
		EP 3398539 A1	07-11-2018
		ES 2683178 T3	25-09-2018
		HK 1198415 A1	24-04-2015
		JP 6162689 B2	12-07-2017
		JP 6374577 B2	15-08-2018
		JP 2014522268 A	04-09-2014
		JP 2017176881 A	05-10-2017
		SG 2014013320 A	30-07-2014
		SG 10201500492V A	30-03-2015
		US 2013317589 A1	28-11-2013
		US 2013325051 A1	05-12-2013
		US 2015018929 A1	15-01-2015
		US 2016354098 A1	08-12-2016
		US 2018221037 A1	09-08-2018
		US 2019374239 A1	12-12-2019
		WO 2012162437 A1	29-11-2012
US 2017112513 A1	27-04-2017	US 2017112513 A1	27-04-2017
		US 2017265878 A1	21-09-2017
		US 2018092652 A1	05-04-2018
WO 2009086482 A1	09-07-2009	CN 102036611 A	27-04-2011
		EP 2231037 A1	29-09-2010
		JP 5385302 B2	08-01-2014
		JP 5914432 B2	11-05-2016
		JP 2011508635 A	17-03-2011
		JP 2013233454 A	21-11-2013
		JP 2016041275 A	31-03-2016
		US 2009299393 A1	03-12-2009
		US 2014005717 A1	02-01-2014
		US 2017325830 A1	16-11-2017
		WO 2009086482 A1	09-07-2009

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, 2, 5-12, 17

Thrombectomy system comprising an inversion support catheter with an expandable funnel and a flexible tube inverting over the distal end of the funnel within the funnel and into the catheter lumen.

---

2. claims: 3, 4, 13, 14, 18, 19, 31-48

Thrombectomy system comprising an inversion support catheter with an expandable funnel and a flexible knitted tube inverting over the distal end of the funnel within the funnel and into the catheter lumen, wherein the funnel comprises openings to allow fluid to pass therethrough.

---

3. claims: 15, 16, 49-64

Thrombectomy system comprising an inversion support catheter with an expandable funnel and a flexible knitted tube inverting over the distal end of the funnel within the funnel and into the catheter lumen, and a tear-away sleeve over the flexible knitted tube configured to be removed when the catheter is loaded in the delivery catheter.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 20-30

Claims 20-30 relate to subject-matter considered by this Authority to be covered by the provisions of Rules 39.1(iv) PCT and 67.1 (iv) PCT, because their subject-matter relates to a method for treatment of the human body by surgery. Consequently, no opinion will be formulated with respect to the subject-matter of this/these claims (Article 34(4)(a)(i) and (b) or 17(2) PCT).

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/US2019/050467	10.09.2019	10.09.2018

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/22 A61B17/221 A61B17/3207

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	Ioanovici, T 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. 3, 4, 13-16, 18-64

because:

☒ the said international application, or the said claims Nos. 20-30 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. 3, 4, 13-16, 18-64

☐ 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, 2, 5-12, 17

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	5
	No:	Claims	1, 2, 6-12, 17
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1, 2, 5-12, 17
Industrial applicability (IA)	Yes:	Claims	1, 2, 5-12, 17
	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

Claims 20-30 relate to subject-matter considered by this Authority to be covered by the provisions of Rules 39.1(iv) PCT and 67.1 (iv) PCT, because their subject-matter relates to a method for treatment of the human body by surgery. Consequently, no opinion will be formulated with respect to the subject-matter of this/these claims (Article 34(4)(a)(i) and (b) or 17(2) 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 3 inventions covered by the claims indicated as follows:

The common matter linking together the independent claims 1, (18,19,31,47), (49,57) is the following: thrombectomy apparatus comprising an inversion support catheter with an expandable funnel at the distal end, a flexible tube extending over the funnel and the catheter and inverting over the distal end of the funnel inside the catheter lumen.

This common matter does not comprise a single general inventive concept, based on same or corresponding technical features, because D1 (WO2017/189535) discloses a thrombectomy apparatus (abstract) comprising an inversion support catheter with an expandable funnel at the distal end (para.[000221], fig.44A-C), a flexible tube (4405) extending over the funnel and the catheter and inverting over the distal end of the funnel inside the catheter lumen(para.[000221]-[000222], fig.44A-C).

Hence, the following separate inventions or groups of inventions are not so linked as to form a single general inventive concept:

Group I - claims: 1, 2, 5-12, 17

Thrombectomy system comprising an inversion support catheter with an expandable funnel and a flexible tube inverting over the distal end of the funnel within the funnel and into the catheter lumen.

Group II -claims: 3, 4, 13, 14, 18, 19, 31-48

Thrombectomy system comprising an inversion support catheter with an expandable funnel and a flexible knitted tube inverting over the distal end of the funnel within the funnel and into the catheter lumen, wherein the funnel comprises openings to allow fluid to pass therethrough.

Dependent claims 3, 4, 13 and 14 have been grouped together with group II because they also refer to an expandable funnel with openings which allow fluid to pass therethrough.

Group III - claims: 15, 16, 49-64

Thrombectomy system comprising an inversion support catheter with an expandable funnel and a flexible knitted tube inverting over the distal end of the funnel within the funnel and into the catheter lumen, and a tear-away sleeve over the flexible knitted tube configured to be removed when the catheter is loaded in the delivery catheter.

Dependent claims 15 and 16 have been grouped together with group III because they also refer to an outer sleeve disposed over the inversion support catheter.

Remaining technical features of Group I:

An inverting thrombectomy system comprising a second region of the flexible tube extending partially over the outer surface of the catheter body proximal of the funnel, wherein the inner diameter of this exterior second region is less than a maximum outer diameter of the funnel.

Problem: The remaining technical features of Group I solve the problem of how to provide suitable dimensions for allowing inversion of the flexible tube inside the catheter.

Remaining technical features of Group II:

An inverting thrombectomy system comprising a flexible knitted tube inverting over the distal end of the funnel within the funnel and into the catheter lumen, wherein the funnel comprises openings to allow fluid to pass therethrough.

Problem: The remaining technical features of Group II solve the problem of how to allow better capture the thrombus.

Remaining technical features of Group III:

An inverting thrombectomy system comprising a flexible knitted tube inverting over the distal end of the funnel within the funnel and into the catheter lumen, and a tear-away sleeve over the flexible knitted tube configured to be removed when the catheter is loaded in the delivery catheter.

Problem: The remaining technical features of Group III solve the problem of how to improve loading and delivering an inverting thrombectomy system.

Consequently, the remaining features of Group I, Group II and Group III are different. As the problems they solve are also different, these features are not corresponding either.

As the claims comprise neither the same, nor corresponding special technical features, the technical relationship between the subject matter of the claims required by Rule 13.1 PCT is lacking and the claims are not so linked as to form a single general inventive concept. The application does not fulfil the requirement for unity of invention in the sense of Rules 13.1 and 13.2 PCT.

The application relates to a plurality of inventions, or groups of inventions, in the sense of Rule 13.1 PCT. They have been divided as defined above. If the applicant pays additional fees for one (or more) not yet searched groups of inventions, then the further search(es) may reveal further prior art that gives evidence of a further lack of unity 'a posteriori' within one (or more) of the not yet searched group(s). In such a case only the first invention in this (each of these) group(s) of inventions, which is considered to lack unity of invention, will be the subject of a search. No further invitation to pay further additional fees will be issued. This is because Article 17(3)(a) PCT stipulates that the ISA shall establish the International Search Report on those parts of the international application which relate to the invention first mentioned in the claims ('main invention') and for those parts which relate to inventions in respect of which the additional fees were paid. Neither the PCT nor the PCT guidelines provide a legal basis for further invitations to pay further additional search fees (W17/00, point 11 and W1/97, points 11-16). In such a case the non-searched claims may be the subject of one or more divisional applications after the application has entered the regional phase before the EPO (see W18/07, point 26).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 WO 2017/189535 A2 (STRYKER CORP [US]) 2 November 2017 (2017-11-02)

D2 US 5 971 938 A (HART CHARLES C [US] ET AL) 26 October 1999 (1999-10-26)

D3 WO 2012/162437 A1 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]; DIECK MARTIN S [US]) 29 November 2012 (2012-11-29)

D4 US 2017/112513 A1 (MARCHAND PHIL [US] ET AL) 27 April 2017 (2017-04-27)

D5 WO 2009/086482 A1 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US] ET AL.) 9 July 2009 (2009-07-09)

The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 is not new.

D1 (abstract; paragraphs [00055], [000122], [000132], [000154] - [000195], [000221] - [000222]; figures 1-44) discloses:

A thrombectomy system (abstract), comprising:
an inversion support catheter (para.[000221]) having an elongate and flexible catheter body, a catheter lumen, and an expandable funnel (4401) disposed at a distal end of the catheter body, wherein a distal end of the funnel defines a distal opening in communication with an interior of the funnel and the catheter lumen, respectively (fig. 44A-C); and
a flexible tube (4405) inverting over the distal end of the funnel such that the flexible tube has a first region at least partially disposed within the interior of the funnel and a second region at least partially extending over an exterior of the funnel, wherein the flexible tube is configured to be pulled proximally into the catheter lumen by pulling the first region proximally so that the second region rolls over the distal end of the funnel as the flexible tube is pulled into the catheter lumen (para.[000221]-[000222], fig.44A-C).

Moreover also D2 (abstract; column 6, line 66 - column 15, line 61; figures 1-34) discloses all the features of claim 1, especially the expandable funnel (43, fig.27G-27H, 28E-28F) and the flexible inverting tube (305-307).

Dependent claims 2, 5-12 and 17 do not appear to contain any additional features which, in combination with the features of any claim to which it refers, meet the requirements of the PCT in respect of novelty and/or inventive step. The technical features of these claims are either disclosed in D1-D5 or are minor constructional detail changes. Some examples of the disclosed features can be seen below:

Claim 2: D1 fig.44C.

Claims 8-9: D1 fig.31-37.

Claims 10-12: D1 para.[00055],[000122],[000221]-[000222], fig.44C

Claim 17: D1 para.[000221]-[000222], fig.44A-C.

Re Item VII

Certain defects in the international application

The present application does not meet the requirements of Rule 6.3(b) PCT regarding the use of the two-part form in claims, of Rule 6.2(b) PCT regarding reference signs, of Rule 10.1(d) PCT regarding internationally recognized units (see claims 12 and 26 and paragraphs [00021], [00030], [00086] for example), nor those of Rule 5.1(a)(ii) PCT regarding mentioning relevant prior art in the description.

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-PCT4		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2017/029472	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. 6I

[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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/029472

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.: 16-41
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/US2017/029472

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1-15
Y	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 5	1-15
A	US 2006/195137 A1 (SEPETKA ET AL.) 31 August 2006 (2006-08-31) abstract; figures	1,15
A	US 2005/085826 A1 (NAIR ET AL.) 21 April 2005 (2005-04-21) figures	1,15

-/--

[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
29 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 2012/049652 A1 (ENDOGROWTH (PROPRIETARY) LIMITED) 19 April 2012 (2012-04-19) figures	1,15
A	US 4 243 040 A (BEECHER) 6 January 1981 (1981-01-06) figures	1,15
X,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document	1-15

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/029472

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 2006195137 A1	31-08-2006	US 2006195137 A1	31-08-2006
		US 2014135814 A1	15-05-2014
		US 2016310152 A1	27-10-2016
		WO 2007044995 A2	19-04-2007
US 2005085826 A1	21-04-2005	AT 428358 T	15-05-2009
		CA 2543211 A1	12-05-2005
		EP 1684647 A1	02-08-2006
		ES 2324915 T3	19-08-2009
		JP 2007508903 A	12-04-2007
		US 2005085826 A1	21-04-2005
		US 2007249998 A1	25-10-2007
		WO 2005041788 A1	12-05-2005
WO 2012049652 A1	19-04-2012	US 2013226196 A1	29-08-2013
		WO 2012049652 A1	19-04-2012
		ZA 201302264 B	30-04-2014
US 4243040 A	06-01-1981	NONE	
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.: 16-41

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/US2017/029472	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. II Priority

1. ☑ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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. 16-41

because:

☒ the said international application, or the said claims Nos. 16-41 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. 16-41

☐ 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	1-15
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-15
Industrial applicability (IA)	Yes:	Claims	1-15
	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

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 III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The methods according to claims 16- 41 are methods of treatment of the living human or animal body by surgery.

The surgical methods claimed, at least include 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 2006/195137 A1 (SEPETKA ET AL.)
D4	US 2005/085826 A1 (NAIR ET AL.)
D5	WO 2012/049652 A1 (ENDOGROWTH (PROPRIETARY) LIMITED)
D6	US 4 243 040 A (BEECHER)

2 Independent claim 1, lack of inventive step (Article 33(3) PCT).

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:

an elongate inversion support comprising a catheter having a distal end and a distal end opening; wherein the tractor inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, and

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.

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.

However, the above mentioned distinguishing features have already been employed for the same purpose in a similar mechanical thrombectomy system (see document **D2**).

In particular document **D2** (Figs.: 1- 3; page 8, line 12- page 11, line 5) discloses a mechanical thrombectomy system for removing a clot from within a vessel, the apparatus comprising:

an elongate inversion support comprising a catheter (12) having a distal end and a distal end opening;

a tractor (14) comprising a flexible tube that extends distally in an un-inverted configuration within the catheter (12), inverts over the distal end opening of the catheter (12) and extends proximally in an inverted configuration along 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) connected to the first end (16) of the tractor (14) extending proximally.

It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to the mechanical thrombectomy system of **D1**, thereby arriving at claim 1.

Hence, no inventive step is present in the subject matter of claim 1.

3 Independent claim 15, lack of inventive step (Article 33(3) PCT).

The same reasoning applies, mutatis mutandis, to the subject matter of the corresponding independent claim 15, which therefore is also considered not inventive.

4 Dependent claim 2- 14 appear to contain no 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, since these features are also present in

the mechanical thrombectomy systems of documents **D1** and **D2**, or are well known alternatives to the skilled person and here applied with no surprising effect.

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

5 Independent claims 1 and 15 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** or **D2** 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).

6 The features of claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

7 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in **D1**- **D6** is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

8 Although claims 1 and 15 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.

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 February 2020 (20.02.2020)

WIPO | PCT

(10) International Publication Number
WO 2020/036809 A1

(51) International Patent Classification:
A61B 17/22 (2006.01) *A61M 25/02* (2006.01)
A61B 17/221 (2006.01) *A61M 25/08* (2006.01)
A61B 17/3207 (2006.01) *A61M 25/09* (2006.01)

(21) International Application Number:
PCT/US2019/045794

(22) International Filing Date:
08 August 2019 (08.08.2019)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/718,248 13 August 2018 (13.08.2018) US
62/718,269 13 August 2018 (13.08.2018) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9272 Jeronimo Road, Suite 124, Irvine, CA 92618 (US).

(72) Inventors: **MERRITT, Ben**; c/o Inari Medical, Inc., 9272 Jeronimo Road, Suite 124, Irvine, CA 92618 (US). **MACIAS, Jaqueline**; c/o Inari Medical, Inc., 9272 Jeronimo Road, Suite 124, Irvine, CA 92618 (US). **STRAUSS, Brian Michael**; c/o Inari Medical, Inc., 9272 Jeronimo Road, Suite 124, Irvine, CA 92618 (US). **TU, Thomas**; c/o Inari Medical, Inc, 9272 Jeronimo Road, Suite 124, Irvine, CA 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** 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, 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,

(54) Title: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

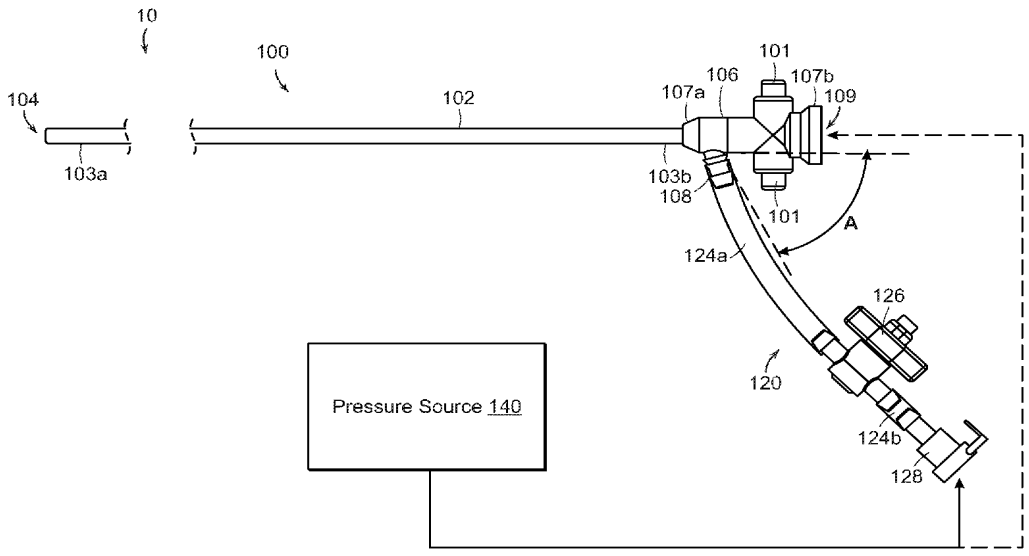


FIG. 1

(57) Abstract: Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. A method in accordance with embodiments of the present technology can include, for example, positioning a distal portion of a catheter proximate to the clot material within the blood vessel. The method can further include coupling a pressure source to the catheter via a tubing subsystem including a valve or other fluid control device and, while the valve is closed, activating the pressure source to charge a vacuum. The valve can then be opened to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material from the blood vessel and into the catheter.

[Continued on next page]

WO 2020/036809 A1

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).

Published:

— *with international search report (Art. 21(3))*

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

TECHNICAL FIELD

[0001] 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 systems for releasing stored vacuum pressure to aspirate clot material from a blood vessel.

BACKGROUND

[0002] 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.

[0003] 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.

[0004] 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.

[0005] 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.

[0006] 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.

[0007] 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.

[0008] 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.

[0009] Thus, there exists a need for improved systems and methods for embolic extraction.

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] Figure 1 is a partially schematic side view of a clot removal system configured in accordance with the present technology.

[0012] Figure 2 is a side view of a locking syringe configured in accordance with the present technology.

[0013] Figure 3A is a side view of a locking syringe configured in accordance with the present technology.

[0014] Figure 3B is a side view of an adaptor for connecting the locking syringe of Figure 3A to the clot removal system of Figure 1 configured in accordance with the present technology.

[0015] Figure 3C is a side view of the adaptor of Figure 3B coupled to the locking syringe of Figure 3A.

[0016] Figure 3D is a side view of the locking syringe of Figure 3A coupled to the clot removal system of Figure 1 via the adaptor of Figure 3B.

[0017] Figure 4A is a perspective side view of another pressure source configured in accordance with the present technology, and Figures 4B and 4C are enlarged schematic side views of the pressure source of Figure 4A during operation.

[0018] Figure 5 is a cross-sectional side view of an automatic release syringe configured in accordance with the present technology.

[0019] Figure 6 is a perspective top view of a syringe configured in accordance with the present technology.

[0020] Figure 7 is a side view of an over-wire locking syringe configured in accordance with the present technology.

[0021] Figure 8 is a flow diagram of a process or method for operating a clot removal system in accordance with the present technology.

[0022] Figures 9A–9C are side views of a proximal portion of the clot removal system of Figure 1 during a clot removal procedure using the locking syringe of Figure 3 in accordance with the present technology.

[0023] Figures 10A and 10B are schematic illustrations of a distal portion of the clot removal system of Figure 1 during a clot removal procedure in accordance with the present technology.

[0024] Figure 11 is a partially schematic side view of another clot removal system configured in accordance with the present technology.

[0025] Figure 12 is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

[0026] Figures 13A–14C are schematic illustrations of a distal portion of the clot removal system of Figure 11 during a clot removal procedure in accordance with the present technology.

[0027] Figure 15 is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

[0028] Figures 16A–16E are schematic illustrations of a distal portion of the clot removal system of Figure 11 during a clot removal procedure in accordance with the present technology.

[0029] Figure 17 is a partially schematic side view of another clot removal system configured in accordance with the present technology.

[0030] Figures 18A–18H are side views of a distal portion of the clot removal system shown of Figure 17 during a clot removal procedure in accordance with the present technology.

[0031] Figure 19 is a perspective side view of a pressure source for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology.

[0032] Figure 20A is a partially-exploded side view of a filter device and pressure source configured in accordance with the present technology.

[0033] Figure 20B is a perspective side view of the syringe of Figure 20A coupled to the filter device of the Figure 20A.

[0034] Figure 20C is a side view of the filter device and syringe of Figure 20B coupled to the clot removal system of Figure 1.

[0035] Figures 20D and 20E are side views of the syringe of Figure 20A coupled to the clot removal system of Figure 1 for reintroducing blood to a patient.

[0036] Figure 21A is a partially-exploded side view of a filter device, a pressure source, and a reinfusion syringe configured in accordance with the present technology.

[0037] Figure 21B is a perspective side view of the filter device of Figure 21A coupled to the pressure source and the reinfusion syringe of Figure 21A.

[0038] Figure 22 is a partially-exploded side view of a filter device configured in accordance with the present technology.

[0039] Figure 23 is a partially-exploded side view of a filter device configured in accordance with the present technology.

[0040] Figure 24 is an enlarged isometric view of the clot removal system of Figure 1 configured in accordance with the present technology.

[0041] Figure 25 is an enlarged isometric view of the clot removal system of Figure 1 configured in accordance with the present technology.

DETAILED DESCRIPTION

[0042] The present technology is generally directed to methods and systems for removing clot material from a blood vessel of a human patient. In some embodiments, a catheter can be intravascularly positioned within a blood vessel such that a distal portion (e.g., a distal opening) of the catheter is positioned proximate to clot material within the blood vessel. The catheter can be fluidly coupled to a pressure source via a valve or other fluid control device positioned outside of the patient. With the valve closed, the pressure source can be activated to charge a vacuum chamber of the pressure source with a vacuum. The valve can then be opened to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material from the blood vessel into the catheter. In some embodiments, an interventional device can be delivered through the catheter and used to engage the clot material before and/or after the vacuum is applied to the catheter.

[0043] In one aspect of the present technology, the pressure source is configured to generate a vacuum and store the vacuum before the pressure source is fluidly connected to the catheter. Therefore, opening the fluid control device can instantaneously or nearly instantaneously apply the stored vacuum pressure to the catheter, thereby generating suction

throughout the catheter. In particular, the suction is applied at the distal portion of the catheter proximate to the clot material. Pre-charging or storing the vacuum before applying the vacuum to the catheter can generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion of the catheter compared to, for example, simply activating the pressure source while it is fluidly connected to the catheter. The greater 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 a human patient.

[0044] Although many of the embodiments are described below with respect to devices, systems, 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 1–25 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 1–25 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 1–25.

[0045] 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 of the present technology can be used in any orientation suitable to the user.

[0046] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Clot Removal Systems

[0047] Figure 1 is a partially schematic side view of a clot treatment or clot removal system comprising an aspiration assembly 10 ("assembly 10") configured in accordance with an embodiment of the present technology. In the illustrated embodiment, the assembly 10 includes a catheter subsystem 100, a tubing subsystem 120, and a pressure source 140. The catheter subsystem 100 includes a catheter 102 (e.g., an aspiration catheter) comprising an elongated shaft defining a lumen 104 and having a distal portion 103a and a proximal portion 103b. The catheter subsystem 100 further includes a valve 106 that can be integral with or coupled to the proximal portion 103b of the catheter 102.

[0048] In the illustrated embodiment, the valve 106 includes a distal portion 107a, a proximal portion 107b, and a lumen 109 extending therethrough from the distal portion 107a to the proximal portion 107b. The valve 106 further includes a flow controller (obscured in Figure 1) in the lumen 109. 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 106 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters (e.g., as described in detail with reference to Figures 11–16E), etc., are inserted through the valve 106 to be delivered through the catheter 102 to a treatment site in a blood vessel. The valve 106 further includes a branch or side port 108 positioned distally of the flow controller in the lumen 109 and configured to fluidly couple the lumen 104 of the catheter 102 to the tubing subsystem 120. In the illustrated embodiment, the valve 106 includes buttons 101 that can be actuated (e.g., depressed) to open a conduit within the lumen 109. In some embodiments, the valve 106 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. In some embodiments, the proximal portion 107b of the valve 106 is further configured to be detachably coupled (e.g., via a snap-fit arrangement) to a retraction/aspiration device for aspirating the lumen 104 of the catheter 102 and/or for retracting an interventional device, catheter, delivery sheath, catheter, etc., positioned within the lumen 104. Specific details of such retraction/aspiration devices and associated methods are disclosed in U.S. Patent Application No. 9,526,864, filed June 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

[0049] The tubing subsystem 120 fluidly couples the catheter subsystem 100 to the pressure source 140. More specifically, the tubing subsystem 120 can include one or more tubing sections 124 (individually labeled as a first tubing section 124a and a second tubing section 124b), at least one fluid control device 126 (e.g., a valve), and at least one connector 128 for fluidly coupling the tubing subsystem 120 to the pressure source 140 and/or other suitable components. More specifically, in the illustrated embodiment, the fluid control device 126 is a stopcock that is fluidly coupled to (i) the side port 108 of the valve 106 via the first tubing section 124a and (ii) the connector 128 via the second tubing section 124b. In some embodiments, the fluid control device 126 can define a lumen having a diameter (or other cross-sectional dimension) that is greater than or equal to a diameter of the lumen 104 of the catheter 102, a diameter of the first tubing section 124a, and/or a diameter of the second tubing section 124b.

[0050] The fluid control device 126 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 104 of the catheter 102 to the pressure source 140. In other embodiments, the fluid control device 126 can be a clamp that can be actuated (e.g., compressed or squeezed by the hand of a user) to partially or fully restrict fluid flow through the tubing section 124a and/or the tubing section 124b. In yet other embodiments, the fluid control device 126 can be omitted and its functionality incorporated into the pressure source 140 (e.g., as described in detail below with reference to Figure 5). In some embodiments, the fluid control device 126 can include a quick-release mechanism (e.g., a spring-loaded apparatus) for rapidly opening, unclamping, etc., the fluid control device 126 to (e.g., instantaneously or nearly instantaneously) fluidly connect the pressure source 140 and the catheter 102. In some embodiments, the fluid control device 126 can be opened/closed automatically (e.g., by a motor, switch, etc.). When the pressure source 140 is pre-charged with a vacuum, as described in detail below, such a quick-release fluid control device 126 can reduce the time needed for pressure in the assembly 10 to equalize after opening of the fluid control device 126, and can thereby increase suction forces generated at the distal portion 103a of the catheter 102.

[0051] In some embodiments, the connector 128 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 102 and the fluid control device 126 to/from the pressure source 140. In other embodiments, the tubing subsystem 120 can have more or fewer tubing sections, connectors, and/or fluid control devices, and can

have other suitable configurations. In some embodiments, one or more of the components can be permanently connected and/or integrally formed.

[0052] The pressure source 140 is configured to generate (e.g., form, create, charge, build-up, etc.) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter subsystem 100. Further details of suitable pressure sources are described in detail below with reference to Figures 2–7. During operation of the assembly 10, a user can first close the fluid control device 126 before activating the pressure source 140 to build up vacuum pressure within the pressure source 140 (e.g., a vacuum chamber of the pressure source 140). In some embodiments, the user can control or select the volume of the generated vacuum. In this manner, a vacuum is charged within the pressure source 140 before the pressure source 140 is fluidly connected to the catheter subsystem 100. To aspirate the lumen 104 of the catheter 102, the user can open the fluid control device 126 to fluidly connect the pressure source 140 to the catheter subsystem 100 and thereby apply or release the vacuum stored in the pressure source 140 to the lumen 104 of the catheter 102. Opening of the fluid control device 126 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing subsystem 120 and the catheter 102, thereby generating suction throughout the catheter 102. In particular, the suction is applied at the distal portion 103a of the catheter 102. In one aspect of the present technology, pre-charging or storing the vacuum before applying the vacuum to the lumen 104 of the catheter 102 is expected to generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion 103a of the catheter 102 compared to simply activating the pressure source 140 while it is fluidly connected to the catheter 102. As described in detail below, 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 a human patient.

II. Selected Embodiments of Pressure Sources for Use with Clot Removal Systems

[0053] As described in detail above with reference to Figure 1, the assembly 10 of the present technology includes a pressure source (e.g., a vacuum source, negative pressure source, etc.) configured to charge a vacuum that can be applied to the catheter subsystem 100 to generate suction forces for aspirating clot material from within a blood vessel. In general, the pressure source can be any suitable source or combination of sources for generating and/or storing negative pressure. In some embodiments, the pressure source can be a pump (e.g., an electric pump coupled to a vacuum chamber) while, in other embodiments, the pressure source can

include one or more syringes that can be actuated or otherwise activated by a user of the assembly 10 to generate and store a vacuum therein.

[0054] Figure 2 is a side view of a pressure source 240 comprising a vacuum-pressure locking syringe ("syringe 240") configured in accordance with the present technology. In some embodiments, the syringe 240 can be of the kind sold under the trademark "VacLok" by Merit Medical System, Inc. In the illustrated embodiment, the syringe 240 includes a plunger 242 slidably and rotatably positioned within a chamber or barrel 244. The barrel 244 is shown as transparent in Figure 2 for the sake of clarity. The plunger 242 includes a seal 243 and a plurality of index members 246 defining slots 248 between adjacent pairs thereof. A tab member 245 projects inwardly from the interior surface of the barrel 244 and is configured to be removably positioned in the slots 248 for locking the plunger 242 in position relative to the barrel 244. In some embodiments, the barrel 244 can be made of a transparent material that permits a user to visualize material (e.g., clot material) within the barrel 244 and to visualize the relative position between the slots 248 and tab member 245 for locking the syringe 240.

[0055] Referring to both Figures 1 and 2 together, the syringe 240 further includes a tip 247 for coupling the syringe 240 to the tubing subsystem 120. In the illustrated embodiment, the tip 247 is a standard luer connector that can be coupled to the connector 128 via one or more suitable adaptors. The tip 247 further defines a lumen or bore 249 having an inner diameter D_1. In some embodiments, the diameter D_1 is about 0.103", or about 0.080" to about 0.200", or about 0.100" to about 0.150", or about 0.100" to about 0.110". In some embodiments, the inner diameter D_1 is about 14 French.

[0056] During operation of the assembly 10, a user can first close the fluid control device 126 and then grip the plunger 242 and/or the barrel 244 to withdraw (e.g., retract) the plunger 242 at least partially out of the barrel 244 to thereby generate a vacuum in the barrel 244. Once the user has withdrawn the plunger 242 to a sufficient or desired volume, the user can lock the plunger 242 by rotating the plunger 242 relative to the barrel 244 such that the tab member 245 is positioned within a corresponding one of the slots 248. In other embodiments, the syringe 240 may not be a locking syringe, and the user can instead hold the plunger 242 in position relative to the barrel 244. Moreover, the user can control the volume of the vacuum—by withdrawing the plunger 242 more or less—to provide a desired amount or level of suction/aspiration upon opening of the fluid control device 126. In some embodiments, the syringe has a volume of about 60 cc or less than about 60 cc.

[0057] Figure 3A is a side view of a pressure source 340 comprising a vacuum-pressure locking syringe ("syringe 340") configured in accordance with the present technology. The syringe 340 can have some features generally similar to the features of the syringe 240 described above with reference to Figure 2. For example, the syringe 340 includes a plunger 342 slidably and rotatably positioned within a barrel 344, and the plunger 342 includes a plurality of index members 346 defining slots 348 between adjacent pairs thereof. The barrel 344 is shown as transparent in Figure 3A (and Figure 3C) for the sake of clarity. While withdrawing the plunger 342, a user can lock the plunger 342 at a specified volume by rotating the plunger 342 relative to the barrel 344 such that a tab member 345 on the interior surface of the barrel 344 is positioned within a corresponding one of the slots 348. In some embodiments, the syringe 340 has a maximum volume of about 60 cc or greater than 60 cc.

[0058] In the illustrated embodiment, the syringe 340 includes a large-bore tip 347, such as a Toomey tip, defining an inner lumen or bore 349. In some embodiments, the bore 349 can have an inner diameter D_2 that is greater than or equal to the largest inner diameter of the assembly 10 (e.g., of the catheter 102 and tubing subsystem 120). In certain embodiments, the tip 347 can be about 26 French or greater. Accordingly, referring to Figures 2 and 3A together, the diameter D_2 can be greater than the dimension D_1. For example, the dimension D_2 can be about two, three, four, or more times greater than the diameter D_1.

[0059] Figure 3B is a side view of an adaptor 350 for connecting the syringe 340 to the catheter subsystem 100 configured in accordance with the present technology. Figure 3C is a side view of the adaptor 350 coupled to the syringe 340, and Figure 3D is a side view of the syringe 340 coupled to the tubing subsystem 120 via the adaptor 350. The adaptor 350 is shown as partially transparent in Figure 3C for the sake of illustration. Referring to Figure 3B, the, the adaptor 350 includes (i) a first portion 351 defining a first lumen or bore 352 having an inner diameter D_3, (ii) a second portion 353 defining a second lumen or bore 354, and (iii) a stepped surface or interface 355 between the first and second portions 351, 353. The first portion 351 can further include a seal 357 such as an O-Ring around an exterior surface thereof.

[0060] Referring to Figures 3A–3D together, the second bore 354 of the adaptor 350 is configured to removably receive the tip 347 of the syringe 340 therein. In some embodiments, the tip 347 can be snuggly received in the second bore 354 via an interference fit. In some embodiments, a seal (e.g., an O-ring) can be positioned between an exterior surface of the tip 347 and an interior surface of the second bore 354. In other embodiments, the syringe 340 can

be permanently coupled or integrally formed with the adaptor 350. The first portion 351 of the adaptor 350 is configured to be removably positioned within the connector 128 of the tubing subsystem 120 to fluidly couple the syringe 340 to the tubing subsystem 120. In some embodiments, the first portion 351 of the adaptor 350 can be pushed into the connector 128 until the interface 355 abuts the connector 128. When the first portion 351 of the adaptor 350 is positioned within the connector 128, the seal 357 seals the interface between the connector 128 and the adaptor 350.

[0061] The diameter D_3 of the first bore 352 of the adaptor 350 can be selected to be about the same as or greater than the greatest inner diameter of the assembly 10 (e.g., of the catheter 102 and the tubing subsystem 120). For example, the catheter 102 can be about 9 French or greater, and the diameter D_3 can be selected to be larger than the size of the catheter 102. Accordingly, when the fluid control device 126 is open, the continuous lumen between the catheter 102 and the syringe 340 can have a generally constant diameter and/or does not contain any narrowing at the interface between the syringe 340 and the tubing subsystem 120. That is, the adaptor 350 can connect the syringe 340 and the tubing subsystem 120 without any restriction or narrowing of the fluid path. In contrast, a standard luer connector (e.g., the syringe 240) can only provide a continuous lumen for catheters of about 8 French or smaller. Any narrowing of the fluid pathway between the catheter 102 and the syringe 340 can reduce the volumetric flow rate (e.g., suction forces and fluid velocities) that can be generated when a vacuum stored in the syringe 340 is applied to the catheter 102.

[0062] In general, the syringe 340 and the adaptor 350 can reduce the fluid resistance in the assembly 10 and therefore facilitate a more rapid pressure equalization in the assembly 10 when the fluid control device 126 is opened to apply the charged vacuum to the catheter 102. In some embodiments, for example, when the syringe 240 (Figure 2) is charged with a 60 cc vacuum and the fluid control device 126 is opened, the pressure in the assembly 10 can take about 1–2 seconds to equalize. In contrast, when the syringe 340 is charged with a 60 cc vacuum and the fluid control device 126 is opened, the pressure in the assembly 10 can take less than about 1 second (e.g., about 0.5 seconds) to equalize. More specifically, Table 1 illustrates representative pressure equalization times and associated flow rates when the syringe 240 is coupled to a 20 French catheter (i.e., the catheter 102). Table 2 illustrates representative pressure equalization times and associated flow rates when the syringe 340 and the adaptor 350 are coupled to a 20 French catheter (i.e., the catheter 102).

Table 1

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
2.0	30.0
1.9	31.6
1.8	33.3
1.7	35.3
1.6	37.5
1.5	40.0
1.4	42.9
1.3	46.2

Table 2

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
0.9	66.7
0.8	75.0
0.7	85.7
0.6	100.0
0.5	120.0
0.4	150.0
0.3	200.0
0.2	300.0
0.1	600.0

[0063] In each instance, the syringe 340 provides for relatively faster equalization times and correspondingly greater flow rates. It is expected that the more rapid pressure equalization and flow rates provided by the syringe 340 will provide correspondingly greater suction forces at the distal portion 103a of the catheter 102. That is, in general, it is expected that increasing

the bore size of a syringe used to provide vacuum pressure 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).

[0064] Moreover, as shown in Figure 3D, the adaptor 350 can couple the syringe 340 to the connector 128 without the need for any intervening tubing sections or additional adaptors. This arrangement can minimize the total length, volume, etc., of the components fluidly coupling the catheter 102 to the syringe 340. It is expected that the magnitude of suction forces generated at the distal portion 103a of the catheter 102—e.g., when a vacuum charged in the syringe 340 is applied to the catheter 102 by opening of the fluid control device 126—is proportional to the length of the fluid path between the pressure source 340 and catheter 102. Thus, operation of the assembly 10 with the syringe 340 and adaptor 350 is expected to increase the suction forces generated at the distal portion 103a of the catheter 102. 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).

[0065] Figure 4A is a side perspective view a pressure source 400 including the syringe 340 ("primary syringe 340") shown in Figures 3A–3D and a secondary syringe 460 configured in accordance with the present technology. The secondary syringe 460 can include a plunger 462 slidably positioned within a chamber or barrel 464. The primary and secondary syringes 340, 460 can have the same volume or different volumes. In the illustrated embodiment, a tip 463 of the secondary syringe 460 is coupled to a first one-way valve (e.g., a check valve) 470 via a coupling member 465, such as a tube. The first one-way valve 470 is configured to fluidly connect the secondary syringe 460 to the ambient environment or another device coupled to the first one-way valve 470. A second one-way valve (e.g., a check valve) 472 spans between and is configured to fluidly connect the primary syringe 340 to the secondary syringe 460. More specially, in the illustrated embodiment the second one-way valve 472 is connected between the first portion 351 of the adaptor 350 and the coupling member 465. In other embodiments, the second one-way valve 472 can couple the primary and secondary syringes 340, 460 in different manners. For example, the second one-way valve 472 can span between and directly connect the barrels 344,464. The primary and secondary syringes 340, 460 can be coupled or fastened

together via one or more connectors 474 that fix the positions of the barrel 344, 464 relative to one another.

[0066] In some embodiments, the second one-way valve 472 is a normally-open check valve configured to (i) permit fluid (e.g., air) flow from the primary syringe 340 and the adaptor 350 to the secondary syringe 460 and (ii) inhibit fluid flow in the opposite direction from the secondary syringe 460 into the primary syringe 340. In some embodiments, the second one-way valve 472 has a cracking (e.g., opening) pressure of about 0 psi. In one aspect of the present technology, this arrangement maximizes the magnitude of the vacuum that can be charged within the primary syringe 340. That is, the cracking pressure of the second one-way valve 472 does not reduce the effective vacuum within the primary syringe 340. In other embodiments a normally-closed or other type of valve could be used for the second one-way valve 472. However, in such embodiments the vacuum efficiency of the pressure source 400 would be reduced by the cracking pressure of the second one-way valve 472. Similarly, the first one-way valve 470 can be a check valve configured to (i) permit fluid flow from the secondary syringe 460 to the ambient environment (or other device) and (ii) inhibit fluid flow in the opposite direction from the ambient environment into the secondary syringe 460.

[0067] Figures 4B and 4C are enlarged schematic side views of the pressure source 400 during operation. More specifically, Figures 4B and 4C illustrate fluid flow paths through the first and second one-way valves 470, 472 during retraction and advancement, respectively, of the plunger 462 through the barrel 464 of the secondary syringe 460. Referring first to Figures 4A and 4B together, during retraction/withdrawal of the plunger 462, (i) the first one-way valve 470 is closed to inhibit fluid from flowing into the secondary syringe 460 while (ii) the second one-way valve is open 472 to permit fluid to flow from the primary syringe 340, the catheter subsystem 100 (Figure 1), and/or the tubing subsystem 120 (Figure 1) into the secondary syringe 460. This flow path is indicated by the arrows R in Figure 4B. Referring to Figures 4A and 4C together, during advancement of the plunger 462, (i) the first one-way valve 470 is open to permit fluid flow (e.g., fluid expulsion) from the secondary syringe 460 to the ambient environment (or other device) while (ii) the second one-way valve 472 is closed to inhibit fluid flow from the secondary syringe 460 into (e.g., back into) the primary syringe 360, the catheter subsystem 100, and/or the tubing subsystem 120. This flow path is indicated by the arrows A in Figure 4C.

[0068] Referring to Figures 1 and 3A–4C together, the pressure source 400 can be coupled to the tubing subsystem 120 by coupling the primary syringe 340 to the connector 128 (e.g., as shown in Figure 3D). When the pressure source is coupled to the tubing subsystem 120, retraction of the plunger 462 of the secondary syringe 460 evacuates an evacuatable volume of the assembly 10. For example, when the fluid control device 126 is closed, retraction of the plunger 462 of the secondary syringe 460 evacuates fluid, through the second one-way valve 472, from (i) the primary syringe 340 (e.g., from the barrel 344, the tip 347, and/or the adaptor 350) and (ii) the portion of the tubing subsystem 120 between the fluid control device 126 and the primary syringe 340. This can enable a greater charged/stored vacuum to be generated for subsequent application to the catheter subsystem 100 for aspirating clot material. In some embodiments, the plunger 462 of the secondary syringe 460 can be withdrawn/advanced (e.g., "cycled") one or more times before withdrawing the plunger 342 of the primary syringe 340 to evacuate air from (i) the tip 347 of the primary syringe 340 and/or (ii) the portion of the tubing subsystem 120 between the fluid control device 126 and the tip 347. In other embodiments, the plunger 462 of the secondary syringe 460 can alternatively or additionally be withdrawn after withdrawing the plunger 342 of the primary syringe 340 to further evacuate the barrel 344 of the primary syringe 340. In some embodiments, the plunger 462 can be cycled when the fluid control device 126 is open to, for example, facilitate the removal of clot material stuck or clogged within the catheter subsystem 100. That is, cycling the secondary syringe 460 when the fluid control device 126 is open can generate vacuum pressure and suction in the catheter 102 to aid in the aspiration/removal of clot material.

[0069] In some embodiments, the volumes of the primary and secondary syringes 340, 460 can be selected based on one or more desired characteristics of a clot removal procedure using the pressure source 400. For example, the secondary syringe 460 can have a larger volume than the primary syringe 340 to permit a high vacuum to be charged within the primary syringe 340 while also limiting blood loss from the patient.

[0070] In one aspect of the present technology, the pressure source 340 permits a greater vacuum to be generated without increasing the volume of the primary syringe 340. For example, the vacuum generated by the primary syringe 340 alone is directly proportional to the volume of the primary syringe 340. Thus, to generate a greater vacuum using the primary syringe 340 alone, the volume of the primary syringe 340 must be increased. In contrast, inclusion of the secondary syringe 460 in the pressure source 400 and the configuration of the first and second

one-way valves 470, 472 allows the (e.g., maximum) generated vacuum to be independent of the volume of the primary syringe 340. Therefore, for example, the generated vacuum can be increased without correspondingly increasing the volume of blood withdrawn from the patient when applying the vacuum to the catheter subsystem 100.

[0071] In some embodiments, (e.g., as described in greater detail below with reference to Figure 19), the primary syringe 340 of the pressure source 400 can be replaced with a simple pressure vessel or other volume, such as a canister, barrel, tube, etc. In such embodiments, a vacuum can be generated in the canister simply by cycling the secondary syringe 460 one or more times. In some embodiments, the secondary syringe 460 can comprise a pump or vacuum source other than a syringe. Likewise, the secondary syringe 460 or other vacuum source can be fluidly coupled to the primary syringe 340 in other manners (e.g., via a different arrangement of check valves) to produce the same or similar flow patterns as shown in Figures 4B and 4C. Moreover, in some embodiments the first and second one-way valves 470, 472 can be other types of flow control devices that are mechanically activated/deactivated (e.g., opened and closed) rather than passively operated via pressure differentials within the pressure source 400. For example, the flow control devices 470, 472 can be mechanically coupled to the plunger 462 of the secondary syringe 460 such that cycling the plunger 462 activates/deactivates the flow control devices 470, 472 to operate the pressure source 400 in the manner illustrated in Figures 4B and 4C.

[0072] Figure 5 is a side cross-sectional view of a pressure source 540 comprising an automatic release syringe ("syringe 540") configured in accordance with the present technology. In general, the syringe 540 is configured to automatically apply a charged vacuum of a selected volume to the catheter subsystem 100 without requiring the actuation of an intervening fluid control device, such as the fluid control device 126 shown in Figure 1. The syringe 540 can have some features generally similar to the features of the syringes 240, 340 described in detail above with reference to Figures 2 and 3A–3D. For example, the syringe 540 includes a first plunger 542 slidably positioned within a chamber or barrel 544. The first plunger 542 further includes a first seal 543 that engages an interior surface of the barrel 544 such that a vacuum is formed within the barrel 544 as the first plunger 542 is withdrawn through the barrel 544. Likewise, referring to both Figures 1 and 5 together, the syringe 540 includes a tip 547 (e.g., a Toomey tip) for coupling the syringe 540 to the tubing subsystem 120 (e.g., via a Toomey tip adaptor) and defining a bore 549. In some embodiments, the bore 549 has a relatively large diameter selected

to provide rapid pressure equalization in the assembly 10 after a vacuum stored in the syringe 540 is released.

[0073] The first plunger 542 can further include (i) a grip portion 541 configured to be engaged by a user for retracting the first plunger 542 and (ii) a lumen 581 extending lengthwise therethrough. In the illustrated embodiment, a plunger assembly 582 is slidably positioned within and extends through the lumen 581 of the first plunger 542. The plunger assembly 582 includes (i) a second plunger 583 and (ii) a release member 584 slidably and/or rotatably positioned within a lumen 585 of the second plunger 583. The release member 584 includes an engagement member 586 configured to engage the grip portion 541 of the first plunger 542 when the first plunger 542 is withdrawn from the barrel 544. The second plunger 583 includes a second seal 587 configured to engage and seal an interior surface of the bore 549 of the syringe 540 to enable a vacuum to be formed in the barrel 544 as the first plunger 542 is withdrawn through the barrel 544. That is, the second seal 587 can seal (e.g., fluidly disconnect) the barrel 544 of the syringe from the tubing subsystem 120 and the catheter subsystem 100. In some embodiments, the syringe 540 can further include an O-ring 579 or other suitable component for sealing an interface between the first and second plungers 542, 582 to maintain the vacuum formed within the barrel 544, while also permitting the first plunger 542 to move (e.g., translate) relative to the second plunger 583.

[0074] The plunger assembly 582 further includes a locking mechanism (not shown) configured to permit/inhibit the release member 584 from moving longitudinally relative to the second plunger 583. In some embodiments, for example, rotation of the release member 584 in a first direction relative to the second plunger 583 can lock the two components in position, while rotation of the release member 584 in a second direction relative to the second plunger 583 can unlock the two components so that the release member 584 can be withdrawn or pushed into the lumen 585 of the second plunger 583. In other embodiments, the release member 584 and the second plunger 583 can be integrally formed or permanently locked together.

[0075] The plunger assembly 582 enables (i) a user of the syringe 540 to select a desired volume for a vacuum to be formed in the syringe 540 and (ii) the automatic release or application of a generated vacuum via opening (e.g., unplugging) of the bore 549. Specifically, during operation of the syringe 540, a user can first unlock the release member 584 and slide the release member 584 to a position corresponding to a desired vacuum volume. For example, the release member 584 can have tick marks 588 or other indicia along its length that correspond to a volume

of the syringe 540 (e.g., a vacuum chamber volume). After selecting a desired volume, the user can lock the release member 584 relative to the second plunger 583 (e.g., by rotating the release member 584) to inhibit relative movement of the two components. After locking the release member 584, the user can grasp the grip portion 541 to retract the first plunger 542 relative to the barrel 544 and the plunger assembly 582 to generate a vacuum within the barrel 544 between the first and second seals 543, 587. When the first plunger 542 has been retracted to the desired volume, the grip portion 541 engages the engagement member 586 of the release member 584 such that further retraction of the first plunger 542 simultaneously retracts the plunger assembly 582. As the plunger assembly 582 is retracted, the second seal 587 of the second plunger 583 is pulled out of the bore 549, thereby releasing the vacuum stored in the barrel 544. In this manner, the syringe 540 provides for the automatic release of charged vacuum pressure at a specified volume and with a single retraction of the first plunger 542. Put differently, the syringe 540 has a built-in fluid control device and thus eliminates the need for a separate fluid control device 126 and/or an additional step for opening the fluid control device 126.

[0076] Figure 6 is a top perspective view of a pressure source 640 comprising a syringe ("syringe 640") configured in accordance with the present technology. The syringe 640 can include some features generally similar to the features of the syringes 240, 340, and 540 described in detail above with reference to Figures 2–3D and 5. For example, the syringe 640 includes a plunger 642 slidably positioned within a barrel 644, and a tip 647 (e.g., a large-bore tip). In the illustrated embodiment, the syringe 640 further includes a lever or handle 690 operably coupled to the plunger 642. The handle 690 provides mechanical leverage for withdrawing the plunger 642 to create a vacuum within the barrel 644. More specifically, the handle 690 can be coupled to a crossbar 691 that rotates relative to the plunger 642 via actuation (e.g., rotation) of the handle 690. The crossbar 691 can be coupled to a gear (obscured in Figure 6) configured to engage a track 692 on the plunger 642. Accordingly, rotation of the handle 690 in a first direction retracts the plunger 642 relative to the barrel 644 to charge a vacuum in the barrel 644. And, rotation of the handle 690 in a second (e.g., opposite) direction advances the plunger 642 into the barrel 644 to, for example, expel fluid, material, etc., from the barrel 644.

[0077] In one aspect of the present technology, the handle 690 provides additional mechanical leverage relative to a standard syringe, and can thus reduce the force (e.g., strain, energy, etc.) required by a user of the syringe 640 to form a vacuum in the syringe 640. Therefore, use of the syringe 640 can reduce the time needed to remove clot material with the

assembly 10. In some embodiments, the syringe 640 can have a volume greater than 60 cc (e.g., greater than 80 cc, greater than 100 cc, greater than 120 cc, greater than 140 cc, etc.). In a particular embodiment, for example, the syringe 640 can have a volume of about 140 cc. With such large volumes, it may be difficult for some users to manually retract the plunger 642 without the additional mechanical leverage provided by the handle 690. Thus, the syringe 640 can enable the use of larger volume syringes that can generate correspondingly greater suction forces in the catheter subsystem 100.

[0078] Referring again to Figure 1, it is expected that less tortuous (e.g., more linear) fluid paths between the pressure source 140 and the catheter subsystem 100 will produce greater suction forces and corresponding fluid velocities at the distal portion 103a of the catheter 102 when stored vacuum pressure is applied to the catheter subsystem 100. Accordingly, in some embodiments the side port 108 of the valve 106 can be formed to have an angle A that is less than about 90°, less than about 75°, less than about 60°, less than about 45°, less than about 30°, less than about 15° etc. Reducing the relative angle between the side port 108 and the lumen 109 of the valve 106 (and thus the lumen 104 of the catheter 102) reduces the tortuosity of the fluid path between the pressure source 140 and the catheter 102. Moreover, in some embodiments, the pressure source 140 can be coupled to the proximal portion 107b of the valve 106 instead of or in addition to the side port 108 to provide a more linear fluid path between the pressure source 140 and the catheter 102. For example, Figure 24 is an enlarged isometric view of the assembly 10 showing the pressure source 340 coupled directly to the proximal portion 107b of the valve rather than to the connector 128 of the tubing subsystem 120 and the side port 108 of the valve 106. Although the pressure source 340 is illustrated in Figure 24, any of the pressure sources described in detail above with reference to Figures 2–6 can be configured to be coupled to the proximal portion 107b of the valve 106 rather than the side port 108. In other embodiments, the side port 108 can be omitted and the valve 106 and the tubing subsystem 120 can be coupled to the catheter 102 via a Y-connector. For example, Figure 25 is an enlarged isometric view of the assembly 10 showing the valve 106 and the tubing subsystem 120 coupled to the catheter 102 via a Y-connector 2590. In yet other embodiments, the tubing system 120 is linearly coupled to the catheter 102, and the valve 106 protrudes at an angle from the catheter 102.

[0079] In some embodiments, however, a guidewire or other component is positioned within the valve 106 during the duration of a clot removal procedure (e.g., for delivering

interventional devices to a treatment site within a patient). Accordingly, in some embodiments, to facilitate coupling of the pressure source 140 to the proximal portion 107b of the valve 106—even when a guidewire is inserted therethrough—the pressure source 140 can be a syringe configured for over-wire delivery. For example, Figure 7 is a side view of a pressure source 740 comprising a vacuum-pressure locking syringe ("syringe 740") configured in accordance with the present technology for delivery and operation over a guidewire 794. The syringe 740 can have some features generally similar to the features of the syringe 340 described in detail above with reference to Figure 3. For example, the syringe 740 includes a plunger 742 slidably and rotatably positioned within a barrel 744. The barrel 744 is shown as transparent in Figure 7 for the sake of clarity. In the illustrated embodiment, the plunger 742 includes a lumen 796 (shown in broken lines) extending longitudinally therethrough. The guidewire 794 can be inserted through the lumen 796 of the plunger 742 such that the syringe 740 can be advanced over the guidewire 794 for attachment to the proximal portion 107b of the valve 106. The syringe 740 can further include one or more sealing components (e.g., valves, O-rings, etc.; not shown) for maintaining a seal between the guidewire 794 and the plunger 742 to permit build-up and storage of a vacuum in the barrel 744.

[0080] In general, one skilled in the art will understand that the various embodiments of pressure sources disclosed herein may be combined to, for example, include multiple pressure sources or pressure sources having different components or combinations of components. For example, in some embodiments the secondary syringe 460 (Figures 4A–4C) can be coupled via one or more one-way valves to the syringes 240, 540, 640 or 740 (Figures 2 and 5–7, respectively) to generate additional vacuum. In some embodiments, multiple pressure sources can be coupled to the catheter 102 via the tubing subsystem 120 and/or via the valve 106. Moreover, the individual pressure sources can be the same or different, and can be coupled to the catheter subsystem 100 via a single fluid control device, such as the fluid control device 126, or can be coupled to the catheter subsystem 100 via separate fluid control devices. Therefore, the profile of the vacuum applied to the catheter 102 can be selected or adjusted by using multiple different pressure sources. For example, a specific vacuum profile can depend at least on (i) the individual characteristics of the multiple pressure sources (e.g., volume, bore-size, etc.), (ii) the manner in which the pressure sources are coupled to the catheter subsystem 100 (e.g., via individual valves, via the same valve, etc.), and (iii) the timing of the application or release of the vacuum of each pressure source to the catheter subsystem 100 (e.g., staggered release, simultaneous release, etc.). As one example, in some embodiments, the syringe 240 (Figure 2)

and the syringe 340 (Figure 3) can both be coupled to the tubing subsystem 120 via, for example, a Y-connector. After charging both syringes 240, 340 with vacuum pressure, opening the fluid control device 126 can simultaneously apply the combined vacuum to the catheter 102. The larger-bored syringe 340 can provide a short but powerful impulse of vacuum pressure, while the smaller-bored syringe 240 can provide a longer and more sustained vacuum pull. This combination can apply a large, fast-acting suction force to dislodge and capture clot material in the catheter 102, and simultaneously apply a more sustained suction force to capture more clot material.

III. Selected Embodiments of Methods of Clot Removal

[0081] Figure 8 is a flow diagram of a process or method 800 for operating a clot removal system including the assembly 10 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figures 9A–9C are side views of a proximal portion of the assembly 10, and Figures 10A and 10B are schematic illustrations of a distal portion of the assembly 10, during a clot removal procedure in accordance with embodiments of the present technology. In particular, Figures 9A–9C are side views of the assembly 10 including the syringe 340 and adaptor 350 (Figures 3A–3D), and Figures 10A and 10B are side views of the catheter 102 with the distal portion 103a of the catheter 102 positioned proximate to an embolism or clot material PE within a blood vessel BV (e.g., a pulmonary blood vessel). Although some features of the method 800 are described in the context of the embodiments shown in Figures 1, 3A–3D, and 9A–10B for the sake of illustration, one skilled in the art will readily understand that the method 800 can be carried out using other suitable systems and/or devices described herein. In particular, although described in the context of the syringe 340, the method 800 can be carried out using any one or combination of the pressure sources described in detail above with reference to Figures 2–7.

[0082] At block 802, the method 800 includes positioning the distal portion 103a of the catheter 102 proximate to clot material within a blood vessel of a human patient (e.g., at a treatment site). For example, in the embodiment illustrated in Figure 10A, a distal terminus of the distal portion 103a of the catheter 102 is positioned proximate to a proximal portion of the clot material PE. It is expected that reducing the distance between the distal terminus of the catheter 102 and the proximal portion of the clot material PE—without contacting the clot material PE with the catheter 102—will maximize the suction forces on the clot material PE when the fluid control device 126 is opened. It is also expected that reducing the distance (e.g.,

clearance) between the inner diameter of the blood vessel BV and the outer diameter of the catheter will maximize the suction forces on the clot material PE. However, in other embodiments, the distal terminus of the catheter 102 can be positioned at least partially within the clot material PE, or the distal terminus of the catheter 102 can be positioned distal of the clot material PE.

[0083] Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the catheter subsystem 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 embolism, 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 102 can be placed over the guidewire and advanced (e.g., as indicated by arrow A1) to a position proximate to the clot material PE as illustrated in Figure 10A.

[0084] In some embodiments, to confirm the position of the distal portion 103a of the catheter 102, a contrast agent can be injected through the catheter 102 and viewed using fluoroscopic imaging techniques, as is known in the art. In some embodiments, the valve 106 can be opened to determine the position of the distal portion 103a of the catheter 102 relative to the clot material PE. For example, the activation buttons 101 can be depressed to open the lumen 109 of the valve 106. If there is substantially no back-bleeding through the valve 106, the operator can determine that the distal portion 103a of the catheter 102 is fully engaged with the clot material PE. Conversely, if there is some back-bleeding through the valve 106, the operator can determine that the distal portion 103a of the catheter is not fully engaged with the clot material PE. Accordingly, to locate the distal portion 103a of the catheter 102 just proximal of the clot material PE, the operator can (i) first determine that distal portion 103a of the catheter is fully engaged with the clot material PE by activating the valve 106 and detecting no back-bleeding and (ii) then reposition the catheter 102 (e.g., by withdrawing the catheter 102 proximally) and activate the valve 106 until back-bleeding is detected—thereby confirming that the distal portion 103a of the catheter 102 is positioned proximal of the clot material PE. In

some embodiments, the valve 106 can be opened during retraction of the catheter 102 until back-bleeding is detected. In other embodiments, the valve 106 can be closed during retraction of the catheter 102, and the catheter 106 can be retracted a set (e.g., predetermined) distance before the valve 106 is opened again. In one aspect of the present technology, determining the position of the distal portion 103a of the catheter 102 via activation of the valve 106 can be used when it is difficult to determine the position of the catheter 102 via radiographic techniques. In contrast, many conventional hemostasis valves cannot be activated in this manner.

[0085] 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 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 pulmonary embolism.

[0086] At block 804, the method 800 includes coupling a pressure source (e.g., the syringe 340) to the catheter 102 via the fluid control device 126. For example, in the embodiment illustrated in Figure 9A, the tip 347 (shown in Figures 3A and 3C but obscured in Figure 9A) of the syringe 340 can be coupled to the connector 128 via the adaptor 350. Once the syringe 340 is coupled to the catheter 102, (i) opening the fluid control device 126 fluidly connects the syringe 340 to the lumen 104 of the catheter 102, and (ii) closing the fluid control device 126 fluidly disconnects the syringe 340 from the lumen 104 of the catheter 102. The fluid control device 126 is in an open position in Figure 9A.

[0087] At block 806, the method 800 includes activating the syringe 340 to generate a vacuum while the fluid control device 126 is closed. For example, as shown in Figure 9B, the user can first actuate the fluid control device 126 to close the fluid control device 126, and then retract the plunger 342 to generate a vacuum in the barrel 344 of the syringe 340. The user can subsequently lock the plunger 342 relative to the barrel 344, as described in detail above, to store or maintain a vacuum of known volume in the syringe 340. In this manner, the syringe 340 can be pre-charged with a vacuum before the vacuum is applied to the catheter 102. In contrast, many conventional aspiration techniques include activating a negative pressure source (e.g., a

pump, a syringe, etc.) while the pressure source is fluidly connected to a lumen to be aspirated. In some embodiments, when the pressure source 400 with the secondary syringe 460 (Figures 4A–4C) is used with the primary syringe 340; the secondary syringe 460 can be cycled one or more times before or after retracting the plunger 342 to increase the vacuum pressure.

[0088] At block 808, the method 800 includes opening the fluid control device 126 to apply the vacuum to the lumen 104 of the catheter 102. For example, with reference to Figure 9C, the user can actuate (e.g., twist a handle of) the fluid control device 126 to open the fluid control device 126 and apply the vacuum stored in the syringe 340 to the catheter subsystem 100. As shown in Figure 10B, application of the vacuum causes suction at the distal tip 103a of the catheter 102 (e.g., as indicated by arrow A2) that aspirates at least a portion of the clot material PE from the blood vessel BV and into the lumen 104 of the catheter 102. In some embodiments, opening the fluid control device 126 instantaneously or nearly instantaneously generates suction at the distal portion 103a of the catheter 102. In certain embodiments, application of the vacuum can generate suction for less than about 1 second (e.g., about 0.5 second), substantially less than about 1 second (e.g., about 0.3 second, about 0.1 second, etc.) less than about 2 seconds, or greater than about 2 seconds—until the pressure in the assembly 10 equalizes. In some embodiments, depending on the volume of the vacuum chamber formed in the syringe 340 and the dimensions of the catheter subsystem 100 and the tubing subsystem 120 (e.g., where the syringe 340 has a volume that is greater than or about equal to a volume of the catheter subsystem 100), at least some of the clot material PE can be aspirated entirely through the lumen 104 of the catheter 102 and into the barrel 344 of the syringe 340. In some such embodiments, the user can determine whether subsequent steps for treating the clot material PE are necessary or desirable by visualizing the amount of clot material collected in the syringe 340. Figure 9C, for example, illustrates the syringe 340 and the tubing subsystem 120 after the fluid control device 126 has been opened to apply the vacuum stored in the syringe 340 to the catheter 102. In the illustrated embodiment, some of the clot material PE is visible in the syringe 340.

[0089] In some embodiments, the fluid control device 126 or another fluid control device can be intermittently operated to provide discrete bursts of suction. For example, the fluid control device 126 can be quickly opened and closed to provide a first burst of suction (e.g., vacuum release) without fully equalizing the pressure in the assembly 10. The fluid control device 126 can then be opened again to provide a second burst of suction, or opened and closed

repeatedly to provide a desired suction pattern. In some embodiments, the assembly 10 can be specifically configured to facilitate the application of multiple bursts of suction. For example, (i) the fluid control device 126 can be spring-loaded, electronically controlled, etc., to rapidly open and close the valve, and/or (ii) the pressure source 140 can have a large vacuum chamber and/or small bore size to increase the time required for pressure in the assembly 10 to equalize (e.g., to increase a discharge time of the pressure source 140).

[0090] Sometimes, as shown in Figure 10B, discharging the vacuum stored in the pressure source to aspirate the lumen 104 of the catheter 102 may not remove all of the clot material PE (or a desired amount of the clot material PE) from the blood vessel BV. That is, a single aspiration may not adequately remove the clot material PE from the blood vessel BV. In such instances, the user of the assembly 10 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 can be disconnected from the tubing subsystem 120 and drained (e.g., aspirated clot removal removed) before the method 800 returns to block 802. For example, the adaptor 350 and the syringe 340 can be decoupled from the connector 128, and the plunger 342 can be pushed into the barrel 344 to expel the clot material PE and associated fluid from the barrel 344 via the tip 347. With the distal portion of the catheter 102 positioned proximate to the remaining clot material PE (e.g., unmoved relative the last aspiration pass), the pressure source can then be re-coupled to the connector 128 (block 804), primed again (block 806), and the vacuum pressure discharged (block 808) to aspirate all or a portion of the remaining clot material PE.

[0091] Blocks 802–808 can be repeated until a desired amount of clot material is removed from the patient or until the catheter 102 becomes clogged. In some embodiments, to check for clogging of the catheter 102, the fluid control device 126 and/or the valve 106 can be opened to check for back bleeding. A lack of back bleeding can indicate that the catheter 102 is likely clogged. Similarly, if the barrel 344 of the syringe 340 contains mostly air and relatively little blood and clot material (e.g., less than 5–10 cc) after aspiration of the catheter 102 (block 808), it can indicate that the catheter 102 is likely clogged. When the catheter 102 is clogged or a sufficient amount of clot material PE has been removed from the patient, the method 800 can proceed to block 810 and the catheter 102 can be removed from the patient. When the catheter 102 is clogged, the catheter 102 can be flushed and cleared prior to reentry into the patient (block

802). In other embodiments, a different (e.g., new, unused, etc.) catheter can be inserted into the patient and positioned to remove the remaining clot material PE from the patient.

[0092] In some embodiments, rather than removing the catheter 102 from the patient if the catheter 102 is clogged, the syringe 340 can be recharged and used to apply one or more subsequent vacuum pulses to the catheter 102. More specifically, the fluid control device 126 can be closed and the syringe 340 can be removed from the connector 128 and evacuated to remove the clot material and blood therein. Then, blocks 804–808 can be repeated to apply another pulse of vacuum to the catheter 102. That is, rather than removing the catheter 102 after a clog is detected, the syringe 340 can be "cycled" until the vacuum force on the clot material PE overcomes the forces between the clot material PE and the catheter 102 and sucks the clot material PE into the syringe 340. In some embodiments, when the pressure source 400 with the secondary syringe 460 (Figures 4A–4C) is used with the primary syringe 340, the secondary syringe 460 can be cycled one or more times to increase the vacuum in the assembly 10 (e.g., in the catheter 102) and thus increase the suction force exerted against the clot material PE. That is, rather than removing the catheter 102 after a clog is detected, the secondary syringe 460 can be cycled until the vacuum force on the clot material PE overcomes the forces between the clot material PE and the catheter 102 and sucks the clot material PE into the syringe 340. In some embodiments, as described in detail below with reference to Figures 15–16E, a second clot removal assembly can be telescoped through the first assembly 10 to facilitate removal of the clogged clot material PE.

[0093] In some embodiments, an interventional device such as a clot removal and/or clot treatment device can be delivered to the treatment site through the catheter 102 for engaging and facilitating clot removal before and/or after application of a stored vacuum to the catheter 102. Suitable interventional devices and associated methods are disclosed in U.S. Patent Application No. 9,526,864, filed June 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," and U.S. Patent Application No. 8,784,434, filed March 15, 2013, and titled "METHODS AND APPARATUS FOR TREATING EMBOLISM," both of which are incorporated herein by reference in their entireties. In some embodiments, for example, the user can first advance an interventional device to the treatment site and at least partially engage the clot material PE with the interventional device to loosen (e.g., scour) the clot material PE. Such loosening of the clot material PE can facilitate the removal of the clot material PE upon a subsequent aspiration pass.

Likewise, in some embodiments, the user can use an interventional device to engage residual clot material PE (Figure 10B) after a first aspiration pass.

IV. Selected Embodiments of Telescoping Clot Removal Systems and Associated Methods of Clot Removal

[0094] Figure 11 is a partially schematic side view of another clot treatment or clot removal system configured in accordance with the present technology. In the illustrated embodiment, the clot removal system includes a first aspiration assembly 20 and a second aspiration assembly 30. The first and second aspiration assemblies 20, 30 ("assemblies 20, 30") can include some features generally similar to the features of the aspiration assembly 10 described in detail above with reference to Figures 1–10B. For example, the first aspiration assembly 20 includes (i) a first catheter subsystem 1000 having a first catheter 1002 and a first valve 1006, (ii) a first tubing subsystem 1020 having a first fluid control device 1026 (e.g., a stopcock), and (iii) a first pressure source 1040 that can be fluidly coupled to the first catheter subsystem 1000 via the first tubing subsystem 1020. Likewise, the second aspiration assembly 30 includes (i) a second catheter subsystem 1100 having a second catheter 1102 and a second valve 1106, (ii) a second tubing subsystem 1120 having a second fluid control device 1126 (e.g., a stopcock), and (iii) a second pressure source 1140 that can be fluidly coupled to the second catheter subsystem 1100 via the second tubing subsystem 1120.

[0095] The first and second catheters 1002, 1102 each comprise an elongated shaft defining a lumen 1004, 1104 and having a distal portion 1003a, 1103a, respectively. The first and second valves 1006, 1106 each include (i) a distal portion 1007a, 1107a, (ii) a proximal portion 1007b, 1107b, (iii) a lumen 1009, 1109 extending therethrough, and (iv) a flow controller (obscured in Figure 10) in the lumen 1009, 1109, respectively. The first fluid control device 1026 is operable to regulate or control fluid flow between (e.g., fluidly connect or disconnect) the first pressure source 1040 and the first catheter subsystem 1000. The second fluid control device 1126 is operable to regulate or control fluid flow between (e.g., fluidly connect or disconnect) the second pressure source 1140 and the second catheter subsystem 1100.

[0096] In the illustrated embodiment, the second catheter 1102 has a smaller cross-sectional dimension (e.g., diameter) than the first catheter 1002 so that the second catheter 1102 can be inserted through the first valve 1006 and into the lumen 1004 of the first catheter 1002. In some embodiments, the second catheter 1102 can be telescoped through the lumen 1004 of the first catheter 1002 until the distal portion 1103a of the second catheter 1102 extends beyond

a distal terminus of the first catheter 1002. Accordingly, the second catheter 1102 can be longer than the first catheter 1002. In some embodiments, the second catheter 1102 can have a size of 16 French or smaller and the first catheter 1002 can have a size of 20 French or greater. The first valve 1006 can provide a hemostatic seal that inhibits fluid flow (e.g., blood flow) through the first valve 1006 and from the first catheter subsystem 1000 when the second catheter 1102 is positioned within the first catheter 1002. In some embodiments (e.g., as described in detail below with reference to Figures 14A–14C), a sealing member 1499 can be positioned between the first catheter 1002 and the second catheter 1102 for sealing the lumen 1004 of the first catheter 1002 when the second catheter 1102 is advanced distally past the sealing member.

[0097] In some embodiments, the first and second pressure sources 1040, 1140 ("pressure sources 1040, 1140") are separate sources each configured to generate and store a vacuum for subsequent application to the first and second catheter subsystems 1000, 1100, respectively, as described in detail above with reference to Figures 1–10B. In other embodiments, one or both of the pressure sources 1040, 1140 can be configured to provide sustained negative pressure rather than a charge or burst of stored vacuum pressure. In yet other embodiments, one of the pressures sources 1040, 1140 can be omitted, or the pressure sources 1040, 1140 can be fluidly coupled and/or integrally formed.

[0098] Figure 12 is a flow diagram of a process or method 1280 for operating a clot removal system including the assemblies 20 and 30 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figures 13A–13C are schematic illustrations of a distal portion of the assemblies 20, 30 during a clot removal procedure in accordance with the present technology. Figures 14A–14C are schematic side views of a distal portion of the assemblies 20, 30 during a clot removal procedure and including an optional sealing member in accordance with the present technology. Although some features of the method 1280 are described in the context of the embodiments shown in Figures 11 and 13A–14C for the sake of illustration, one skilled in the art will readily understand that the method 1280 can be carried out using other suitable systems and/or devices.

[0099] At block 1282, the method 1280 includes intravascularly positioning the first catheter 1002 within a human patient. Figure 13A, for example, illustrates the first catheter 1002 after it has been advanced (e.g., as indicated by arrow A1) to a position within a blood vessel BV (e.g., a pulmonary blood vessel). More specifically, the first catheter 1002 can be advanced within the blood vessel BV until the distal portion 1003a of the first catheter 1002 is positioned

proximal to clot material PE within the blood vessel BV. In some embodiments, the position of the distal portion 1003a of the first catheter 1002 relative to the clot material PE can be determined by activating the first valve 1006 and determining whether there is back-bleeding through the first valve 1006, as described in detail above. In the illustrated embodiment, the clot material PE is located within a branch (e.g., a reduced diameter portion) of the blood vessel BV. In some embodiments, access to the blood vessel BV can be achieved using an introducer and guidewire as described in detail above with reference to Figure 8.

[0100] At block 1284, the method 1280 includes advancing the second catheter 1102 through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned proximate to the clot material PE within the blood vessel BV (e.g., at a treatment site). To advance the second catheter 1102 through the first catheter 1002, the user can first insert the distal portion 1103a of the second catheter 1102 through the first valve 1006 before advancing the second catheter 1102 (e.g., as indicated by the arrow A1) through the lumen 1004 of the first catheter 1002. In some embodiments, the first valve 1006 can be actuated (e.g., by depressing one or more buttons) to open the lumen 1009 of the first valve 1006 so that the second catheter 1102 can be inserted therethrough. In some embodiments, the position of the distal portion 1103a of the second catheter 1102 relative to the clot material PE can be determined by activating the second valve 1106 and determining whether there is back-bleeding through the second valve 1106, as described in detail above. In other embodiments, the (smaller) second catheter 1102 can be intravascularly positioned proximate to the clot material PE before intravascularly positioning the (larger) first catheter 1002. In such embodiments, the second catheter 1102 can act as a guide or rail for guiding the advancement of the first catheter 1002 to the treatment site.

[0101] Figure 13A illustrates the second catheter 1102 after it has been advanced through the first catheter 1002 and past a distal terminus of the first catheter 1002 to position a distal terminus of the second catheter 1102 proximate to a proximal portion of the clot material PE. In other embodiments, the distal terminus of the second catheter 1102 can be positioned at least partially within the clot material PE, or the distal terminus of the second catheter 1102 can be positioned distal of the clot material PE. In one aspect of the present technology, because the second catheter 1102 has a smaller cross-sectional dimension than the first catheter 1002, the second catheter 1102 can be advanced to narrower (e.g., more distal) treatment sites within the blood vessel BV. In the embodiment illustrated in Figure 13A, for example, the first catheter

1002 may be too large to be positioned within the branch of the blood vessel BV, while the second catheter 1102 can be positioned within the branch proximate to or within the clot material PE.

[0102] At block 1286, the method 1280 includes coupling the second pressure source 1140 to the second catheter 1102 via the second fluid control device 1126. For example, any one or combination of the pressure sources described in detail above with reference to Figures 2–7 can be coupled to the second catheter 1102 via the second tubing subsystem 1120. Once the second pressure source 1140 is coupled to the second catheter 1102, (i) opening of the second fluid control device 1126 fluidly connects the second pressure source 1140 to the lumen 1104 of the second catheter 1102, and (ii) closing of the second fluid control device 1126 fluidly disconnects the second pressure source 1140 from the lumen 1104 of the second catheter 1102. In some embodiments, the method 1280 can further include coupling the first pressure source 1040 to the first catheter 1002 (e.g., via the first tubing subsystem 1020).

[0103] At block 1288, the method 1280 includes activating the second pressure source 1140 to generate a vacuum while the second fluid control device 1126 is closed. In particular, the second pressure source 1140 can be activated to build-up or pre-charge a vacuum for subsequent application to the second catheter 1102. In some embodiments, the first pressure source 1040 can also be activated to generate and store a vacuum for subsequent application to the first catheter 1002.

[0104] At block 1290, the method 1280 includes opening the second fluid control device 1126 to apply the vacuum stored in second pressure source 1140 to the lumen 1104 of the second catheter 1102. As shown in Figure 13B, application of the vacuum causes suction (e.g., as indicated by arrow A2) that aspirates at least a portion of the clot material PE from the blood vessel BV and into the lumen 1104 of the second catheter 1102. In some embodiments, opening the second fluid control device 1126 instantaneously or nearly instantaneously generates suction at the distal portion 1103a of the second catheter 1102. In one aspect of the present technology, pre-charging or storing the vacuum before applying the vacuum to the lumen 1104 of the second catheter 1102 is expected to generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion 1103a of the second catheter 1102 compared to simply activating the second pressure source 1140 while it is fluidly connected to the second catheter 1102.

[0105] In some embodiments, where the first pressure source 1040 is also activated to generate and store a vacuum (e.g., at block 1288), the method 1280 can further comprise opening the first fluid control device 1026 to generate suction at the distal portion 1003a of the first catheter 1002. One skilled in the art will understand that the suction profile in the blood vessel BV can be selected or modified based on the characteristics of the pressure sources 1040, 1140 (e.g., volume, bore size, etc.) and the timing of the opening of the first and second fluid control devices 1026, 1126. For example, the first fluid control device 1026 can be opened at the same time as the second fluid control device 1126 to generate a combined and relatively large suction force in the blood vessel BV. In other embodiments, the first fluid control device 1026 can be opened after the second fluid control device 1126 to generate staggered or stepped suction forces in the blood vessel BV. For example, the first fluid control device 1026 can be opened after the second fluid control device 1126 to aspirate any of the clot material PE (i) remaining in the blood vessel BV after aspiration of the second catheter 1102 and/or (ii) stuck to or extending from the second catheter 1102. In other embodiments, the first pressure source 1040 can be a pump or other source for providing sustained negative pressure—rather than a built-up charge of negative pressure—and thus can generate sustained (e.g., constant) suction at the distal portion 1003a of the first catheter 1002. In some such embodiments, the first fluid control device 1026 can remain open during the clot removal procedure to provide sustained suction throughout the procedure.

[0106] In some embodiments, an interventional device can be delivered through the second catheter 1102 and used to engage the clot material PE before and/or after the vacuum is applied to the second catheter 1102. Specific details of suitable interventional devices and associated methods of use are disclosed in, for example, provisional U.S. Patent Application No. 16/258,344, filed January 25, 2019, and titled "SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

[0107] At block 1292, the method 1280 includes retracting the second catheter 1102 proximally through the first catheter 1002. In some embodiments, multiple aspiration passes can be performed with the second catheter 1102 before retracting the second catheter 1102. In some embodiments, as shown in Figure 13C, the first pressure source 1040 or another pressure source coupled to the first catheter 1002 can be activated to generate suction (e.g., as indicated by arrow A3) at the distal portion 1003a of the first catheter 1002 during retraction of the second catheter 1102. The suction can be constant or provided in one or more bursts, as described in

detail above. In some embodiments, the second catheter 1102 can be fully withdrawn from the patient and disposed of or cleaned (e.g., flushed with a sterile liquid) for reuse.

[0108] Sometimes, the clot material PE is not fully pulled into the second catheter 1102 when the vacuum is applied to the second catheter 1102 (block 1290) and can therefore stick to or dangle from the distal portion 1103a of the second catheter 1102. Figure 14A, for example, is an enlarged view of the distal portion of the assemblies 20, 30 shown in Figure 13C and illustrating a portion of the clot material PE stuck to or dangling from the distal portion 1103a of the second catheter 1102. In the illustrated embodiment, an optional seal 1499 is disposed between the first and second catheters 1002, 1102 to facilitate the removal of such dangling clot material PE. More specifically, the seal 1499 (shown in cross-section) can be disposed between an outer surface of the second catheter 1102 and an inner surface of the first catheter 1002. The seal 1499 can be an O-ring, grommet, or other suitable component that fluidly disconnects the lumen 1004 of the first catheter 1002 from the blood vessel BV when the second catheter 1102 is positioned therethrough (e.g., when the distal terminus of the second catheter 1102 is positioned distally of the seal 1499).

[0109] Figures 14B and 14C are enlarged views of the distal portion of the assemblies 20, 30 and illustrating further retraction of the second catheter 1102 (and the dangling clot material PE) into the lumen 1004 of the first catheter 1002. In some embodiments, the first pressure source 1040 can be activated to charge a vacuum in the lumen 1004 of the first catheter 1002. For example, after the second catheter 1102 is advanced through the first catheter 1002 and past the seal 1499 (e.g., block 1284)—thereby sealing the lumen 1004 of the first catheter 1002—the operator can open the first fluid control device 1026 and activate the first pressure source 1040 to build up the vacuum in the lumen 1004 of the first catheter 1002. Referring to Figure 14C, when the distal terminus of the second catheter 1102 is retracted proximally past the seal 1499, the lumen 1004 of the first catheter 1002 becomes fluidly connected to the blood vessel BV and the vacuum is instantaneously or nearly instantaneously released to generate suction (e.g., as indicated by arrows A4). In the illustrated embodiment, the suction acts to separate or otherwise dislodge the clot material PE from the second catheter 1102 and pull the clot material PE proximally through the lumen 1004 of the first catheter 1002. In this manner, a second burst of suction is automatically applied via the first catheter 1002 during retraction of the second catheter 1102. In one aspect of the present technology, the user does not need to take any

additional step to release the vacuum stored in the first catheter 1002—as release is automatically triggered by retraction of the second catheter 1102.

[0110] At block 1294, the user can determine whether it is necessary or desirable to redeploy the second catheter 1102 or another catheter through the first catheter 1002 in order to remove any residual clot material PE that was not removed during the first aspiration pass and/or any clot material located elsewhere in the blood vessel BV (e.g., to initiate a second aspiration pass). In some embodiments, the operator can visualize the amount of clot material PE collected in the first pressure source 1040 and/or the second pressure source 1140 to at least partially determine whether another aspiration pass is needed. In other embodiments, the operator can rely on imaging (e.g., fluoroscopic imaging) of the blood vessel BV or other techniques known in the art to determine whether an additional aspiration pass is necessary or desirable.

[0111] If another pass is not needed (e.g., the clot material PE was adequately removed), the user can elect to fully withdraw the assemblies 20, 30 from the patient at block 1296. If clot material PE remains in the vessel, the method can return to block 1284. In particular, the same second catheter 1102 can be cleaned (e.g., flushed with saline) and advanced again through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned proximate to the remaining clot material PE within the blood vessel BV. In some embodiments, a new second catheter 1102 can be used for each pass to reduce the likelihood of contamination (e.g., reintroduction of clot material PE). In some embodiments, the first catheter 1002 can be aspirated (e.g., via the first pressure source 1040) prior to redeployment of the second catheter 1102 to, for example, remove any clot material PE that may be in the first catheter 1002 to inhibit its reintroduction into the blood vessel BV as the second catheter 1102 is advanced therethrough during another pass. Once the desired amount of clot material PE has been removed from the patient, the assemblies 20, 30 may be fully withdrawn from the patient (block 1294).

[0112] In one aspect of the present technology, the method 1280 provides for an aspiration catheter to be deployed multiple times without requiring that the first catheter 1002 be removed after each deployment. Accordingly, the present technology allows for only a single insertion of a guide catheter during a procedure including multiple passes to remove clot material—increasing the speed of the procedure and reducing trauma to the patient since the guide catheter does not need to be reintroduced (e.g., advanced through the vasculature and past the heart) before each pass. Moreover, in certain embodiments, the present technology can enable the first catheter 1002 to be relocated to an alternate treatment site within the patient without removing

the first catheter 1002 from the patient and, therefore, without reintroducing the first catheter 1002 through the heart. For example, the first catheter 1002 can be relocated to another treatment site within the lungs including a treatment site in the opposite lung. More specifically, (i) a dilator can be reintroduced into the first catheter 1002, (ii) the first catheter 1002 can be withdrawn into the main pulmonary artery, (iii) a guidewire can be redirected to the new treatment site, (iv) the first catheter 1002 can be advanced over the guidewire to the new treatment site, and (v) the dilator can be removed.

[0113] Figure 15 is a flow diagram of another process or method 1580 for operating a clot removal system including the assemblies 20, 30 (Figure 1) to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figure 16A is an enlarged side view of a distal portion of the first assembly 20, and Figures 16B–16E are side views of a distal portion of the assemblies 20, 30 during a clot removal procedure in which clot material clogs the first assembly 20 in accordance with the present technology. Although some features of the method 1580 are described in the context of the embodiments shown in Figures 11 and 16A–16E for the sake of illustration, one skilled in the art will readily understand that the method 1580 can be carried out using other suitable systems and/or devices.

[0114] Some features of the method 1580 are generally similar to those of the methods 880 and/or 1280 described in detail above with reference to Figures 8 and 12, respectively. For example, at block 1582 the method includes intravascularly positioning the first catheter 1002 of the first assembly 20 within a human patient. At block 1584, the method 1580 includes coupling the first pressure source 1040 to the first catheter 1002 via the first fluid control device 1026. For example, any one or combination of the pressure sources described in detail above with reference to Figures 2–7 can be coupled to the second catheter 1002 via the first tubing subsystem 1020. At block 1586, the method 1580 includes activating the first pressure source 1040 to generate a vacuum while the first fluid control device 1026 is closed. In particular, the first pressure source 1040 can be activated to build-up or pre-charge a vacuum for subsequent application to the first catheter 1002. At block 1588, the method 1580 includes opening the first fluid control device 1026 to apply the vacuum stored in the first pressure source 1040 to the lumen 1004 of the first catheter 1002. As described in detail above, opening the first fluid control device 1026 instantaneously or nearly instantaneously generates suction at the distal portion 1003a of the first catheter 1002.

[0115] Sometimes, however, clot material is not fully pulled into the first catheter 1002 and/or clogs the first catheter 1002 when the vacuum is applied to the first catheter 1002 (block 1588). Figure 16A, for example, is an enlarged view of the distal portion of the first assembly 20 illustrating a portion of clot material PE that extends beyond from the distal portion 1003a of the first catheter 1002 and blocks/clogs the lumen 1004 of the first catheter 1002. As such, a portion of the clot material PE is not within the first catheter 1002. Accordingly, at block 1590, the method 1580 can include determining whether the first catheter 1002 is clogged. In some embodiments, the operator can determine that the first catheter 1002 is clogged based on the vacuum chamber of the first pressure source 1040 containing little to no clot material PE and blood. For example, since the clot material PE clogs the first catheter 1002, the vacuum chamber of the first pressure source 1040 cavitates when the first fluid control device 1026 is opened. If the first catheter 1002 is not clogged, the method 1580 can proceed to block 1598 and the first catheter 1002 can be withdrawn from the patient or the operator can perform another aspiration pass (e.g., as described in detail above with reference to blocks 808 and 810 of the method 800 shown in Figure 8).

[0116] If the first catheter 1002 is clogged, the method 1580 can proceed to block 1592 which includes advancing the second catheter 1102 through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned in or proximate to the clogging clot material PE. For example, Figure 16B illustrates the second catheter 1102 after it has been advanced to a position within the first catheter 1002 in which the distal terminus of the second catheter 1102 is at or proximate to the clogging clot material PE. To advance the second catheter 1102 through the first catheter 1002, the user can first insert the distal portion 1103a of the second catheter 1102 through the first valve 1006 (Figure 11) before advancing the second catheter 1102 through the lumen 1004 of the first catheter 1002.

[0117] At block 1594, the method 1580 includes activating the second pressure source 1140 (Figure 11) coupled to the second catheter 1102. More specifically, the second pressure source 1140 (e.g., any one or combination of the pressure sources described in detail above with reference to Figures 2–7) can be coupled to the second catheter 1102 via the second fluid control device 1126 (Figure 11), and the second pressure source 1140 can be activated to build-up or pre-charge a vacuum while the second fluid control device 1126 is closed. The second fluid control device 1126 can then be actuated to apply the vacuum stored in the second pressure source 1140 to the lumen 1104 of the second catheter 1102. In other embodiments, the second

pressure source 1140 can simply provide a sustained vacuum rather than an instantaneous release of vacuum. That is, in some embodiments the second pressure source 1140 is not pre-charged with a vacuum.

[0118] Applying the vacuum to second catheter 1102 can aspirate at least a portion of the clogging clot material PE into the second catheter 1102 and/or suck the clot material PE against the distal terminus of the second catheter 1102. Figure 16C, for example, illustrates a portion of the clot material PE stuck to or extending from the distal portion 1103a of the second catheter 1102 after aspirating the second catheter 1102. In the embodiment illustrated in Figure 16C, the added vacuum pressure generated through the second catheter 1102 is still not enough to break apart the clot material PE such that it can be fully aspirated through the first and/or second catheters 1002, 1102. That is, the clot material PE clogs the lumen 1004 of the first catheter 1002. In other embodiments, the added vacuum pressure from the second pressure source 1140 is sufficient to break apart the clot material PE such that it is aspirated into, for example, the vacuum chambers of the first and/or second pressure sources 1040, 1140.

[0119] At block 1596, the method can include retracting the second catheter 1102 and the clot material PE through the lumen 1004 of the first catheter 1002. For example, Figure 16D illustrates retracting the second catheter 1102, which in turn retracts the attached clot material PE, through the lumen 1004 of the first catheter 1002. In some embodiments, the second catheter 1102 and clot material PE can be fully withdrawn through the first catheter 1002. In other embodiments, retracting the clot material PE through the first catheter 1002 causes the clot material PE to break apart and be aspirated into the vacuum chambers of the first and/or second pressure sources 1040, 1140. Figure 16E, for example, illustrates the clot material PE breaking apart as the vacuum of the first and/or second pressure sources 1040, 1140 is instantaneously or nearly instantaneously released to suck the clot material PE proximally (e.g., as indicated by arrows A5).

[0120] At block 1598, the first and second catheters 1002, 1102 can be withdrawn from the patient or the operator can perform another aspiration pass using one or both of the first and second catheters 1002, 1102.

[0121] In one aspect of the present technology, the method 1580 removes clot material even when a first aspiration pass clogs the first catheter 1002. More particularly, the second catheter 1102 can be used to remove clogged clot material PE without requiring the first catheter 1002 and the clogged clot material PE to be withdrawn through the blood vessel BV.

V. Additional Selected Embodiments of Clot Removal Systems and Associated Methods of Clot Removal

[0122] From the foregoing, it will be appreciated that specific embodiments of the present technology have been described herein for purposes of illustration, but that various modifications may be made without deviating from the scope of the present technology. For example, in many of the embodiments described above, stored vacuum pressure can be used to aspirate or suck clot material from a blood vessel and into a catheter without the need to engage an interventional device with the clot material. However, one skilled in the art will understand that the aspiration devices and techniques disclosed herein can be used in conjunction with any suitable interventional device and/or during a clot removal procedure utilizing an interventional device. In some embodiments, for example, a clot removal system can be configured to apply stored vacuum pressure to a guide catheter to generate a burst of suction while an interventional device is retracted into and/or through the guide catheter.

[0123] Figure 17, for example, is a partially schematic view of a clot removal system 1700 ("system 1700") configured in accordance with the present technology. The system 1700 includes some features generally similar to the features of the clot removal system described in detail above with reference to Figure 1. For example, the system 1700 includes a catheter or sheath 1702 comprising an elongated shaft, and a valve 1706 coupled to a proximal portion of the sheath 1702. The valve 1706 has a side port 1708 that fluidly couples a lumen of the sheath 1702 to a tubing subsystem 1720 and a pressure source 1740 (shown schematically). A fluid control device 1726 (e.g., a stopcock or clamp; shown schematically) is operable to fluidly disconnect or connect the pressure source 1740 from/to the lumen of the sheath 1702. The pressure source 1740 can be any suitable pressure source for generating and storing vacuum pressure, as described in detail above.

[0124] In the illustrated embodiment, the system 1700 further includes (i) a self-expanding (e.g., mesh) funnel 1780 coupled to a proximal portion of the sheath 1702 and (ii) an interventional device (e.g., a thrombus extraction device) 1790. In the illustrated embodiment, the interventional device 1790 includes an expandable coring element (e.g., a first portion) 1792 coupled to an expandable cylindrical element (e.g., a second portion) 1794. In some embodiments, the interventional device 1790 is configured to self-expand from a compressed delivery state to an expanded deployed state. The interventional device 1790 is shown in the deployed state in Figure 17. An elongated shaft 1782 and/or one or more shafts positioned within the elongated shaft 1782 (e.g., an intermediate shaft 1884 and an inner shaft 1886 as shown in

Figures 18E and 18F, respectively) are coupled to the interventional device 1790 and configured to retract, advance, and/or manipulate (e.g., move between the delivery and deployed states) the interventional device 1790. In some embodiments, the system 1700 can be generally the same as or similar to any of the clot removal systems disclosed in U.S. Patent Application Publication No. 2018/0193043, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

[0125] In the illustrated embodiment, the system 1700 is shown intravascularly positioned within a blood vessel BV of a human patient and proximate to clot material DV (e.g., a deep vein thrombus) within the blood vessel BV. Specifically, Figure 17 shows the system 1700 after (i) advancing the sheath 1702 to a position proximate to a proximal portion 1785b of the clot material DV, (ii) deploying the funnel 1780, (iii) deploying the interventional device 1790 from the sheath 1702 (e.g., by advancing the interventional device 1790 through the valve 1706 and the sheath 1702 to a position distal of a distal portion 1785a of the clot material DV), and (iv) expanding the interventional device 1790 from the compressed delivery state to the deployed state.

[0126] Figures 18A–18H are enlarged views of a distal portion of the system 1700 during a clot removal procedure in accordance with the present technology. In general, Figures 18A–18H illustrate the proximal retraction of the interventional device 1790 through the clot material DV to capture at least a portion of the clot material DV, and the subsequent joint retraction of the interventional device 1790 and the captured clot material DV into the funnel 1780 and the sheath 1702. In one aspect of the present technology, charged vacuum pressure generated in the vacuum source 1740 can be applied to the sheath 1702 at one or more times during the illustrated process to generate suction for aspirating the captured clot material DV through the sheath 1702 and/or to inhibit clogging of the sheath 1702.

[0127] Referring first to Figure 18A, proximal retraction of the interventional device 1790 causes the coring element 1792 to separate and/or core the distal end portion 1785a of the clot material DV from the walls W of the blood vessel BV. As shown in Figure 18B, continued proximal retraction of the interventional device 1790 through the clot material DV causes the cylindrical element 1794 to capture the distal end portion 1785a of the clot material therein. Figures 18C–18E illustrate further proximal retraction of the interventional device 1790 which causes further separation, coring, and/or capture of the clot material DV. As seen in Figure 18E,

the proximal end portion 1785b of the clot material DV is cored and captured as the interventional device 1790 is proximally retracted toward the funnel 1780 and the sheath 1702. As further shown in Figure 18E, a first radiopaque marker 1887a can be positioned on a distal end portion of the inner shaft 1884 and a second radiopaque marker 1887b can be positioned on a distal end portion of the sheath 1702.

[0128] In some embodiments, as shown in Figure 18F, the interventional device 1790 can be proximally retracted until a portion of the coring element 1792 is contained (e.g., positioned) within the funnel 1780. More specifically, the interventional device 1790 can be proximally retracted until a mouth 1895 of the coring element 1792 is contained within the funnel 1780. In some embodiments, the containment of the mouth 1895 within the funnel 1780 can be fluoroscopically verified by visualization of the radiopaque markers 1887 (Figure 18E). In some embodiments, for example, the mouth 1895 can be determined as wholly contained within the funnel 1780 via fluoroscopic monitoring based on the alignment of the distal end portion of the inner shaft 1884 (e.g., the first radiopaque marker 1885a) relative to the distal end portion of the sheath 1702 (e.g., the second radiopaque marker 1885b). In some embodiments, when the mouth 1895 of the coring element 1792 is positioned within the funnel 1780, the interventional device 1790 can be moved or transformed from the expanded deployed state to the compressed delivery state to compress and secure the clot material DV captured by the interventional device 1790. In some embodiments, for example, the intermediate shaft 1884 can be unlocked and/or decoupled from the inner shaft 1886 (e.g., via user actuation of a plunger or other device) such that the inner shaft 1886 can be advanced distally relative to the intermediate shaft 1884 to collapse or compress the interventional device 1790.

[0129] After the interventional device 1790 has been collapsed, the interventional device 1790 can be proximally retracted through the funnel 1780 and into the sheath 1702 as depicted in Figure 18G. As shown in Figure 18H, the interventional device 1790 can continue to be proximally retracted until the interventional device 1790 and the captured clot material DV are fully contained within the sheath 1702. In some embodiments, the interventional device 1790 and the captured clot material DV can then be withdrawn through the sheath 1702 and the valve 1706 (Figure 17), and from the patient's body.

[0130] In some embodiments, the collapse of the interventional device 1790 and/or the retraction of the interventional device 1790 into the funnel 1780 and/or the sheath 1702 can result in one or more portions of the clot material DV breaking away from the clot material DV

contained in the interventional device 1790. For example, all or a portion of the captured clot material DV can be extruded through pores of the (e.g., mesh) cylindrical element 1794 as the interventional device 1790 collapses. In some embodiments, any such clot material can be captured by the funnel 1780. Referring to Figure 17, in some embodiments, the pressure source 1740 can be activated to charge a vacuum, and the fluid control device 1726 can subsequently be opened to apply the charged vacuum to the sheath 1702 (as described in detail above). The vacuum can be applied to the sheath 1702 at any point during retraction of the interventional device 1790. As shown in Figures 18G and 18H, application of the vacuum can generate instantaneous or nearly instantaneous suction (e.g., as indicated by arrows A6) at the distal end portion the sheath 1702 that can aspirate the extruded portions and/or other portions of the clot material DV into and/or through the sheath 1702. In particular, the generated suction can aspirate some or all of the clot material DV captured by the funnel 1780. Moreover, in some embodiments, application of a vacuum from the pressure source 1740 can facilitate smooth retraction of the captured clot material DV through the sheath 1702. For example, a burst of suction generated by application of the vacuum can help inhibit clogging of the sheath 1702, and/or help resolve (e.g., break apart) a clog formed in the sheath 1702 during retraction.

VI. Selected Embodiments of Clot Removal Systems Having Filters and Associated Methods of Clot Removal

[0131] The systems and methods for clot removal described herein can include applying a pre-charged vacuum to generate suction for aspirating clot removal from the blood vessel of a patient. In one aspect of the present technology, aspiration of the clot material also aspirates blood from the patient. It can be advantageous to reintroduce the aspirated blood to the patient to lessen the trauma to the patient—especially where the removal procedure may comprise multiple aspiration passes that can together withdraw a significant amount of blood. However, the aspirated blood is often mixed with clot material and is therefore not suitable for reintroduction into the patient. Figures 19–20E illustrate various devices for filtering aspirated blood from removed clot material to reintroduce the aspirated blood into the patient without reintroducing a significant amount of clot material.

[0132] For example, Figure 19 is a perspective side view of a pressure source 1900 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The pressure source 1900 is generally similar to the pressure source 400 described in detail above with reference to Figures 4A–4C. For example,

the pressure source 1900 includes the secondary syringe 460 ("syringe 460") and the first and second one-way valves 470 and 472. However, the secondary syringe 460 is coupled to a canister 1940 rather than the primary syringe 340 (Figures 4A–4C). The canister 1940 includes a tip (obscured) coupled to the adaptor 350 and is configured to be removably positioned within the connector 128 of the tubing subsystem 120 (Figure 1) to fluidly couple the canister 1940 to the tubing subsystem 120. Because the canister 1940 does not include a plunger or other component for changing a volume thereof, the syringe 460 is the only vacuum source for evacuating the canister 1940 (e.g., via repeated cycling of the secondary syringe 460).

[0133] In the illustrated embodiment, the canister 1940 further includes a filter 1942. The canister 1940 is shown as transparent in Figure 19 for the sake of clarity. The filter 1942 is coupled to and/or covers a removable end cap 1944 having a blood separation port 1946. In operation, when blood and clot material are aspirated into the canister 1940 (e.g., via any of the methods described in detail above), the filter 1942 separates the blood from the clot material within the canister 1940. The filtered blood can be removed via the blood separation port 1946. For example, a syringe (not shown) or other device can be fluidly coupled to the blood separation port 1946 and used to draw the blood through the filter 1942 and out of the canister 1940. The filtered blood can then be reintroduced to the patient via, for example, the fluid control device 126 and/or the connector 128 of the tubing subsystem 120. Once the blood is removed from the canister 1940, the end cap 1944 can be removed from the canister 1940 (e.g., by unscrewing the end cap 1944 from the body of the canister 1940) for removing the captured clot material. In some embodiments, the filter 1942 is attached to the end cap 1944 such that removing the end cap 1944 removes the filter 1942 and permits clot material to be dumped, scooped, or otherwise removed from the canister 1940.

[0134] Figures 20A–20E illustrate a filter device 2050 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2050 is configured as an in-line filter for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. For example, Figure 20A is a partially-exploded side view of the filter device 2050 and the pressure source 340 (Figures 3A–3D). In the illustrated embodiment, the filter device 2050 comprises a filter portion 2060 that is removably positionable within a barrel portion 2070. In the illustrated embodiment, the barrel portion 2070 includes a barrel 2072 that defines a chamber 2074, and a large bore tip 2076 configured to fluidly couple the chamber 2074 to external components, such

as the tubing subsystem 120 (e.g., as shown in Figure 20C). The filter portion 2060 includes a seal 2062 configured to engage (i) an interior surface of the barrel 2072 when the filter portion 2060 is positioned within the chamber 2074 of the barrel portion 2070 and (ii) an exterior surface of the syringe 340 (e.g., an exterior surface of the barrel 344) when the syringe 340 is inserted into the filter device 2050. In other embodiments, the filter portion 2060 can be permanently attached to or integrally formed with the barrel portion 2070. The filter portion 2060 further includes a filter (e.g., a mesh) 2064 configured (e.g., sized and shaped) to inhibit clot material from passing therethrough. In some embodiments, the filter 2064 can be configured to inhibit clots larger than about 100 μm (e.g., larger than about 110 μm) from passing therethrough.

[0135] Figure 20B is a perspective side view of the syringe 340 coupled to the filter device 2050. The barrel 2072 of the barrel portion 2070 is shown as transparent in Figure 20B (and Figures 20C–20E) for the sake of clarity. In the illustrated embodiment, the seal 2062 is positioned between the exterior surface of the barrel 344 of the syringe 340 and the interior surface of the barrel 2072 of the barrel portion 2070. The filter 2064 is positioned around (e.g., covers) the tip 347 of the syringe 340 to inhibit clot material from entering the barrel 344 of the syringe 340 during operation.

[0136] Figure 20C is a side view of the filter device 2050 and syringe 340 coupled to the tubing subsystem 120 of the assembly 10. More specifically, the tip 2076 can be inserted into the connector 128 of the tubing subsystem 120 as described in detail above. When the filter device 2050 and the syringe 340 are coupled to the tubing subsystem 120, the filter device 2050 is positioned in-line (e.g., in series) with the syringe 340. In the embodiment illustrated in Figure 20C, the plunger 342 of the syringe 340 has been withdrawn to generate negative pressure in the combined volume of the barrels 2072 and 344. As described in detail above, opening the fluid control device 126 nearly instantaneously applies the negative pressure to the catheter 102 to generate suction therein. When clot material and blood are aspirated through the catheter 102 and the tubing subsystem 120, the filter portion 2060 inhibits the clot material from entering the barrel 344 of the syringe 340. Thus, aspirated blood is collected in the barrel 344 of the syringe 340 while the aspirated clot material is collected in the barrel 2072 of the barrel portion 2070 of the filter device 2050. In this manner, clot material and blood can be separated during aspiration.

[0137] In one aspect of the present technology, separating the blood from the clot material such that the blood is within the syringe 340 permits the blood to be easily reintroduced to the patient. For example, Figures 20D and 20E are side views of the syringe 340 coupled to the

tubing subsystem 120 of the assembly 10 for reintroducing blood to a patient. In some embodiments, as shown in Figure 20D, the syringe 340 can be decoupled from the filter device 2050 and directly coupled to the connector 128. With the fluid control device 126 in an open position, the blood can then be reintroduced to the patient through the assembly 10 by depressing the plunger 342 of the syringe 340. In some embodiments, as shown in Figure 20E, the syringe 340 can be decoupled from the filter device 2050 and directly coupled to a port on the fluid control device 126. With the fluid control device 126 in a closed position, the blood can then be reintroduced to the patient through the assembly 10 by depressing the plunger 342 of the syringe 340. Referring to Figures 20A–20E together, after or before reintroducing filtered blood to the patient, the filter portion 2060 of the filter device 2050 can be removed from the barrel portion 2070 so that the collected clot material can be removed and the filter device 2050 cleaned. In some embodiments, the filter device 2050 and a coupled pressure source can be used to filter blood from clot material after—as opposed to during—an aspiration pass. For example, the filter device 2050 and coupled pressure source could be used to withdraw blood and clot material collected in the canister 1940 of the pressure source 1900 (e.g., where the canister 1940 does not include the filter 1942).

[0138] Figures 21A and 21B illustrate a filter device 2150 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2150 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. For example, Figure 21A is a partially-exploded side view of the filter device 2150 and the pressure source 340 (Figures 3A–3D). In the illustrated embodiment, the filter device 2150 includes a housing 2152 defining a chamber 2154, a filter 2156 configured to be positioned within the housing 2152, and a cap assembly 2160 configured to be releasably coupled to the housing 2152 (e.g., via a threaded connection, snap-fit connection, etc.). In some embodiments, the filter 2156 can have a porosity of between about 50–200 microns.

[0139] The housing 2152 can include a port 2153 configured to be removably, fluidly coupled to the pressure source 340 via a tubing subsystem 2120. In the illustrated embodiment, the tubing subsystem 2120 includes tubing sections 2124 (individually labeled as a first tubing section 2124a and a second tubing section 2124b), a fluid control device 2126 (e.g., a valve, stop cock, clamp, etc.), and a connector 2128 (e.g., a large bore connector) for fluidly coupling the tubing subsystem 2120 to the pressure source 340. In the illustrated embodiment, the cap

assembly 2160 includes a fluid connector 2162 (e.g., a standard Luer or large bore connector) configured to be connected to a receiving/reinfusion syringe 2170 via, for example, a tubing section 2164. In some embodiments, the cap assembly 2160 can include a valve (e.g., a one-way valve, a check valve, etc.) that provides for one-way fluid flow through filter assembly 2150.

[0140] In operation, during a clot removal procedure, the pressure source 340 can be decoupled from the connector 128 (Figure 1) after an aspiration pass and when the pressure source 340 is full of blood and clot material. After connecting the filter device 2150 to the receiving syringe 2170, the pressure source 340 can be coupled to the filter device 2150. For example, Figure 21B is a perspective side view of the filter device 2150 coupled to (i) the pressure source 340 via the tubing subsystem 2120 and (ii) the reinfusion syringe 2170 via the tubing section 2164. More specifically, referring to Figures 21A and 21B together, the tip 347 of the pressure source 340 can be coupled to the connector 2128 of the tubing subsystem 2120, and a tip 2172 of the reinfusion syringe 2170 can be coupled to the tubing section 2164. In other embodiments, the filter device 2150 can be coupled to the pressure source 340 and/or the reinfusion syringe 2170 in other manners (e.g., directly such that the all or part of the tubing subsystem 120 is omitted). Alternatively, the filter device 2150 can be directly attached to the side port 108 (Figure 1), an IV line (not shown), or another suitable connection point for reintroducing blood to the patient,

[0141] After coupling the pressure source 340 to the filter device 2150, the fluid control device 2128 can be opened to fluidly connect the pressure source 340 to the filter device 2150. Then, the operator can depress the plunger 342 of the pressure source 340 to drive the blood and clot material from the pressure source 340 into and/or through the filter device 2150. The filter 2156 of the filter device 2150 filters the blood from the clot material such that the blood flows into the reinfusion syringe 2170 and the clot material remains in the chamber 2154 of the filter device 2150. For example, as shown in Figure 21B, blood B fills the reinfusion syringe 2170 and clot material PE remains within the chamber 2154 of the filter device 2150 after depressing the plunger 342 of the pressure source 340 in the direction indicated by the arrow H.

[0142] Next, the reinfusion syringe 2170 can be decoupled from the filter device 2150 so that the blood B can be reintroduced to the patient. For example, the reinfusion syringe 2170 could be directly coupled to a port on the fluid control device 126 (Figure 1). The cap assembly 2160 can be decoupled from the housing 2152 of the filter device 2150 to, for example, permit

an operator to remove the clot material PE collected in the housing 2152 and thereby clean and prepare the filter device 2150 for another use.

[0143] Figure 22 is a partially-exploded side view of a filter device 2250 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2250 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. In general, the filter device 2250 is generally similar to the filter device 2150 described in detail with reference to Figures 21A and 21B. For example, the filter device 2250 includes a housing 2252 defining a chamber 2254, a filter 2256 configured to be positioned within the housing 2252, and a cap assembly 2260 configured to be releasably coupled to the housing 2252. However, in the illustrated embodiment the filter device 2250 includes a port 2253 that is directly connected to a connector 2228 configured to be coupled to a pressure source (e.g., the pressure source 340 shown in Figures 3A–3D). The cap assembly 2260 includes a fluid connector 2162 (e.g., a standard Luer or large bore connector) configured to be connected to a reinfusion syringe, a sheath, an IV line, etc., (not shown). In some embodiments, the fluid connector 2262 is angled relative to the filter 2260 and/or the housing 2252. For example, the fluid connector 2262 is formed to have an approximately right angle in Figure 22. In one aspect of the present technology, this arrangement makes the filter device more ergonomic during use.

[0144] Figure 23 is a partially-exploded side view of a filter device 2350 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2350 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. The filter device 2350 is generally identical to the filter device 2250 described in detail with reference to Figure 22—including, for example, the housing 2252 ("a first housing 2252"), the filter 2256 ("a first filter 2256"), and the cap assembly 2260 including the fluid connector 2262 ("a first fluid connector 2262"). However, in the illustrated embodiment a second housing 2382 and a second filter 2386 are fluidly connected to the fluid connector 2262. The second housing 2382 includes a second fluid connector 2384 that can be fluidly connected to a reinfusion syringe, a sheath, an IV line, etc., (not shown). The second filter 2386 is configured to provide a second stage of filtration. For example, in some embodiments the first filter 2256 has a larger porosity than the second filter 2386. For example, the first filter 2256 can have a porosity of between about 50–200 microns and the second filter 2386 can have a porosity of between about 50–170 microns.

[0145] In general, one skilled in the art will understand that the various embodiments of filter devices disclosed herein may have different components or combinations of components. For example, the filter devices 2050, 2150, 2250, and/or 2350 ("the filter devices") could be utilized with any of several different pressure sources other than the syringe 340 (e.g., those shown in Figures 2 and 4–7). In some embodiments, the filter devices can be formed as a component of the tubing subsystem 120 (Figure 1). Moreover, the filter devices can include any number of filters and/or housings to provide any number of filtration stages.

VII. Examples

[0146] Several aspects of the present technology are set forth in the following examples: [[TO ADD ONCE CLAIMS ARE FINALIZED]]

Conclusion

[0147] 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.

[0148] 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.

[0149] 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 method for the intravascular treatment of clot material from within a blood vessel of a human patient, the method comprising:

positioning a distal portion of a catheter proximate to the clot material within the blood vessel;

coupling a pressure source to the catheter via a fluid control device, wherein (a) opening of the fluid control device fluidly connects the pressure source to the catheter and (b) closing of the fluid control device fluidly disconnects the pressure source from the catheter;

activating the pressure source to generate a vacuum while the fluid control device is closed; and

opening the fluid control device to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material into the catheter.

2. The method of claim 1 wherein the catheter defines a lumen having a first diameter, wherein the pressure source includes a syringe having a tip, and wherein the tip defines a bore having a second diameter greater than the first diameter.

3. The method of claim 2 wherein the syringe is a vacuum-pressure locking syringe.

4. The method of claim 1 wherein opening the fluid control device to apply the vacuum to the catheter includes generating suction at the distal portion of the catheter for less than about 1 second.

5. The method of claim 1 wherein the pressure source includes a pressure vessel and a syringe fluidly coupled to the pressure vessel via a one-way valve, wherein—

coupling the pressure source to the catheter includes coupling the pressure vessel to the catheter; and

activating the pressure source to generate the vacuum includes actuating the syringe one or more times to evacuate the pressure vessel.

6. The method of claim 5 wherein the syringe is a second syringe and the pressure vessel is a first syringe, and wherein activating the pressure source includes (i) actuating the first syringe and (ii) actuating the second syringe.

7. The method of claim 6 wherein activating the pressure source includes actuating the second syringe before actuating the first syringe.

8. The method of claim 1 wherein the pressure source includes a syringe having a first plunger and a second plunger, wherein activating the pressure source includes retracting the first plunger, and wherein opening the fluid control device includes retracting the second plunger.

9. The method of claim 8 wherein, after retracting the first plunger a first distance, the first plunger engages the second plunger such that further retraction of the first plunger simultaneously retracts the second plunger.

10. The method of claim 1 wherein the pressure source is a syringe having a volume of greater than about 60 cc, and wherein activating the pressure source includes rotating a handle to retract a plunger of the syringe.

11. The method of claim 1 wherein opening the fluid control device to apply the vacuum includes providing nearly instantaneous suction at the distal portion of the catheter.

12. The method of claim 1 wherein positioning the distal portion of the catheter includes positioning the distal portion proximally of the clot material.

13. The method of claim 1 wherein positioning the distal portion of the catheter includes positioning the distal portion at least partially within the clot material.

14. The method of claim 1 wherein the method further comprises filtering the clot material from blood via a filter fluidly coupled between the pressure source and the catheter.

15. The method of claim 14 wherein the method further comprises reintroducing the filtered blood into the blood vessel via the catheter.

16. The method of claim 15 wherein filtering the clot material from the blood includes filtering the clot material from the blood within the pressure source.

17. A method for the intravascular treatment of clot material from within a blood vessel of a human patient, the method comprising:

positioning a distal portion of a first catheter at a treatment site proximate to the clot material within the blood vessel;

coupling a pressure source to the first catheter via a fluid control device, wherein (a) opening of the fluid control device fluidly connects the pressure source to the first catheter and (b) closing of the fluid control device fluidly disconnects the pressure source from the first catheter;

activating the first pressure source to generate a vacuum while the fluid control device is closed;

opening the fluid control device to apply the vacuum to the first catheter to thereby aspirate at least a portion of the clot material into the first catheter; and

retracting the first catheter into a distal portion of a second catheter.

18. The method of claim 17, further comprising:

withdrawing the first catheter through the second catheter and from the patient; and

advancing a third catheter through the second catheter to the treatment site.

19. The method of claim 17 wherein the pressure source is a first pressure source, and wherein the method further comprises:

coupling a second pressure source to the second catheter; and

activating the second pressure source to generate suction at the distal portion of the second catheter.

20. The method of claim 17 wherein the pressure source is a first pressure source, wherein the fluid control device is a first fluid control device, and wherein the method further comprises coupling a second pressure source to the second catheter via a second fluid control

device, wherein (a) opening of the second fluid control device fluidly connects the second pressure source to the second catheter and (b) closing of the fluid control device fluidly disconnects the second pressure source from the second catheter.

21. The method of example 20, further comprising:

activating the second pressure source to create a vacuum while the second fluid control device is closed; and

opening the second fluid control device to apply the vacuum to the second catheter to thereby generate suction at the distal portion of the second catheter.

22. The method of claim 17 wherein the pressure source is a first pressure source, wherein positioning the distal portion of the first catheter at the treatment site includes advancing the first catheter through a lumen of the second catheter and past a seal, wherein the seal fluidly disconnects the lumen of the second catheter from the blood vessel, and wherein the method further comprises:

coupling a second pressure source to the second catheter;

activating the second pressure source to generate a vacuum in the lumen of the second catheter; and

after opening the fluid control device, retracting the first catheter through the lumen of the second catheter and past the seal to thereby aspirate another portion of the clot material into the second catheter.

23. The method of claim 17 wherein the method further comprises positioning the distal portion of the second catheter proximate to the treatment site within the vessel.

24. The method of claim 23 wherein positioning the distal portion of the first catheter includes advancing the first catheter through the blood vessel before positioning the second catheter, and wherein positioning the distal portion of the second catheter includes advancing the second catheter over the first catheter.

25. The method of claim 23 wherein positioning the distal portion of the second catheter includes advancing the second catheter through the blood vessel before positioning the

first catheter, and wherein positioning the first catheter includes advancing the first catheter through a lumen of the second catheter.

26. A system for the intravascular treatment of clot material from within a blood vessel of a human patient, the system comprising:

a catheter configured to be intravascularly positioned at a treatment site proximate to the clot material within the blood vessel;

a tubing assembly coupled to the catheter and including a fluid control device; and

a pressure source to generate negative pressure,

wherein the pressure source includes a tip configured to be coupled to the tubing assembly,

wherein the tip defines a bore having a diameter greater than or equal to a diameter of the catheter, and

wherein the fluid control device is movable between (a) a first position in which the pressure source is fluidly connected to the catheter via the tubing assembly and (b) a second position in which the pressure source is fluidly disconnected from the catheter.

27. The system of claim 26 wherein the pressure source is a syringe, and wherein the diameter of the bore is greater than 20 French.

28. The system of claim 26 wherein the pressure source includes—

a pressure vessel having the tip;

a syringe having a plunger;

a first one-way valve coupling the pressure vessel to the syringe; and

a second one-way valve coupled to the syringe,

wherein movement of the plunger in a first direction draws fluid from the pressure vessel into the syringe through the one-way valve, and

wherein movement of the plunger in a second direction forces fluid out of the syringe through the second one-way valve.

29. The system of claim 28 wherein the first one-way valve is closed during movement of the plunger in the second direction.

30. The system of claim 28 wherein the second one way-valve is closed during movement of the plunger in the first direction.

31. The system of claim 28 wherein the pressure vessel is a syringe.

32. A method for intravascularly positioning an aspiration catheter proximate to clot material within a blood vessel of a human patient, the method comprising:

advancing the aspiration catheter through the blood vessel toward the clot material;

opening a valve fluidly connected to the aspiration catheter;

determining that a distal portion of the aspiration catheter is engaged with the clot material by determining that there is substantially no flow of blood through the valve;

retracting the aspiration catheter proximally;

determining that the distal portion of the aspiration catheter is positioned proximal to the clot material by determining that there is a flow of blood through the valve; and

closing the valve.

33. The method of claim 32 wherein the method further comprises closing the valve before retracting the aspiration catheter proximally.

34. The method of claim 32 wherein opening the valve includes depressing a button on the valve.

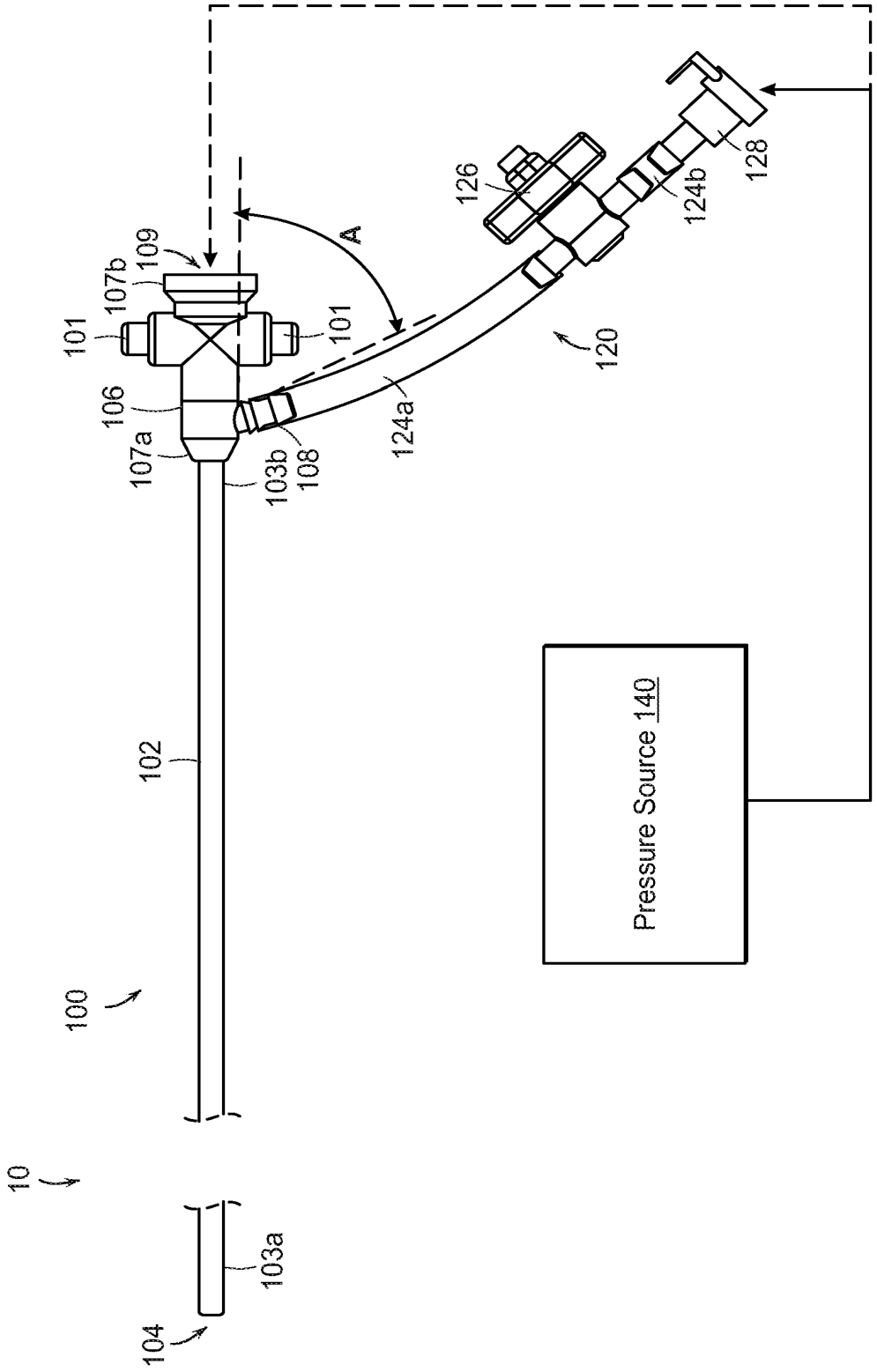

10
100
101
101
102
103a
103b
104
106
107a
107b
108
109
120
124a
124b
126
128
A
Pressure Source 140

FIG. 1

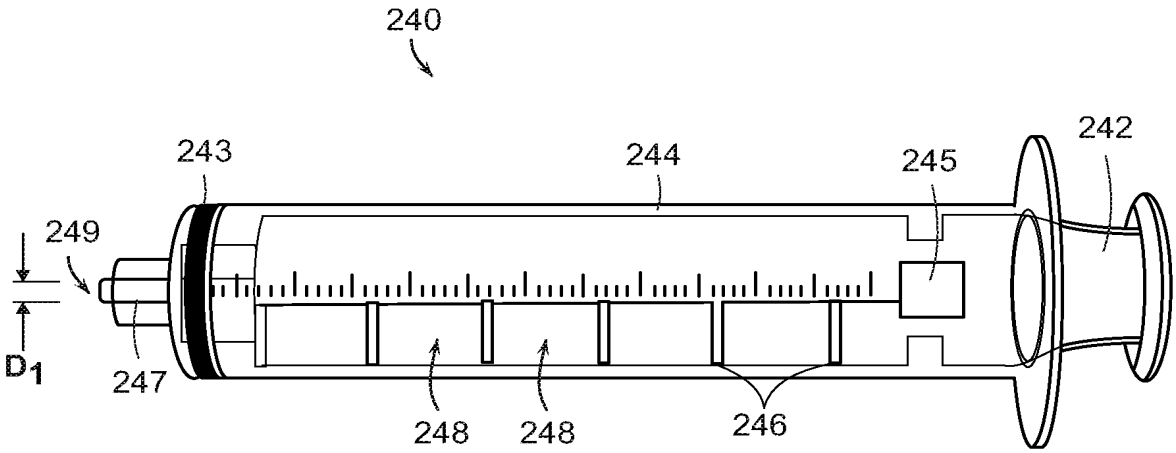

240
243
244
245
242
249
D_1
247
248
248
246

FIG. 2

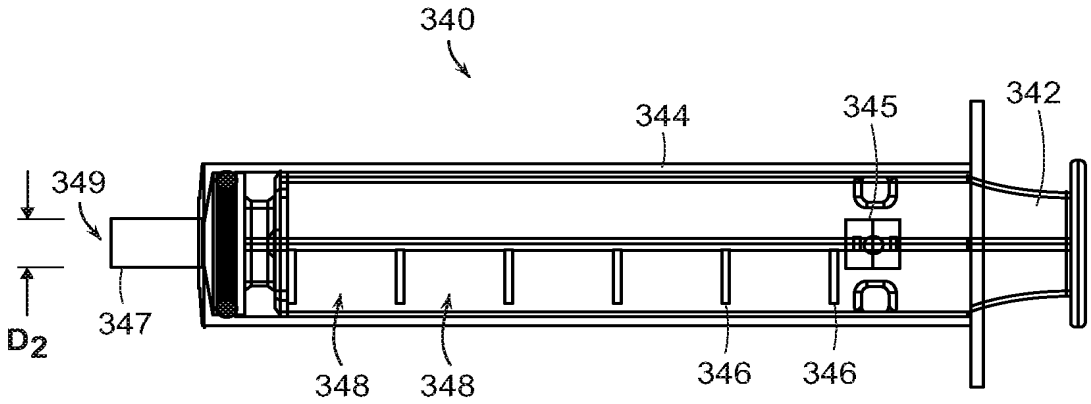

340
344
345
342
349
D_2
347
348
348
346
346

FIG. 3A

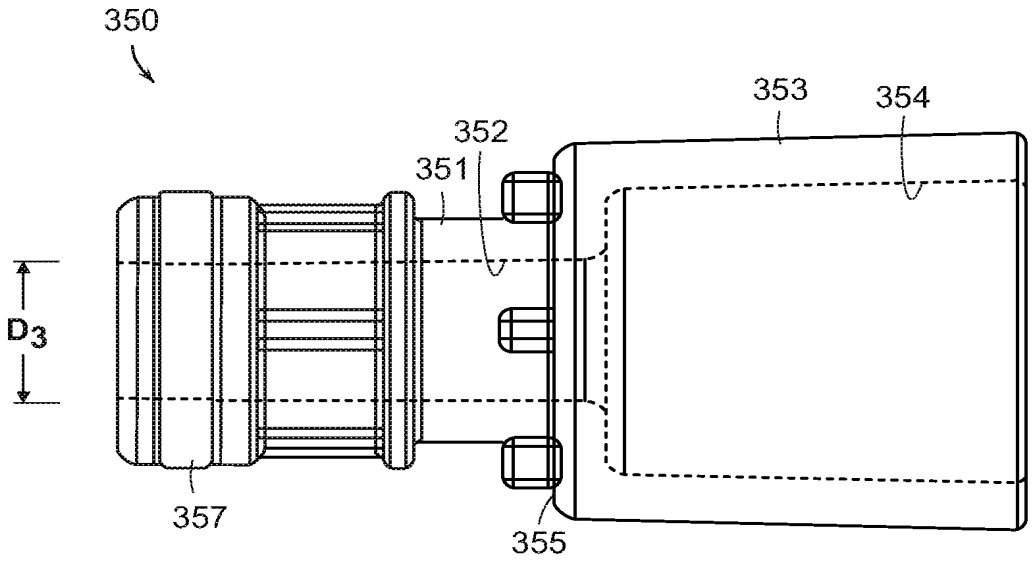


FIG. 3B

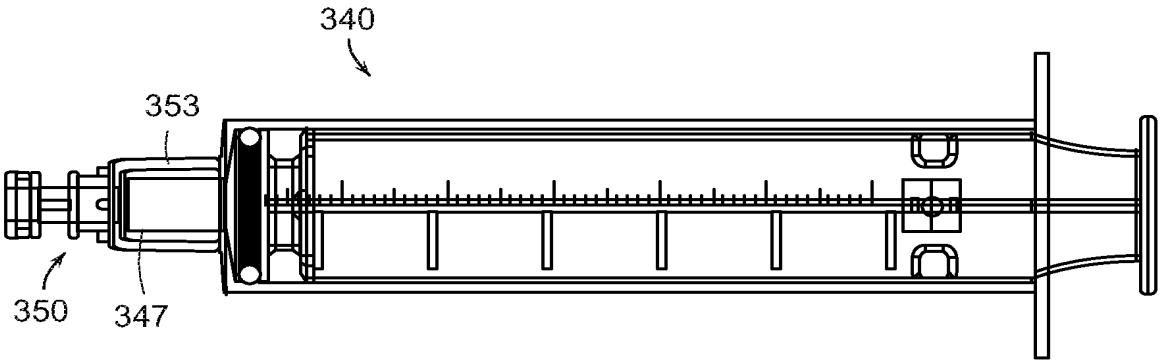


FIG. 3C

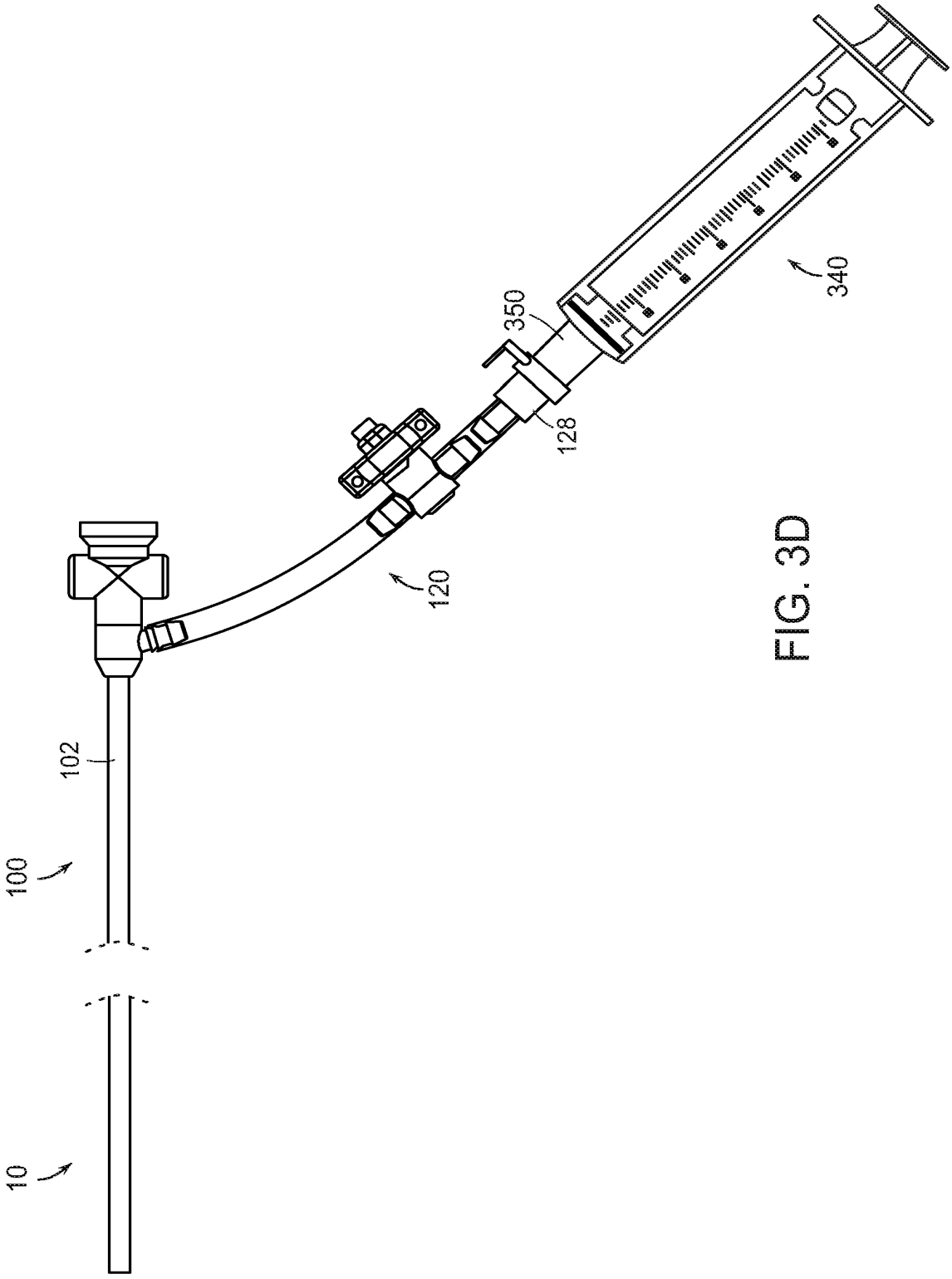
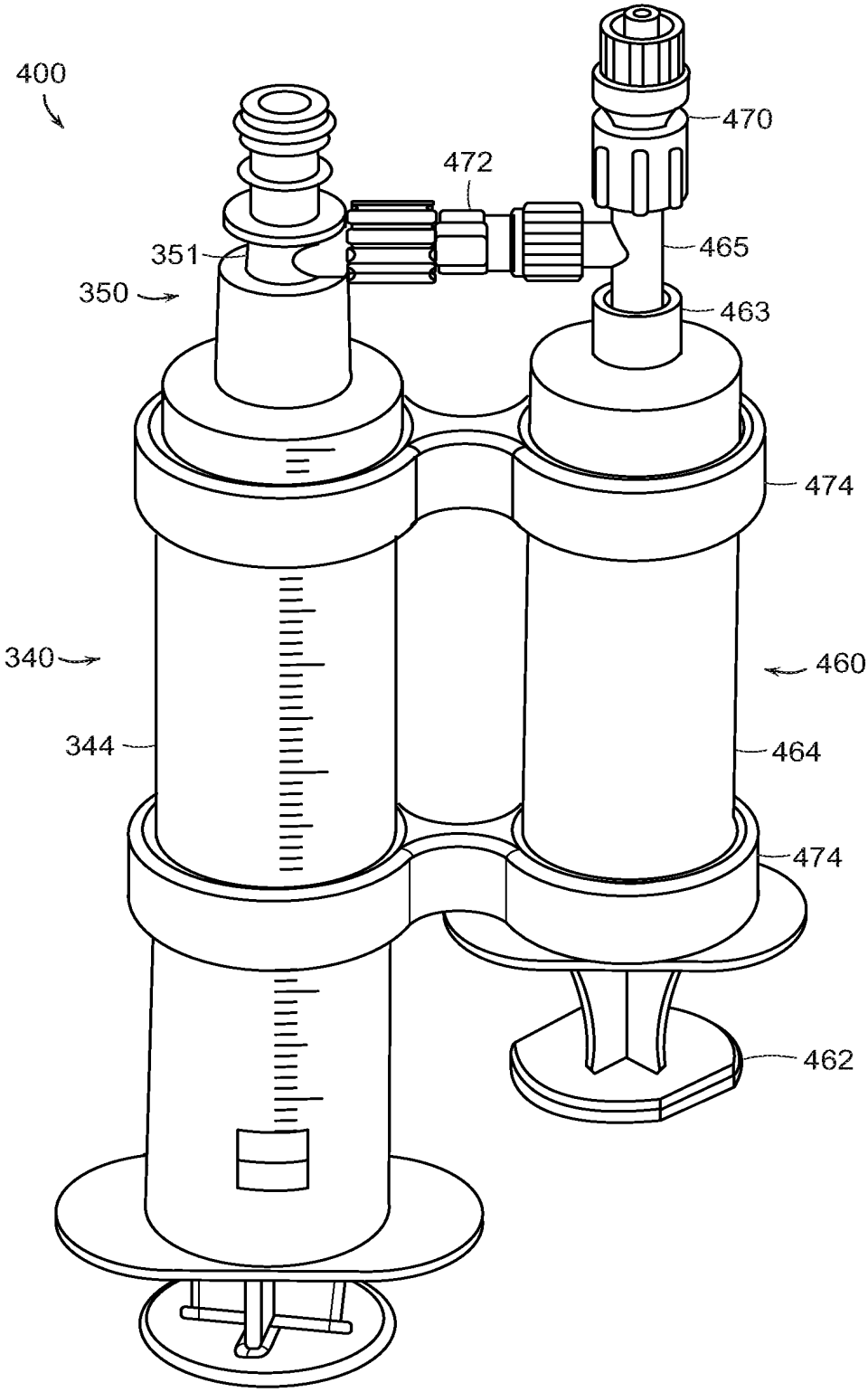


FIG. 3D

FIG. 4A



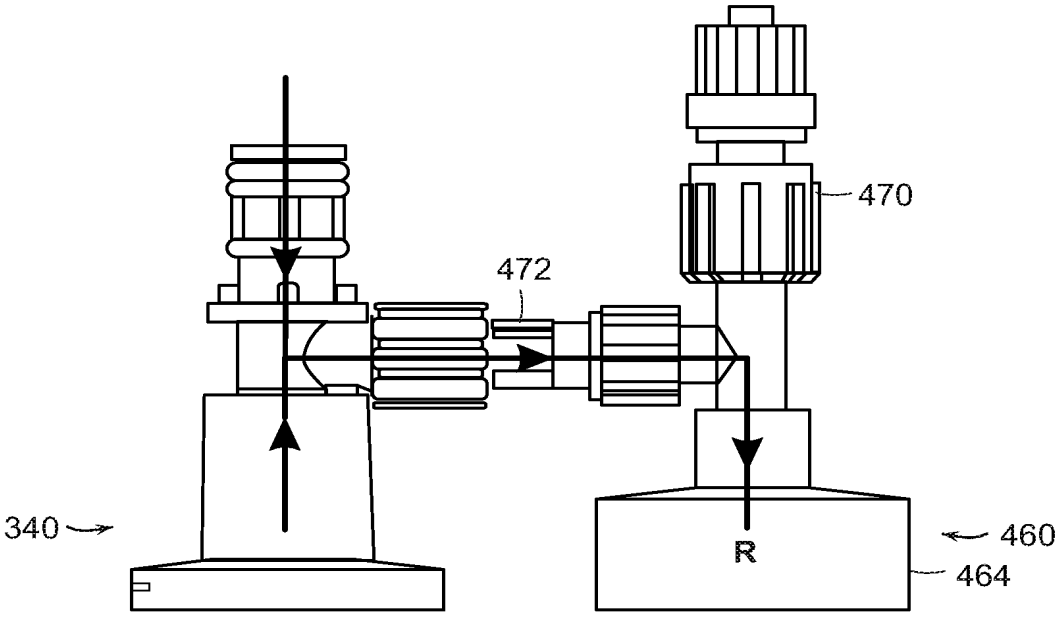


FIG. 4B

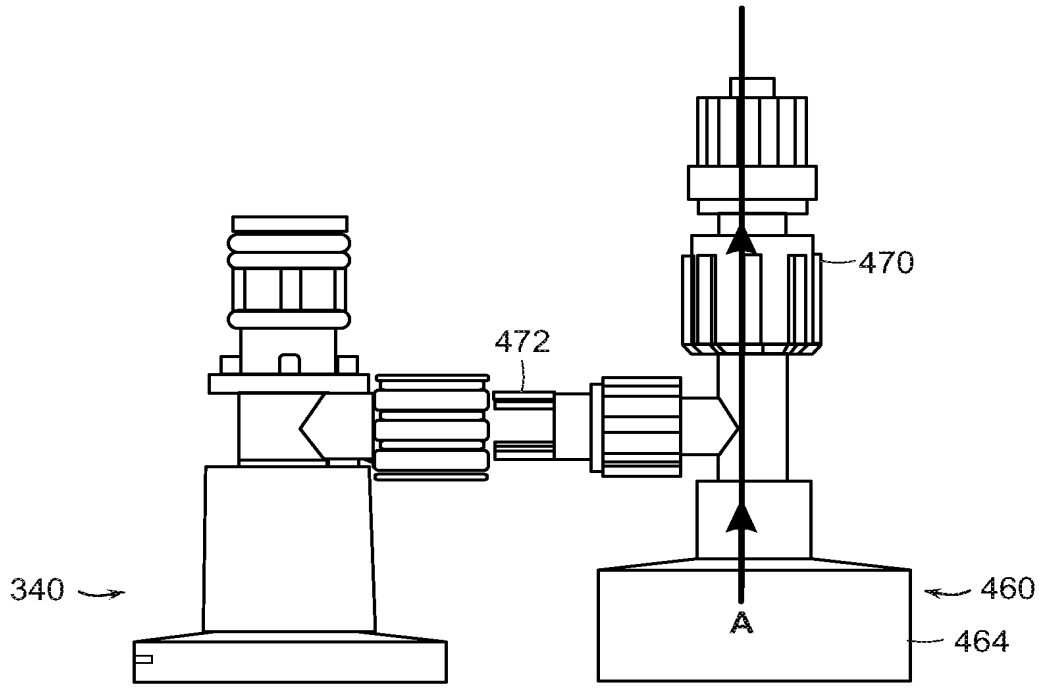


FIG. 4C

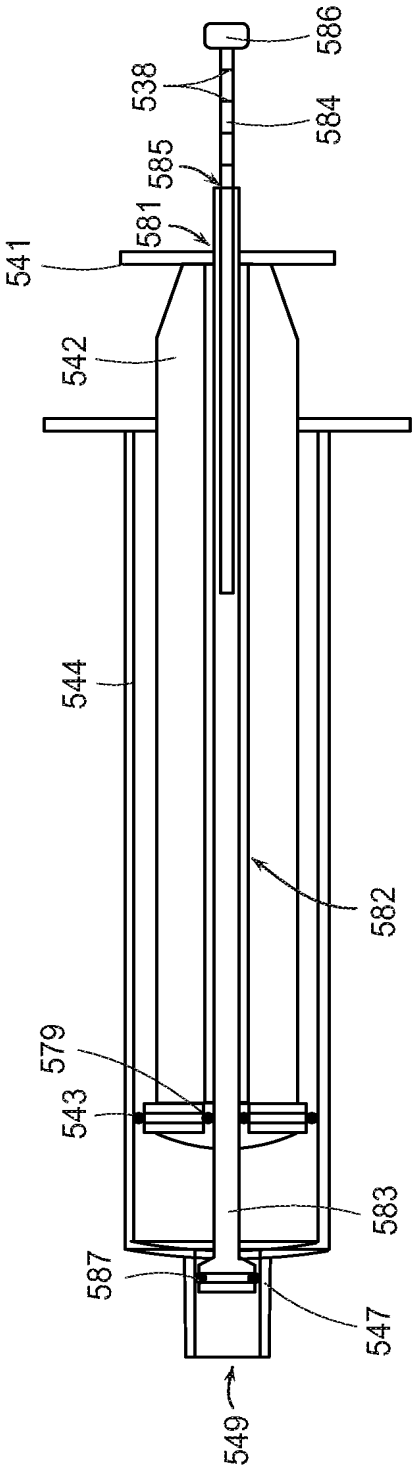


FIG. 5

FIG. 6

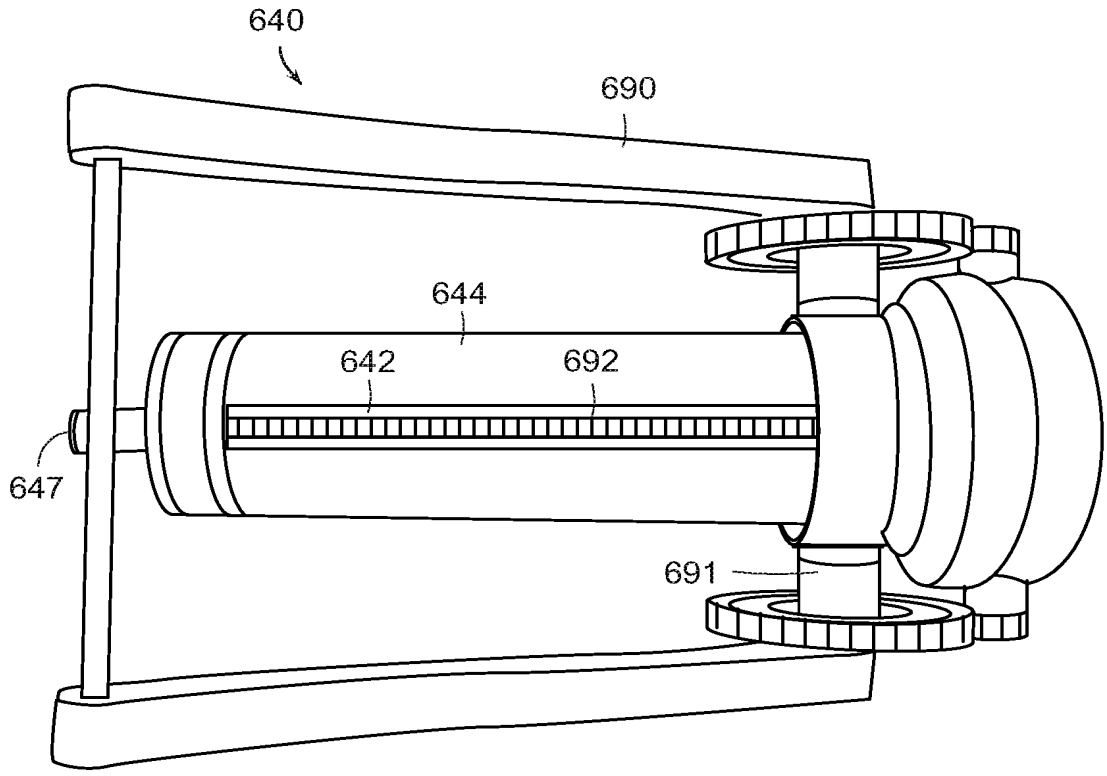
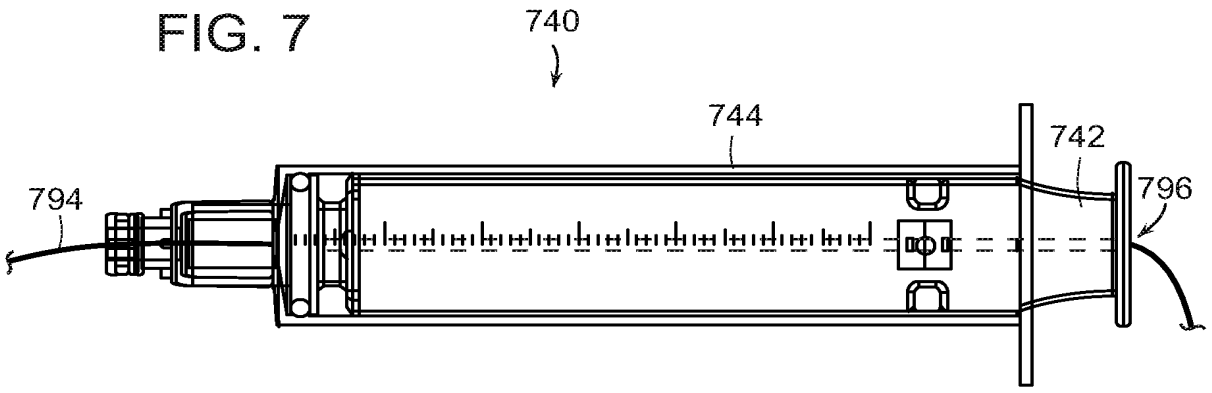


FIG. 7



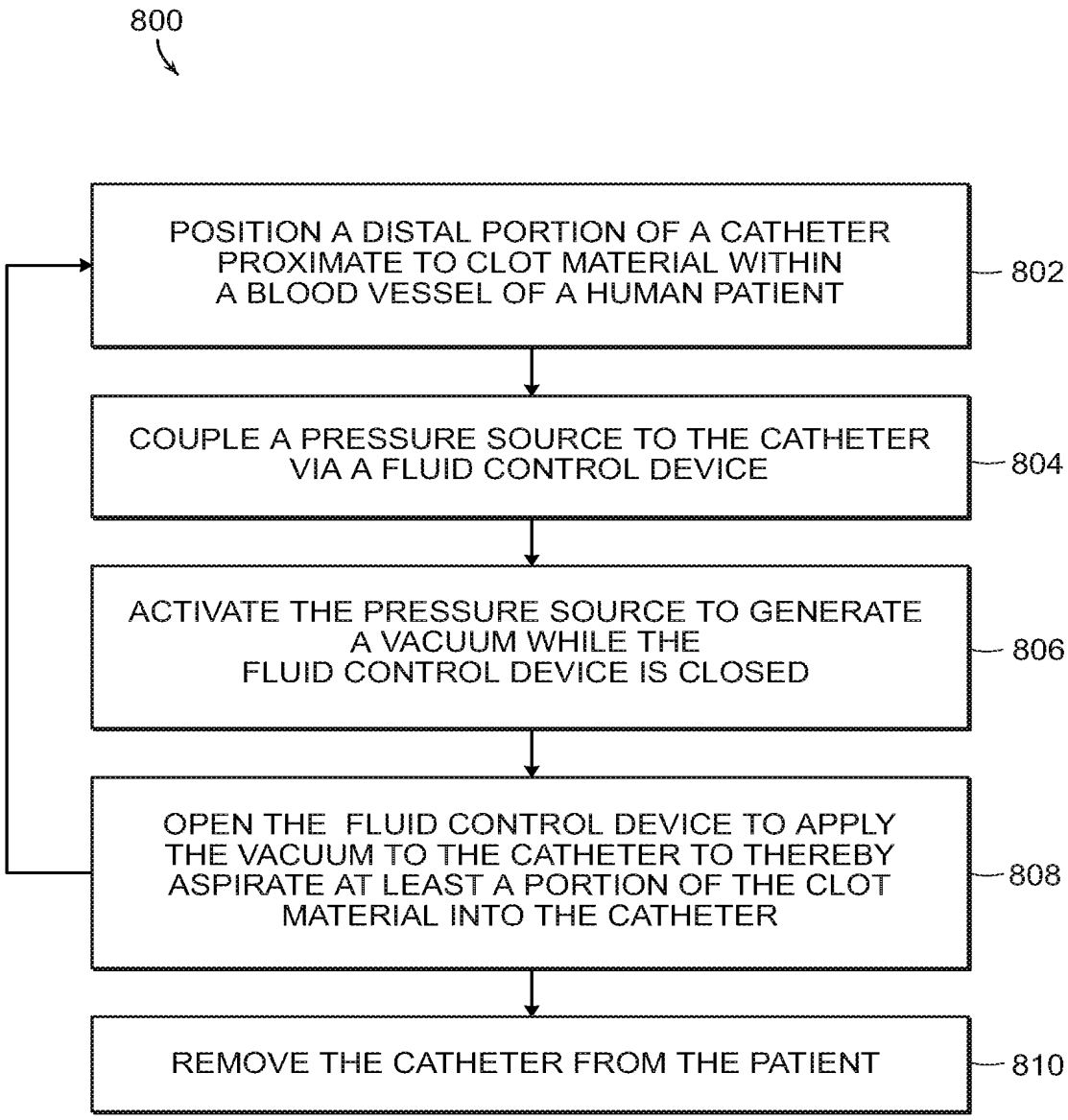

800
POSITION A DISTAL PORTION OF A CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF A HUMAN PATIENT
802
COUPLE A PRESSURE SOURCE TO THE CATHETER VIA A FLUID CONTROL DEVICE
804
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
806
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE CATHETER
808
REMOVE THE CATHETER FROM THE PATIENT
810

FIG. 8

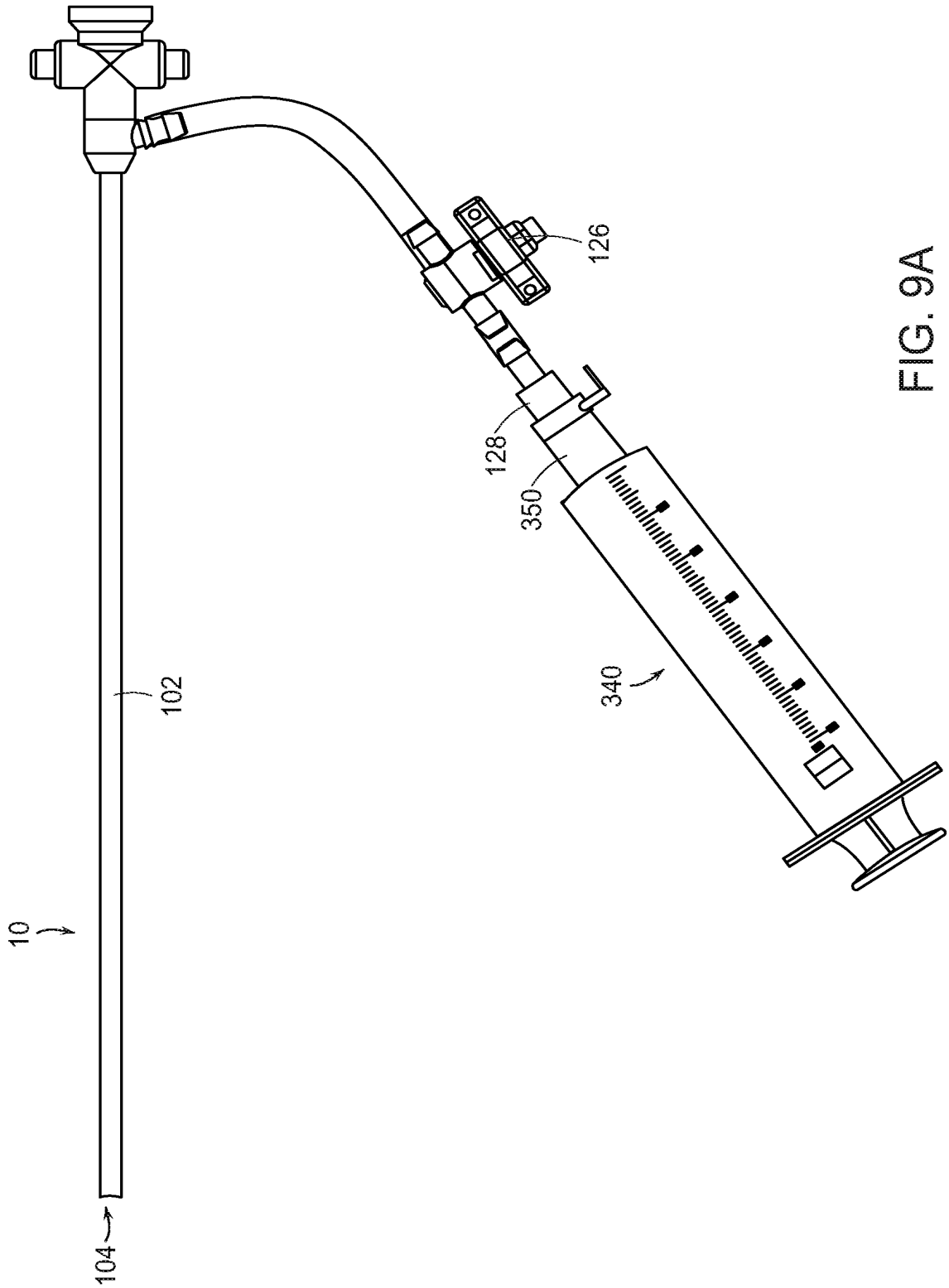


FIG. 9A

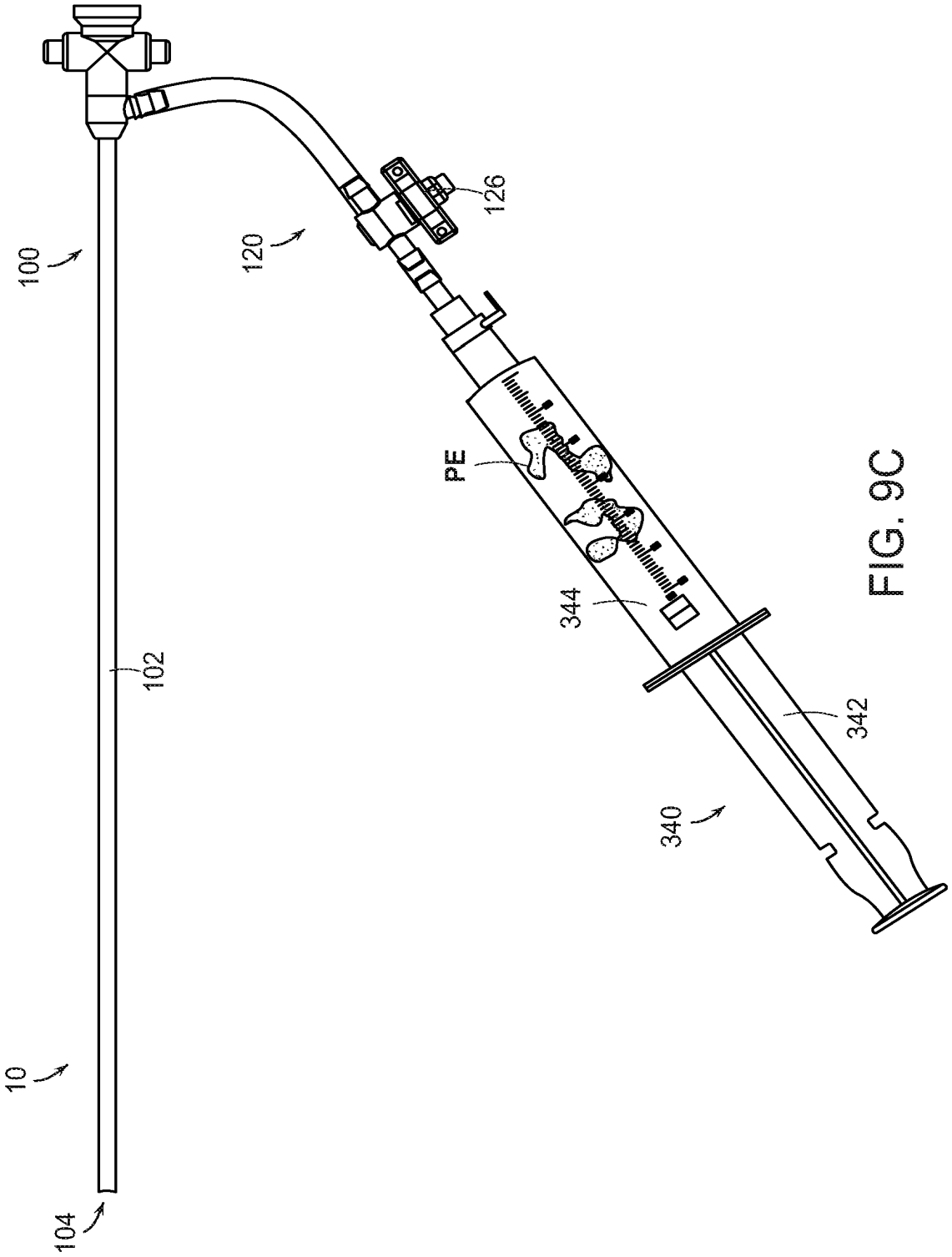


FIG. 9C

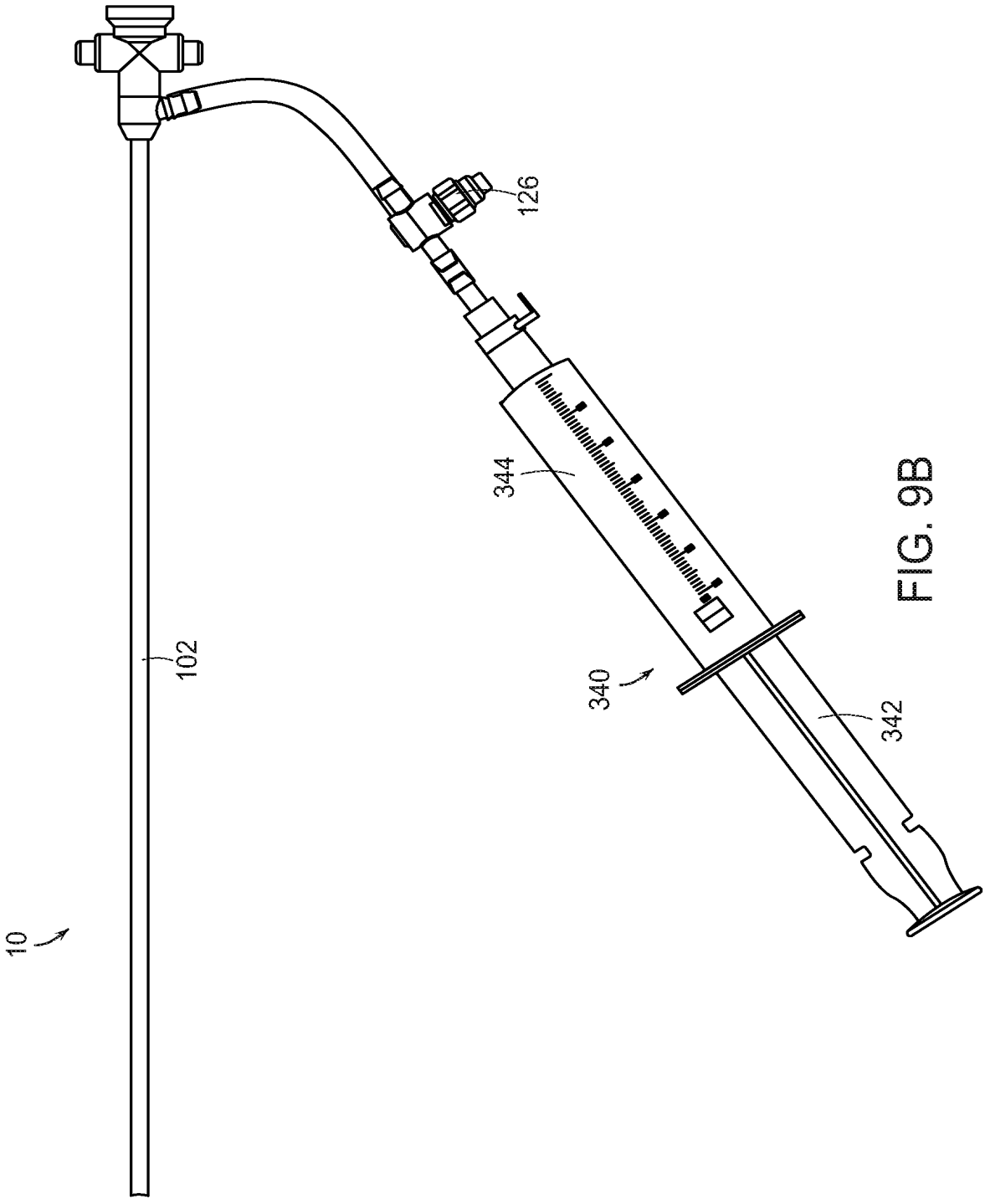


FIG. 9B

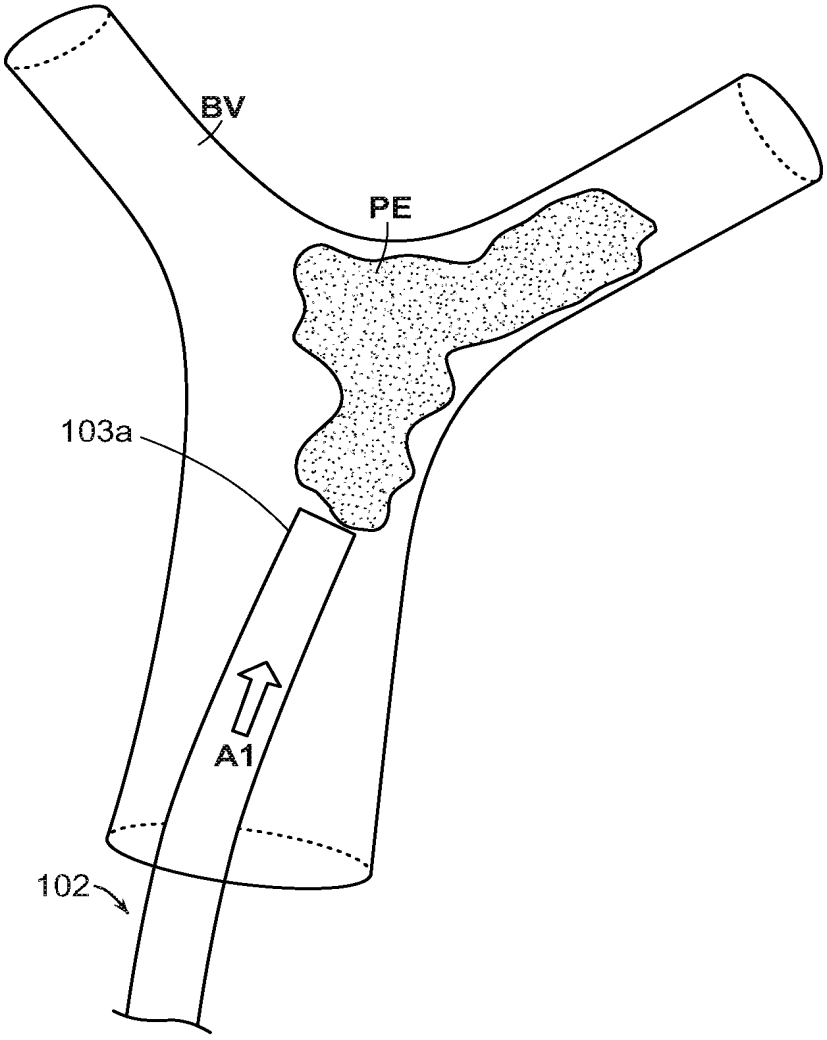


FIG. 10A

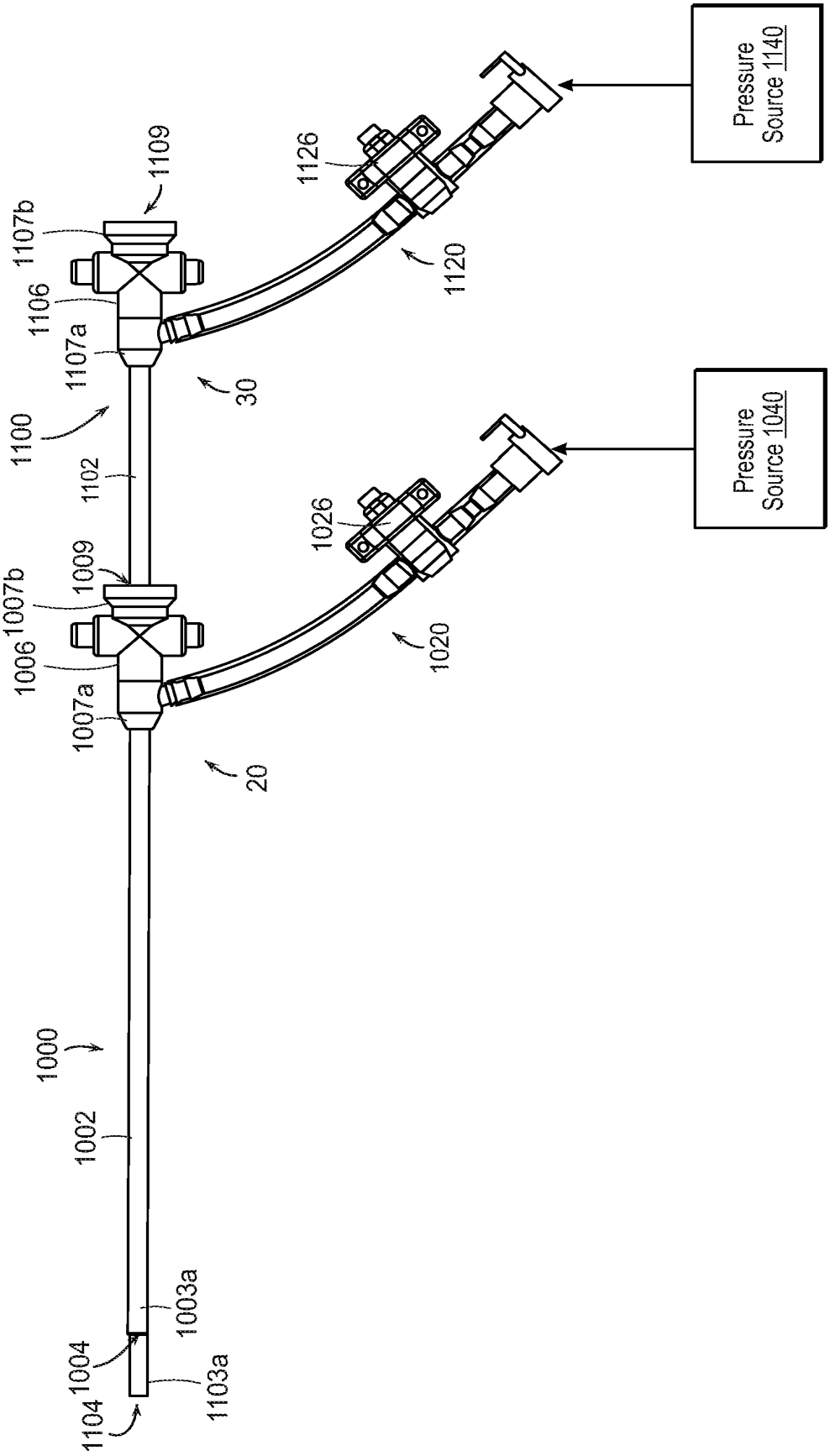

Pressure Source 1140
Pressure Source 1040
1109
1126
1107b
1106
1107a
1120
30
1100
1102
1026
1009
1007b
1006
1007a
1020
20
1000
1002
1003a
1004
1103a
1104

FIG. 11

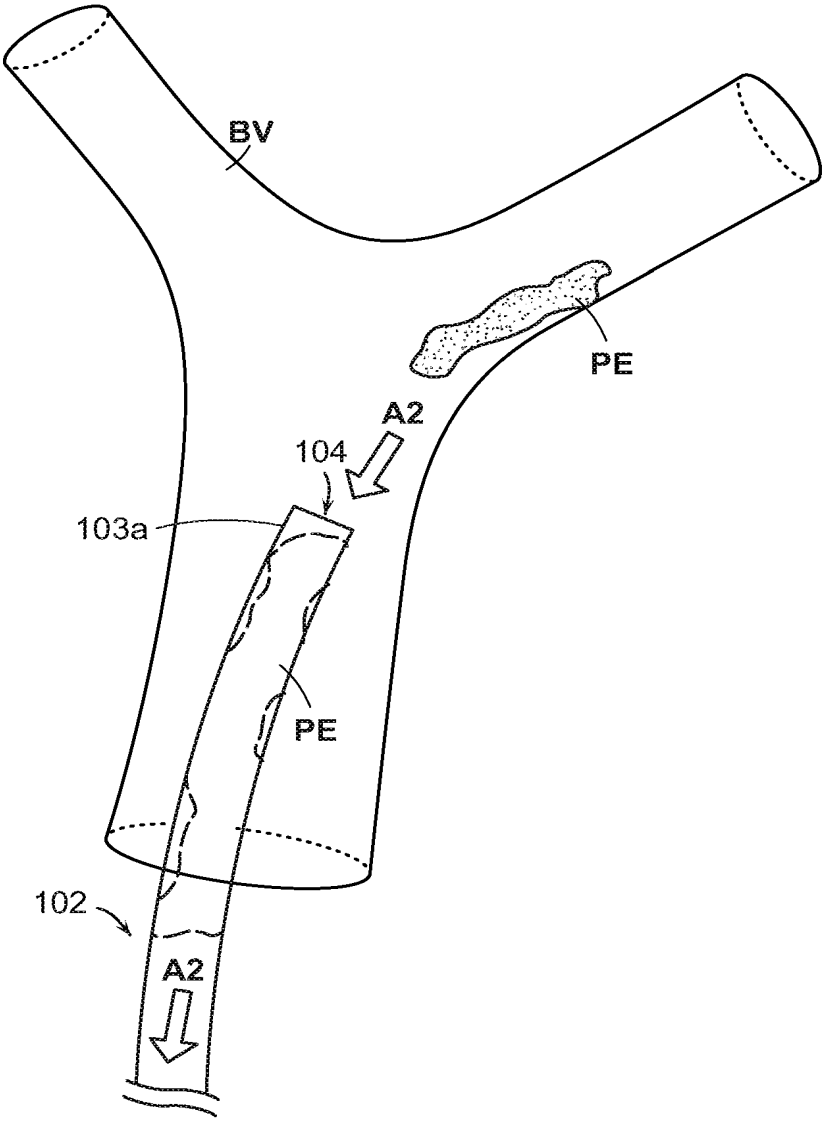


FIG. 10B

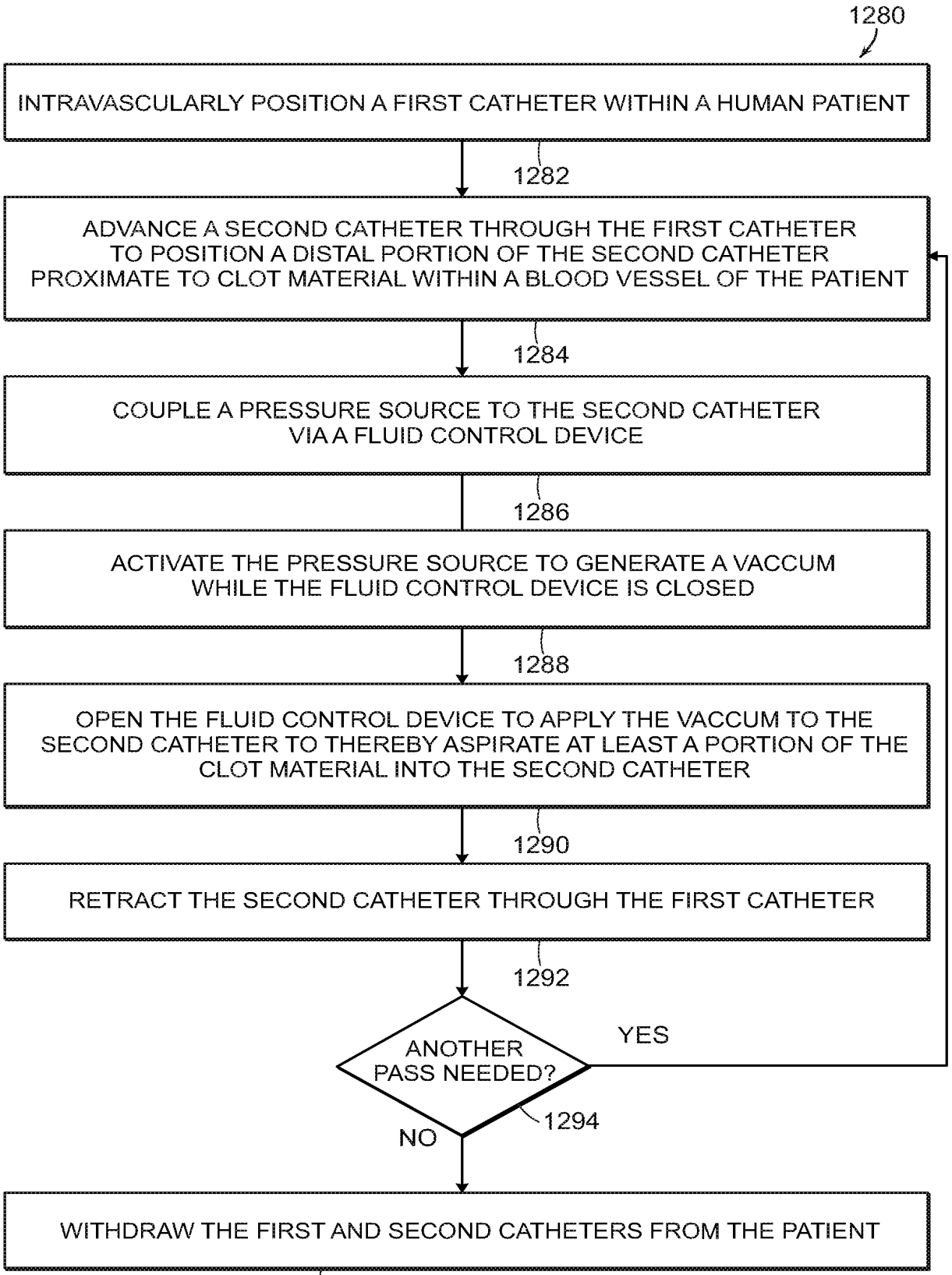

1280
INTRAVASCULARLY POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT
1282
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF THE PATIENT
1284
COUPLE A PRESSURE SOURCE TO THE SECOND CATHETER VIA A FLUID CONTROL DEVICE
1286
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACCUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
1288
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACCUM TO THE SECOND CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE SECOND CATHETER
1290
RETRACT THE SECOND CATHETER THROUGH THE FIRST CATHETER
1292
ANOTHER PASS NEEDED?
YES
1294
NO
WITHDRAW THE FIRST AND SECOND CATHETERS FROM THE PATIENT
1296

FIG. 12

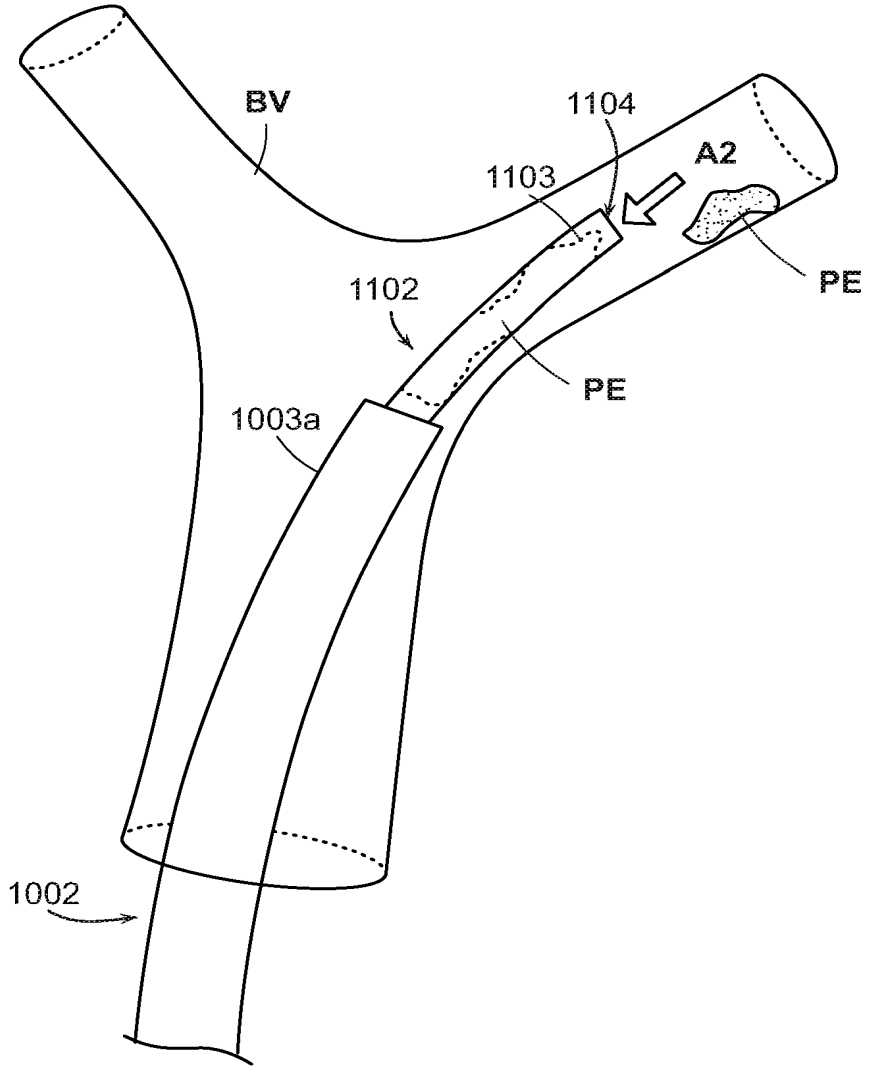


FIG. 13B

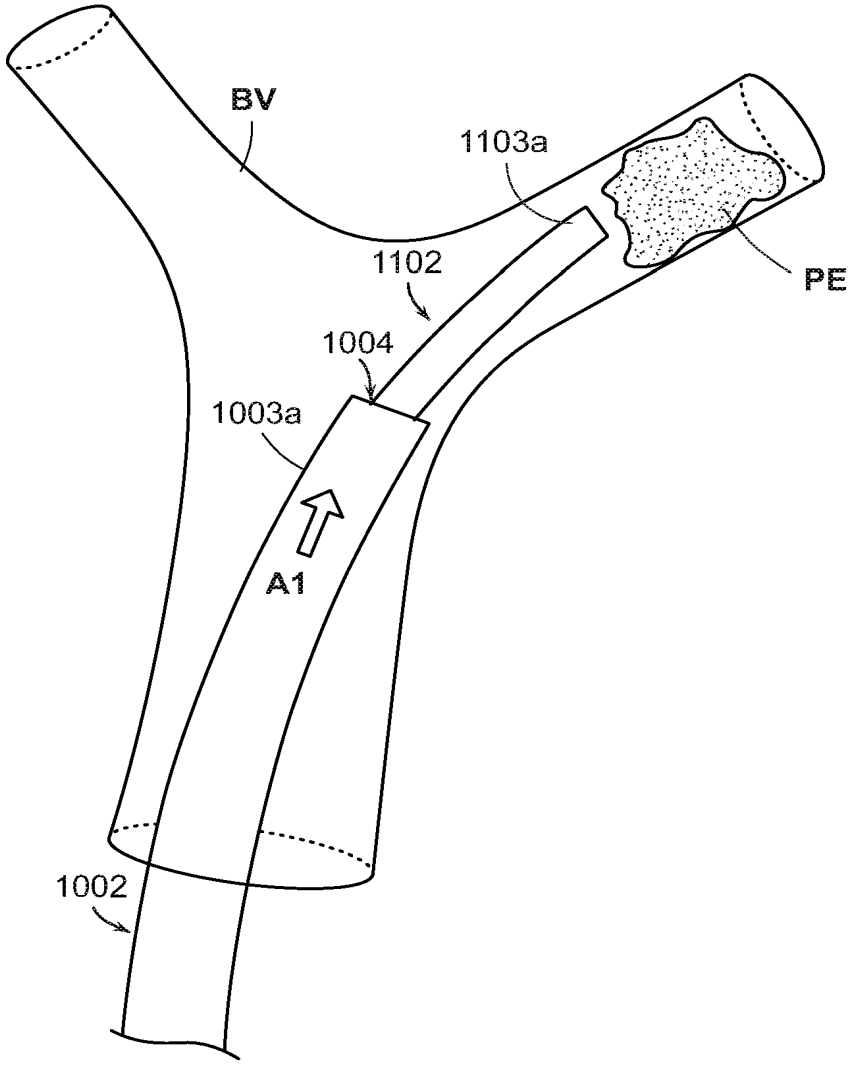


FIG. 13A

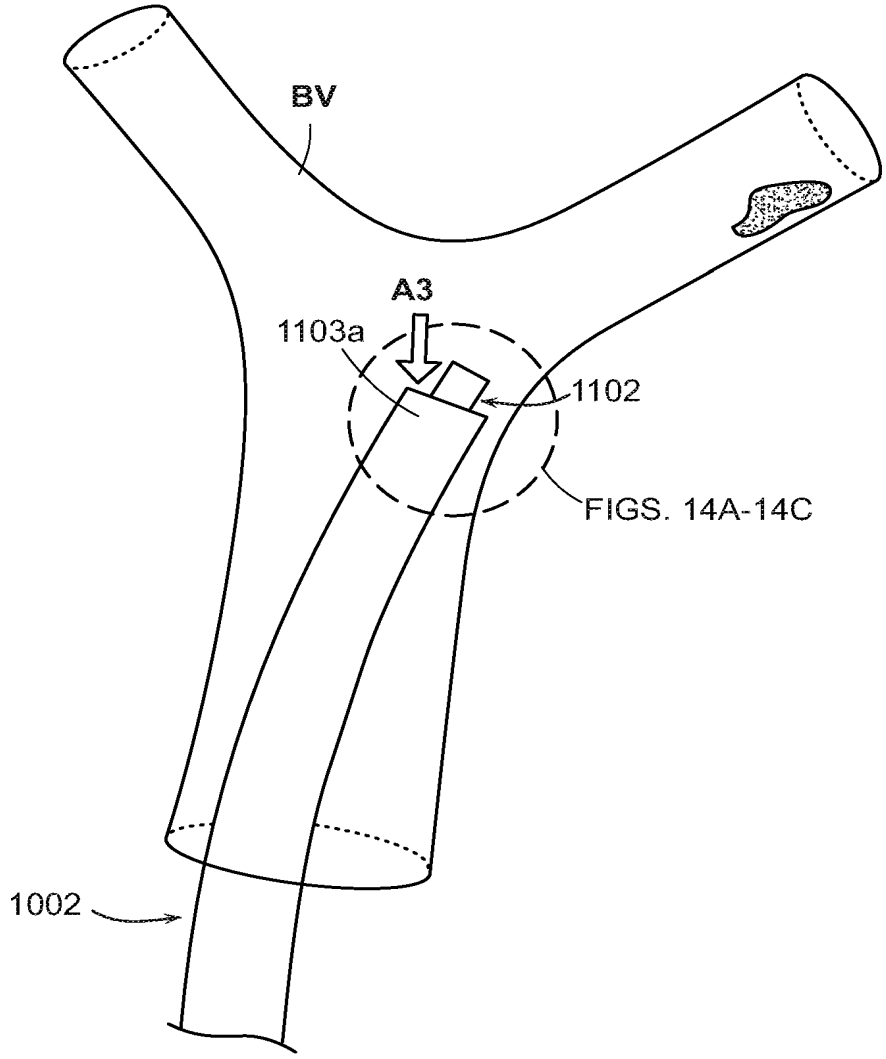


FIG. 13C

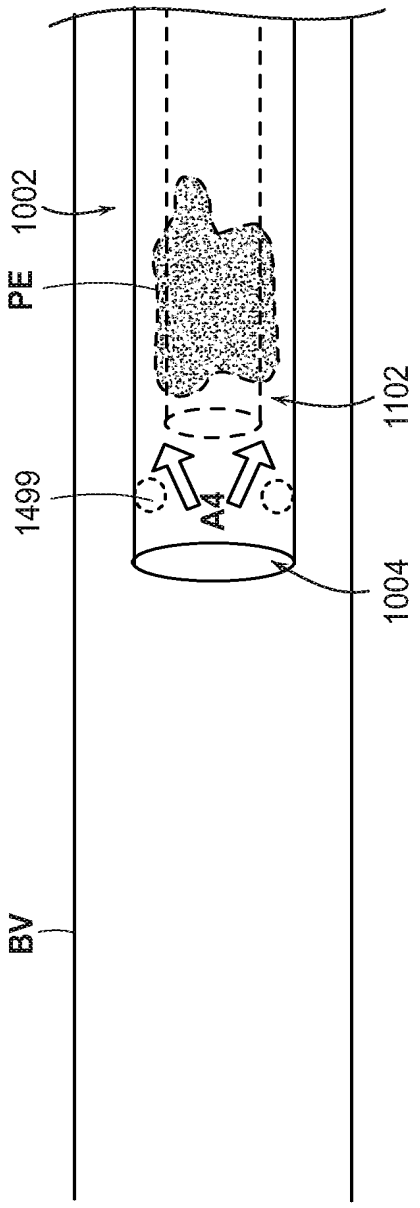


FIG. 14C

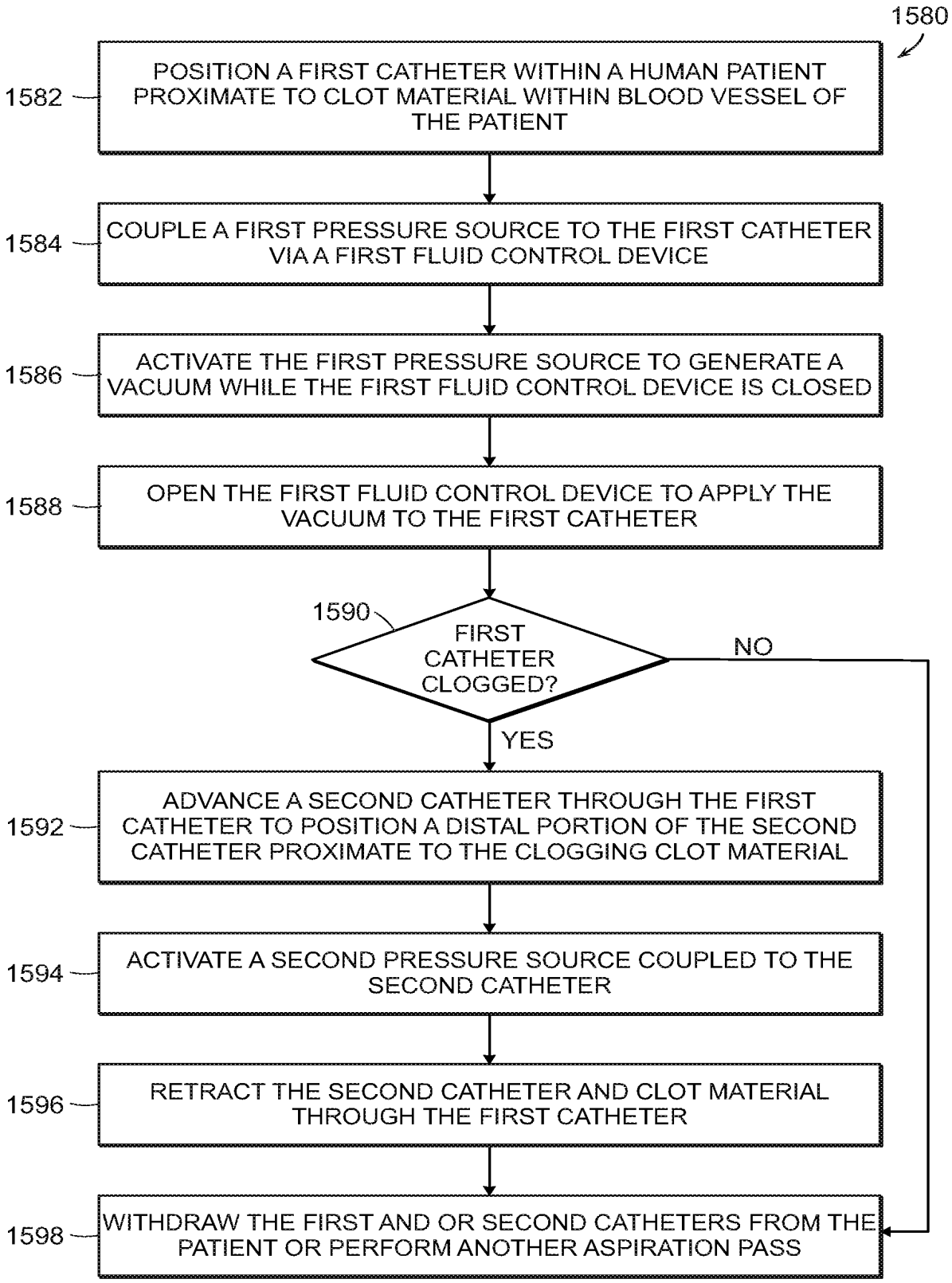

1580
1582
POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT PROXIMATE TO CLOT MATERIAL WITHIN BLOOD VESSEL OF THE PATIENT
1584
COUPLE A FIRST PRESSURE SOURCE TO THE FIRST CATHETER VIA A FIRST FLUID CONTROL DEVICE
1586
ACTIVATE THE FIRST PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FIRST FLUID CONTROL DEVICE IS CLOSED
1588
OPEN THE FIRST FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE FIRST CATHETER
1590
FIRST CATHETER CLOGGED?
NO
YES
1592
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO THE CLOGGING CLOT MATERIAL
1594
ACTIVATE A SECOND PRESSURE SOURCE COUPLED TO THE SECOND CATHETER
1596
RETRACT THE SECOND CATHETER AND CLOT MATERIAL THROUGH THE FIRST CATHETER
1598
WITHDRAW THE FIRST AND OR SECOND CATHETERS FROM THE PATIENT OR PERFORM ANOTHER ASPIRATION PASS

FIG. 15

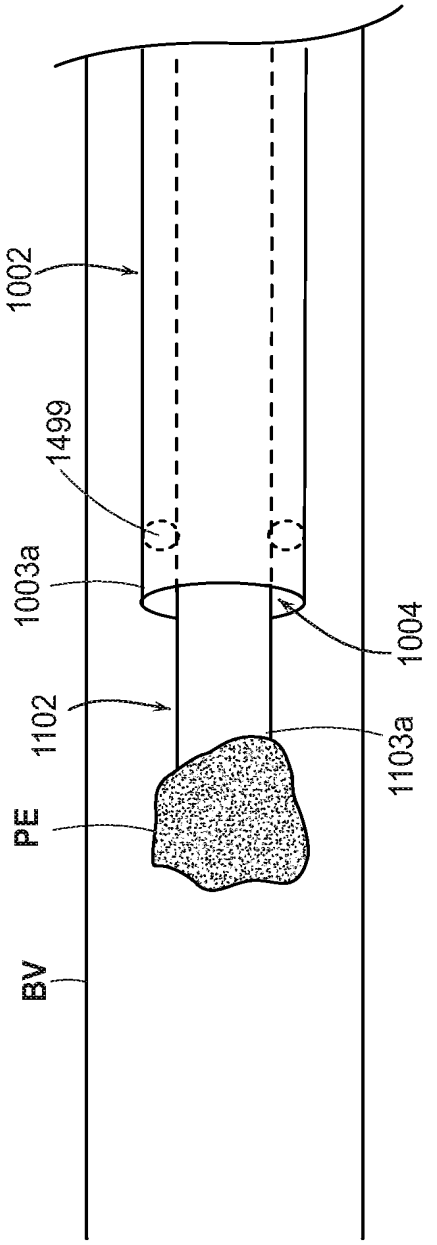


FIG. 14A

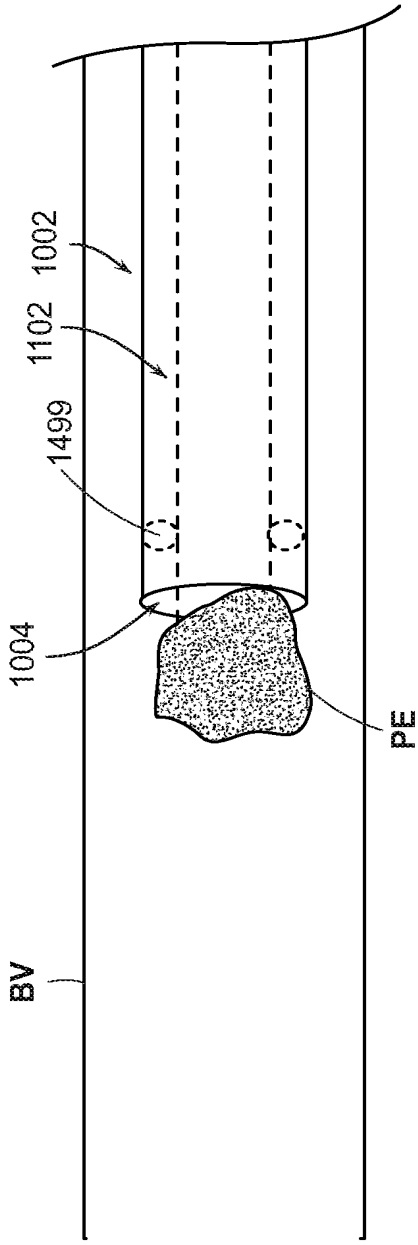


FIG. 14B

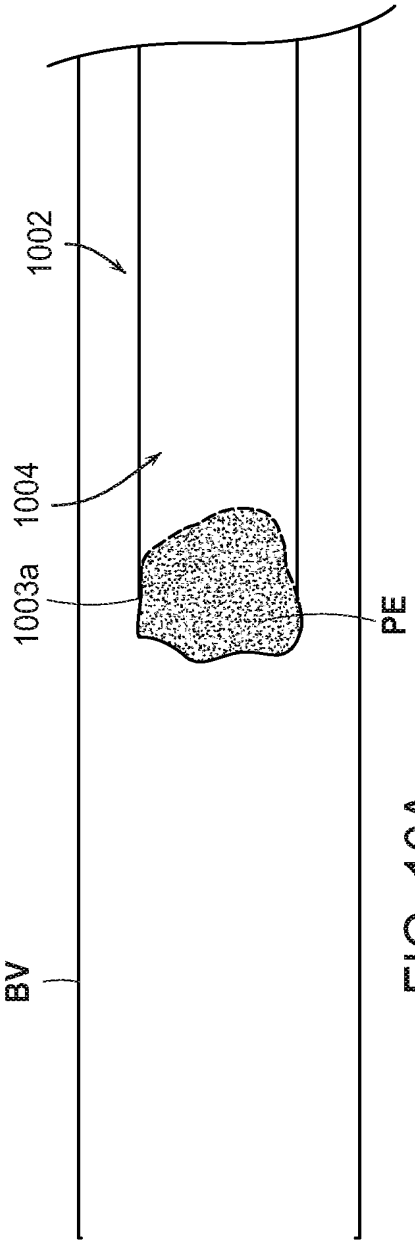


FIG. 16A

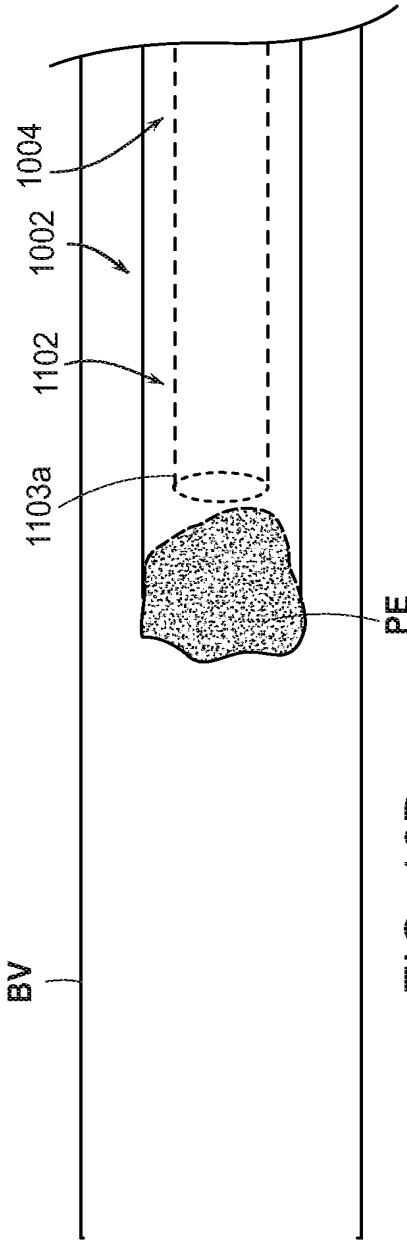


FIG. 16B

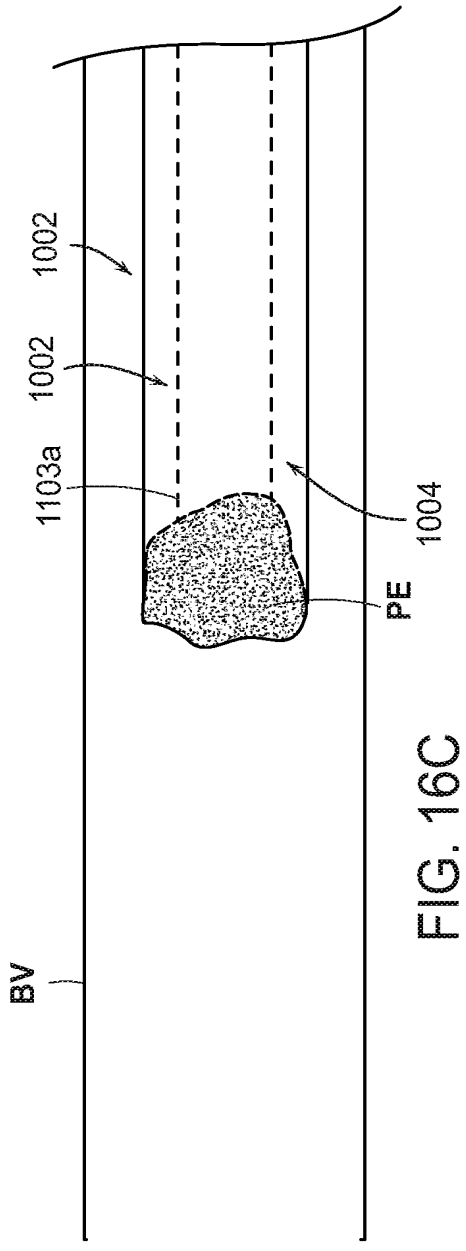


FIG. 16C

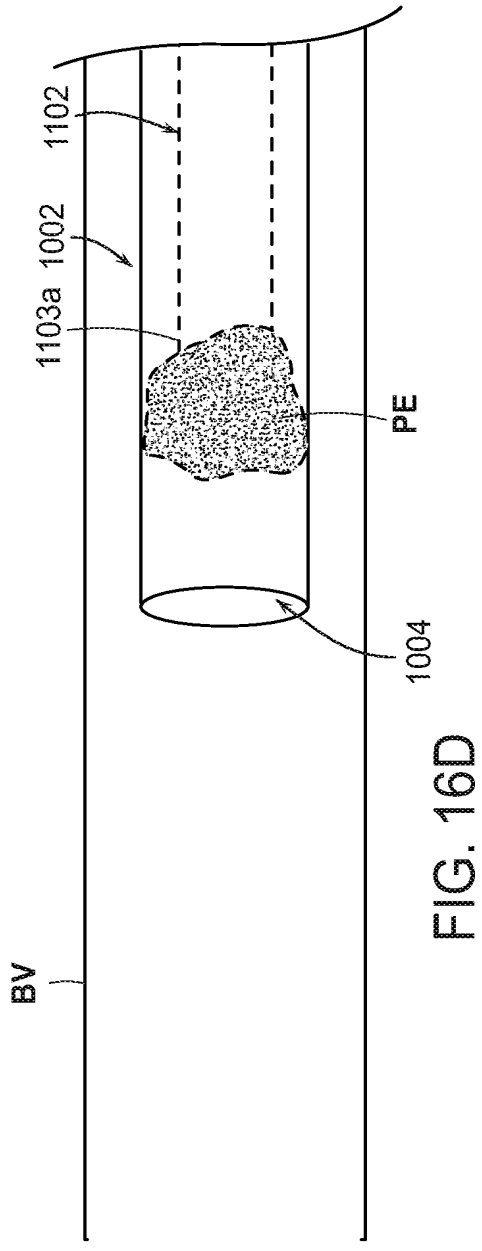


FIG. 16D

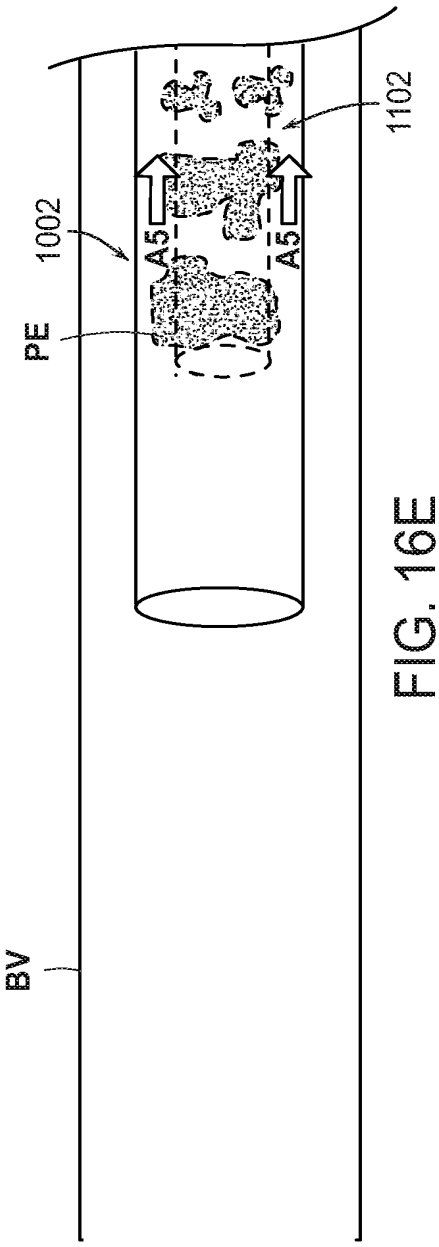


FIG. 16E

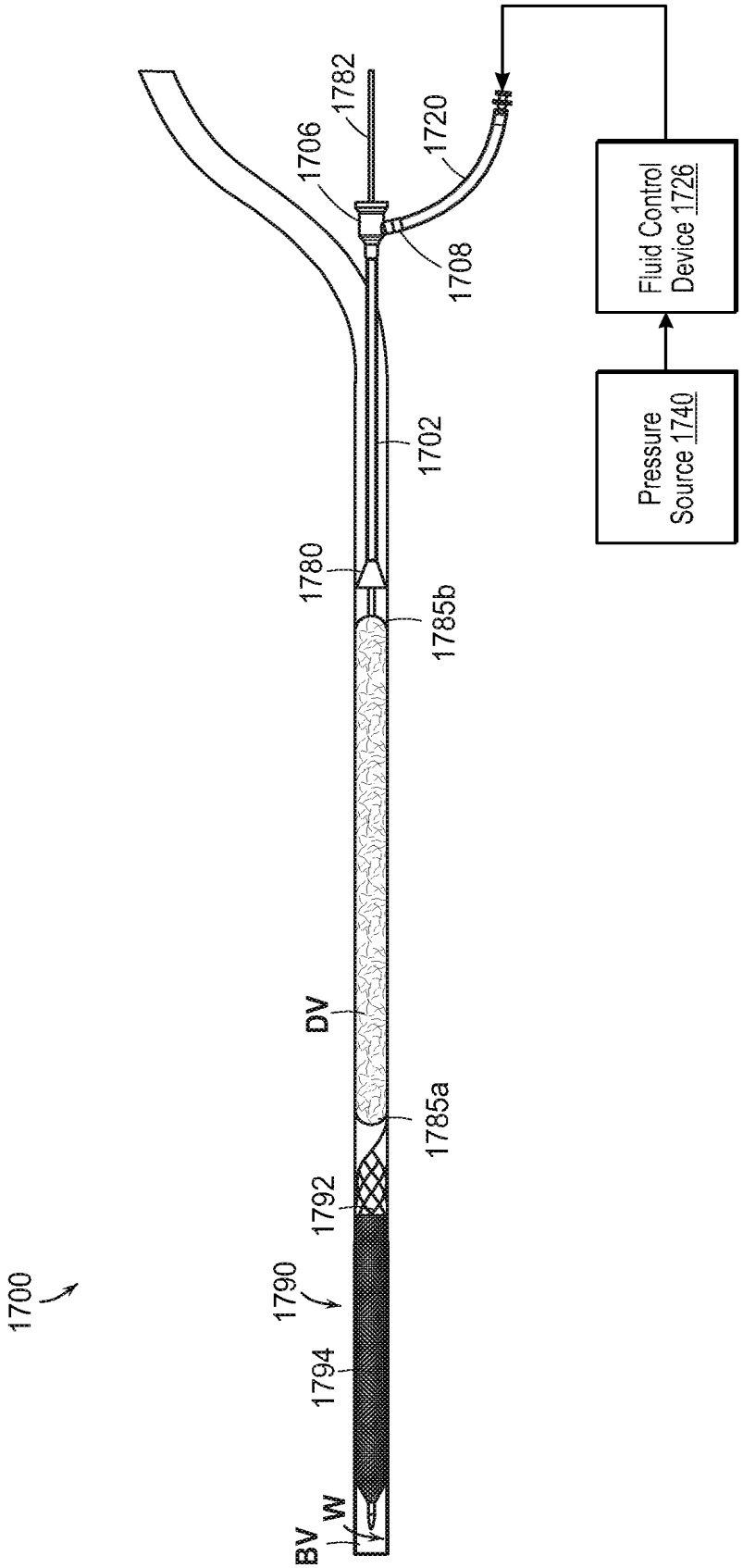

1700
1782
1706
1720
1708
1702
1780
1785b
DV
1785a
1792
1790
1794
BV
W
Fluid Control Device 1726
Pressure Source 1740

FIG. 17

FIG. 18A

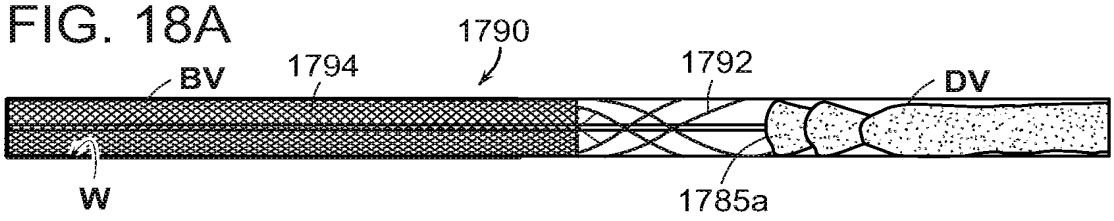


FIG. 18B

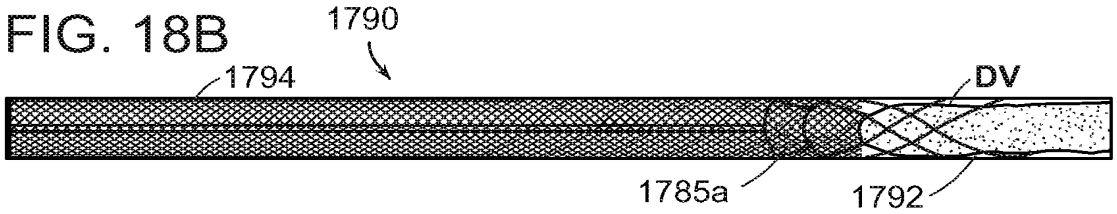


FIG. 18C

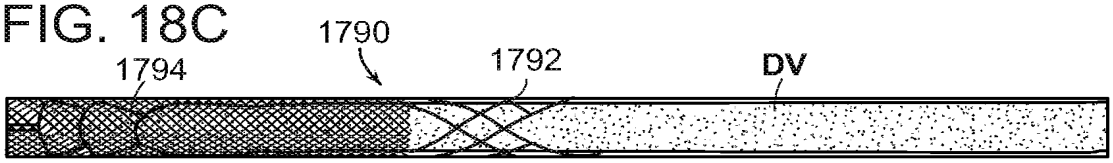


FIG. 18D

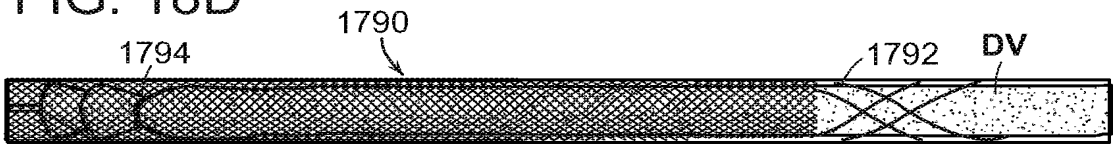


FIG. 18E

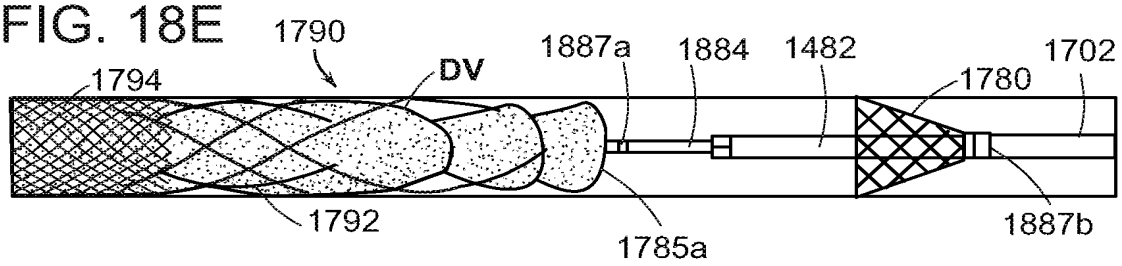


FIG. 18F

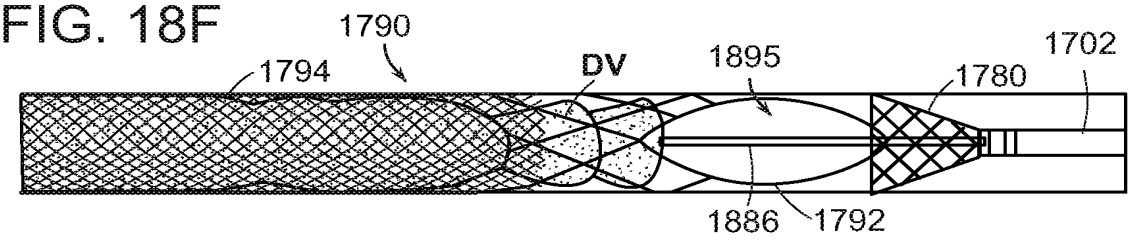


FIG. 18G

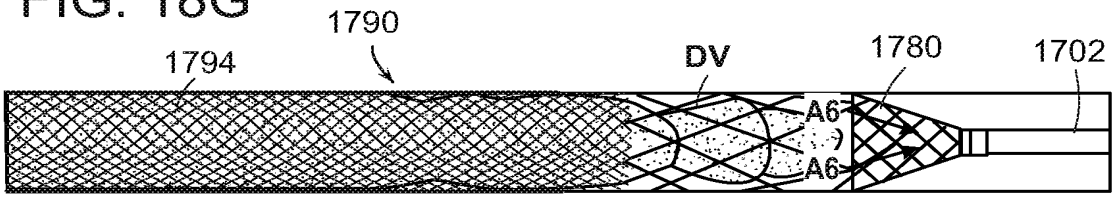
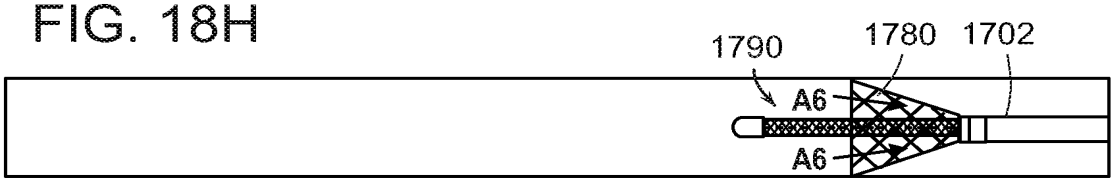


FIG. 18H



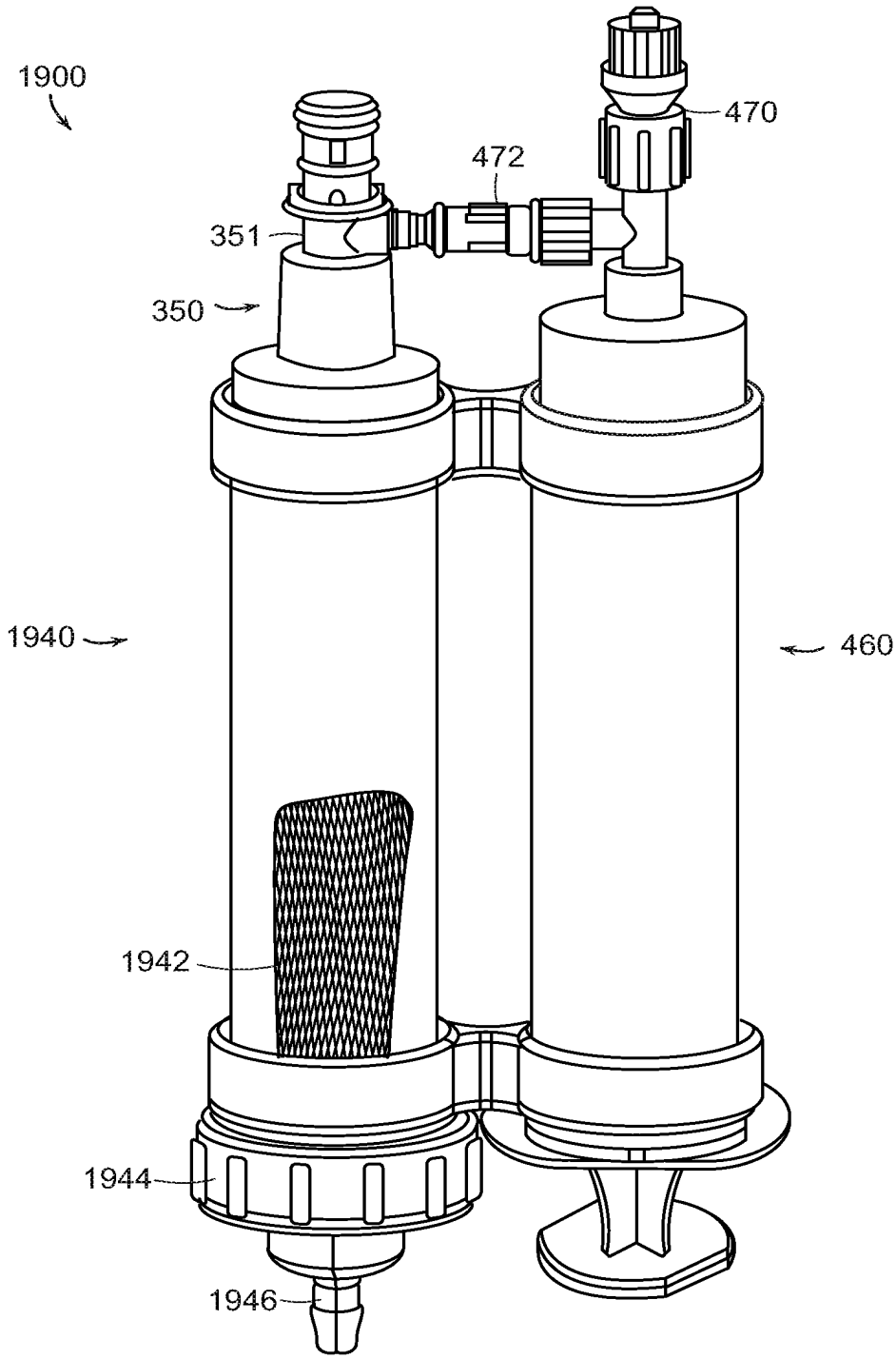


FIG. 19

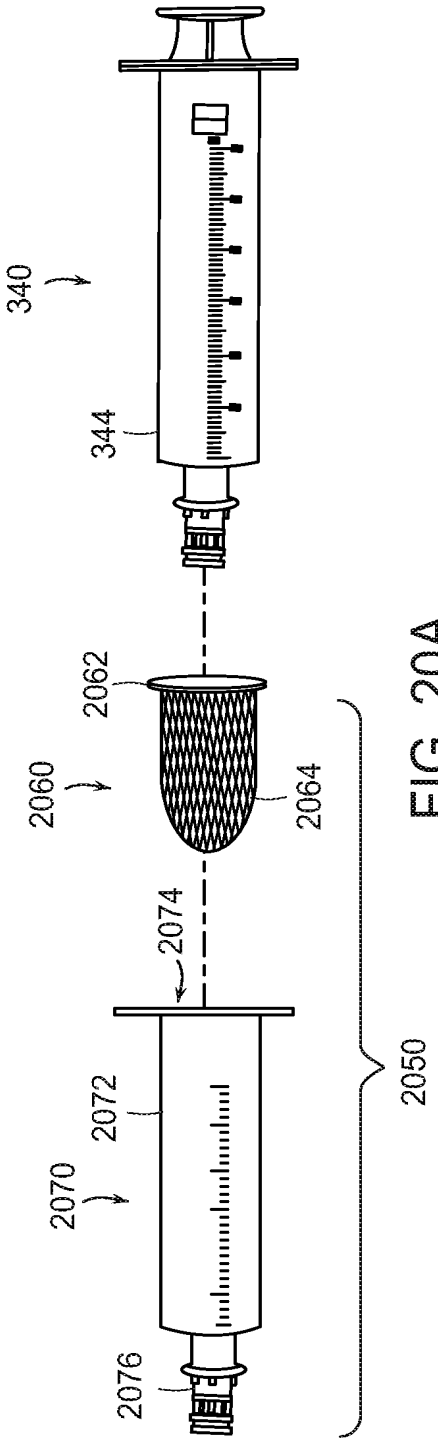


FIG. 20A

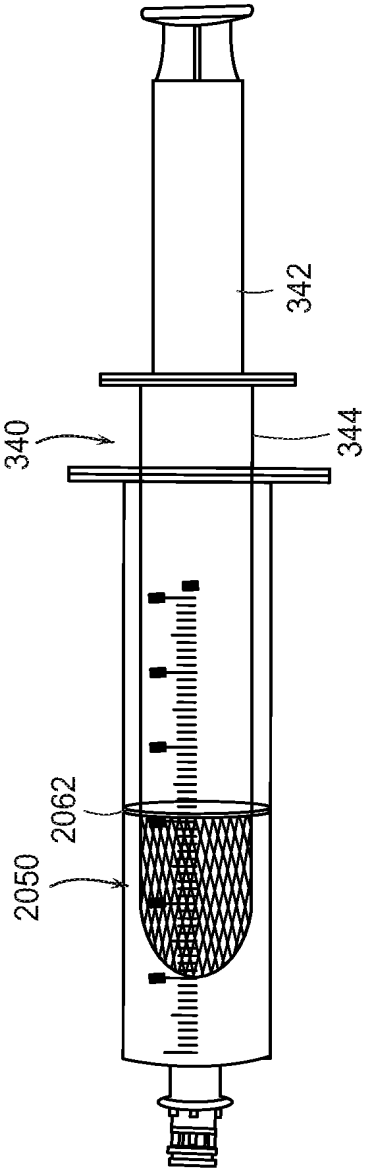


FIG. 20B

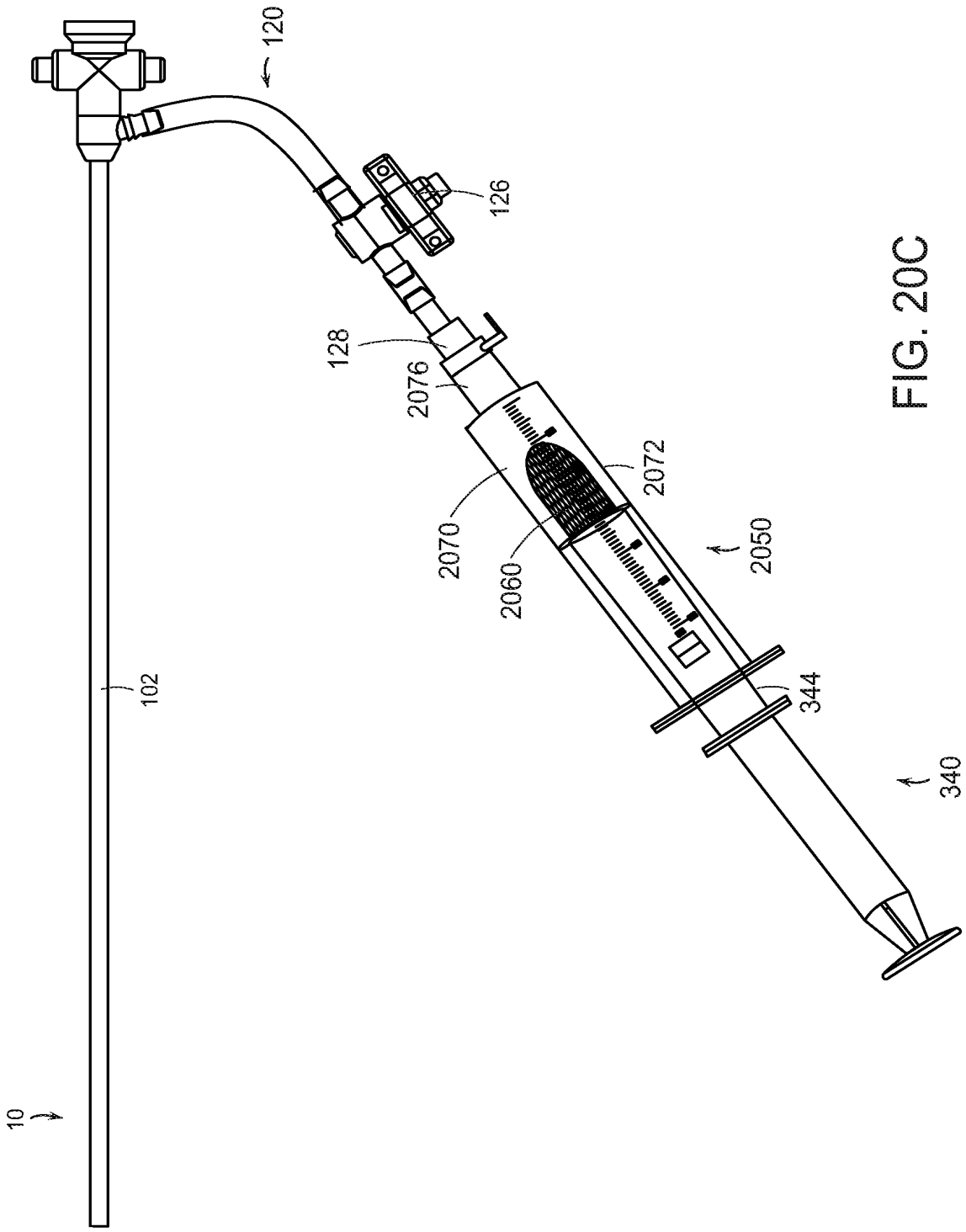


FIG. 20C

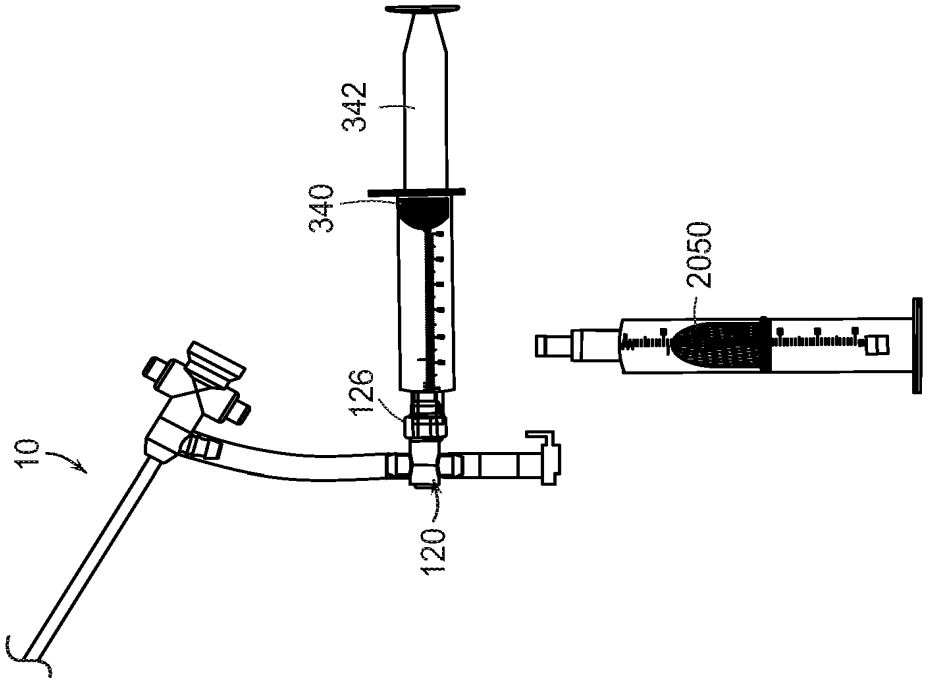


FIG. 20E

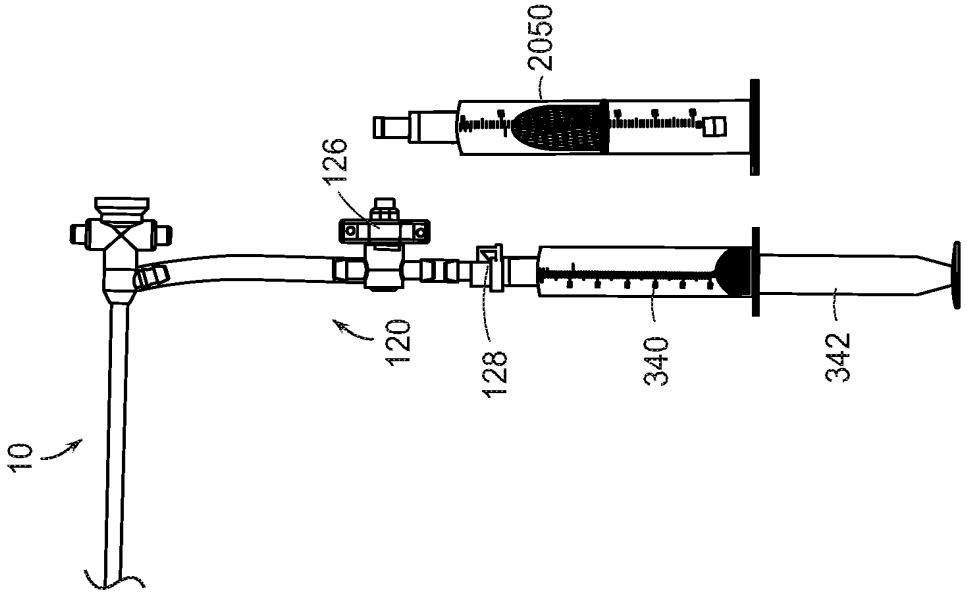


FIG. 20D

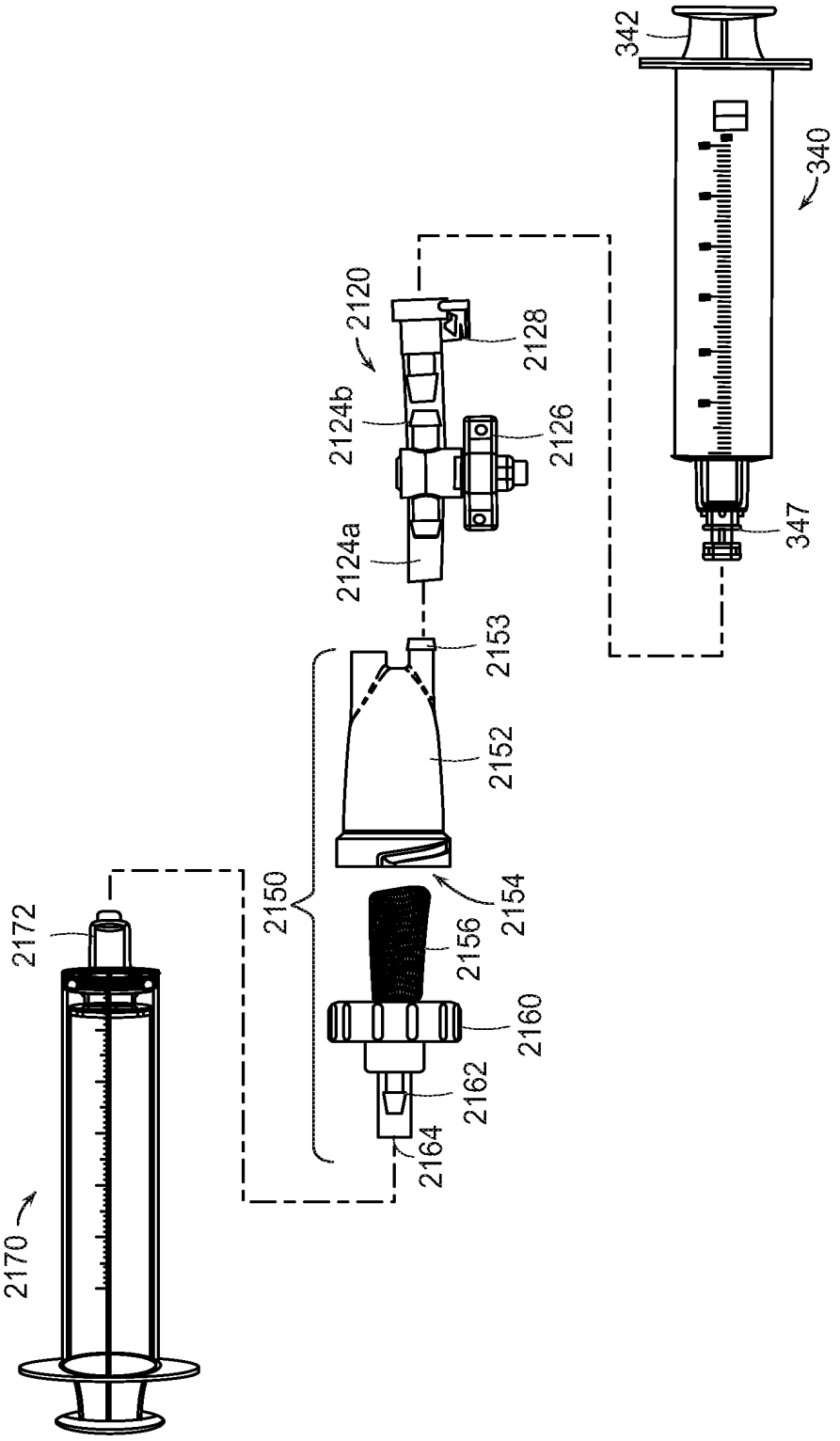

342
340
2120
2128
2124b
2126
2124a
347
2153
2152
2150
2154
2156
2160
2162
2164
2172
2170

FIG. 21A

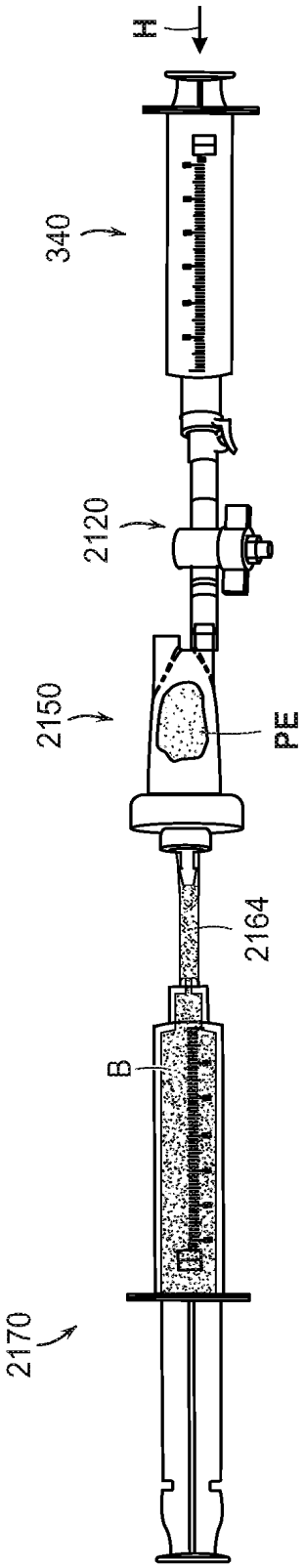


FIG. 21B

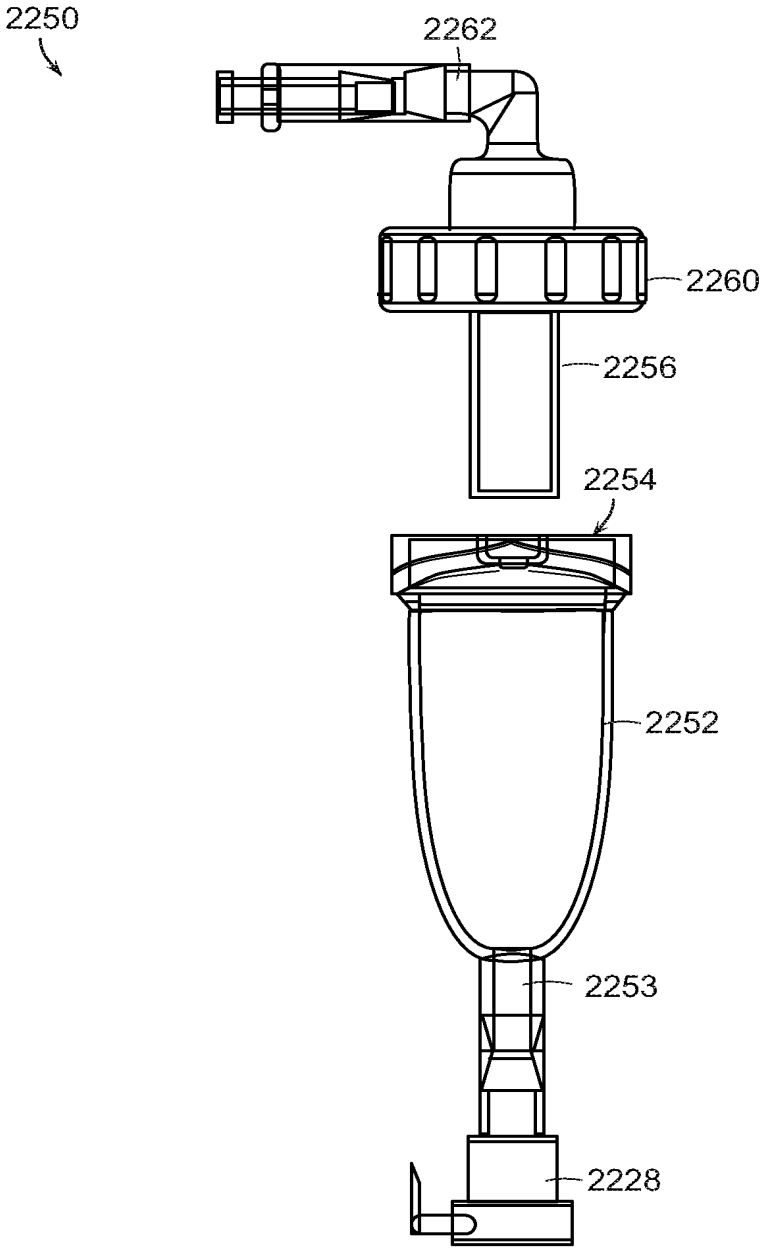


FIG. 22

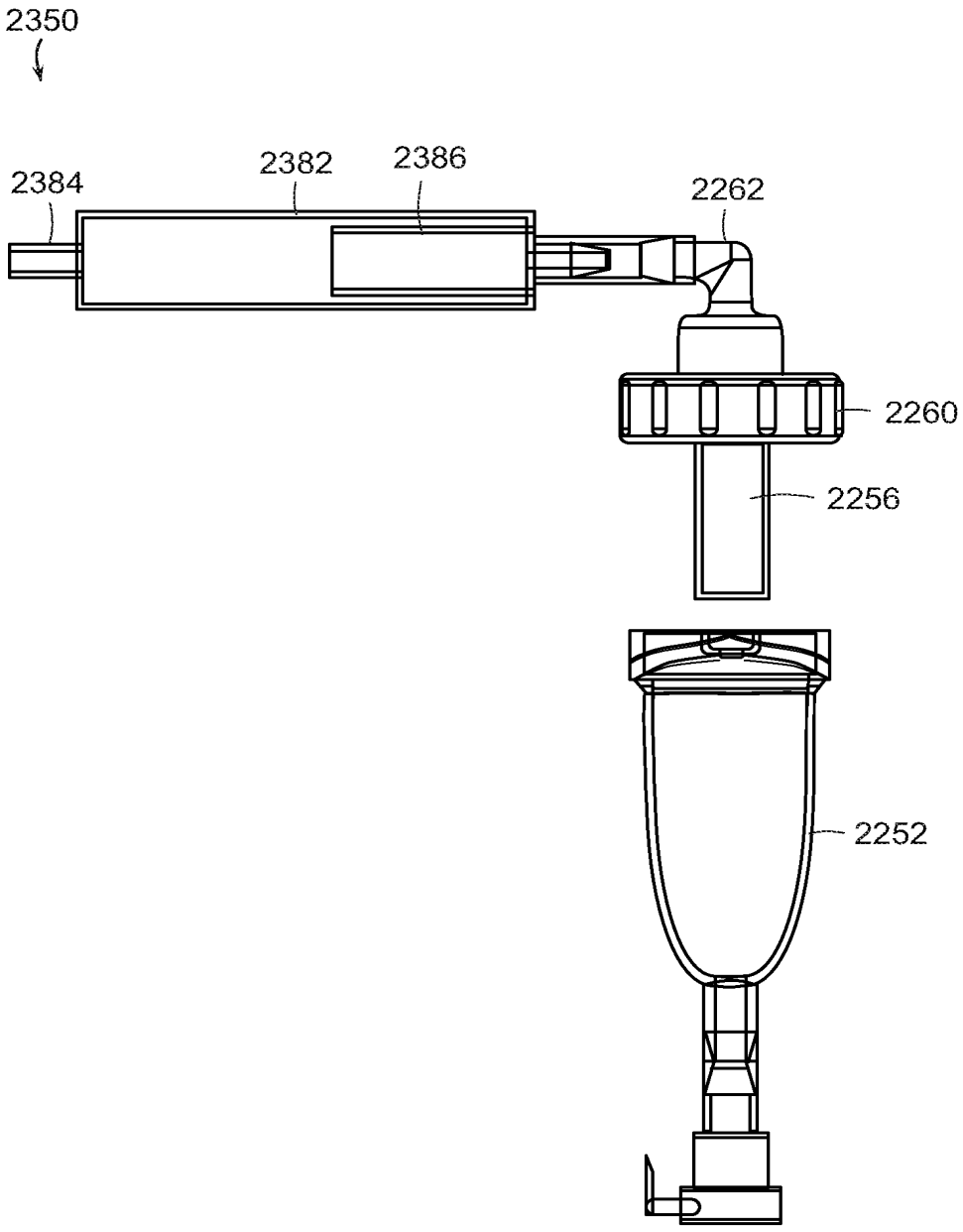


FIG. 23

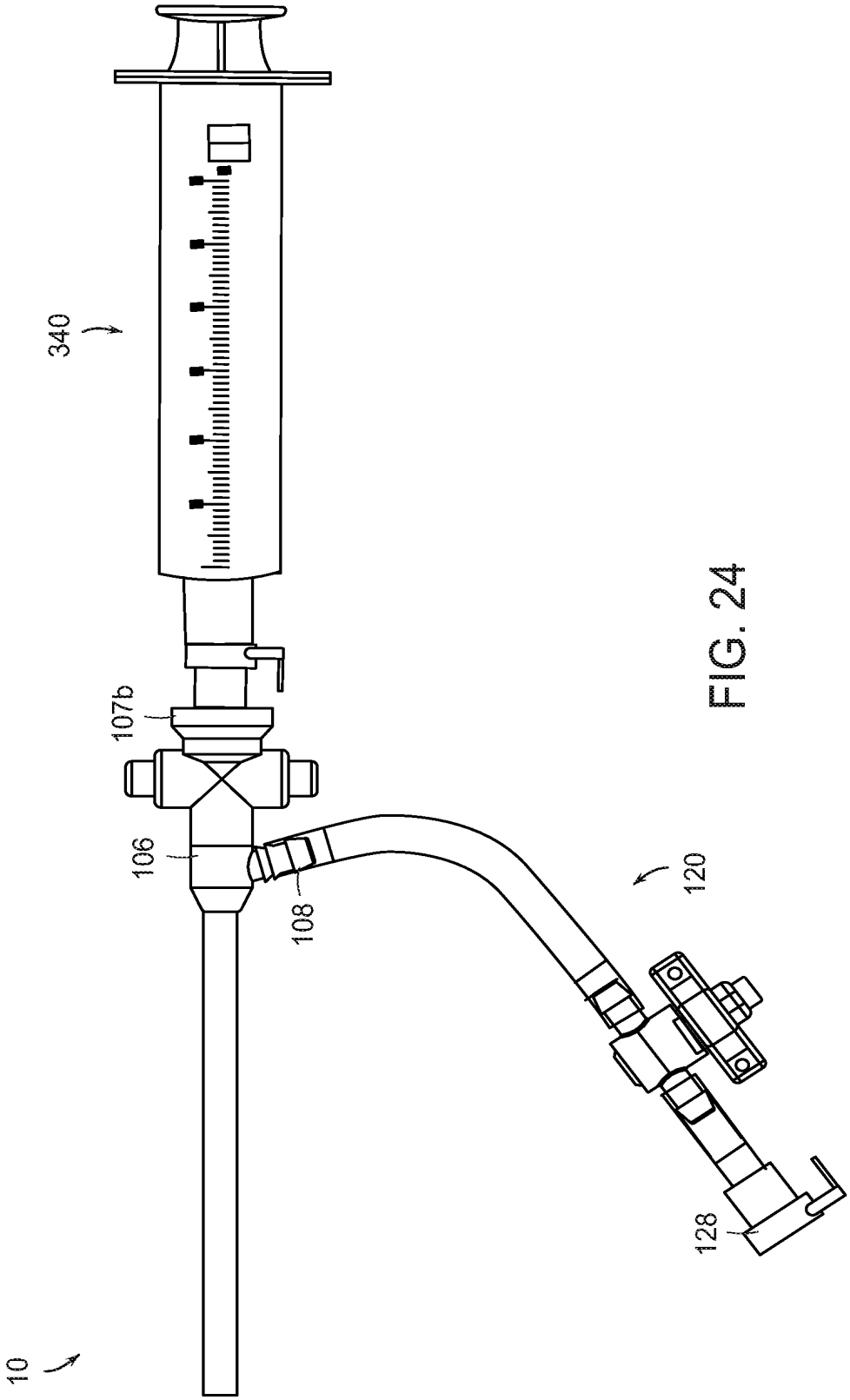


FIG. 24

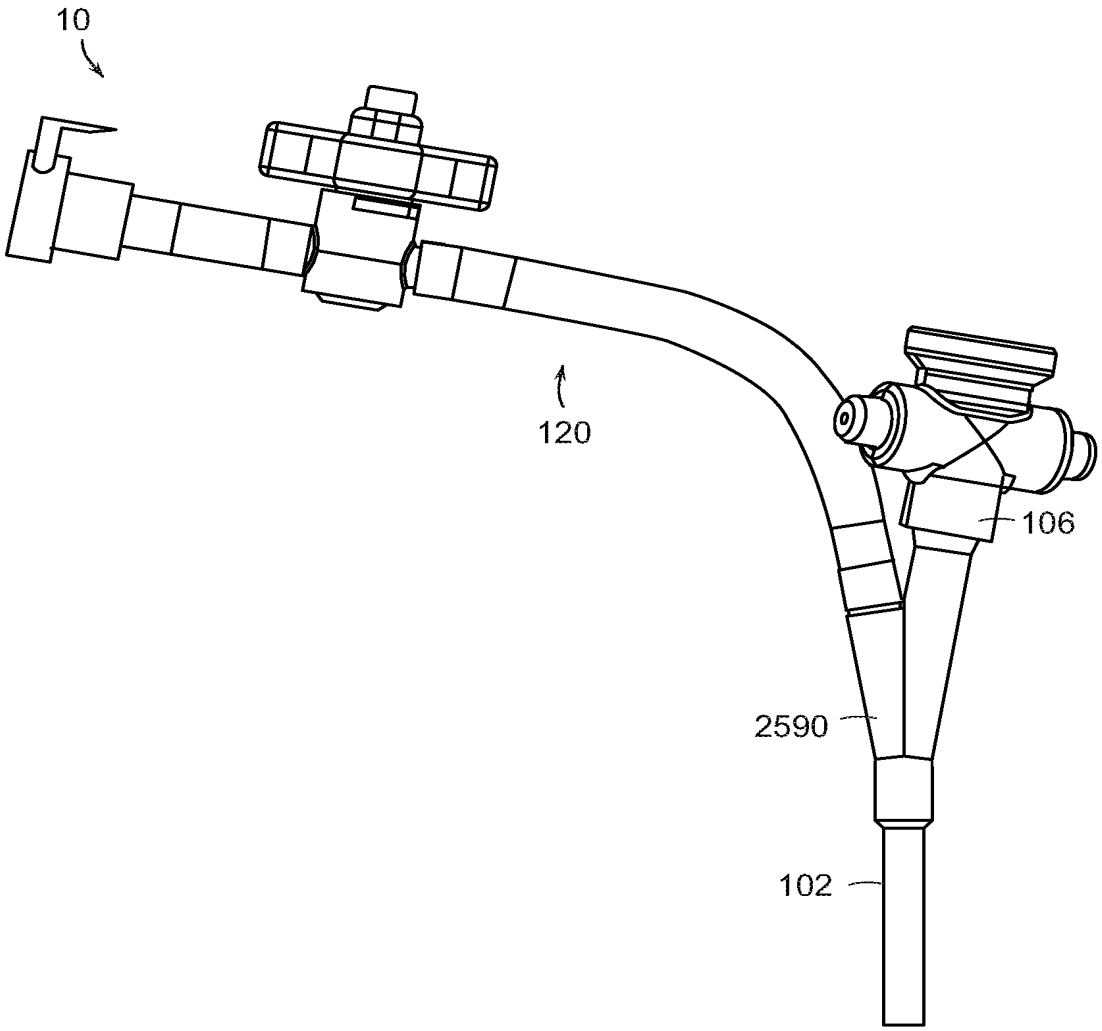


FIG. 25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/045794

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/22; A61B 17/221; A61B 17/3207; A61M 25/02; A61M 25/08; A61M 25/09 (2019.01)

CPC - A61B 17/22; A61B 17/221; A61B 2017/22034; A61B 2017/22094; A61M 25/0082; A61M 25/0155; A61M 25/10; A61M 39/22 (2019.08)

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

USPC - 606/159; 606/127; 606/191; 606/200 (keyword delimited)

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 2018/0193043 A1 (INARI MEDICAL INC) 12 July 2018 (12.07.2018) entire document	1, 12, 13, 17
---		---
Y		14
Y	CN 103932756 A (WU et al) 23 July 2014 (23.07.2014) see entire document and machine translation	14
A	US 2017/0079672 A1 (INCEPTUS MEDICAL LLC) 23 March 2017 (23.03.2017) entire document	1-34
A	US 2017/0014560 A1 (INTEGRATED SURGICAL LLC) 19 January 2017 (19.01.2017) entire document	1-34
A	US 2013/0102996 A1 (STRAUSS) 25 April 2013 (25.04.2013) entire document	1-34

☐ 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
24 September 2019	01 NOV 2019
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 PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
09 December 2021 (09.12.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/248042 A1

(51) International Patent Classification:
A61B 17/00 (2006.01) *A61M 25/10* (2013.01)
A61B 17/22 (2006.01) *A61M 1/00* (2006.01)
A61B 17/3207 (2006.01)

(21) International Application Number:
PCT/US2021/035965

(22) International Filing Date:
04 June 2021 (04.06.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/035,605 05 June 2020 (05.06.2020) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventors: **THRESS, John Coleman**; 9 Parker, Suite #100, Irvine, California 92618 (US). **MERRITT, Benjamin Edward**; 9 Parker, Suite #100, Irvine, California 92618 (US). **LOUW, Jacob F.**; 9 Parker, Suite #100, Irvine, California 92618 (US). **MACIAS, Jacqueline**; 9 Parker, Suite #100, Irvine, California 92618 (US). **STRAUSS, Brian Michael**; 9 Parker, Suite #100, Irvine, California 92618 (US). **ZOZULENKO, Marcus Ian Tambongco**; 9 Parker, Suite #100, Irvine, California 92618 (US). **ZIKRY, Christopher Andrew**; 9 Parker, Suite #100, Irvine, California 92618 (US). **IAN, Cheng Lance**; 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: RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS

Fig. 10C

(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 funnel catheter assembly includes an outer shaft and an inner shaft extending through and coaxial with the outer shaft. An expandable funnel can be coupled to a distal portion of the inner shaft. The funnel catheter assembly further includes a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position. In the first position, the outer shaft is positioned at least partially over the funnel to constrain the funnel in a compressed state. In the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can expand to an expanded state.

WO 2021/248042 A1

RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/035,605, filed June 5, 2020, and titled "RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to systems, methods, and devices for embolic protection during procedures for extracting thrombi from blood vessels of human patients.

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 partially transparent and partially cross-sectional side view of a funnel catheter assembly in accordance with embodiments of the present technology.

[0009] Figures 2A and 2B are side views of the funnel catheter assembly in a first position and a second position, respectively, in accordance with embodiments of the present technology.

[0010] Figure 3 is a side view of the funnel catheter assembly in the first position with a dilator inserted therethrough in accordance with embodiments of the present technology.

[0011] Figure 4 is a side view of the funnel catheter assembly including a non-self-expanding funnel in accordance with embodiments of the present technology.

[0012] Figures 5–8 are schematic views illustrating various thrombectomy techniques for removing a thrombus from a blood vessel of a human patient utilizing the funnel catheter assembly in accordance with embodiments of the present technology.

[0013] Figures 9A and 9B are enlarged, partially transparent side and side cross-sectional views, respectively, of a portion of a funnel catheter assembly in accordance with additional embodiments of the present technology.

[0014] Figures 10A–10C are side views of the funnel catheter assembly of Figures 9A and 9B in a sheathed position, a partially-unsheathed or intermediate position, and an unsheathed position, respectively, in accordance with embodiments of the present technology

[0015] Figure 11 is a flow diagram of a process or method for operating the funnel catheter assembly during an intravascular procedure in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0016] 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. More particularly, the present technology is directed to funnel catheter assemblies configured to provide embolic protection during a clot removal or other intravascular procedure. In some embodiments, a funnel catheter assembly includes an outer shaft and an inner shaft extending through and coaxial with the outer shaft. An expandable funnel, such as a self-expanding funnel, can be coupled to a distal portion of the inner shaft. The funnel catheter assembly further includes a control assembly operably coupled to the proximal portion of the outer shaft. The funnel catheter assembly can be actuated by an operator (e.g., a physician) to move the outer shaft between a first position and a second position. In the first position, the outer shaft is positioned at least partially over the funnel to constrain the funnel in a compressed state. In the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can expand to an expanded state. Accordingly, the funnel catheter assembly enables the funnel to be unsheathed and sheathed during an intravascular procedure via the movement of the outer shaft between the first and second positions.

[0017] In one aspect of the present technology, the control assembly is operable to compress the funnel after it has been expanded within a blood vessel of a patient. This can permit the funnel catheter assembly to be repositioned within the blood vessel without fully withdrawing the funnel catheter assembly from the patient. Similarly, the funnel catheter assembly can be fully withdrawn from the patient (e.g., at the conclusion of a thrombectomy procedure) in the first position with the funnel compressed inside the outer shaft. Thus, the funnel catheter assembly is configured to inhibit or even prevent the funnel from contacting the wall of the blood vessel during movement of the funnel catheter assembly within the blood vessel. This can help inhibit injury/damage to the patient that could otherwise be caused by the moving the funnel through a blood vessel or an associated organ in the expanded state.

[0018] 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, etc.). 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, 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 1–11 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 1–11 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 1–11.

[0019] 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 of the present technology can be used in any orientation suitable to the user.

[0020] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Funnel Catheter Assemblies

[0021] Figure 1 is a partially transparent and partially cross-sectional side view of a funnel catheter assembly 100 in accordance with embodiments of the present technology. In the illustrated embodiment, the funnel catheter assembly 100 includes an elongate outer shaft 102 and an elongate inner shaft 104 coaxial with the outer shaft 102. The outer and inner shafts 102,

104 ("shafts 102, 104") can also be referred to as sheaths, catheters, hollow members, and so on. The outer shaft 102 defines a lumen 106 and includes a proximal portion 107a and a distal portion 107b. The inner shaft 104 extends through the lumen 106 of the outer shaft 102 and similarly defines a lumen 108 and includes a proximal portion 109a and a distal portion 109b. The proximal portions 107a and 109a can each terminate at a proximal end/terminus, and the distal portions 107b and 109b can each terminate at a distal end/terminus. The shafts 102, 104 can be elastic and/or flexible and can have any suitable length and diameter.

[0022] In the illustrated embodiment, the funnel catheter assembly 100 further includes a sealable hub 110 coupled to the proximal portion 109a of the inner shaft 104. In some embodiments, as described in greater detail below with reference to Figures 9A–9C, the sealable hub 110 can be rotatable coupled to the inner shaft 104 such that the sealable hub 110 can rotate independently of the inner shaft 104. The sealable hub 110 is configured to allow access to the lumen 108 of the inner shaft 104 and can be self-sealing and/or can comprise a self-sealing seal. For example, in the illustrated embodiment the sealable hub 110 is a hemostasis valve that is configured to maintain hemostasis (e.g., during a thrombus extraction procedure) by inhibiting or even preventing fluid flow in the proximal direction through the sealable hub 110 as, for example, various components (e.g., dilator assemblies, thrombus extraction devices, etc.) are inserted through the sealable hub 110 to be delivered through the inner shaft 104 to a treatment site in a blood vessel. More specifically, the sealable hub 110 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 110 can include one or more buttons or actuators that enable an operator to selectively seal/unseal the sealable hub 110.

[0023] The funnel catheter assembly 100 can further include an aspiration port 112 connected to the sealable hub 110 (e.g., to a side port of the sealable hub 110) and/or the inner shaft 104 (e.g., to the proximal portion 109a of the inner shaft 104) via, for example, a connecting tube 114. The aspiration port 112 can be connected to a syringe connector 116 that can be selectively coupled to a syringe or other aspiration device, or the aspiration port 112 can be connected to other suitable elements. In some embodiments, the funnel catheter assembly 100 includes a fluid control device 118 configured to selectively fluidly connect the aspiration port 112 to the lumen 108 of the inner shaft 104. In the illustrated embodiment, the fluid control device 118 is a stopcock operably coupled to the connecting tube 114 between the lumen 108 of the inner shaft 104 and the aspiration port 112. In other embodiments, the fluid control device

118 can be a clamp or another suitable valve. In some embodiments, a vacuum source (not shown; e.g., a syringe) can be coupled to the syringe connector 116 and used to aspirate the lumen 108 of the inner shaft 104. In some embodiments, as described in greater detail below with reference to Figures 9A–9C, the aspiration port 112 and the connecting tube 114 can be rotatable relative to the sealable hub 110 and/or the inner shaft 104.

[0024] In the illustrated embodiment, a funnel 120 is coupled to the distal portion 109b of the inner shaft 104. As described in greater detail below, in operation of the funnel catheter assembly 100 during an intravascular procedure, the funnel 120 is configured to expand (e.g., radially expand) into apposition with a blood vessel and/or other bodily lumen (e.g., of an organ) and act as a proximal or distal thrombus/embolic protection device that inhibits any thrombus from moving past the funnel 120 and embolizing in an unwanted location (e.g., the right heart, the pulmonary arteries, another arterial space, etc.). The funnel 120 can be fused to the distal portion 109b of the inner shaft 104, and/or attached to the inner shaft 104 via welding, adhesives, fasteners, etc. In Figure 1, the funnel catheter assembly 100 is in a first position/state/configuration in which the distal portion 107b of the outer shaft 102 extends beyond the distal portion 109b of the inner shaft 104 such that the funnel 120 is at least partially (e.g., entirely) positioned within the lumen 106 of the outer shaft 102. The funnel 120 can be configured to expand (e.g., self-expand) and, accordingly, the funnel 120 can be in a first, constrained position/state/configuration when the funnel catheter assembly 100 is in the first position. In some embodiments, the funnel 120 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 120 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 120 can be permeable to blood. In some embodiments, the funnel 120 can include a covering over at least a portion thereof that is permeable or non-permeable to blood.

[0025] In the illustrated embodiment, the proximal portion 107a of the outer shaft 102 is operably coupled to a control assembly 130. The control assembly 130 is operable to move the outer shaft 102 distally and proximally relative to the inner shaft 104 to constrain and release the funnel 120 from within the lumen 106 of the outer shaft 102. More specifically, in the illustrated embodiment the control assembly 130 includes (i) a housing 132 having a proximal portion 133a and a distal portion 133b, and (ii) an actuation member 134 operably/movably coupled to the housing 132. The housing 132 defines a lumen 135 extending between the proximal and distal

portions 133a, b thereof. The proximal portion 133a of the housing 132 can be coupled to the sealable hub 110. In some embodiments, the proximal portion 133a of the housing 132 is integrally formed with the sealable hub 110.

[0026] In the illustrated embodiment, the actuation member 134 includes a body portion 136 positioned within the lumen 135 of the housing 132 and coupled to the proximal portion 107a of the outer shaft 102 via, for example, adhesive, fasteners, welding, etc. The actuation member 134 further includes one or more grip members 138 extending from the body portion 136 to outside of the lumen 135. More specifically, the grip members 138 can extend through corresponding slots 140 formed in/along the housing 132. The housing 132 can define a proximal terminus 142a and a distal terminus 142b for each of the slots 140. In some embodiments, the control assembly 130 can include one, or more than the illustrated two of the grip members 138 and corresponding slots 140.

[0027] In operation, an operator (e.g., a physician) can slide the actuation member 134 along the housing 132 to distally advance and proximally retract the outer shaft 102 relative to the inner shaft 104 to constrain and release the funnel 120, respectively. More specifically, Figures 2A and 2B are side views of the funnel catheter assembly 100 in the first position and in a second position, respectively, in accordance with embodiments of the present technology. Referring to Figures 1–2B together, to move the funnel catheter assembly 100 from the first position (Figures 1 and 2A) to the second position (Figure 2B), the operator can grip the grip members 138 of the actuation member 134 and slide the grip members 138 proximally (e.g., in the direction of arrow P in Figure 2A) relative to the housing 132 to drive the body portion 136 through the lumen 135 to thereby drive the outer shaft 102 proximally relative to the inner shaft 104. The funnel 120 is released/unsheathed from within the lumen 106 of the outer shaft 102 as the distal portion 107b of the outer shaft 102 moves proximally past the funnel 120, thereby allowing the funnel 120 to expand. In some embodiments, the actuation member 134 can abut the proximal termini 142a of the slots 140 in the second position such that the housing 132 inhibits further proximal movement of the outer shaft 102.

[0028] In some embodiments, the distal terminus of the outer shaft 102 is positioned at or proximal of the distal terminus of the inner shaft 104 in the second position such that the funnel 120 is fully released from (e.g., positioned fully outside of) the lumen 106 of the outer shaft 102. In other embodiments, the distal terminus of the outer shaft 102 can be positioned distal of the distal terminus of the inner shaft 104 in the second position such that the funnel 120 is only

partially released from the lumen 106 of the outer shaft 102. Moreover, as shown in Figure 2B, the funnel 120 can have a conically shaped portion 222 (e.g., a truncated-conically shaped portion) and a cylindrical portion 224 once expanded. In other embodiments, the funnel 120 can have other suitable shapes. For example, in some embodiments the funnel 120 can be inverted relative to the embodiment shown in Figure 2B. That is, the cylindrical portion 224 of the funnel 120 can be coupled to the distal portion 109b of the inner shaft 104 while the conically shaped portion 222 extends distally from the cylindrical portion 224.

[0029] To move the funnel catheter assembly 100 from the second position (Figure 2B) to the first position (Figures 1 and 2A), the operator can grip the grip members 138 of the actuation member 134 and slide the grip members 138 distally (e.g., in the direction of arrow D in Figure 2B) relative to the housing 132 to drive the body portion 136 through the lumen 135 to thereby drive the outer shaft 102 distally relative to the inner shaft 104. The funnel 120 is captured/sheathed in the lumen 106 of the outer shaft 102 as the distal portion 107b of the outer shaft 102 moves distally over the funnel 120, thereby collapsing/compressing the funnel 120 within the lumen 106. In some embodiments, the actuation member 134 can abut the distal termini 142b of the slots 140 in the first position such that the housing 132 inhibits further distal movement of the outer shaft 102.

[0030] In some embodiments the actuation member 134 is configured to be releasably secured/locked to the housing 132 in the first and second positions to inhibit or even prevent unintended movement of the actuation member 134. For example, referring again to Figure 1, the housing 132 of the control assembly 130 can include (i) proximal engagement members 144a (e.g., tabs, protrusions, etc.) configured to engage the actuation member 134 in the first position and (ii) distal engagement members 144b configured to engage the actuation member 134 in the second position. More specifically, in some embodiments the proximal and distal engagement members 144a, b can mate with corresponding slots/grooves in the actuation member 134 (e.g., formed in/on the grip members 138) to releasably secure the actuation member 134 in the first or second positions via a snap fit arrangement.

[0031] In some embodiments, the inner shaft 104 is sized to slidably receive one or more medical instruments inserted through the sealable hub 110 during an intravascular procedure using the funnel catheter assembly 100, such as a thrombectomy procedure. Figure 3, for example, is a side view of the funnel catheter assembly 100 in the first position with a dilator 350 inserted through the sealable hub 110 and the lumen 108 of the inner shaft 104 (Figure 1) in

accordance with embodiments of the present technology. The dilator 350 can extend entirely through the inner shaft 104 and past the distal terminus of the distal portion 107b of the outer shaft 102 such that a distal tip 352 (e.g., an atraumatic tip) is positioned beyond the distal terminus of the outer shaft 102.

[0032] In some embodiments, the dilator 350 and the funnel catheter assembly 100 together define an introducer assembly that can be inserted into a patient (e.g., a human patient) and subsequently used to introduce intravascular medical devices into the patient. For example, the dilator 350 and the funnel catheter assembly 100 can be inserted into and advanced together through a blood vessel of the patient to a target location in the blood vessel. The dilator 350 can then be retracted proximally through the funnel catheter assembly 100, and the funnel catheter assembly 100 can be moved to the second position to expand the funnel 120 at the target location.

[0033] Referring to Figures 1–3 together, in one aspect of the present technology the inner shaft 104 is the "working" shaft of the funnel catheter assembly 100 that can be aspirated and/or receive various medical components (e.g., the dilator 350). In contrast, the outer shaft 102 is used to compress/expand the funnel 120. Accordingly, the shafts 102, 104 can be sized to maximize the size of the inner shaft 104 to permit larger-sized components to be inserted therethrough, or to provide greater aspiration force/power. For example, the outer shaft 102 can have an inner diameter that is only slightly greater than an outer diameter of the inner shaft 104. In some embodiments, the inner shaft 104 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 108 of the inner shaft 104 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.

[0034] In another aspect of the present technology, the control assembly 130 is operable, via the movement of the actuation member 134 from the second position to the first position, to compress the funnel 120 after it has been expanded within a blood vessel. This can permit the funnel catheter assembly 100 to be repositioned within the blood vessel without fully withdrawing the funnel catheter assembly 100 from the patient. For example, after (i)

introducing the funnel catheter assembly 100 into the blood vessel with the dilator 350 and (ii) removing the dilator 350, the funnel catheter assembly 100 can be repositioned proximally simply by moving the funnel catheter assembly 100 back to the first position to collapse the funnel 120 and then retracting the funnel catheter assembly 100 proximally. To reposition the funnel catheter assembly 100 distally, the dilator 350 can be reinserted and the funnel catheter assembly 100 pushed proximally in the first position with the funnel 120 compressed. Similarly, the funnel catheter assembly 100 can be fully withdrawn from the patient (e.g., at the conclusion of a thrombectomy procedure) in the first position with the funnel 120 compressed in the lumen 106 of outer shaft 102. Thus, the funnel catheter assembly 100 is configured to inhibit or even prevent the funnel 120 from contacting the wall of the blood vessel during advancement/withdrawal. This can help inhibit injury/damage to the patient that could otherwise be caused by the moving the funnel 120 through the blood vessel or an associated organ in the expanded state.

[0035] In some embodiments, the funnel catheter assembly 100 and/or methods of operating the funnel catheter assembly 100 can include some features the same as or similar to the thrombectomy systems (e.g., the introducer assemblies) 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.

[0036] In other embodiments, the control assembly 130 can be configured to drive the distal and proximal movement of the outer shaft 102 in other manners. For example, the actuation member 134 can comprise a rotatable member (e.g., a ring gear, corkscrew, rotatable handle, etc.) coupled to the outer shaft 102. In some embodiments, the rotatable member can be a ratcheting member that is rotatable to a plurality of discreet positions between the first and second positions.

[0037] Similarly, in other embodiments the control assembly 130 can be operably coupled to the inner shaft 104 rather than the outer shaft 102. Accordingly, operation of the control assembly 130 can move the inner shaft 104 and the sealable hub 110 relative to the outer shaft 102 to move the funnel catheter assembly 100 between the first and second positions to constrain/compress and release/expand the funnel 120, respectively.

[0038] In yet other embodiments, the funnel 120 can be operably coupled to the outer shaft 102 such that movement of the outer shaft 102 between the first and second positions expands the funnel 120. More specifically, for example, Figure 4 is a side view of the funnel catheter assembly 100 including a non-self-expanding funnel 420 in accordance with embodiments of the present technology. In some embodiments, the funnel 420 can have a similar shape as the funnel 120 described in detail above with reference to Figures 1–3, but can be formed of one or more non-self-expanding materials such as metal (e.g., a non-heat-activated metal), plastic, fiber, polymer, etc. In the illustrated embodiment, the funnel 420 is coupled to (i) the distal portion 109b of the inner shaft 104 (Figure 1) and (ii) the distal portion 107b of the outer shaft 102 via a plurality of flexible tethers 426. The tethers 426 are configured (e.g., shaped, sized, and/or positioned) such that movement of the control assembly 130 from the first position to the second position pulls the tethers 426 to thereby pull and expand the funnel 420 as it is unsheathed from within the outer shaft 102.

[0039] In some embodiments, the funnel catheter assembly 100 can include one or more features for actuating/manipulating the funnel 420 (or the funnel 120 described in detail with reference to Figures 1–3). For example, the control assembly 130 can include an actuation member 454 (shown schematically) operably coupled to the funnel 420 via one or more control lines 462 (e.g., wires, tethers, rigid members etc.). The actuation member 454 can be a slider, rotatable member, or other component configured to exert a force on the funnel 420 via the control lines 462. In some embodiments, the control lines 462 can be asymmetrically/eccentrically coupled to the funnel 420 such that actuation of the actuation member 454 bends the funnel 420 away from a longitudinal axis of the shafts 102, 104. In one aspect of the present technology, this arrangement can be used to help steer the funnel 420 into a tortuous region of a patient (e.g., a tortuous vessel, the left atrial appendage (LAA), etc.) that may otherwise be difficult to position the funnel 420 in. Additionally or alternatively, the funnel catheter assembly 100 can include one or more components (e.g., pull wires) for steering (e.g., bending, deflecting, etc.) the outer shaft 102 and/or the inner shaft 104 to facilitate positioning of the funnel 420.

II. Selected Embodiments of Procedures Utilizing Funnel Catheter Assemblies for Embolic Protection

[0040] Referring to Figures 1–4 together, the funnel catheter assembly 100 can be used in a myriad of procedures to capture thrombi and inhibit the thrombi from embolizing in portions

of a patient's vasculature. For example, Figures 5–8 are schematic views illustrating various thrombectomy techniques for removing a thrombus T from a blood vessel BV of a human patient utilizing the funnel catheter assembly 100 in accordance with various embodiments of the present technology.

[0041] Referring first to Figure 5, in some embodiments the thrombus T (e.g., clot material) can be accessed through a popliteal access site 560. The funnel catheter assembly 100 can extend from the popliteal access site 560 to a deployment position 562 in the blood vessel BV at which the funnel 120 (or the funnel 420) can be deployed. The deployment position 562 can be proximate to and proximal of the thrombus T. The funnel 120 can at least partially appose a wall of the blood vessel BV after the funnel catheter assembly 100 is moved from the first position to the second position to expand the funnel 120, as described in detail above with reference to Figures 1–4.

[0042] In the illustrated embodiment, a thrombus extraction device 564 has been (i) inserted through the funnel catheter assembly 100, (ii) passed through the thrombus T in the direction of blood flow, and (iii) expanded distal of the thrombus T. The thrombus extraction device 564 can include a coring element 565 (e.g., a stent-like device) and a capture element 566 (e.g., a braided mesh bag). In some embodiments, some or all of the thrombus extraction device 564 can extend into one of the iliac veins and/or the inferior vena cava. After expansion distal of the thrombus T, the thrombus extraction device 564 can be retracted through the thrombus T and into the lumen 108 of the inner shaft 104 (Figure 1) through the funnel 120. During retraction, the coring element 565 can core/separate the thrombus T and the capture element 566 can capture all or a portion of the thrombus T. In some embodiments, the thrombus extraction device 564 and the associated thrombectomy procedure can be generally similar or identical to the thrombus extraction devices and associated methods 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.

[0043] In one aspect of the present technology, as the thrombus extraction device 564 and the captured thrombus T are retracted through the funnel 120, the funnel 120 can capture/retain any of the thrombus T that breaks free of the thrombus extraction device 564 as the thrombus

extraction device 564 is compressed into the inner shaft 104. Accordingly, the funnel 120 can inhibit portions of the thrombus T from traveling upstream where they could potentially embolize. In some embodiments, a vacuum (e.g., a pre-charged vacuum) can be applied to the inner shaft 104 (e.g., via a syringe coupled to the syringe connector 116 shown in Figure 1) at any point during retraction of the thrombus extraction device 564. In some embodiments, application of the vacuum can generate instantaneous or nearly instantaneous suction at the distal portion 109b of the inner shaft 104 that can aspirate any remaining portions of the thrombus T into and/or through the inner shaft 104.

[0044] Referring next to Figure 6, in some embodiments the thrombus T (not shown in Figure 6; e.g., positioned lower in the iliac or femoral veins) can be accessed through an internal jugular access site 670, and the funnel catheter assembly 100 can be inserted into the patient's body via the internal jugular access site 670. The funnel catheter assembly 100 can extend from the internal jugular access site 670 to a deployment position 672 at which the funnel 120 (or the funnel 420) can be deployed proximal to the thrombus T. In the illustrated embodiment, the outer shaft 102 and the inner shaft 104 (obscured in Figure 6) extend from the internal jugular access site 670 through the superior vena cava and the inferior vena cava to the deployment position 672 in one of the common iliac veins. In some embodiments, the deployment position 672 can be located in, for example, the inferior vena cava, one of the iliac veins, the femoral vein, the popliteal vein, before or beyond the iliac arch, or any other location proximate to and/or proximal to the thrombus T. In some embodiments, the thrombus extraction device 564 can be inserted through the funnel catheter assembly 100 and withdrawn through the thrombus T to capture the thrombus T, as described in detail above with reference to Figure 5.

[0045] In one aspect of the present technology, accessing the thrombus T via the internal jugular access site 670 allows the funnel 120 to be positioned downstream of the thrombus T. Accordingly, the funnel 120 can capture any of the thrombus T that may break off and be carried downstream toward the heart during operation of the thrombus extraction device 564. In another aspect of the present technology, the funnel 120 can be compressed—for example, by moving the actuation member 134 from the second position to the first position as described in detail above with reference to Figures 1–4—before withdrawing the funnel catheter assembly 100 at the conclusion of the thrombectomy procedure. This prevents the funnel 120 from being withdrawn in the expanded configuration through the heart of the patient (e.g., through the right atrium) which could potentially damage the heart.

[0046] Referring next to Figure 7, in some embodiments the thrombus T can be accessed by the thrombus extraction device 564 through the popliteal access site 560 using a separate introducer assembly 774, while the funnel catheter assembly 100 can be inserted into the patient's body via the internal jugular access site 670 (Figure 6). The funnel 120 can be expanded at the deployment position 672 during a thrombectomy procedure using the thrombus extraction device 564. The funnel 120 can therefore capture any of the thrombus material T that may break away and flow downstream during the procedure. In the illustrated embodiment, the thrombus extraction device 564 is inserted through an outer shaft 776 of the introducer assembly 774. In one aspect of the present technology, in comparison to using the funnel catheter assembly 100 as the introducer for the thrombus extraction device 564, the outer shaft 776 can be made relatively larger than the inner shaft 104 because the outer shaft 102 need not be positioned thereabout for constraining the funnel 120. This can permit the thrombus extraction device 564 to be made larger and/or enable greater aspiration forces to be generated through the outer shaft 776.

[0047] Referring next to Figure 8, in some embodiments the thrombus T can be accessed by the thrombus extraction device 564 through the popliteal access site 560 using the introducer assembly 774, while the funnel catheter assembly 100 can be inserted into the patient's body via a femoral access site 880. The funnel catheter assembly 100 can traverse the common iliac veins to the deployment position 672, or another suitable deployment position.

[0048] In other embodiments, the funnel catheter assembly 100 can be inserted into a patient's body via other venous or arterial access sites, and can be used in a myriad of different procedures. For example, additional applications of the funnel catheter assembly 100 include but are not limited to:

[0049] Internal jugular vein (IJ) access for deployment in the inferior vena cava (IVC) for treatment of lower extremity deep vein thrombsis (DVT);

[0050] IJ access for deployment in the IVC for removal of IVC filters and/or treatment of thrombus located in the IVC;

[0051] IJ access for deployment in the deep veins of the lower extremity veins (iliac, femoral, popliteal veins, etc.) for treatment of lower extremity DVT;

[0052] Common femoral vein (CFV) access for deployment in the superior vena cava (SVC) for treatment of upper extremity DVT and/or SVC thrombus;

[0053] CFV access for deployment in the upper extremity veins (brachiocephalic, subclavian, axillary veins, etc.) for treatment of upper extremity DVT and/or SVC thrombus;

[0054] CFV access for deployment in the pulmonary arteries (PAs) for treatment of pulmonary embolism;

[0055] CFV access with transseptal access for deployment in the left atrium ostium and the left atrial appendage (LAA) for thrombus removal;

[0056] Internal Carotid Artery (ICA) accesss for deployment in the common carotid artery (CCA) for carotid endarterectomy (CEA);

[0057] ICA accesss for deployment in descending thoracic aorta for treatment of thoraco-abdominal and/or abdominal aortic (AA) thrombus and/or aorto-arterial thrombosis;

[0058] ICA accesss for deployment in the descending/thoracic aorta for treatment of renal thrombosis;

[0059] ICA accesss for intra-atrterial placement for treament of superior mesenteric artery (SMA) thrombosis (MAT);

[0060] Common Femoral Artery (CFA) access for treatment of atherosclerosis in the brachial artery, radial artery, popiteal artery, or dorsalis pedis artery;

[0061] CFA access for deployment in the common iliac artery for treatment of aorto-arterial thrombosis and/or occlusions;

[0062] CFA access for deployment in the abdominal aorta for treatment of renal artery thrombosis; and/or

[0063] CFA access for deployment in the aorta for treatment of thoraco-abdominal and/or AA thrombus and/or aorto-arterial thrombosis.

[0064] Figures 9A and 9B are enlarged, partially transparent side and side cross-sectional views, respectively, of a portion of a funnel catheter assembly 900 in accordance with additional embodiments of the present technology. Referring to Figures 9A and 9B together, the funnel catheter assembly 900 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the funnel catheter assembly 100 described in detail above with reference to Figures 1–8, and can operate

in a generally similar or identical manner to the funnel catheter assembly 100. In the illustrated embodiment, for example, the funnel catheter assembly 900 includes the sealable hub 110, the connecting tube 114, the aspiration port 112, the outer shaft 102, and the inner shaft 104 (obscured in Figure 9A). The funnel catheter assembly 900 further includes a control assembly 930 including a housing 932 and an actuation member 934 having a pair of grip member 938. As shown in Figure 9B, the actuation member 934 includes a hub 936 positioned within the housing 932 and coupled to the outer shaft 102 (e.g., the proximal portion 107a of the outer shaft 102). The actuation member 934 is movable (e.g., slidable) relative to the housing 932 to advance/retract the outer shaft 102 relative to the inner shaft 104 and a funnel (e.g., the funnel 120 shown in Figures 10B and 10C) attached to a distal portion thereof.

[0065] The funnel catheter assembly 900 is in a first, sheathed position in Figure 9A in which the funnel is constrained by the outer shaft 102 and in a second, unsheathed position in Figure 9B in which the funnel is not constrained by the outer shaft 102. Referring to Figure 9A, in some embodiments the housing 932 can include a marking 931 indicating a position of the actuation member 934 in which the funnel is in the unsheathed position. In some embodiments, a proximal portion 933a of the housing 932 can include gripping features, such as a groove 935, a cross-hatched pattern 937, and/or other features for increasing the grip-ability of the housing 932. In some embodiments, an operator can grip the housing 932 (e.g., via the groove 935 and/or the pattern 937) while moving (i) the actuation member 934 relative to the housing 932 and/or (ii) the housing 932 relative to the actuation member 934. In some embodiments, the funnel catheter assembly 900 can further include a lock mechanism 911 that can be attached to the sealable hub 110 (e.g., to buttons thereof) to lock the sealable hub 110 in the open/unsealed position.

[0066] In the illustrated embodiment, the funnel catheter assembly 900 further includes a rotatable side port 950 fluidly connecting the sealable hub 110, the connecting tube 114, and the inner shaft 104. Figure 9C is an enlarged isometric cross-sectional view of a portion of the sealable hub 110, the rotatable side port 950, and the control assembly 930 in accordance with embodiments of the present technology. Referring to Figure 9C, the side port 950 defines a lumen 952 that provides a fluid path from the inner shaft 104 to the sealable hub 110. In the illustrated embodiment, the side port 950 includes a first groove 954 and a second groove 956 that each extend circumferentially about an outer surface of the side port 950. The sealable hub 110 includes a first projection 964 positioned in the first groove 954 and the housing 932 includes a second projection 966 positioned in the second groove 956. The engagement of the first and

second projections 964, 966 in the first and second grooves 954, 956 couples the housing 932 to the sealable hub 110. Moreover, the first and second projections 964, 966 are rotatable within the first and second grooves 954, 956 such that the sealable hub 110, the side port 114, and the housing 932 can each rotate independently of one another while remaining coupled together.

[0067] In some embodiments, the control assembly 930 can further include a connector 958 coupled to the proximal portion 109a of the inner shaft 104 and positioned at least partially between the side port 950 and the housing 932. The connector 958 can be rotatable within the housing 932 such that the housing 932 can rotate independently of the connector 958 and the inner shaft 104. Accordingly, in some aspects of the present technology rotation of the sealable hub 110, the side port 950 (e.g., the aspiration port 112 shown in Figures 9B and 9C), and/or the housing 932 will not substantially rotate the inner shaft 104. This can help inhibit the funnel attached to the inner shaft 104 from rotating within a vessel during a procedure using the funnel catheter assembly 900—while still allowing for movement of the sealable hub 110, the side port 950, and/or other components of the funnel catheter assembly 900.

[0068] Figures 10A–10C are side views of the funnel catheter assembly 900 in the sheathed position, a partially-unsheathed or intermediate position, and the unsheathed position, respectively, in accordance with embodiments of the present technology. Referring to Figures 10A–10C together, the funnel catheter assembly 900 can be moved between the sheathed and unsheathed positions by moving the actuation member 934 relative to the housing 932 and/or by moving the housing 932 (and the coupled sealable hub 110) relative to the actuation member 934. In some embodiments, for example, the operator can slide the actuation member 134 relative to the housing 932 in the direction indicated by the arrow P in Figure 10B to retract the outer shaft 102 to unsheathe the funnel 120. In some aspects of the present technology, moving the actuation member 934 rather than the housing 932 moves only the outer shaft 102 such that the funnel 120 remains in a constant or generally constant position (e.g., stationary position). In other embodiments, the operator can advance the housing 932 relative to the actuation member 934 in the direction indicated by the arrow D in Figure 10A to unsheathe the funnel 120. In some aspects of the present technology, moving the housing 932 relative to the actuation member 934 advances the inner shaft 104 and the funnel 120 distally relative to the outer shaft 102.

[0069] In the unsheathed position shown in Figure 10C, the actuation member 934 can be positioned adjacent or near the marking 931 to indicate to the operator that the funnel 120 is deployed. In some embodiments, to re-sheathe the funnel 120 (e.g., from the unsheathed position

shown in Figure 10C to the sheathed position shown in Figure 10A), the operator can retract the housing 932 relative to the actuation member 934 (e.g., in the direction of the arrow P) to pull the funnel 120 into the outer shaft 102. In some aspects of the present technology, such a retracting motion can be intuitive to the user as the motion of the housing 932 is in the same direction as the removal/collapse of the funnel 120. Nevertheless, in other embodiments the operator can advance the actuation member 934 relative to the housing 932 to sheathe the funnel 120 within the outer shaft 102.

[0070] Figure 11 is a flow diagram of a process or method 1110 for operating the funnel catheter assembly 100 and/or the funnel catheter assembly 900 (collectively referred to as "the funnel catheter assembly") during an intravascular procedure in accordance with embodiments of the present technology. Although some features of the method 1110 are described in the context of the embodiments shown in Figures 1–10C for the sake of illustration, one skilled in the art will readily understand that the method 1110 can be carried out using other suitable systems and/or devices described herein.

[0071] At block 1111, the method 1110 includes inserting the funnel catheter assembly into a patient's body via a vascular site. For example, the dilator 350, the outer shaft 102, and inner shaft 104 can be inserted together through a venous or arterial access site.

[0072] At block 1112, the method 1110 includes advancing the funnel catheter assembly to a deployment position within the vasculature of the patient. For example, the dilator 350, the outer shaft 102, and inner shaft 104 can be advanced together through the vasculature to the selected deployment position. The funnel catheter assembly can be advanced in the first position such that the funnel 120 is constrained/compressed within the outer shaft 102. The deployment position can be a portion of a blood vessel, a portion of the heart, or another suitable location.

[0073] At block 1113, the method 1110 includes expanding the funnel 120 at the deployment position. For example, the control assembly 130 of the funnel catheter assembly 100 can be moved from the first position to the second position to release/unsheathe the funnel 120 from within the outer shaft 102, thereby allowing the funnel 120 to expand at the deployment position. Likewise, the actuation member 934 can be slid relative to the housing 932 to unsheathe the funnel 120. After expansion, the funnel 120 can appose/contact the anatomy surrounding the deployment position, such as a wall of a blood vessel. In some embodiments, the dilator 350 can be removed from the funnel catheter assembly before expanding the funnel 120.

[0074] At block 1114, the method 1110 optionally includes compressing and repositioning the funnel 120. For example, the control assembly 130 can be moved from the second position to the first position to constrain/sheathe the funnel 120 within the outer shaft 102. Likewise, the housing 932 of the funnel catheter assembly 900 can be retracted proximally relative to the actuation member (and/or the actuation member 934 can be advanced distally relative to the housing) to sheathe the funnel 120. Then, the funnel catheter assembly can be repositioned to a different deployment position (block 1112) and expanded once again (block 1113). In some embodiments, the dilator 350 can be reinserted into the funnel catheter assembly 100 before repositioning the funnel catheter assembly 100.

[0075] At block 1115, the method 1110 includes maintaining the funnel 120 in the expanded position during an intravascular procedure. As described in detail above, the funnel 120 can capture thrombi that break free during the intravascular procedure to inhibit their embolization elsewhere in the vasculature of the patient.

[0076] At block 1116, the method 1110 includes compressing the funnel 120 and withdrawing the funnel catheter assembly 100 from the patient. For example, the control assembly 130 of the funnel catheter assembly 100 can be moved from the second position to the first position to constrain/sheathe the funnel 120 within the outer shaft 102, and the funnel catheter assembly 100 can then be withdrawn proximally to and from the vascular access site. Likewise, the housing 932 of the funnel catheter assembly 900 can be retracted proximally relative to the actuation member (and/or the actuation member 934 can be advanced distally relative to the housing) to sheathe the funnel 120.

III. Examples

[0077] Several aspects of the present technology are set forth in the following examples:

1. A funnel catheter assembly, comprising:

an outer shaft defining a lumen;

an inner shaft extending through the lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly configured to move the funnel between a first position and a second position, wherein—

in the first position, the funnel is constrained within the lumen of the outer shaft, and

in the second position, the funnel is positioned at least partially outside the lumen of the outer shaft such that the funnel can expand.

2. The funnel catheter assembly of example 1 wherein the control assembly is coupled to the outer shaft and configured to move the outer shaft relative to the inner shaft.

3. The funnel catheter assembly of example 1 or example 2 wherein the control assembly includes an actuator movable to move the funnel between the first and second positions.

4. The funnel catheter assembly of example 3 wherein the actuator is a slider.

5. The funnel catheter assembly of any one of examples 2–4 wherein the funnel includes a proximal portion and a distal portion, and wherein the proximal portion of the funnel is coupled to the distal portion of the inner shaft.

6. The funnel catheter of example 5 wherein the distal portion of the funnel is coupled to the outer shaft.

7. The funnel catheter assembly of any one of examples 1–6, further comprising a sealable hub and a side port, wherein the side port is rotatably coupled between the control assembly and the sealable hub.

8. A funnel catheter assembly, comprising:

an outer shaft defining an outer lumen;

an inner shaft extending through the outer lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position, wherein—

in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel, and

in the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can radially expand.

9. The funnel catheter assembly of example 8 wherein the control assembly includes a housing and an actuation member, wherein the actuation member is coupled to a proximal portion of the outer shaft, and wherein the actuation member is slidable along the housing to move the outer shaft between the first and second positions.

10. The funnel catheter assembly of example 8 or example 9 wherein the funnel is configured to self-expand.

11. The funnel catheter assembly of example 8 or example 9 wherein the funnel is non-self-expanding, wherein the funnel is further coupled to a distal portion of the outer shaft, and wherein movement of the outer shaft from the first position to the second position is configured to expand the funnel.

12. The funnel catheter assembly of example 11 wherein a distal portion of the funnel is coupled to the distal portion of the outer shaft via one or more tethers.

13. The funnel catheter assembly of any one of examples 8–12 wherein the inner shaft defines an inner lumen sized to receive a dilator.

14. A method of operating a funnel catheter assembly during an intravascular procedure on a patient, the method comprising:

at least partially inserting an inner shaft, an outer shaft, and a funnel of the funnel catheter assembly into the vasculature of the patient;

advancing the inner shaft, the outer shaft, and the funnel together to a deployment position within the vasculature of the patient, wherein the funnel is sheathed within a lumen of the outer shaft during the advancement;

moving the outer shaft relative to the inner shaft to unsheathe the funnel and permit the funnel to expand to an expanded position;

maintaining the funnel in the expanded position during at least a portion of the intravascular procedure;

moving the outer shaft relative to the inner shaft and/or moving the inner shaft relative to the outer shaft to sheath the funnel within the lumen of the outer shaft; and

withdrawing the funnel catheter assembly from the patient.

15. The method of example 14 wherein the funnel is self-expandable, and wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes permitting the funnel to self-expand to the expanded position.

16. The method of example 14 or example 15 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving a slider of a control assembly of the funnel catheter assembly from a first position to a second position, and wherein the slider is coupled to a proximal portion of the outer shaft.

17. The method of any one of examples 14–16 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes rotating a rotatable element of a control assembly of the funnel catheter assembly from a first position to a second position.

18. The method of any one of examples 14, 16, and 17 wherein the funnel is non-self-expanding, and wherein the method further comprises actuating the funnel to expand to the expanded position.

19. The method of any one of examples 14–18 wherein—

inserting the inner shaft, the outer shaft, and the funnel into the vasculature of the patient further includes at least partially inserting a dilator positioned within the inner shaft into the vasculature of the patient; and

advancing the inner shaft, the outer shaft, and the funnel further includes advancing the inner shaft, the outer shaft, the funnel, and the dilator together to the deployment position.

20. The method of any one of examples 14–19 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving the outer shaft in a first

direction, and wherein the method further comprises moving the outer shaft relative to the inner shaft to sheath the funnel by moving the outer shaft in a second direction opposite to the first direction.

IV. Conclusion

[0078] 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.

[0079] 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.

[0080] 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 funnel catheter assembly, comprising:

an outer shaft defining a lumen;

an inner shaft extending through the lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly configured to move the funnel between a first position and a second position, wherein—

in the first position, the funnel is constrained within the lumen of the outer shaft, and

in the second position, the funnel is positioned at least partially outside the lumen of the outer shaft such that the funnel can expand.

2. The funnel catheter assembly of claim 1 wherein the control assembly is coupled to the outer shaft and configured to move the outer shaft relative to the inner shaft.

3. The funnel catheter assembly of claim 1 wherein the control assembly includes an actuator movable to move the funnel between the first and second positions.

4. The funnel catheter assembly of claim 3 wherein the actuator is a slider.

5. The funnel catheter assembly of claim 1 wherein the funnel includes a proximal portion and a distal portion, and wherein the proximal portion of the funnel is coupled to the distal portion of the inner shaft.

6. The funnel catheter of claim 5 wherein the distal portion of the funnel is coupled to the outer shaft.

7. The funnel catheter assembly of claim 1, further comprising a sealable hub and a side port, wherein the side port is rotatably coupled between the control assembly and the sealable hub.

8. A funnel catheter assembly, comprising:

an outer shaft defining an outer lumen;

an inner shaft extending through the outer lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position, wherein—

in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel, and

in the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can radially expand.

9. The funnel catheter assembly of claim 8 wherein the control assembly includes a housing and an actuation member, wherein the actuation member is coupled to a proximal portion of the outer shaft, and wherein the actuation member is slidable along the housing to move the outer shaft between the first and second positions.

10. The funnel catheter assembly of claim 8 wherein the funnel is configured to self-expand.

11. The funnel catheter assembly of claim 8 wherein the funnel is non-self-expanding, wherein the funnel is further coupled to a distal portion of the outer shaft, and wherein movement of the outer shaft from the first position to the second position is configured to expand the funnel.

12. The funnel catheter assembly of claim 11 wherein a distal portion of the funnel is coupled to the distal portion of the outer shaft via one or more tethers.

13. The funnel catheter assembly of claim 8 wherein the inner shaft defines an inner lumen sized to receive a dilator.

14. A method of operating a funnel catheter assembly during an intravascular procedure on a patient, the method comprising:

at least partially inserting an inner shaft, an outer shaft, and a funnel of the funnel catheter assembly into the vasculature of the patient;

advancing the inner shaft, the outer shaft, and the funnel together to a deployment position within the vasculature of the patient, wherein the funnel is sheathed within a lumen of the outer shaft during the advancement;

moving the outer shaft relative to the inner shaft to unsheathe the funnel and permit the funnel to expand to an expanded position;

maintaining the funnel in the expanded position during at least a portion of the intravascular procedure;

moving the outer shaft relative to the inner shaft and/or moving the inner shaft relative to the outer shaft to sheath the funnel within the lumen of the outer shaft; and

withdrawing the funnel catheter assembly from the patient.

15. The method of claim 14 wherein the funnel is self-expandable, and wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes permitting the funnel to self-expand to the expanded position.

16. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving a slider of a control assembly of the funnel catheter assembly from a first position to a second position, and wherein the slider is coupled to a proximal portion of the outer shaft.

17. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes rotating a rotatable element of a control assembly of the funnel catheter assembly from a first position to a second position.

18. The method of claim 14 wherein the funnel is non-self-expanding, and wherein the method further comprises actuating the funnel to expand to the expanded position.

19. The method of claim 14 wherein—

inserting the inner shaft, the outer shaft, and the funnel into the vasculature of the patient further includes at least partially inserting a dilator positioned within the inner shaft into the vasculature of the patient; and

advancing the inner shaft, the outer shaft, and the funnel further includes advancing the inner shaft, the outer shaft, the funnel, and the dilator together to the deployment position.

20. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving the outer shaft in a first direction, and wherein the method further comprises moving the outer shaft relative to the inner shaft to sheath the funnel by moving the outer shaft in a second direction opposite to the first direction.

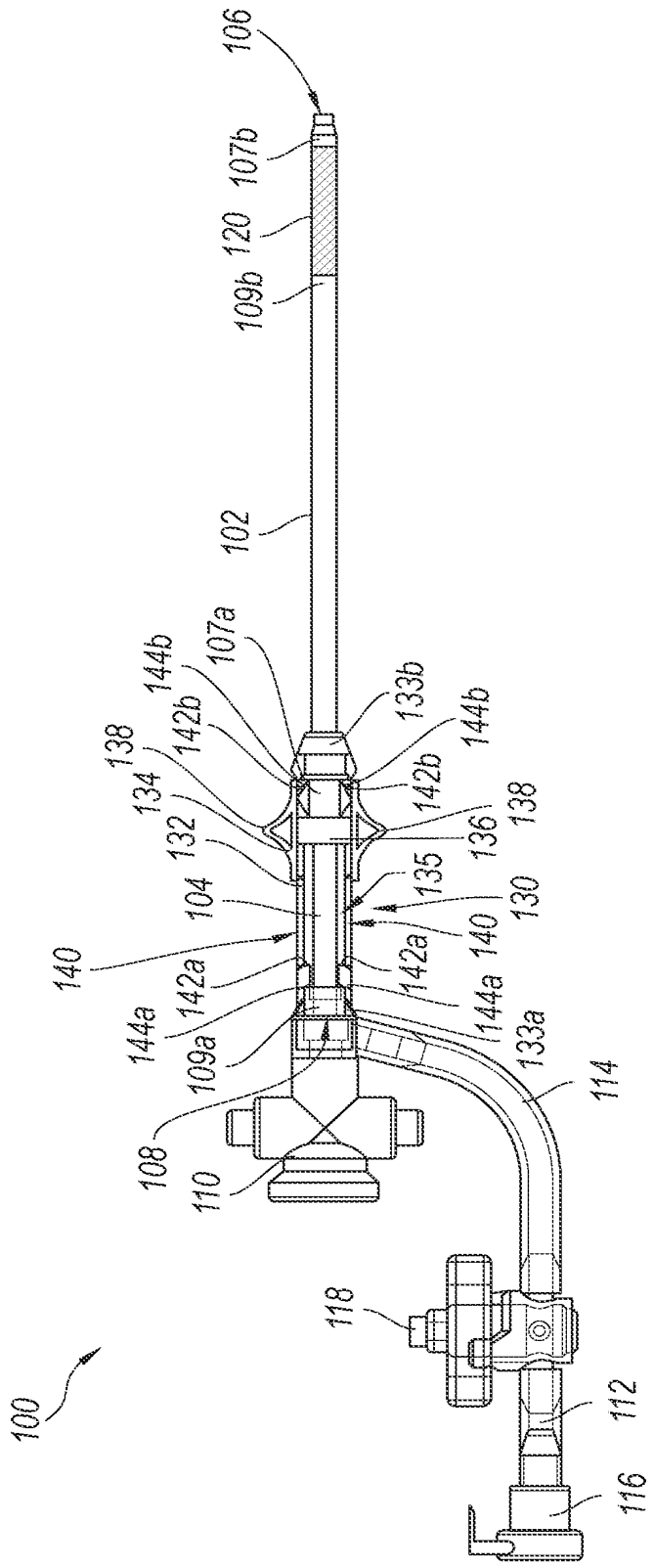

106
107b
120
109b
102
107a
144b
142b
138
134
132
104
140
142a
144a
109a
108
110
133b
144b
142b
138
136
135
130
140
142a
144a
133a
114
118
112
116
100

Fig. 1

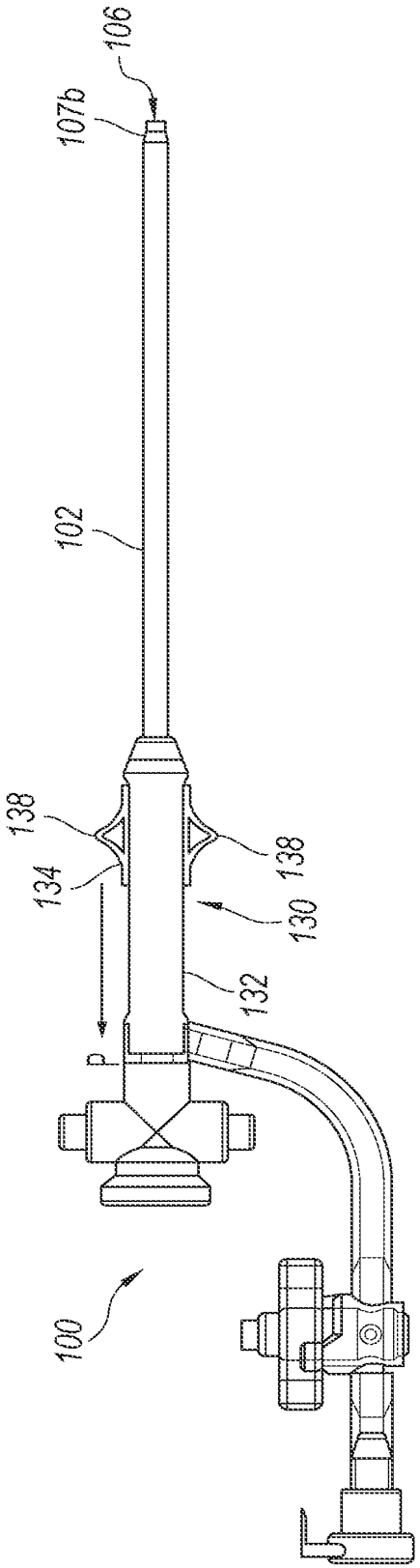

106
107b
102
138
134
138
130
132
P
100

Fig. 2A

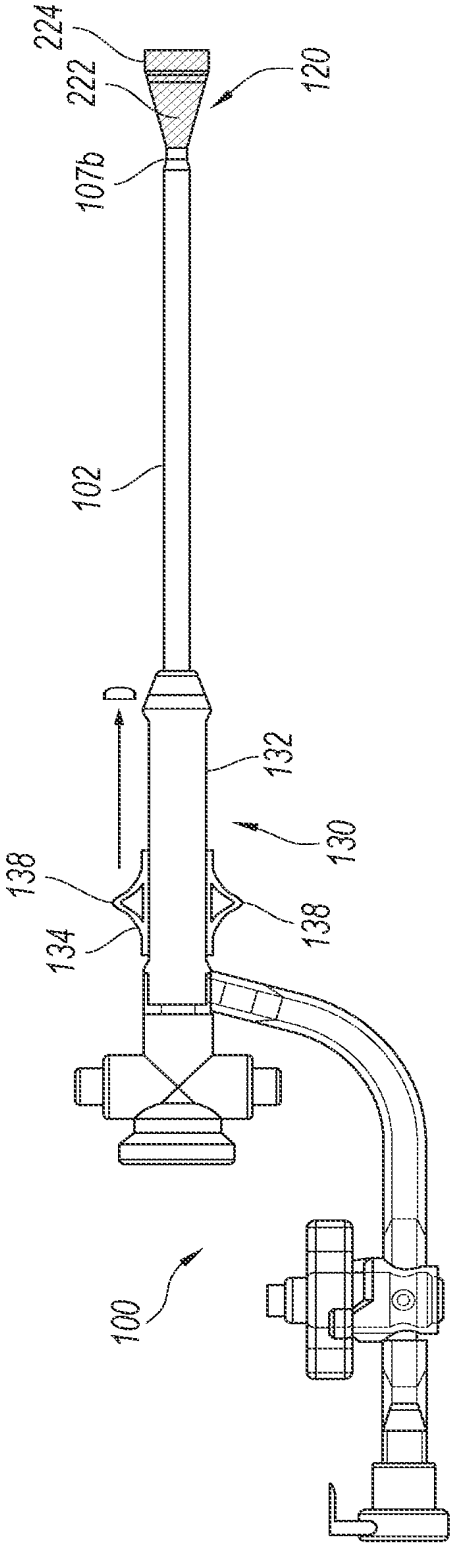

224
222
120
107b
102
D
132
130
138
134
138
100

Fig. 2B

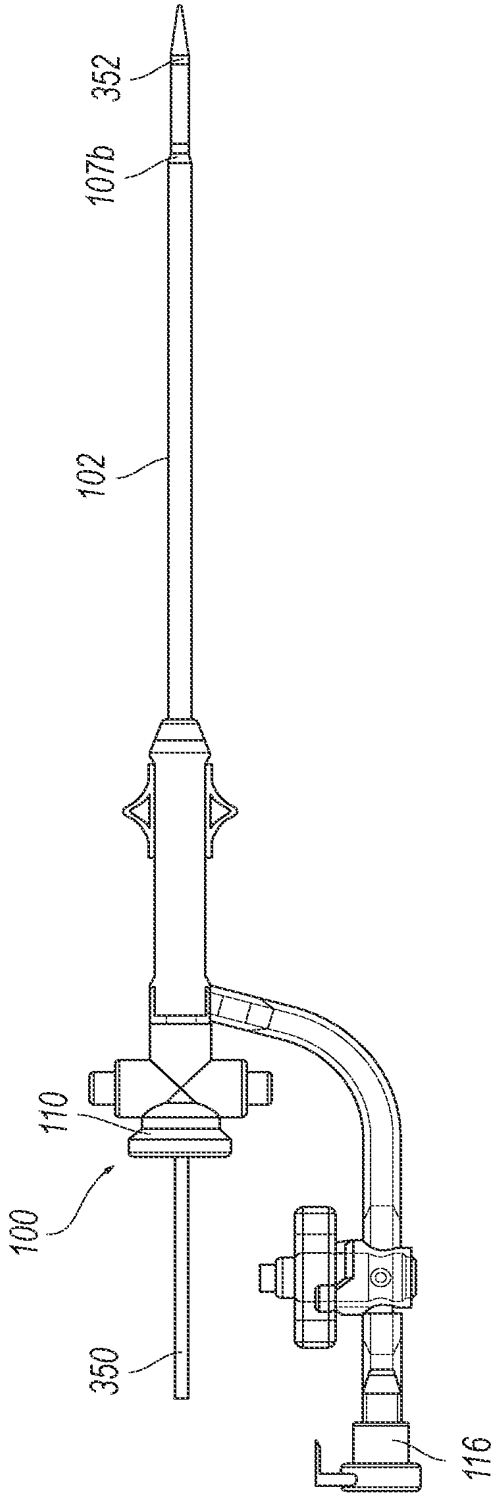


Fig. 3

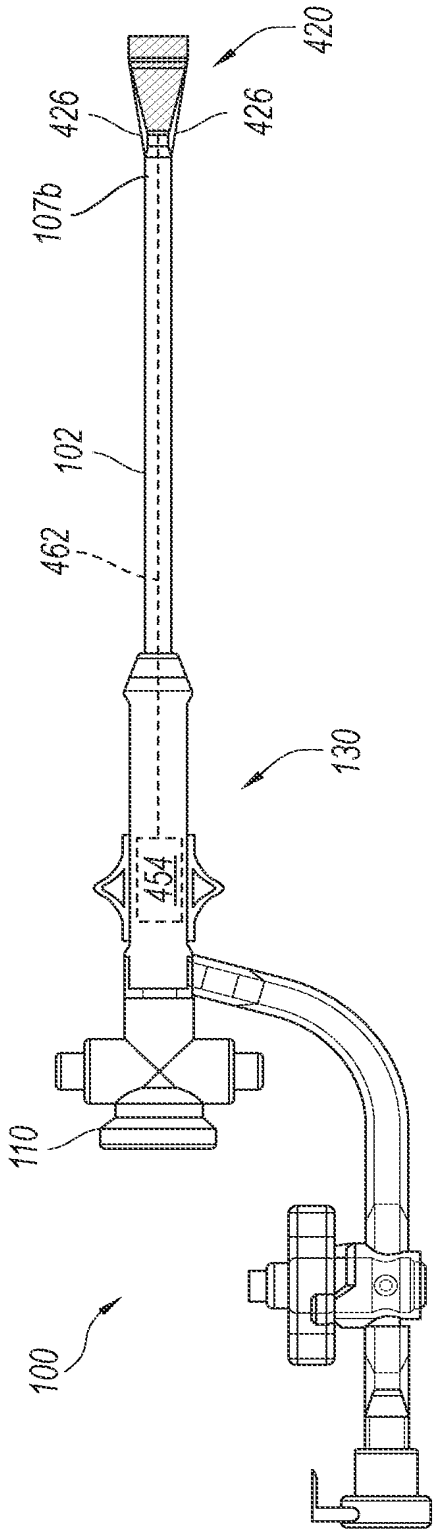


Fig. 4

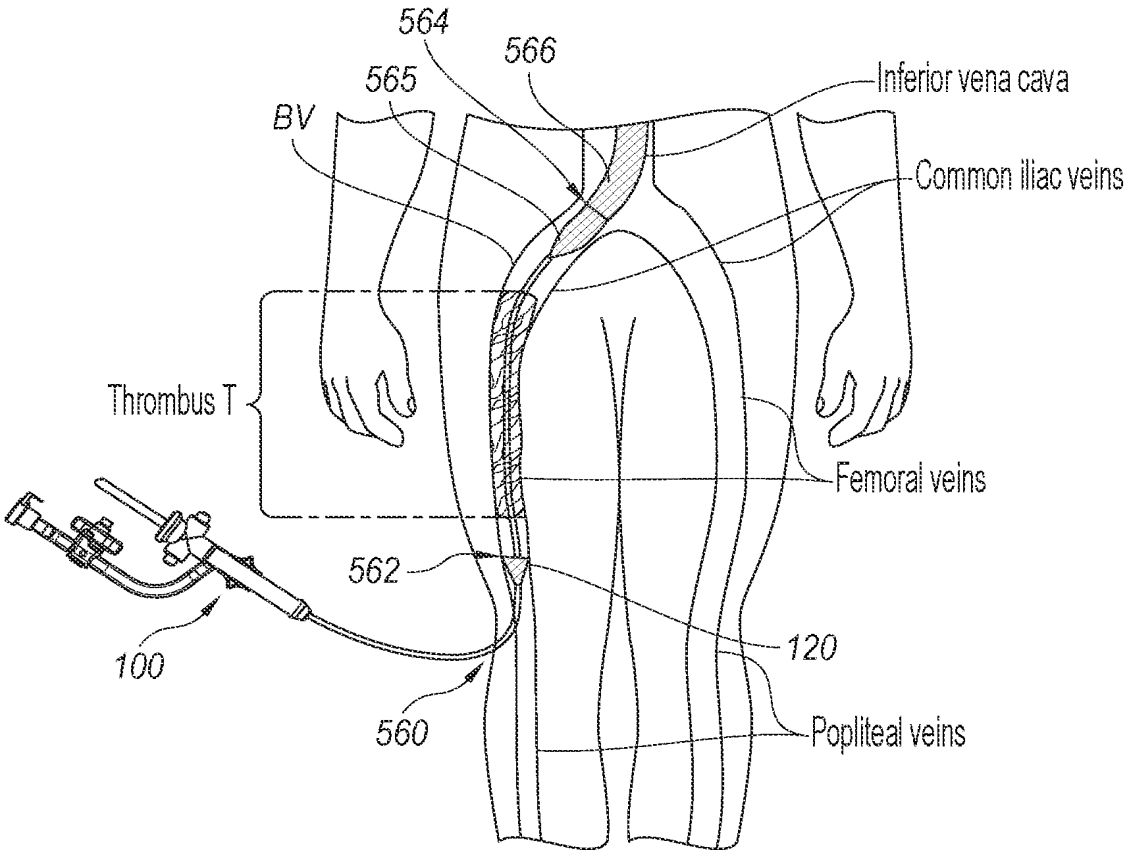

564
566
565
BV
Inferior vena cava
Common iliac veins
Thrombus T
Femoral veins
562
120
100
560
Popliteal veins

Fig. 5

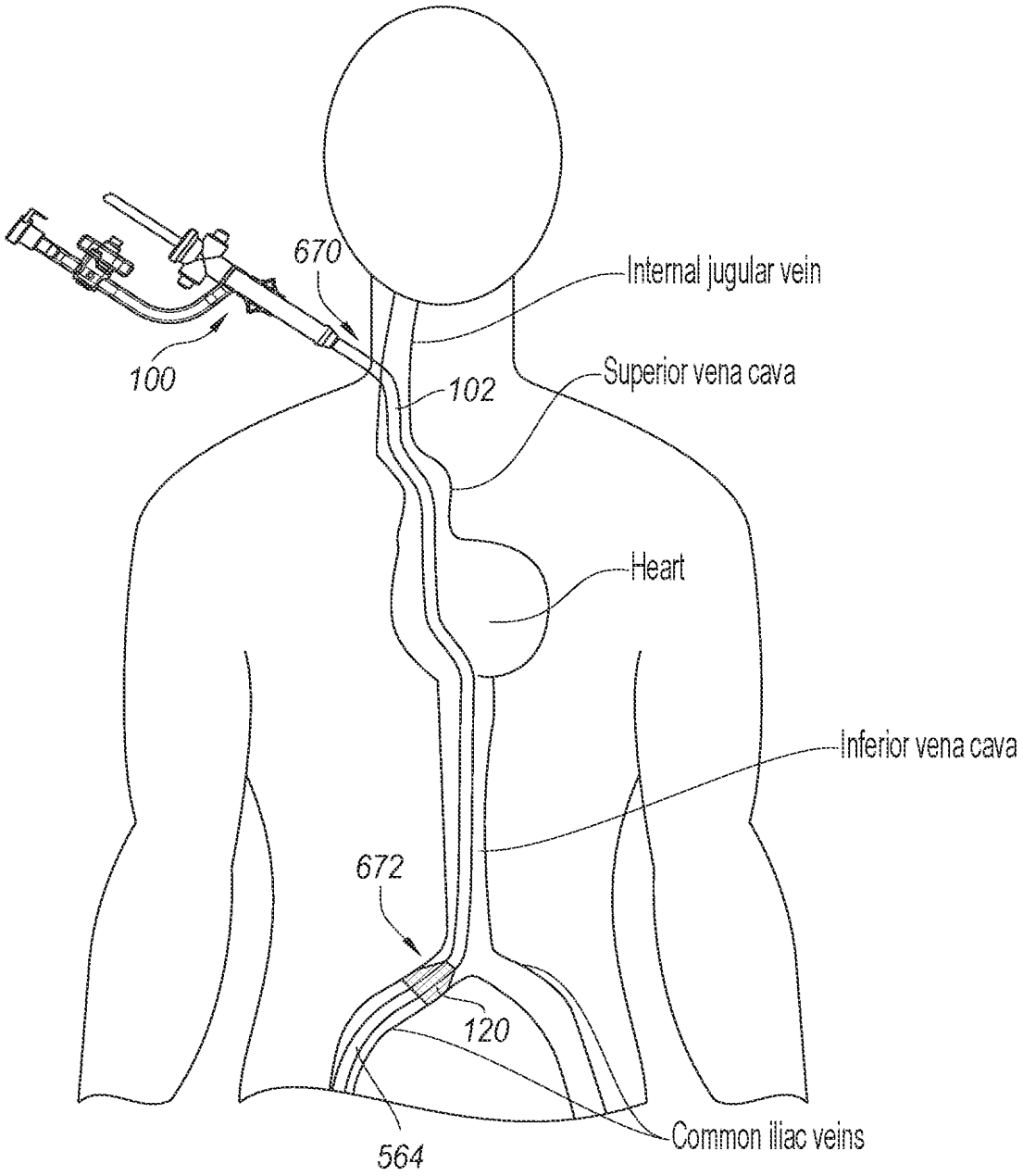

670
Internal jugular vein
100
102
Superior vena cava
Heart
Inferior vena cava
672
120
564
Common iliac veins

Fig. 6

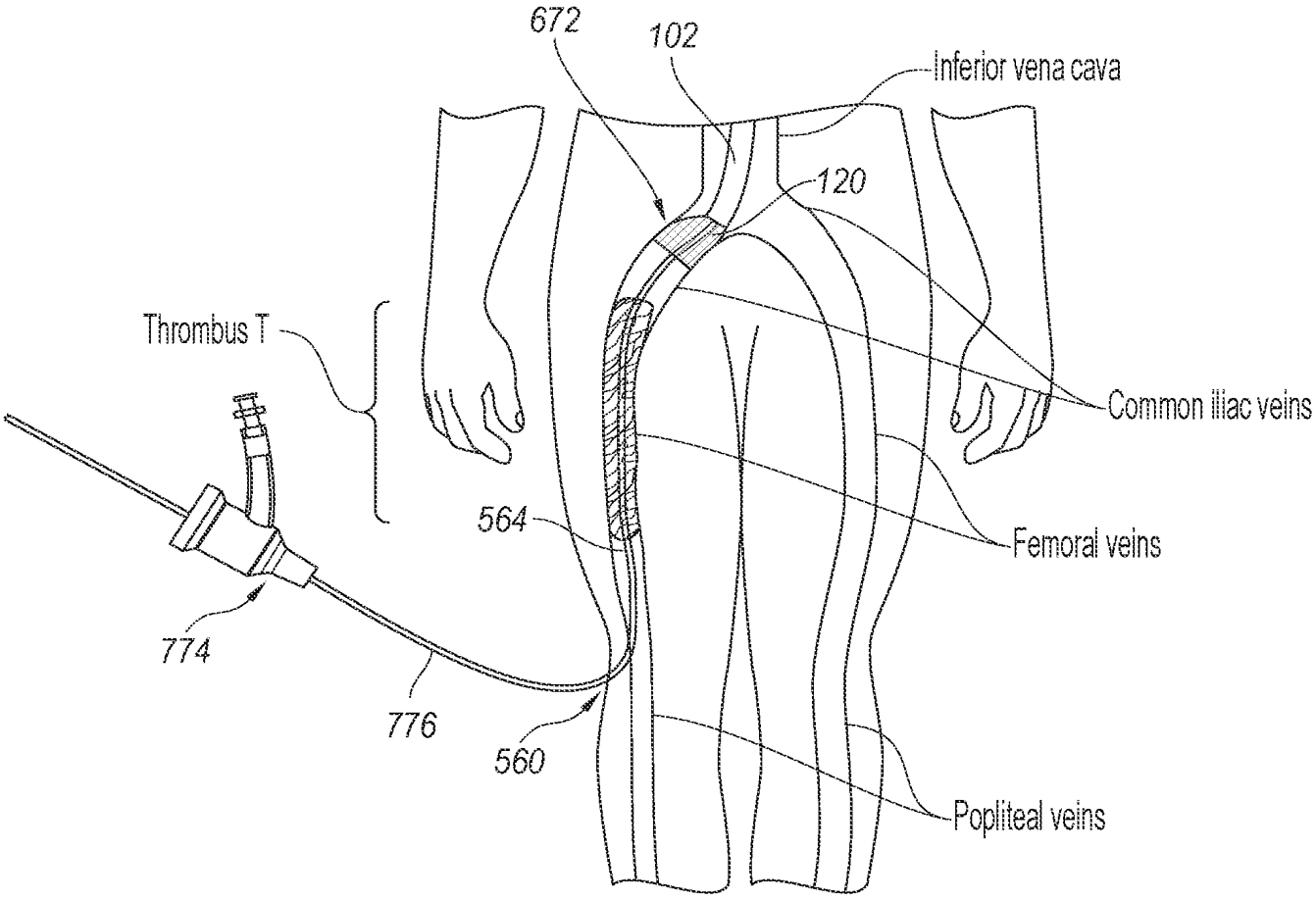

672
102
Inferior vena cava
120
Thrombus T
Common iliac veins
564
Femoral veins
774
776
560
Popliteal veins

Fig. 7

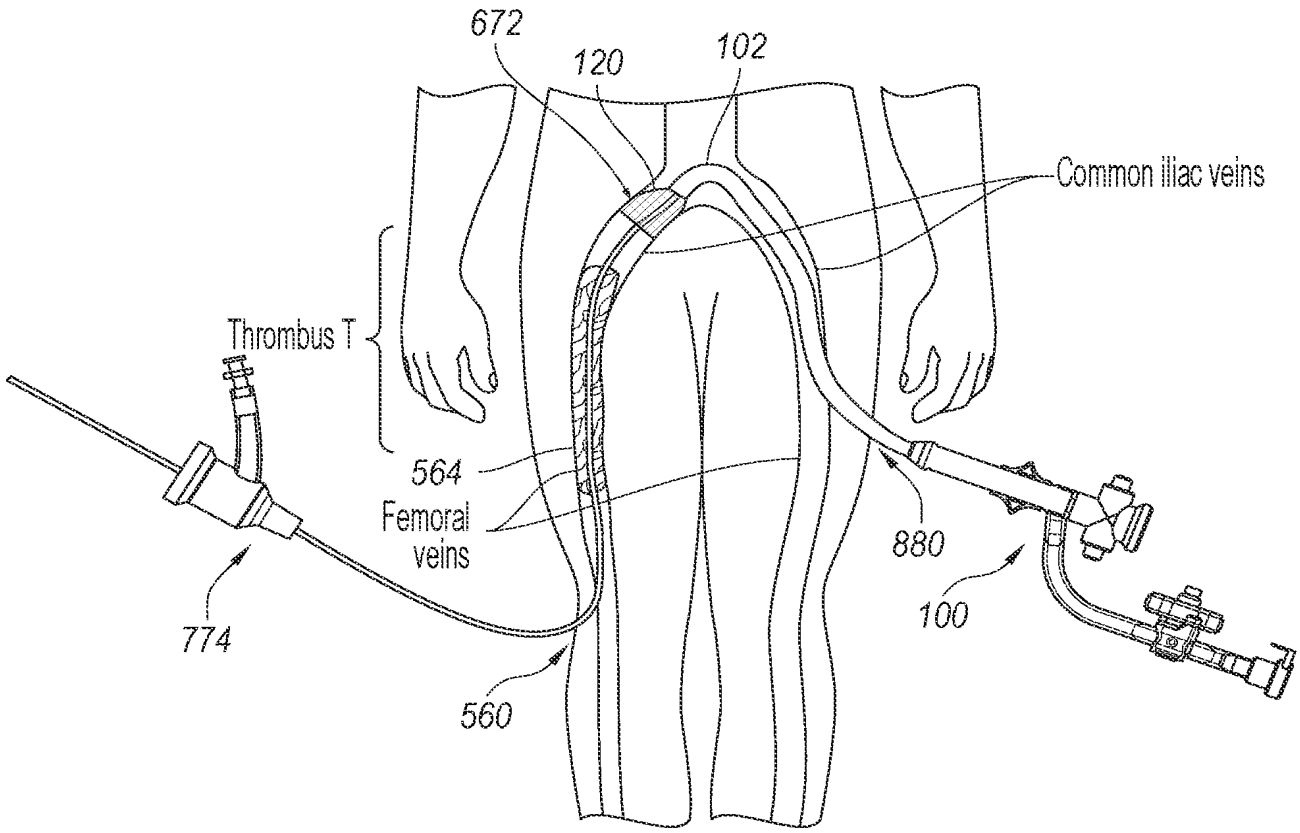

672
120
102
Common iliac veins
Thrombus T
564
Femoral veins
880
100
774
560

Fig. 8

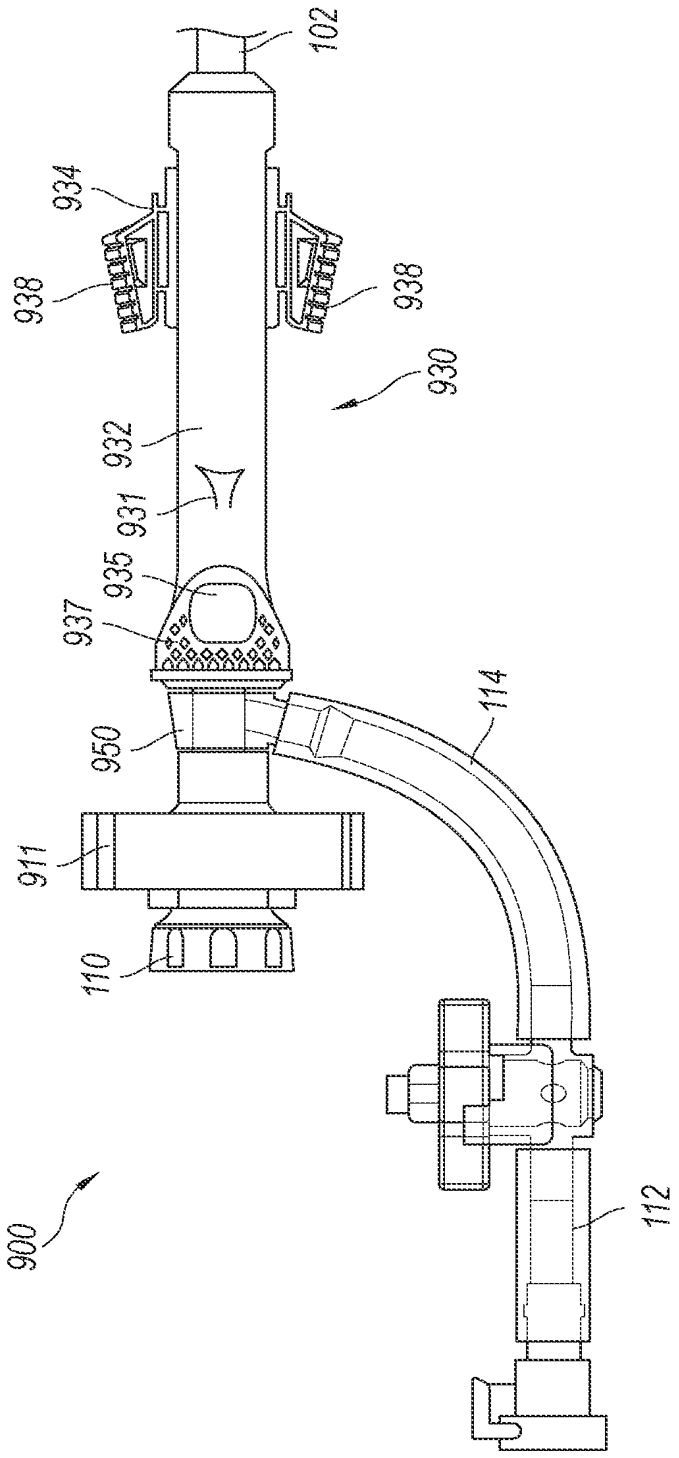


Fig. 9A

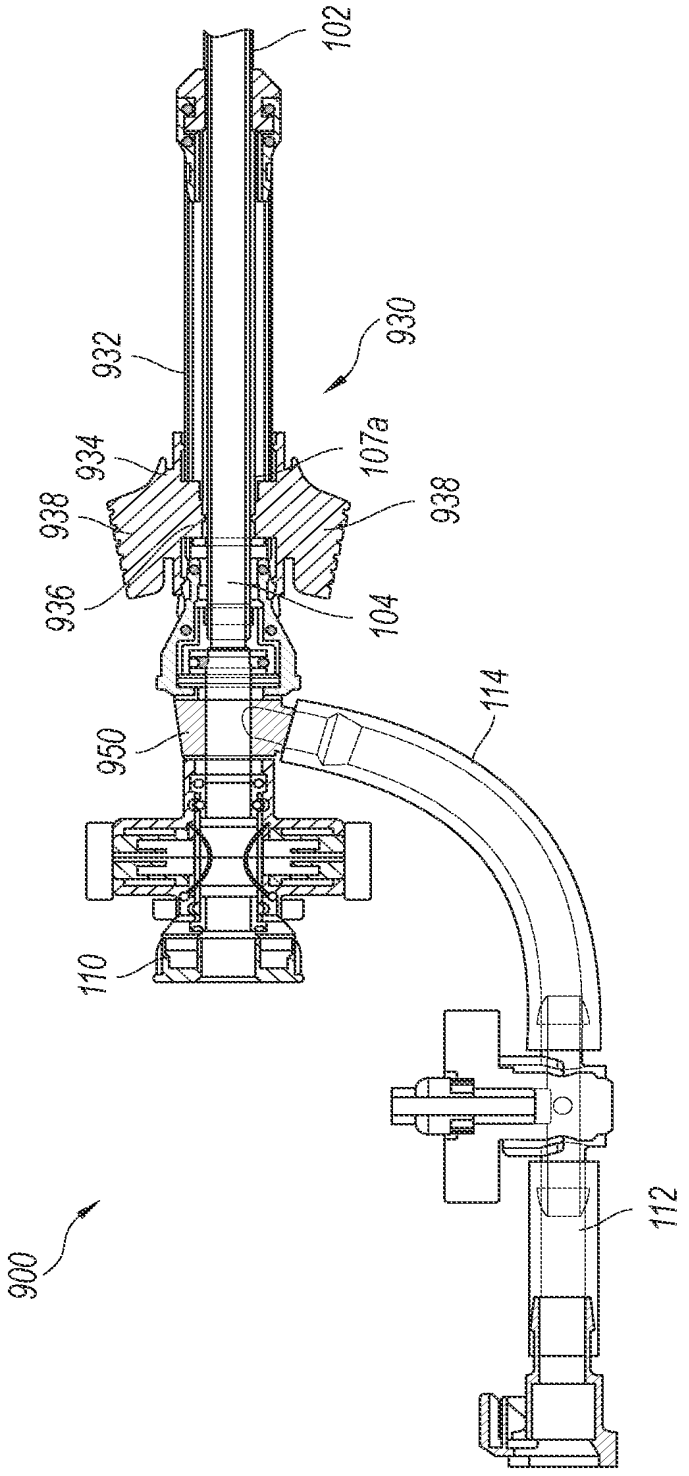


Fig. 9B

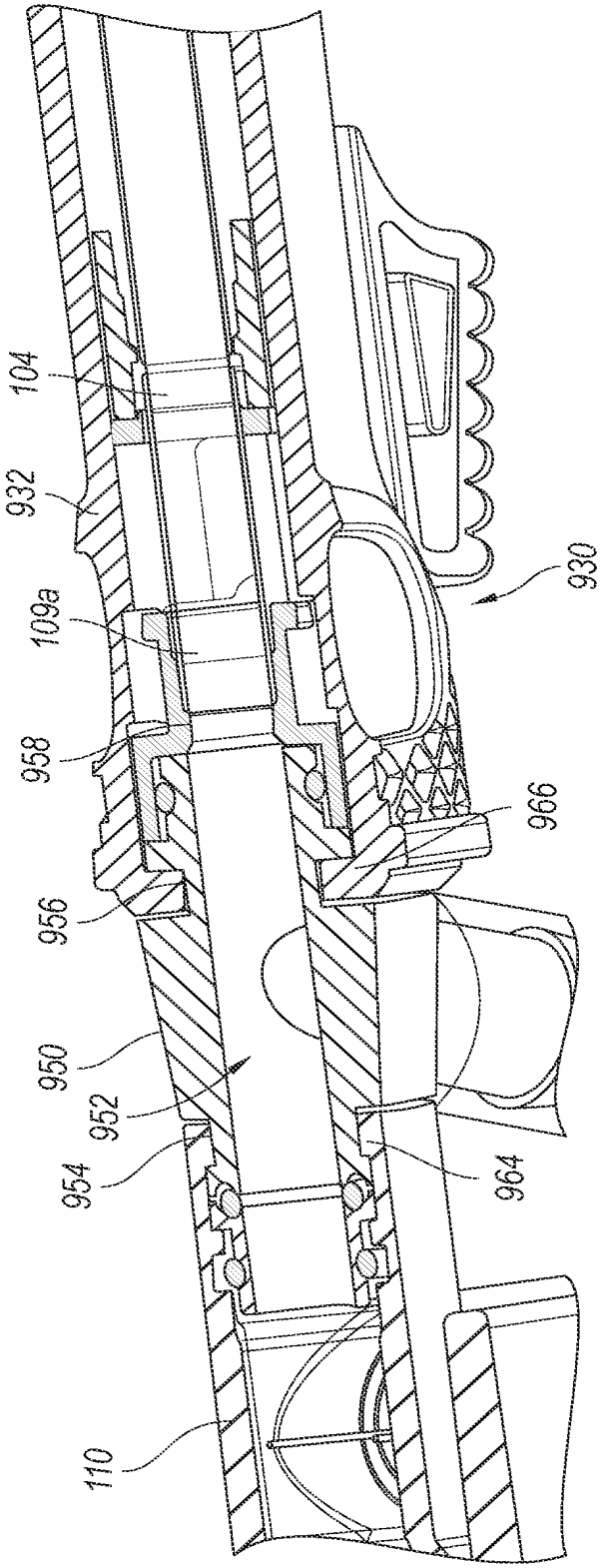


Fig. 9C

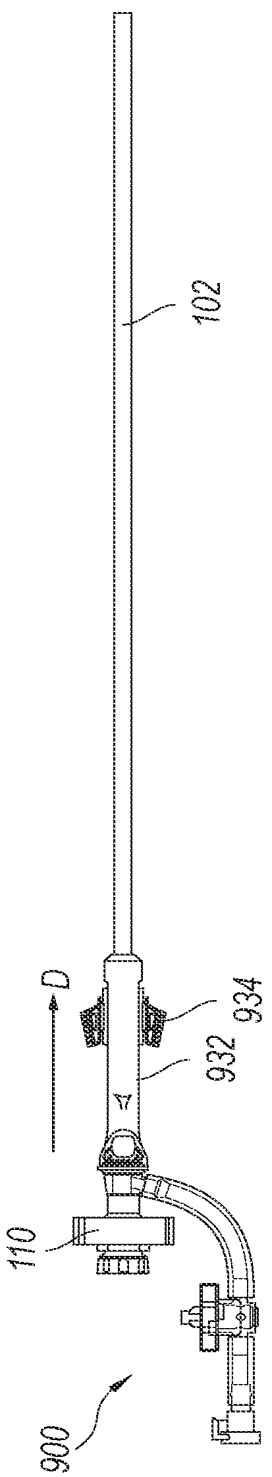


Fig. 10A

Fig. 10B

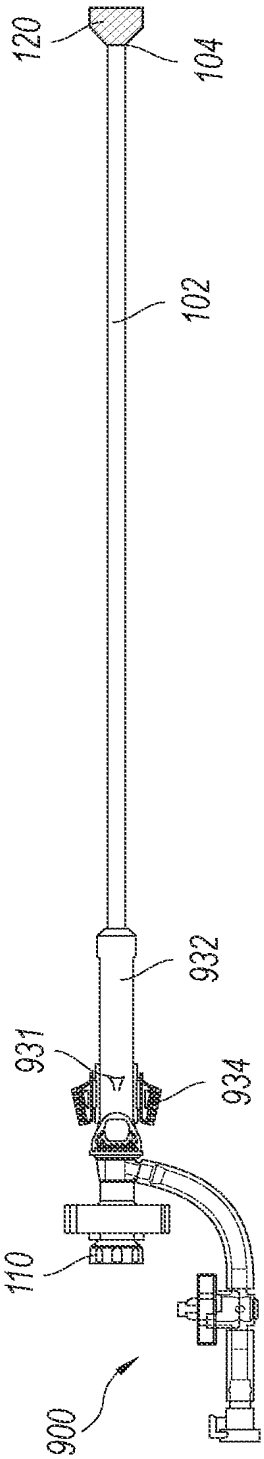


Fig. 10C

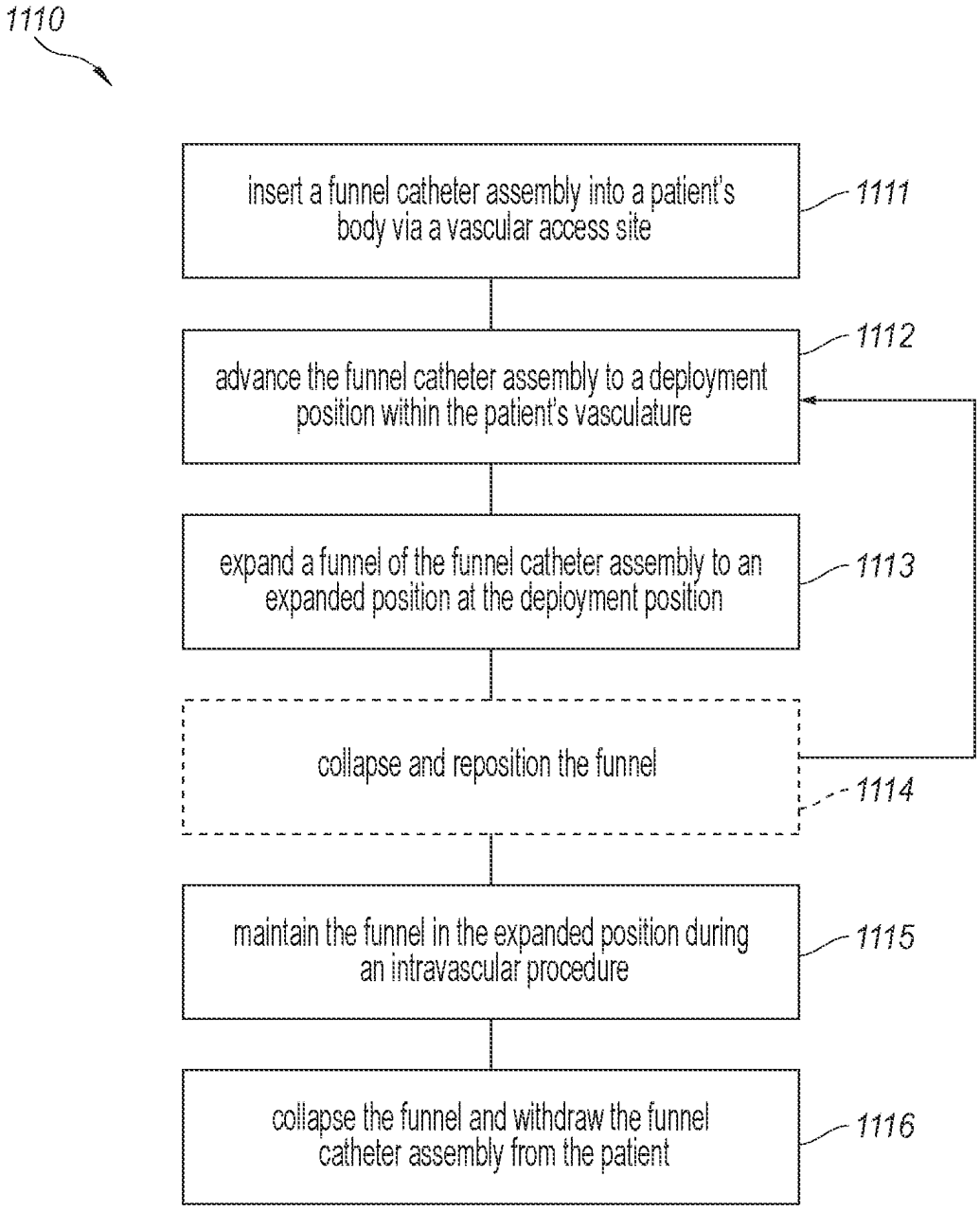

1110
insert a funnel catheter assembly into a patient's body via a vascular access site
1111
advance the funnel catheter assembly to a deployment position within the patient's vasculature
1112
expand a funnel of the funnel catheter assembly to an expanded position at the deployment position
1113
collapse and reposition the funnel
1114
maintain the funnel in the expanded position during an intravascular procedure
1115
collapse the funnel and withdraw the funnel catheter assembly from the patient
1116

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/35965

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/00, A61B 17/22, A61B 17/3207, A61M 25/10, A61M 1/00 (2021.01)

CPC - A61M 2025/1045, A61B 17/22, A61B 17/221, A61B 2217/005, A61M 2025/109

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	US 5,011,488 A (Ginsburg) 30 April 1991 (30.04.1991), entire document	1-10, 13-17, 19-20 ---------- 18
X	US 5,800,457 (Gelbfish) 1 Septemebr 1998 (01.09.1998), entire document	8, 11-12
Y	WO 2009/082513 A1 (Tex Medical) 2 July 2009 (02.07.2009), entire document	18
A	US 2002/0161392 A1 (Dubrul) 31 October 2002 (31.10.2002), entire document	1-20
A	WO 2018/148174 A1 (KP Medcure, Inc) 16 August 2018 (16.08.2018), entire document	1-20

☐ 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
6 August 2021	SEP 28 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 Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

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

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 December 2019 (26.12.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/246240 A1

(51) International Patent Classification:
A61B 1/00 (2006.01) *A61M 25/01* (2006.01)
A61B 1/005 (2006.01) *A61B 17/00* (2006.01)
A61B 1/018 (2006.01) *A61B 34/20* (2016.01)
A61B 1/267 (2006.01) *G02B 23/24* (2006.01)

(21) International Application Number:
PCT/US2019/037954

(22) International Filing Date:
19 June 2019 (19.06.2019)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/687,120 19 June 2018 (19.06.2018) US

(71) Applicant: **INTUITIVE SURGICAL OPERATIONS, INC.** [US/US]; 1020 Kifer Road, Sunnyvale, California 94086 (US).

(72) Inventors: **BOGUSKY, Joseph D.**; c/o Intuitive Surgical Operations, Inc., 1020 Kifer Road, Sunnyvale, California 94086 (US). **SCHLESINGER, Randall L.**; c/o Intuitive Surgical Operations, Inc., 1020 Kifer Road, Sunnyvale, California 94086 (US).

(74) Agent: **GENCO, Brian C.** et al.; Meunier Carlin & Curfman LLC, 999 Peachtree St. NE, Suite 1300, Atlanta, Georgia 30309 (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).

Published:
— *with international search report (Art. 21(3))*

(54) **Title:** SYSTEMS AND METHODS FOR HOLDING A FLEXIBLE ELONGATE DEVICE IN A POSE

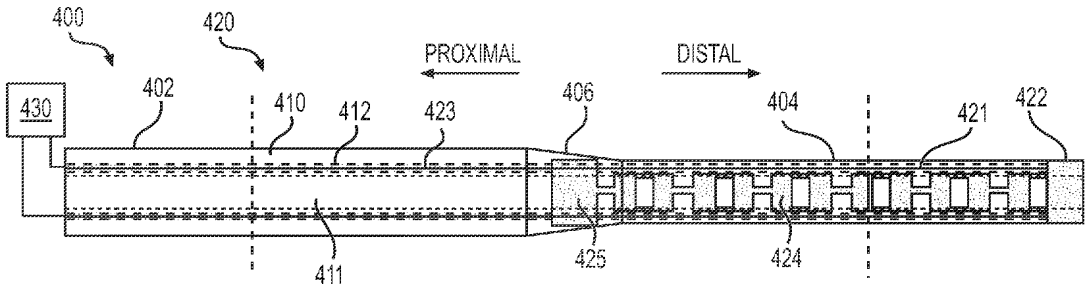


FIG. 4A

(57) **Abstract:** Disclosed herein are a range of stiffening mechanisms or systems that assist or enable holding a pose or shape of a flexible body (1010, 216, 410, 420, 801). These stiffening mechanisms may be part of the steering mechanism (500, 800), may be separately actuated and/or may themselves also enable steering of the flexible elongate device (400). Further, the stiffening mechanisms may use information from sensor (826) systems, such as a shape sensor (222, 314, 426) in the form of an optical fiber, a plurality of EM sensors (426, 826) distributed along the length of a flexible device, and/or navigation systems, such as a sensor system (108) that computes the approximate location of medical instruments (such as a flexible body) within the anatomy of the patient and/or medical tools that are delivered through a main lumen (411, 811) of the flexible body (1010, 216, 410, 420, 801), to inform a control system (112, 116) which then controls formation and holding of a shape of the flexible body (1010, 216, 410, 420, 801).

WO 2019/246240 A1

SYSTEMS AND METHODS FOR HOLDING A FLEXIBLE ELONGATE DEVICE IN A POSE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 62/687,120 filed June 19, 2018, the disclosure of which is expressly incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure is directed to teleoperated systems and in particular teleoperated systems involving use of flexible elongate devices.

BACKGROUND

[0003] Flexible elongate devices can be employed in range of fields needing access to restricted openings such as for the exploration of pipes or in medical procedures, especially minimally invasive medical techniques.

[0004] Minimally invasive medical techniques are intended to reduce the amount of tissue that is damaged during medical procedures, thereby reducing patient recovery time, discomfort, and harmful side effects. Such minimally invasive techniques may be performed through natural orifices in a patient anatomy or through one or more surgical incisions. Through these natural orifices or incisions physician may insert minimally invasive medical instruments (including surgical, diagnostic, therapeutic, or biopsy instruments) to reach a target tissue location.

[0005] One such minimally invasive technique is to use a flexible and/or steerable elongate device, such as a flexible catheter, that can be inserted into anatomic passageways and navigated toward a region of interest within the patient anatomy. In some applications, the flexible and/or steerable elongate device needs to be held in a particular shape to enable or improve the safety of a procedure. It would be advantageous to provide improvements to systems and methods for holding a flexible elongate device in a desired pose.

SUMMARY OF THE INVENTION

[0006] Disclosed herein are a range of stiffening mechanisms or systems that assist or enable holding a pose or shape of a flexible body. These stiffening mechanisms may be part of the steering mechanism, may be separately actuated and/or may themselves also enable steering of the flexible elongate device. Further, the stiffening mechanisms may use information from sensor systems, such as a shape sensor in the form of an optical fiber, a plurality of EM sensors distributed

along the length of a flexible device, and/or navigation systems, such as a sensor system that computes the approximate location of medical instruments (such as a flexible body) within the anatomy of the patient and/or medical tools that are delivered through a main lumen of the flexible body, to inform a control system which then controls formation and holding of a shape of the flexible body.

[0007] One embodiment includes a flexible elongate device having a flexible body, a support structure, and a stiffening mechanism. The flexible body has a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends. The flexible body has sufficient flexibility to form a pose. The support structure is coupled with the flexible body. The support structure includes a plurality of sub-elements arranged in series. At least a portion of the sub elements are configured to spread apart when the flexible body flexes into the pose. The stiffening mechanism has at least one stiffening element extending along at least a portion of the flexible body and is configured for actuation independent of the support structure. Actuation of the at least one stiffening element stiffens the support structure to hold at least a portion of the pose of the flexible body. The stiffening element includes a compression feature configured to engage the support structure.

[0008] The support structure includes a coil and the sub-elements include windings of the coil in another embodiment. The support structure includes a spine in another embodiment.

[0009] In various embodiments, the stiffening mechanism includes an inflatable system wherein the inflatable system includes a balloon configured to engage the support structure. The balloon can be configured to extend in between the sub-elements. For example, the balloon can be configured to extend between the sub-elements due to application of a vacuum pressure causing the balloon to collapse into an exterior of the support structure and in between the sub-elements. In yet another embodiment, the balloon is configured to extend in between the sub-elements due to the application of an inflation pressure causing the balloon to expand into an interior defined within the support structure and in between the sub-elements.

[0010] The balloon system, in other embodiments, includes a plurality of balloon portions. For example, the balloon portions can be selectively inflatable to hold the at least the portion of the pose. The balloon portions can be positioned between the sub elements. Further, the balloon portions can spiral between the sub elements.

[0011] In yet another embodiment, the stiffening mechanism can comprise a plurality of control elements extending along the flexible body and configured to exert tension on the flexible body in conjunction with selective inflation of the balloon portions to further hold the at least the portion of the pose.

[0012] Other embodiments can include a shape sensor configured to determine the pose of the flexible body and a controller. The controller can be connected in communication with the shape sensor and the controller is configured to activate the stiffening mechanism to hold at least the portion of the pose of the flexible body.

[0013] In another embodiment, the medical system includes a flexible body, a shape sensor, a stiffening mechanism and a controller. The flexible body has a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends, wherein the flexible body includes a plurality of sub-portions. The shape sensor extends along at least a portion of the flexible body. The stiffening mechanism has a plurality of stiffening elements, each of the stiffening elements positioned within one of the plurality of sub-portions, wherein the sub-portions extend along the flexible body. The controller is connected in communication with the shape sensor, configured to selectively activate the stiffening elements based in part on data received from the shape sensor.

[0014] In another embodiment, the controller is further configured to selectively activate the stiffening elements based in part on a type of instrument for insertion through the flexible body. For example, the controller can be configured to energize selected ones of the stiffening elements to reduce curvature of the flexible body to match a stiff type of instrument.

[0015] In another embodiment, the controller is further configured to selectively activate the stiffening elements based in part on anatomical information. The anatomical information can also information identifying a target area of anatomy and wherein the controller is further configured to actuate selected ones of the stiffening elements to protect the target area of anatomy.

[0016] In another embodiment, the shape sensor includes at least one of a shape sensing fiber extending along the flexible body or a plurality of EM sensors extending along the flexible body.

[0017] In other embodiments, the stiffening mechanism includes a longitudinal balloon array having a plurality of balloon portions and wherein each of the stiffening elements is one of the plurality of balloon portions.

[0018] In another embodiment, the flexible body includes a coil with a plurality of adjacent windings and wherein each of the balloon portions are configured to extend between the adjacent windings with the application of pressure. Further, controller may be configured to selectively apply pressure to each of the balloon portions to urge apart adjacent windings to shape the flexible body.

[0019] Other embodiments further comprise a steering mechanism configured to control the distal end portion of the flexible body. For example, the steering mechanism can include a plurality of pull wires and wherein the controller is further configured to adjust tension in the pull

wires along with selective activation of the stiffening elements to hold the portion of the flexible body in the pose.

[0020] In other embodiments, the plurality of stiffening elements includes a plurality of nitinol actuators. For example, the flexible body can include a wall structure and the plurality of nitinol actuators are embedded in the wall structure. The plurality of nitinol actuators can be distributed circumferentially within the wall structure.

[0021] Other embodiments include a method of holding at least a portion of a pose of a flexible body. The method can include engaging a stiffening element of a stiffening mechanism within a spacing between at least a pair of the plurality of sub-elements, wherein the plurality of sub-elements extend along the flexible body.

[0022] In another embodiment, engaging stiffening element includes urging a portion of the stiffening element into the spacing between the at least the pair of the plurality of sub-elements.

[0023] In another embodiment, urging the portion of the stiffening element includes one of inflating or deflating the stiffening element.

[0024] In another embodiment, actuating a plurality of pull wires extending within a wall structure of the flexible body including adjusting tension in the plurality of pull wires while selectively activating the stiffening elements to hold the pose of the flexible body.

[0025] Other embodiments include a method of holding a pose of a flexible body using a controller. The method includes measuring a current configuration of a flexible body based at least in part on a sensor coupled to the flexible body, determining a desired configuration of the flexible body, and selectively activating a stiffening mechanism to position the flexible body from the current configuration to the desired configuration, wherein the stiffening mechanism includes a plurality of stiffening elements distributed down the length of the flexible body.

[0026] In another embodiment, positioning the flexible body in the desired configuration includes activating each of the plurality of stiffening elements independently.

[0027] In another embodiment, the current configuration includes a measured shape of the flexible body.

[0028] In another embodiment, the method can comprise identifying a small radius in the measured shape, wherein selectively activating the stiffening mechanism includes activating select ones of the plurality of the stiffening elements to increase a bend radius of the flexible body at the identified small radius in the measured shape.

[0029] In another embodiment, the method can comprise receiving information describing stiffness of an instrument to be delivered by the flexible body, wherein the identifying of the small radius in the measured shape includes determining a minimum bend radius corresponding to the

stiffness of the instrument.

[0030] In another embodiment, determining the desired configuration comprises receiving information identifying a target area of anatomy and setting the desired configuration to activate select ones of the plurality of the stiffening elements at the identified target area of anatomy. The information received identifying the target area of anatomy may be based on live imaging.

[0031] In another embodiment, determining the desired configuration comprises receiving a preoperatively recorded surgical image, registering the flexible body to the preoperatively recorded surgical image using sensor data from the sensor coupled to the flexible body, and identifying a portion of the flexible body positioned within the identified target area of anatomy based on the registration. The information received identifying the target area of anatomy is based on the preoperatively recorded surgical image

[0032] In other embodiments, the plurality of the stiffening elements includes a plurality of nitinol actuators extending within a wall structure of the flexible body, and wherein the selectively activating the stiffening mechanism includes energizing at least one of the plurality of nitinol actuators.

[0033] In yet other embodiments, the plurality of the stiffening elements includes a plurality of balloons, and wherein the selectively activating the stiffening mechanisms includes inflating or deflating at least one of the plurality of balloons.

[0034] Embodiments of the present invention have a range of advantages. For example, in the environment of articulating devices that navigate the tortuosity of human anatomy, it is advantageous to securely hold the contorted position of said device while instruments are being delivered through the device. Frequently, devices that pass through an articulating device will exert forces that have a tendency to straighten a contorted and articulated portion of the device. Embodiments of the invention provides various apparatus and methods to hold the pose of a catheter in a contorted position for stable delivery of instruments

BRIEF DESCRIPTIONS OF THE DRAWINGS

[0035] FIG. 1 is a simplified diagram of a teleoperated medical system according to some embodiments.

[0036] FIG. 2A is a simplified diagram of a medical instrument system according to some embodiments.

[0037] FIG. 2B is a simplified diagram of a medical instrument with an extended medical tool according to some embodiments.

[0038] FIGS. 3A and 3B are simplified diagrams of side views of a patient coordinate space

including a medical instrument mounted on an insertion assembly according to some embodiments.

[0039] FIGS. 4A-4C are simplified diagrams of a flexible elongate device according to some embodiments.

[0040] FIG. 5 is a simplified cross-sectional view of a control element conduit according to some embodiments.

[0041] FIGS. 6A-6D are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0042] FIGS. 7A-7D are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0043] FIGS. 8A-8E are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0044] FIGS. 9A-9B are simplified diagrams of methods of using a flexible elongate device with a stiffening mechanism of other embodiments.

[0045] FIGS. 10A-10B are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0046] FIG. 11 is a simplified flow diagram of a method for identifying target areas of anatomy and activating a stiffening mechanism according to some embodiments.

[0047] FIG. 12 is a simplified flow diagram of a method for identifying an external force and activating a stiffening mechanism according to some embodiments.

DETAILED DESCRIPTION

[0048] In the following description, specific details are set forth describing some embodiments consistent with the present disclosure. Numerous specific details are set forth in order to provide a thorough understanding of the embodiments. It will be apparent, however, to one skilled in the art that some embodiments may be practiced without some or all of these specific details. The specific embodiments disclosed herein are meant to be illustrative but not limiting. One skilled in the art may realize other elements that, although not specifically described here, are within the scope and the spirit of this disclosure. In addition, to avoid unnecessary repetition, one or more features shown and described in association with one embodiment may be incorporated into other embodiments unless specifically described otherwise or if the one or more features would make an embodiment non-functional.

[0049] In some instances well known methods, procedures, components, and circuits have not been described in detail so as not to unnecessarily obscure aspects of the embodiments.

[0050] This disclosure describes various instruments and portions of instruments in terms of their state in three-dimensional space. As used herein, the term "position" refers to the location of an object or a portion of an object in a three-dimensional space (e.g., three degrees of translational freedom along Cartesian x-, y-, and z-coordinates). As used herein, the term "orientation" refers to the rotational placement of an object or a portion of an object (three degrees of rotational freedom – e.g., roll, pitch, and yaw). As used herein, the term "pose" refers to the position of an object or a portion of an object in at least one degree of translational freedom and to the orientation of that object or portion of the object in at least one degree of rotational freedom (up to six total degrees of freedom). As used herein, the term "shape" refers to a set of poses, positions, or orientations measured along an object.

[0051] FIG. 1 is a simplified diagram of a teleoperated medical system 100 according to some embodiments. In some embodiments, teleoperated medical system 100 may be suitable for use in, for example, surgical, diagnostic, therapeutic, or biopsy procedures. While some embodiments are provided herein with respect to such procedures, any reference to medical or surgical instruments and medical or surgical methods is non-limiting. The systems, instruments, and methods described herein may be used for animals, human cadavers, animal cadavers, portions of human or animal anatomy, non-surgical diagnosis, as well as for industrial systems and general robotic or teleoperational systems.

[0052] As shown in FIG. 1, medical system 100 generally includes a manipulator assembly 102 for operating a medical instrument 104 in performing various procedures on a patient P. The manipulator assembly 102 may be teleoperated, non-teleoperated, or a hybrid teleoperated and non-teleoperated assembly with select degrees of freedom of motion that may be motorized and/or teleoperated and select degrees of freedom of motion that may be non-motorized and/or non-teleoperated. Manipulator assembly 102 is mounted to or near an operating table T. A master assembly 106 allows an operator (e.g., a surgeon, a clinician, or a physician as illustrated in FIG. 1) to view the interventional site and to control manipulator assembly 102. Master assembly 106 generally includes one or more control devices for controlling manipulator assembly 102.

[0053] Manipulator assembly 102 supports medical instrument 104 and may optionally include a plurality of actuators or motors that drive inputs on medical instrument 104 in response to commands from the control system (e.g., a control system 112). The actuators may optionally include drive systems that when coupled to medical instrument 104 may advance medical instrument 104 into a naturally or surgically created anatomic orifice. Other drive systems may move the distal end of medical instrument 104 in multiple degrees of freedom, which may include three degrees of linear motion (e.g., linear motion along the X, Y, Z Cartesian axes) and in three

degrees of rotational motion (e.g., rotation about the X, Y, Z Cartesian axes). Additionally, the actuators can be used to actuate an articulable end effector of medical instrument 104 for grasping tissue in the jaws of a biopsy device and/or the like. Actuator position sensors such as resolvers, encoders, potentiometers, and other mechanisms may provide sensor data to medical system 100 describing the rotation and orientation of the motor shafts. This position sensor data may be used to determine motion of the objects manipulated by the actuators.

[0054] Teleoperated medical system 100 may include a sensor system 108 with one or more sub-systems for receiving information about the instruments of manipulator assembly 102. Such sub-systems may include a position/location sensor system (e.g., an electromagnetic (EM) sensor system); a shape sensor system for determining the position, orientation, speed, velocity, pose, and/or shape of a distal end and/or of one or more segments along a flexible body that may make up medical instrument 104; and/or a visualization system for capturing images from the distal end of medical instrument 104.

[0055] Teleoperated medical system 100 also includes a display system 110 for displaying an image or representation of the surgical site and medical instrument 104 generated by sub-systems of sensor system 108. Display system 110 and master assembly 106 may be oriented so operator O can control medical instrument 104 and master assembly 106 with the perception of telepresence. Display system 110 may present images of a surgical site recorded pre-operatively or intra-operatively using image data from imaging technology such as, computed tomography (CT), magnetic resonance imaging (MRI), fluoroscopy, thermography, ultrasound, optical coherence tomography (OCT), thermal imaging, impedance imaging, laser imaging, nanotube X-ray imaging, and/or the like. The pre-operative or intra-operative image data may be presented as two-dimensional, three-dimensional, or four-dimensional (including e.g., time based or velocity-based information) images and/or as images from models created from the pre-operative or intra-operative image data sets. In some embodiments, often for purposes of imaged guided surgical procedures, display system 110 may display a virtual navigational image in which the actual location of medical instrument 104 is registered (i.e., dynamically referenced) with the preoperative or concurrent images/model.

[0056] In some embodiments, display system 110 may display a virtual navigational image in which the actual location of medical instrument 104 is registered with preoperative or concurrent images to present the operator O with a virtual image of medical instrument 104 within the surgical site from an external viewpoint. An image of a portion of medical instrument 104 or other graphical or alphanumeric indicators may be superimposed on the virtual image to assist operator O in the control of medical instrument 104. As described herein, visual representations of data

points may be rendered to display system 110. For example, measured data points, moved data points, registered data points, and other data points described herein may be displayed on display system 110 in a visual representation.

[0057] Teleoperated medical system 100 may also include control system 112. Control system 112 includes at least one memory and at least one computer processor (not shown) for effecting control between medical instrument 104, master assembly 106, sensor system 108, and display system 110. Control system 112 also includes programmed instructions (e.g., a non-transitory machine-readable medium storing the instructions) to implement some or all of the methods described in accordance with aspects disclosed herein, including instructions for providing information to display system 110. While control system 112 is shown as a single block in the simplified schematic of FIG. 1, the system may include two or more data processing circuits with one portion of the processing optionally being performed on or adjacent to manipulator assembly 102, another portion of the processing being performed at master assembly 106, and/or the like. The processors of control system 112 may execute instructions comprising instruction corresponding to processes disclosed herein and described in more detail below. Any of a wide variety of centralized or distributed data processing architectures may be employed. Similarly, the programmed instructions may be implemented as a number of separate programs or subroutines, or they may be integrated into a number of other aspects of the teleoperational systems described herein. In one embodiment, control system 112 supports wireless communication protocols such as Bluetooth, IrDA, HomeRF, IEEE 802.11, DECT, and Wireless Telemetry.

[0058] In some embodiments, control system 112 may receive force and/or torque feedback from medical instrument 104. Responsive to the feedback, control system 112 may transmit signals to master assembly 106. In some examples, control system 112 may transmit signals instructing one or more actuators of manipulator assembly 102 to move medical instrument 104. Control system 112 may optionally further include a virtual visualization system to provide navigation assistance to operator O when controlling medical instrument 104 during an image-guided surgical procedure.

[0059] During a virtual navigation procedure, sensor system 108 may be used to compute an approximate location of medical instrument 104 with respect to the anatomy of patient P. The location can be used to produce both macro-level (external) tracking images of the anatomy of patient P and virtual internal images of the anatomy of patient P. The system may implement one or more electromagnetic (EM) sensor, fiber optic sensors, and/or other sensors to register and display a medical implement together with preoperatively recorded surgical images, such as those from a virtual visualization system. For example, PCT Publication WO 2016/191298 (published

December 1, 2016) (disclosing "Systems and Methods of Registration for Image Guided Surgery"), which is incorporated by reference herein in its entirety, discloses such one system.

[0060] FIG. 2A is a simplified diagram of a medical instrument system 200 according to some embodiments. Medical instrument system 200 includes elongate device 202, such as a flexible catheter, coupled to a drive unit 204. Elongate device 202 includes a flexible body 216 having proximal end 217 and distal end or tip portion 218.

[0061] Medical instrument system 200 further includes a tracking system 230 for determining the position, orientation, speed, velocity, pose, and/or shape of distal end 218 and/or of one or more segments 224 along flexible body 216 using one or more sensors and/or imaging devices as described in further detail below. The entire length of flexible body 216, between distal end 218 and proximal end 217, may be effectively divided into segments 224. Tracking system 230 may optionally be implemented as hardware, firmware, software or a combination thereof which interact with or are otherwise executed by one or more computer processors, which may include the processors of control system 112 in FIG. 1.

[0062] Tracking system 230 may optionally track distal end 218 and/or one or more of the segments 224 using a shape sensor 222. Shape sensor 222 may optionally include an optical fiber aligned with flexible body 216 (e.g., provided within an interior channel (not shown) or mounted externally). In one embodiment, the optical fiber has a diameter of approximately 200 μm. In other embodiments, the dimensions may be larger or smaller. The optical fiber of shape sensor 222 forms a fiber optic bend sensor for determining the shape of flexible body 216. In one alternative, optical fibers including Fiber Bragg Gratings (FBGs) are used to provide strain measurements in structures in one or more dimensions. Various systems and methods for monitoring the shape and relative position of an optical fiber in three dimensions are described in U.S. Patent Application No. 11/180,389 (filed July 13, 2005) (disclosing "Fiber optic position and shape sensing device and method relating thereto"); U.S. Patent Application No. 12/047,056 (filed on Jul. 16, 2004) (disclosing "Fiber-optic shape and relative position sensing"); and U.S. Patent No. 6,389,187 (filed on Jun. 17, 1998) (disclosing "Optical Fibre Bend Sensor"), which are all incorporated by reference herein in their entireties.

[0063] In some embodiments, tracking system 230 may optionally and/or additionally track distal end 218 using a position sensor system 220. Position sensor system 220 may be a component of an EM sensor system with position sensor system 220 including one or more conductive coils that may be subjected to an externally generated electromagnetic field. Each coil of the EM sensor system then produces an induced electrical signal having characteristics that depend on the position and orientation of the coil relative to the externally generated electromagnetic field. In some

embodiments, position sensor system 220 may be configured and positioned to measure six degrees of freedom, e.g., three position coordinates X, Y, Z and three orientation angles indicating pitch, yaw, and roll of a base point or five degrees of freedom, e.g., three position coordinates X, Y, Z and two orientation angles indicating pitch and yaw of a base point. Further description of a position sensor system is provided in U.S. Patent No. 6,380,732 (filed August 11, 1999) (disclosing "Six-Degree of Freedom Tracking System Having a Passive Transponder on the Object Being Tracked"), which is incorporated by reference herein in its entirety. In some examples, a series of positional sensors (not shown), such as electromagnetic (EM) sensors similar to the sensors in position sensor 220 may be positioned along flexible body 216 and then used for shape sensing. Flexible body 216 includes a channel 221 sized and shaped to receive a medical instrument 226.

[0064] FIG. 2B is a simplified diagram of flexible body 216 with medical instrument 226 extended according to some embodiments. In some embodiments, medical instrument 226 may be used for procedures such as surgery, biopsy, ablation, illumination, irrigation, or suction.

[0065] Medical instrument 226 may additionally house cables, linkages, or other actuation controls (not shown) that extend between its proximal and distal ends to controllably bend the distal end of medical instrument 226. Steerable instruments are described in detail in U.S. Patent No. 7,316,681 (filed on Oct. 4, 2005) (disclosing "Articulated Surgical Instrument for Performing Minimally Invasive Surgery with Enhanced Dexterity and Sensitivity") and U.S. Patent Application No. 12/286,644 (filed Sept. 30, 2008) (disclosing "Passive Preload and Capstan Drive for Surgical Instruments"), which are incorporated by reference herein in their entireties.

[0066] Flexible body 216 may also house cables, linkages, or other steering controls (not shown) that extend between drive unit 204 and distal end 218 to controllably bend distal end 218 as shown, for example, by broken dashed line depictions 219 of distal end 218. Steerable elongate devices are described in detail in U.S. Patent Application No. 13/274,208 (filed Oct. 14, 2011) (disclosing "Catheter with Removable Vision Probe"), which is incorporated by reference herein in its entirety. In embodiments in which medical instrument system 200 is actuated by a teleoperational assembly, drive unit 204 may include drive inputs that removably couple to and receive power from drive elements, such as actuators, of the teleoperational assembly. In some embodiments, medical instrument system 200 may include gripping features, manual actuators, or other components for manually controlling the motion of medical instrument system 200. Elongate device 202 may be steerable or, alternatively, the system may be non-steerable with no integrated mechanism for operator control of the bending of distal end 218. In some examples, one or more lumens, through which medical instruments can be deployed and used at a target surgical location, are defined in the walls of flexible body 216.

[0067] The information from tracking system 230 may be sent to a navigation system 232 where it is combined with information from visualization system 231 and/or the preoperatively obtained models (e.g., anatomic models of the patient anatomy) to provide the physician or other operator with real-time position information. In some examples, the real-time position information may be displayed on display system 110 of FIG. 1 for use in the control of medical instrument system 200. In some examples, control system 116 of FIG. 1 may utilize the position information as feedback for positioning medical instrument system 200. Various systems for using fiber optic sensors to register and display a surgical instrument with surgical images are provided in U.S. Patent Application No. 13/107,562, filed May 13, 2011, disclosing, "Medical System Providing Dynamic Registration of a Model of an Anatomic Structure for Image-Guided Surgery," which is incorporated by reference herein in its entirety.

[0068] In some examples, medical instrument system 200 may be teleoperated within medical system 100 of FIG. 1. In some embodiments, manipulator assembly 102 of FIG. 1 may be replaced by direct operator control. In some examples, the direct operator control may include various handles and operator interfaces for hand-held operation of the instrument.

[0069] FIGS. 3A and 3B are simplified diagrams of side views of a patient coordinate space including a medical instrument mounted on an insertion assembly according to some embodiments. As shown in FIGS. 3A and 3B, a surgical environment 300 includes a patient P is positioned on the table T of FIG. 1. Instrument carriage 306 or insertion stage 308 may include actuators, such as servomotors, (not shown) that control motion of instrument carriage 306 along insertion stage 308. Elongate device 310 is coupled to an instrument body 312. Instrument body 312 is coupled and fixed relative to instrument carriage 306. In some embodiments, an optical fiber shape sensor 314 is fixed at a proximal point 316 on instrument body 312. Shape sensor 314 measures a shape from proximal point 316 to another point such as distal end 318 of elongate device 310. Point gathering instrument 304 may be substantially similar to medical instrument system 200. A position measuring device 320 provides information about the position of instrument body 312 as it moves on insertion stage 308 along an insertion axis A. Position measuring device 320 may include resolvers, encoders, potentiometers, and/or other sensors that determine the rotation and/or orientation of the actuators controlling the motion of instrument carriage 306 and consequently the motion of instrument body 312. In some embodiments, insertion stage 308 is linear. In some embodiments, insertion stage 308 may be curved or have a combination of curved and linear sections.

[0070] FIG. 3A shows instrument body 312 and instrument carriage 306 in a retracted position along insertion stage 308. In FIG. 3B, instrument body 312 and instrument carriage 306 have

advanced along the linear track of insertion stage 308 and distal end 318 of elongate device 310 has advanced into patient P.

[0071] FIGS. 4A-4C are simplified diagrams of a flexible elongate device 400 according to some embodiments. According to some embodiments consistent with FIGS. 1-3, flexible elongate device 400 may correspond to elongate device 202 of medical instrument system 200. As depicted in FIG. 4A, flexible elongate device 400 can include a proximal section 402, a distal section 404 and a transition section 406 therebetween.

[0072] Flexible elongate device 400 can include a flexible body 410 with a flexible wall having a thickness extending from an inner surface to an outer surface of the flexible body 410. A main lumen 411 can extend within the flexible body 410, through the proximal section 402, the transition section 406, and the distal section 404. The main lumen 411 can provide a delivery channel for a medical tool, such as an endoscope, biopsy needle, ultrasound (EBUS or IVUS) probe, ablation tool, chemical delivery tool, and/or the like, to be inserted through flexible body 410. According to some embodiments, a plurality of control element lumens 412 extend through the flexible wall of the flexible body 410 arranged circumferentially in the flexible wall around the main lumen 411. According to some embodiments, a sensor lumen 419 extends through the flexible wall of the flexible body 410. The sensor lumen 419 can extend from the proximal end of the flexible elongate device 400, through the proximal section 402, transition section 406, terminating at a distal portion of the distal section 404. In some examples, flexible body 410 may include various other types of lumens for electrical wires, fibers, sensors, small medical instruments, chemical delivery, and/or the like. In alternative embodiments, flexible body 410 may include an all-purpose lumen that can be used for a variety of purposes, including accommodating multiple concurrently inserted instruments, control elements, sensors, and/or the like.

[0073] As depicted in FIGS. 4A-4C, within each of the control element lumens 412, a coil pipe or conduit 423 can extend through the proximal section 402 of the flexible body 410, providing channels through which a plurality of control elements 421 extends. In some examples, control elements 421 can include pull wires, tendons, push rods and/or the like. The conduits 423 terminate at the transition section 406, proximal to the distal section 404. The control elements 421 extend out of the conduits 423 at the transition section 406, entering the distal section 404 through control element lumens 412, and attach to a distal mount 422. The one or more control elements 421 can be used to actuate distal section 404 of flexible elongate device 400. As depicted in FIGS. 4B and 4C, four control elements 421 can be disposed within control element lumens 412 and evenly spaced around the circumference of flexible elongate device 400.

[0074] In the illustrative example provided in FIG. 4B, a pair of lumens that includes sensor lumen 419 and one of control element lumens 412 is approximately centered along a side of the rounded square formed by main lumen 411. Consequently, neither sensor lumen 419 nor control element lumens 412 are individually centered along the side of the rounded square. Moreover, because control elements 421 are equally spaced around the perimeter of the rounded square, none of the control element lumens 412 are centered relative to the rounded square. As a result, the square formed by control elements 421 and the rounded square formed by main lumen 411 are offset by approximately 30 degrees. However, it is to be understood that different numbers and/or arrangements of control elements 421 are possible. For example, control elements 421 may be unevenly spaced around the circumference of flexible elongate device 400 and/or centered relative to the sides of main lumen 411.

[0075] Distal section 404 is actuated by applying actuation forces to control elements 421 (e.g., pulling and/or pushing on control elements 421 in an unequal manner). Applying actuation forces causes distal section 404 to bend in the direction defined by the net actuation forces. In some examples, the actuation forces may be applied manually, robotically, and/or the like. For example, the actuation forces may be applied using an actuator 430 positioned at the proximal end of flexible elongate device 400. Conduits 423 transfer the actuation forces applied to control elements 421 from the proximal end to the distal end of proximal section 402 at transition section 406. Consequently, even when unequal actuation forces are applied to control elements 421, little actuation force appears within proximal section 402. In some examples, conduits 423 may be flexible to retain the flexibility of proximal section 402. Further examples of conduits are provided in P.C.T. Patent Application PCT/US14/62188 entitled "Flexible Instrument with Embedded Actuation Conduits," filed October 24, 2014, which is hereby incorporated by reference in its entirety.

[0076] Any bend along the length of the proximal section 402 of the flexible elongate device 400 results in a change of length of control element lumens 412. For example, with reference to FIG. 4A, if the flexible body bends in a downward motion, the control element lumens 412 on the lower portion of flexible body 410 will decrease in length while the control element lumens 412 on the upper portion of flexible body will increase in length. Thus, it can be necessary for the conduits 423 to axially slide within the control element lumens 412. In some examples, the conduits can be constrained (e.g., fixed and/or prevented from sliding proximally along a conduit longitudinal axis) at a proximal end of the flexible elongate device within the actuator 430 and can terminate at the transition section 406. The conduits may be constrained (e.g., fixed and/or prevented from sliding distally along a conduit longitudinal axis) at the transition section 406. In

this example, within transition section 406, a stopper 425 is coupled between conduits 423 on the stopper proximal side and an axial support structure 424 on the distal stopper side. Stopper 425 prevents conduits 423 from shifting distally along flexible elongate device 400. In alternative examples, the conduits may be fixed to stopper 425.

[0077] Within distal section 404, axial support structure 424 is configured to bend in response to actuation forces applied to control elements 421. Consequently, when unequal actuation forces are applied to control elements 421, distal section 404 bends in the direction defined by the net actuation forces. Axial support structure 424 supports distal section 404 against axial loads generated by the actuation forces applied to control elements 421. In particular, axial support structure 424 may prevent or reduce distortion, compression and/or collapse of distal section 404 under axial loads. Further examples of axial support structures are provided in U.S. Provisional Patent Application 62/378,943 entitled "Axial Support Structure for a Flexible Elongate Device," which is hereby incorporated by reference in its entirety.

[0078] Although axial support structure 424 is depicted as having a spine-like structure in FIG. 4A, other structures are possible. In some examples, axial support structure 424 may be formed as a single large coil that encloses main lumen 411. Additionally, while FIG. 4C illustrates control elements 421 within control element lumens 412, in a similar configuration as shown in FIG 4B for proximal section 402, axial support structure 424 may be include conduits similar to conduits 423. In some embodiments, conduits 423 may continue to run through both proximal and distal sections of flexible body 420. In alternative embodiments, separate conduits 423 may run in the proximal section and distal section. Whereas the conduits of conduits 423 are arranged concentrically around control elements 421 to counteract the actuation forces applied to control elements 421, the conduits of axial support structure 424 may be offset from control elements 421 (e.g., located at different positions around the circumference of flexible body 410) to allow axial support structure 424 to bend in response to actuation forces. Alternately or additionally, the conduits of axial support structure 424 may be more flexible (e.g., smaller diameter and/or constructed using smaller gauge wire) than the conduits of conduits 423.

[0079] In some examples, one or more of lumens 411, 412, 419, and/or sections thereof, may be keyed. That is, a lumen and/or a portion of a lumen may have a non-circular cross-sectional shape that prevents or constrains the rotation of a tool (e.g., a medical instrument, sensor, fiber, electrical wire, actuation element, and/or the like) with a matching non-circular cross-sectional shape when inserted through the lumen. As depicted in FIG. 4B, main lumen 411 of proximal section 402 is keyed. In particular, the main lumen 411 has a rounded square cross-sectional shape that supports four keyed orientations.

[0080] In some examples, a localization sensor 426, such as an optical fiber of shape sensor 222, extends through sensor lumen 419. Like conduits 423, localization sensor may be constrained (e.g., fixedly attached and/or prevented from sliding axially) at each end of flexible elongate device 400. In one example, the localization sensor is fixedly attached to distal mount 422, free-floating within sensor lumen 419, and fixedly attached at actuator 430. In some examples, a service loop can be provided within actuator 430 between a fixed localization attachment and a proximal end of flexible elongate device 400 to accommodate the varying length of sensor lumen 419 due to bending. In alternative examples, the service loop can be provided between actuator 430 and the distal end of flexible elongate device 400 or within the flexible elongate device.

[0081] In some examples, the cross-sectional shape of lumens 411-419 may change between proximal section 402 and distal section 404. For example, main lumen 411 may be keyed within proximal section 402 and unkeyed within distal section 404. As depicted in FIG. 4C, main lumen 411 of distal section 404 is unkeyed, having a circular cross-sectional shape that does not constrain the rotation of a medical instrument inserted therein. Examples of keyed lumens are discussed in greater detail below with reference to FIG. 10.

[0082] In some examples, the diameter of lumens 411-419 may change between proximal section 402 and distal section 404. Accordingly, lumens 411-419 may be tapered within transition section 406 to provide a gradual transition between the different cross-sectional shapes, e.g., a keyed lumen on the proximal side and an unkeyed lumen on the distal side.

[0083] In some examples, the flexible wall of the flexible body 410 may vary between the proximal section 402 and distal section 404. In some examples, a required bending flexibility and/or compressive strength may vary along the length of the catheter based on potential positioning within patient anatomy. Thus, the flexible wall may include a plurality of layers which can vary within a proximal section flexible wall and within a distal section flexible wall.

[0084] Despite the advantages of the above-described construction of the flexible elongate device 400 being able to actuate distal section 404 of flexible elongate device 400 by, for example, operation of the control elements 421 within conduits 423, in certain situations, once the flexible elongated device 400 is positioned in a desired pose, attempting to hold the shape of the flexible body in a desired configuration can be difficult. In addition, instances occur in which it would be advantageous to adapt the shape of the flexible body 410 based on known information about the surrounding anatomy and/or the instruments to be inserted through the main lumen 411, or other lumens. To this end, a range of stiffening mechanisms or systems are described that assist or enable holding a pose or shape of the flexible body 410. These stiffening mechanisms may be part of the steering mechanism, may be separately actuated and/or may themselves also enable steering

of the flexible elongate device 400. Further, the stiffening mechanisms may use information from sensor systems, such as shape sensor 426 in the form of an optical fiber, a plurality of EM sensors distributed along the length of a flexible device, a plurality of force sensors distributed along the length of a flexible device, and/or navigation systems, such as sensor system 108 that computes the approximate location of medical instruments (such as the flexible body 410) within the anatomy of the patient and/or medical tools that are delivered through main lumen 411, to inform the control system 112 which then controls formation and holding of a shape of the flexible body 410.

[0085] In some embodiments, stiffening mechanisms, especially stiffening mechanisms with sub-elements, exhibit behaviors that can be used to stiffen the shape of the flexible body 410. In one embodiment, as shown in FIGS. 6A-6D, for example, a stiffening system or mechanism 500 uses the characteristics of the coil pipe 423 within the control element lumen 412 to stiffen the pose of the flexible body 410.

[0086] FIG. 5 is an enlarged schematic showing an example of the conduit or coil pipe 423 within control element lumen 412 extending around the control element 421, such as a pull wire. Notably, in this example, the coil pipe 423 includes a plurality of windings 504. In this configuration, the windings 504 of the coil pipe 423 extend linearly in a stacked array with very little (or no) distance between them. The windings 504 are shown as rings but the coil pipe 423 can be a helical structure that extends helically along a central axis of the control element lumen 412. The control element lumen 412 and the control element 421 are shown in a straight, or un-bent, configuration.

[0087] The stiffening mechanism 500 shown in FIGS. 6A – 6D, includes a restricting balloon 502 sleeved over the coil pipe 423. During actuation and steering of the flexible elongate device 400, the restricting balloon is in a passive or natural state. Once the flexible elongate device has been positioned at a desired target location, vacuum can be applied using a pump (not shown), deflating balloon 502 to interdigitate within the spaces between a plurality of windings 504 of the coil pipe. This interdigitation stiffens to hold the shape of the coil pipe 423 subsequently holding the shape and pose of the flexible elongate body 400 and providing a more stable platform for delivery of instruments through the flexible body 410.

[0088] FIG. 6A shows a cross-sectional view of the control element lumen 412, and the stiffening mechanism 500 including the balloon 502. The external circle denotes the outline of the control element lumen 412 within which is a balloon layer or internal wall 506a. The balloon wall extends around (e.g., is sleeved over) the coil pipe 423. In the illustrated embodiment of FIGS. 6A-6D, the balloon 502 can be formed as a tubular structure with an open center lumen such that

the balloon 502 can extend between the coil pipe 423 and an inner surface of the control element lumen 412. FIG. 6B shows a cross-sectional view taken along the longitudinal axis of a portion of the flexible body 410.

[0089] FIG. 6C shows a cross-sectional view of the control element lumen 412 bending under tension from the control element 421 (or other forces and manners of application thereof) into a curved pose along with the surrounding wall structure of the flexible body 410. In this bent pose, the windings 504 of the coil pipe 423 spread apart on the outer curvature due to tracing a longer path and compress more together on the inner curvature as they are tracing a shorter path. The balloon 502, not yet under an inflation pressure or deflation vacuum pressure, passively bends along with the control element lumen 412 and the coil pipe 423.

[0090] In FIG. 6D, the stiffening mechanism is activated by using the pump to apply a suction pressure or vacuum within the lumen of the balloon 502. The suction pressure draws the compliant balloon wall 506a inward into conforming contact with the windings 504 of the coil pipe 423. Generally, on an outside curvature where the windings are spread apart, the balloon wall 506a fills the gap between adjacent pairs of the windings. Even on an inner curvature formed in the coil pipe 423, the balloon wall 506a could achieve some interdigitation between the windings 504. In this embodiment, the adherence of the balloon wall 506a tightens the relationship between it and the windings 504 causing friction which interferes with the coil pipe 423 thus holding it in its current configuration or pose. The presence of the balloon wall 506a in between the windings 504 may wedge the adjacent pairs of windings 504 into the spread apart relationship.

[0091] FIGS. 7A-7D show another embodiment using a balloon 502 that is similar to the embodiment of FIGS. 6A-6D, except the balloon 502 is positioned within the coil pipe 423 such that an external balloon wall 506b is positioned along an inner surface of the coil pipe 423. In the illustrated embodiment of FIGS. 7A-7D, the balloon 502 can be formed as a tubular structure with an open center lumen such that the balloon 502 can extend between the control element 421 and the coil pipe 423, as shown in FIG. 7A. In an alternative embodiment, a pull wire is not used to control actuation of the elongate flexible device 400, so the balloon 502 can be positioned within a lumen of the coil pipe 423, filling the entire coil pipe lumen when inflated. In either configuration, the balloon is inflated (FIG. 7C to FIG. 7D) to adhere against and interdigitate between the windings 504 of the coil pipe 423. This embodiment could be combined with, or substituted for, the embodiment of FIGS. 6A-6D (or used with other embodiments within the scope of this disclosure) depending on the desired level of friction or mechanical blocking and strength of the hold.

[0092] While a single coil pipe 423 is shown for FIGS. 6A-6D and 7A-7D, it should be understood that multiple coil pipes may be distributed within a single elongated flexible device 400. For example, as shown in the embodiments above of FIGS. 4A-4C, there are four control element lumens 412 and each of these could include one or more balloons 502 extending over the coil pipes 23 within the lumens 412. Alternatively or additionally, in another example without pull wires, as shown in FIG 10A, a single coil pipe 1023 could surround a lumen 1011 of an elongated flexible device 1000 including flexible body 1010. Regardless, multiple coil pipes 423 with multiple balloons 502 or balloon portions could be used for one, several, or all the control elements 421 used in the flexible elongate device 400. Each of these balloons 502 could be selectively drawn inward with a vacuum to engage the respective windings 504 of the coils or expanded outward with pressure to engage respective windings 504 of the coils, depending on the shape or pose of the flexible body 410. Additionally, separate balloons or balloon portions could be distributed down the length of each coil pipe, such that stiffening or holding of coil pipe positions could vary down the length of the coil pipe. Thus, by controlling the amount and distribution of the applied vacuum and pressure to different balloons or balloon portions, an entire length of a flexible body can be actively controlled depending upon where and how stiff and what shape is required by the particular anatomy or particular medical procedure.

[0093] As noted above, the axial support structure 424 of the flexible body 410 may include a single large coil that encloses the main lumen 411. The structure of this larger coil, like the coil pipe 423, can be used to stiffen the flexible body 410 in a pose or shape in other embodiments. FIGS. 10A-10B show a cross-section of an embodiment including a coil pipe 1023 surrounding a lumen 1011 of an elongated flexible device 1000 including flexible body 1010. In one embodiment, a single balloon 1002 can spiral along between windings of the coil pipe 1023. As shown in FIG. 10A, the balloon is in a deflated configuration showing a cross-section which bows inward. In this embodiment, the balloon can be inflated (not shown) to force the windings of the coil pipe 1023 to expand against adjacent windings, causing the flexible body 1010 to stiffen or hold a current pose. In an alternative embodiment, a set of separate balloons or a single balloon may be partitioned into balloon portions 1002a-1002d, each positioned within different windings of the coil pipe 1023. As illustrated in FIG. 10B, each balloon portion 1002a-1002d are selectively inflated or deflated to stiffen the flexible body 1010 in a bent configuration. In this example, selected inflation of balloon portions 1002a and 1002c, can cause hold an angle between adjacent segments of the coil support structure 1023 and, along with it, the shape of the flexible body 410. On an inner bend of the flexible body 1010, balloon portions 1002b and 1002d, are deflated to allow for compression of adjacent segments along the inner bend.

[0094] The actuator 430 may include actuation for both control of the pump for inflating or drawing vacuum in the balloons and mechanisms for varying the amount of tension in the control elements 421. Thus, the actuator 430 may vary inflation and or vacuum in the balloons and tension of the control elements 421 in a coordinated relationship to achieve the desired amount of stiffness of the shape or pose of the flexible body 410. The control system 112's actuation of the balloons 502 (or other stiffening elements) and control elements 421 can be based on feedback from various sensors (such as localization sensor 426) to accomplish other objectives, such as adapting to instruments or avoiding injury to sensitive anatomy or withstanding different loading profiles. In this case, the shaping function of the control elements 421 can be facilitated by the stiffening mechanism 500, rather than the stiffening mechanism just being used to stiffen and hold a current pose or shape of the flexible body 410.

[0095] The balloon 502 can be generally constructed of similar materials as balloons for other medical applications, such as for deployment of various medical devices, such as cardiovascular devices. Such balloons can have varied beginning and end shapes depending upon the processes and molds employed in their creation. For example, balloons with large inflated diameters can be compressed down to compact configurations due to careful folding or forming. Generally, however, the balloons used in the embodiments of FIGS. 6A-6D and 7A-7D benefit from sufficient toughness to withstand multiple uses and the friction of interaction with the support structure – such as being able to be trapped or pinched between the windings 504 of the coil pipe 423. At the same time, the balloons benefit from sufficient flexibility to conform to the coil pipe 423 where spread apart to achieve a sufficient amount of friction or blocking for higher stiffnesses of holding the pose under a range of loading conditions.

[0096] The stiffening mechanism 500 could also employ other stiffening elements for holding the shape of the flexible body 410. For example, a foam could be expanded between the coil pipe 423 and the control element lumen 412 or MEMS technology employed to drive wedges or blockers between the spread apart windings 504. The balloons 502 could also be deployed in arrays of multiple balloons and the balloons themselves could be shaped to have features – such as wedge shapes configured for urging between the spread apart coils if inflated or vacuumed into contact with the coil pipe 423. Although the illustrated use of a coil pipe 423 works particularly well because of the nature of the windings 504 forming stacked, adjacent elements that spread apart during bending. Balloons could also be employed with other support structures than the coil pipe. For example, an interconnected linkage may be used in association with (or as) the control elements 421 wherein the linkages have a shape or articulation relative to each other that is stiffened upon being adhered to or wedged between by a balloon. The spacing and shape of the

sub-elements could also be configured to work well with the shape and features of the stiffening elements of the stiffening mechanism. For example, wedge-shaped spaces between sub-elements of the support structure could be locked by insertion of conforming wedge-shaped stiffening elements.

[0097] It should be noted that some embodiments of the invention work well with any type of flexible elongate device 400 with the flexible body 410, wherein the flexible body has some changing structural characteristic that can be trapped, blocked, adhered to or otherwise intervened in with the operative elements of the stiffening mechanism 500 to stiffen the pose or shape of the flexible body. In previously described embodiments, the structural characteristics are within coil pipes. However, in alternative or additional examples, a support structure such as axial support structure 424 may be used in conjunction with one or more balloons surrounding the support structure or positioned within a lumen of the support structure. Particularly useful is a support structure that uses a plurality of sub-elements arranged in series, where the sub-elements exhibit differential characteristics (such as spreading apart) when adjusted into various shapes by flexing or shaping of the flexible body 410 in which they are embedded.

[0098] FIGS. 8A-8E show another embodiment of a stiffening mechanism 800 for a flexible elongate device with a flexible body 801 defining a lumen 811 and divided into a plurality of portions or segments 812. In this embodiment, the stiffening mechanism includes a plurality of nitinol wires 810 distributed circumferentially around each of the plurality of segments 812. Generally, selective activation or energizing of the nitinol wires 810 causes them to engage – by changing their length – the portion of the flexible body to hold or change its pose. The controller of the stiffening mechanism 800 can then modulate its energizing of the nitinol wires 810 based on feedback from various sensors, such as the sensor 826, to hold the pose in varying conditions. In another aspect, the nitinol wires 810 could be employed to just hold the pose of the portion of the flexible body 801 rather than be involved in shaping or steering the flexible body 410.

[0099] FIG. 8A shows the nitinol wires 810, in one aspect, can be embedded in a wall structure of the flexible body 801. For example, four of the nitinol wires 810 are distributed circumferentially with about 90 degrees between them. Also, FIG. 8A shows a sensor lumen such as sensor lumen 819, defined within the wall structure of the flexible body 801 about equidistant between two of the nitinol wires 810. This distribution of the nitinol wires 810 and positioning of the sensor lumen 819, with the sensors 826, such as a fiber-based shape sensor, extending therein, facilitates 360-degree bending control of the flexible body 801 by selectively controlling the amount of energization of the four nitinol wires 810 based on feedback from the shape sensor. The sensors 826 within the sensor lumen 819 may include one or more additional sensors instead of or

in addition to the optical fiber shape sensor. For example, the sensors 826 may include a plurality of EM sensors distributed along the length of the flexible body 801, a plurality of force sensors distributed along the length of the flexible body 801, and/or navigation systems, such as sensor system 108 that computes the approximate location of medical instruments (such as the flexible body 801) within the anatomy of the patient and/or medical tools that are delivered through main lumen 811, to inform the control system 112 which then controls formation and holding of a shape of the flexible body 801. Fewer or more embedded nitinol wires 810 are possible with different relative distributions within the wall structure depending on the desired amount and distribution of actuation and holding forces from the stiffening mechanism 800.

[0100] FIGS. 8B-8E show how the flexible body 801 can be formed of a plurality of portions or segments 812. Each of the segments is a short cylindrical portion of the whole flexible body 801. In this embodiment, the nitinol wires 810 are short lengths beginning and ending in the segment. The actuator 430 may be coupled to each of these lengths of nitinol wires 810 and able to energize those wires to be able to hold or adjust the pose of the segment. FIGS. 8D and 8E show how the segments 812 can be arranged end-to-end to form a longitudinal array 814 and a larger portion (or the entire) flexible body 801. In addition, FIG. 8E shows how the cumulative change in pose of each of the segments 812 results in a change in, and/or holding of shape of, the flexible body 801.

[0101] The nitinol wires are comprised of a shape memory material in the form of a nickel-titanium alloy with a transition temperature. The actuator 430 can selectively change the length of the nitinol wires by heating them, such as with electrical power, through the transition temperature to change between shapes. For example, the memorized shape of the nitinol wires may be a shorter length than the starting length. Thus, heating the nitinol wire causes it to shorten and then change the pose of the segment by compressing the segment 812. Memorized shapes could also be various curves or other configurations to help with shaping. Notably, embodiments of the present invention may also include shape memory materials other than nitinol or mechanical devices that are able to expand, retract and/or change shape to cause and hold pose changes.

[0102] In the previously described balloon and nitinol wire embodiments, the flexible body can be driven to a target location with balloon portions or nitinol wires deactivated or otherwise in a natural configuration, using pull wires or other control elements 421 for steering. Once in position, the current shape of the flexible body 410 or 801 can be measured using a shape sensing system such as tracking system 230. Then, the balloon portions 508 or nitinol wires 810 can be selectively inflated, deflated, or actuated in varying amounts to help maintain the measured shape.

[0103] In the case of nitinol wires, using the data from the optical fiber or other shape sensor, the controller system 112 can be configured to energize the appropriate nitinol wires 810 of the longer composite tube (with multiple segments) to hold its shape. Also, using shape data from the optical fiber sensor, such as sensing deviations from a desired pose or shape, forces could be applied in appropriate regions to maintain a measured shape. Additionally, the nitinol wires 810 can be used to apply greater force to increase bending moments when a stiff instrument is inserted through the device.

[0104] In another example, the balloon portions 508 can be inflated/deflated or nitinol wires can be activated, and pull wires can be additionally controllably altered in tension to maintain the measured shape. Both examples include automatic maintenance of a measured shape or the automatic hold of a pose using pull wires to further stiffen the flexible body 410.

[0105] In other embodiments, the flexible body 410/801 can be navigated within tortuous anatomy 516 in a flexible state, parked within anatomy to position a distal end of the flexible body 410/801 at a target location, then select portions of the flexible body may be stiffened or rigidized depending on different conditions. For example, during a pre-procedure planning stage, a user can identify target areas of the anatomy on a pre-operative model or map, about which one or more proximate portions of the flexible body 410/801 may be selectively rigidize. For example, target areas of the anatomy may include anatomy which are particularly sensitive (e.g., a lung airway is near the pleura, or in a different application, the path of a flexible body 410/801 is near an organ). Alternatively or additionally, imaging techniques can be used to automatically identify target areas of the anatomy. Using registration of a flexible elongate device 400 and real time tracking previously described in reference to FIGS. 2A and 2B, and by identifying the target areas of the anatomy, the flexible body 410/801 can be parked at a target, then portions of the flexible body 410/801 which are proximate the target areas of the anatomy (e.g. various discrete portions along the length of flexible body 410/801) can be selectively discretely rigidized, using stiffening mechanisms such as stiffening mechanism 500/800, to provide protection for the target area of the anatomy (e.g., sensitive anatomy) during delivery of devices through the catheter.

[0106] In another embodiment, the flexible body 410/801 is positioned in tortuous anatomy 516 forcing it adapt to and form tight bends, as shown in FIG. 9A. Thus, delivering a stiff device through a working lumen of the flexible body is challenging. Using selective stiffening control of the embodiments above, a tight bend 518 could be identified as a target area of the anatomy manually by a user, automatically by the control system analyzing the pre-operative model using imaging techniques, and/or by the control system 112 using shape sensing data and a threshold setting for a minimum bend radius. Along the length of the catheter positioned around the tight

bend 518, the control system 112 can command the actuator 430 and stiffening mechanism 500/800 to reconfigure the shape of the flexible body 410 into a larger radius to allow for delivery of the stiff device, as shown in FIG. 9B.

[0107] More generally, in some embodiments, the control system 112 measures a current configuration of the flexible body 410/801 and determines a desired configuration of the flexible body 410/801. The current configuration of the flexible body 410/801 may include a current pose, for example, measuring the current configuration includes measuring a shape of the current pose, such as a radius of a curve along the flexible body 410/801. As discussed above, the current pose may be determined using shape sensing data from an optical fiber sensor or other shape sensor (e.g. a plurality of EM or strain sensors) along the length of the flexible body 410/801. Alternatively, shape may be determined using kinematic data describing the flexible body 410/801 and actuator 430 such as which actuators are activated, a tension in actuators, or pressure applied by actuators.

[0108] The control system 112 may determine deviations from the current configuration to a desired configuration of the flexible body 410/801. Responsive to the determined deviations, the control system 112 can command the actuator 430 to selectively stiffen one or more stiffening mechanisms 500/800 along the length of the flexible body 410/801 to apply forces in appropriate regions to position the flexible body from the current configuration to the desired configuration. For example, the stiffening mechanisms may include a plurality of the balloon portions 508/1002 and/or nitinol wires 810 distributed down the length of the flexible body 410/801 to stiffen discrete portions of the flexible body 410/801 down the length of the flexible body 410/801. Each of the stiffening mechanisms (e.g. each of the balloon portions 508/1002 and/ or each of the nitinol wires 810) may be independently activated by the actuator 430.

[0109] Following the examples above, the control system 112 may determine deviations from the measured radius of a curve at a location along the flexible body 410/801 (e.g., current configuration) and the minimum bend radius (e.g., desired configuration). The minimum bend radius may be determined by the control system 112 based on receiving information describing stiffness of an instrument to be delivered by the flexible body 410/801. Accordingly, the control system 112 can command the actuator 430 to selectively stiffen ones of the stiffening mechanisms along the length of the flexible body 410/801 to apply forces in appropriate regions to position the flexible body to increase a bend radius of the curve at the location along the flexible body 410/801.

[0110] Again following the examples above, the control system 112 may determine the desired configuration by identifying target areas of the anatomy. FIG. 11 is a simplified flow diagram of a method 1100 performed by the control system 112 for identifying target areas of the anatomy

and activating a stiffening mechanism according to some embodiments. For example, the target areas of the anatomy may be identified based on the control system 112 receiving live images or preoperatively recorded surgical images and identifying portions of the flexible body 410/801 that are proximate to the target areas of the anatomy. For example, at 1102, live images or pre-operative images are received by the control system 112. The images may be received from imaging technology such as, computed tomography (CT), magnetic resonance imaging (MRI), fluoroscopy, thermography, ultrasound, optical coherence tomography (OCT), thermal imaging, impedance imaging, laser imaging, nanotube X-ray imaging, and/or the like. In one embodiment, a pre-operative model may be generated from pre-operative images.

[0111] At 1104, target areas of the anatomy may be identified within the pre-operative model, by a user, or automatically using imaging techniques. In another embodiment, target areas of the anatomy can be identified (by users or automatically using imaging techniques) within captured live images. The identified target areas of the anatomy include sensitive anatomy or anatomy with tight bends within anatomical passageways (e.g. small radius bends where the radius is less than the minimum bend radius), for example.

[0112] At 1106, the control system 112 may be used to register the flexible body 410/801 to the live images or to the pre-operative model using sensor data from one or more sensors 426 (or 826) positioned along the flexible body 410/801, while the flexible body is being navigated within anatomy. The registration of the flexible body 410/801 to the pre-operative model/live image is based on the relative known positions between position/shape sensors (e.g. fiber optic shape sensors, EM sensors, etc.) and stiffening mechanism components 502/1002/810. Various systems for using fiber optic sensors to register and display a surgical instrument with surgical images are provided in U.S. Patent Application No. 13/107,562, filed May 13, 2011, disclosing, "Medical System Providing Dynamic Registration of a Model of an Anatomic Structure for Image-Guided Surgery," which is incorporated by reference herein in its entirety. Systems for registering live imaging devices to a pre-operative image or imaging system are provided in PCT application PCT/US2017/017433, filed February 2, 2017, disclosing, "Systems and Methods for Using Registered Fluoroscopic Images in Image-Guided Surgery" and PCT application PCT/US17/17391, filed February 2, 2017, disclosing, "Systems and Methods of Pose Estimation and Calibration of Perspective Imaging System in Image Guided Surgery", which are each incorporated by reference herein in their entirety.

[0113] Information from tracking system 230 may be sent to a navigation system 232 where it is combined with information from visualization system 231 and/or the pre-operatively obtained models (e.g., anatomic models of the patient anatomy) to provide the physician or other operator

with real-time position information. At 1108, the real-time position information, including the current configuration of the flexible body 410/801 is received by the control system 112. At 1110, based on the real time position information of the flexible body 410/801, and the identified target areas of the anatomy, the control system 112 can identify portions of the flexible body 410/801 that are positioned at the target areas of the anatomy. At 1112, the control system 112 can command actuators 430, to selectively stiffen one or more stiffening mechanisms 500/800 along the length of the flexible body 410/801 proximate the target areas of the anatomy (the determined portion/s of the flexible body 410/801) to provide protection for sensitive anatomy or to reconfigure the specific length of the flexible body to form a larger radius bend that is greater than or equal to the minimum bend radius.

[0114] In some examples, the real-time position information may be displayed on display system 110 of FIG. 1 for use in the control of medical instrument system 200. In some examples, a virtual image of the flexible body may be overlaid or integrated into the pre-operative model and the identified target areas of the, such as sensitive anatomy and/or tight bends may be displayed. The virtual image of the flexible body may be updated based on the real-time position information obtained from tracking system 230.

[0115] In another embodiment, the flexible body 410/801 is positioned in anatomy which may apply an external force against the flexible body 410/801. For example, anatomy may apply an external force as part of respiration, circulation, or excretion. Using selective discrete stiffening control of the embodiments above, upon detecting an external force at a location at a distal end or along the length of the flexible body 410/801, the control system 112 can command the actuator 430 to selectively stiffen discrete portions along the length of the flexible body 410/801 at the location of the external force.

[0116] FIG. 12 is a simplified flow diagram of a method 1200 performed by the control system 112 for identifying an external force and activating a stiffening mechanism according to some embodiments. At 1202, the control system 112 receives sensor data sensor data from one or more sensors 426 (or 826) positioned along the flexible body 410/801 for detecting application of an external force. At 1204, the control system 112 determines whether any of the received sensor data is out of a predetermined threshold for identifying application of an external force to the flexible body 410/801.

[0117] For example, the external force may be detected based on detecting a change in the shape of the flexible body 410/801 as determined by the shape sensor. In some examples, the external force is detected based on a change in shape determined by the shape sensor or a change in shape viewed by live imaging that is not a result of control of the actuator 430 or movement of

a medical instrument through the main lumen 411/811. In other words, the external force is detected based on a change in shape determined by the shape sensor that is independent of operation of the actuator 430 or movement of a medical instrument through the main lumen 411/811. In another example, a fiber optic shape sensor can be configured to calculate both shape and force along the length of the flexible body 410/810.

[0118] In another example, the external force may be detected based on readings from one or more force sensors positioned along the length of the flexible body 410/801. The force sensors may include one or more of a strain gauge, a load cell, a force sensing resistor, or any other suitable force sensor. Each of the force sensors may correspond to a particular location, region, or segment of the flexible body 410/801.

[0119] At 1208, the control system 112 identifies a corresponding location, region, or segment of the flexible body 410/801 where the sensor data is out of threshold. For example, the control system 112 identifies a corresponding location, region, or segment of the flexible body 410/801 where an external force is being applied to the flexible body 410/801. At 1210, upon one of the force sensors detecting where the external force is being applied to the flexible body 410/801, the control system 112 can command the actuator 430 to selectively stiffen the flexible body 410/801 at the corresponding location of the external force. In some examples, the external force detected based on the force sensors is independent of operation of the actuator 430 or movement of a medical instrument through the main lumen 411/811.

[0120] In one embodiment as described above, the flexible body 410/801 is fully positioned in anatomy such that a distal end of the flexible body 410/801 is positioned at or near an anatomical target to be used as a working channel for delivery of therapeutic and/or diagnostic tools. In order to protect anatomy, the controller may selectively stiffen discrete portions of the flexible body. Shape sensing and or external force measurements can be used to determine a portion (or plurality of portions) of the flexible body 410/801 is/are currently configured in a tight radius bend or experiencing external force. Additionally or alternatively, shape sensing can be used in conjunction with a registered pre-operative model where target areas of anatomy have been previously identified, to determine whether a portion (or plurality of portions) of the flexible body 410/801 is/are currently configured in a tight radius bend (e.g., a radius less than the minimum bend radius) or experiencing external force due to the current positioning of the flexible body 410/801 in anatomy. The controller can then selectively activate discrete stiffening elements 502/1002/810 to selectively stiffen portions of the flexible body 410/801 located at the determined portions of the flexible body 410/810.

[0121] In an alternative embodiment, the flexible body is navigated through anatomy and as a portion of the flexible body is actively inserted through a portion of anatomy that has been identified as a target area of the anatomy (e.g. tight bend, sensitive anatomy, etc.), the controller selectively activates the portion situated within the target area of anatomy. In one example, shape sensing can be used in conjunction with a registered pre-operative model by the controller to determine which portion of the flexible body is currently positioned within a target area of the anatomy. In another example, the controller can use shape sensing and/or force sensing to instantly determine which portion or plurality of portions of the flexible body is/are positioned within a tight bend or experience an excessive external force beyond a threshold. The controller can then selectively active discrete stiffening elements 502/1002/810 to selectively stiffen portions of the flexible body 410/801 located at the determined portions of the flexible body which are positioned within a target area of the anatomy, experience a tight bend, and/or experience excessive external force. The controller can propagate the selective stiffness down the length of the flexible device as the flexible device is inserted in anatomy. Accordingly, the flexible body may be stiffened in a controlled manner into a desired pose that protects anatomy from damage the flexible body as it is inserted into anatomy. For example, as a most distal section of the flexible body is positioned near to a target area of the anatomy, the controller selectively stiffens the most distal section only. Then as the flexible body is further inserted in anatomy, the most distal section is relaxed and a section just proximal the most distal section is selectively stiffened. Thus, as the flexible body is being inserted within anatomy, the flexible body can be positioned in a known and controlled pose to protect anatomy instead of allowing a fully flexible device to potentially rub or press against anatomical walls.

[0122] Embodiments above disclose embodiments of stiffening mechanism 500 that provide for selective stiffening of portions of the elongate body along its length and actuation of discrete balloon, nitinol wire or other stiffening elements for selective stiffening to hold a pose or shape. In other embodiments, selective inflation and deflation of balloon portions 1002a-1002d can be used to additionally or alternatively actuate and control steering of the elongated flexible device 1000 in addition to holding pose of the flexible body 1010 of the elongated flexible device 1000. This same ability to steer the flexible body 410 can be employed to hold the pose or shape of the flexible body 410. For example, feedback from the shape sensor 426 could be used to selectively adjust to pressure in the balloons to hold the pose or shape of the flexible body 410.

ADDITIONAL EXAMPLES

[0123]

1. A method of holding a pose of a flexible body using a controller, the method comprising:

measuring a current configuration of a flexible body based at least in part on a sensor coupled to the flexible body;

determining a desired configuration of the flexible body; and

selectively activating a stiffening mechanism to position the flexible body from the current configuration to the desired configuration, wherein the stiffening mechanism includes a plurality of stiffening elements distributed down the length of the flexible body.

2. The method of example 1, wherein positioning the flexible body in the desired configuration includes activating each of the plurality of stiffening elements independently.

3. The method of examples 1 or 2, wherein the current configuration includes a measured shape of the flexible body.

4. The method of example 3 further comprising identifying a small radius in the measured shape, wherein selectively activating the stiffening mechanism includes activating select ones of the plurality of the stiffening elements to increase a bend radius of the flexible body at the identified small radius in the measured shape.

5. The method of example 4 further comprising receiving information describing stiffness of an instrument to be delivered by the flexible body, wherein the identifying of the small radius in the measured shape includes determining a minimum bend radius corresponding to the stiffness of the instrument.

6. The method of any of examples 1-5, wherein determining the desired configuration comprises:

receiving information identifying a target area of anatomy; and

setting the desired configuration to activate select ones of the plurality of the stiffening elements at the identified target area of anatomy.

7. The method of any of examples 1-5, wherein determining the desired configuration comprises:

receiving information identifying anatomical passageways including small radius bends; and

setting the desired configuration to activate select ones of the plurality of the stiffening elements at the small bends.

8. The method of example 6 or 7, wherein the information received is based on live imaging.

9. The method of example 6 or 7, wherein determining the desired configuration further comprises:

receiving a preoperatively recorded surgical image;

registering the flexible body to the preoperatively recorded surgical image using sensor data from the sensor coupled to the flexible body;

identifying a portion of the flexible body positioned within the identified target area of anatomy or the small bends based on the registration.

10. The method of example 6 or 7, wherein the information received is based on the preoperatively recorded surgical image.

11. The method of any of examples 1-10, wherein the current configuration includes an external force applied to the flexible body.

12. The method of any of examples 1-11, wherein the plurality of the stiffening elements includes a plurality of nitinol actuators extending within a wall structure of the flexible body, and wherein the selectively activating the stiffening mechanism includes energizing at least one of the plurality of nitinol actuators.

13. The method of any of examples 1-11, wherein the plurality of the stiffening elements includes a plurality of balloons, and wherein the selectively activating the stiffening mechanisms includes inflating or deflating at least one of the plurality of balloons.

CLAIMS

What is claimed is:

1. A medical system comprising:

a flexible elongate device including:

a flexible body with a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends, wherein the flexible body includes a plurality of sub-portions;

a shape sensor extending along at least a portion of the flexible body; and

a stiffening mechanism having a plurality of stiffening elements, each of the stiffening elements positioned within one of the plurality of sub-portions, wherein the sub-portions extend along the flexible body; and

a controller connected in communication with the shape sensor, configured to selectively activate the stiffening elements based in part on data received from the shape sensor.

2. The medical system of claim 1, wherein the controller is further configured to selectively activate the stiffening elements based in part on a type of instrument for insertion through the flexible body.

3. The medical system of claim 2, wherein the controller is configured to energize selected ones of the stiffening elements to reduce curvature of the flexible body to match a stiff type of instrument .

4. The medical system of claim 1, wherein the controller is further configured to selectively activate the stiffening elements based in part on anatomical information.

5. The medical system of claim 4, wherein the anatomical information includes information identifying a target area of anatomy and wherein the controller is further configured to actuate selected ones of the stiffening elements to protect the target area of anatomy.

6. The medical system of claim 4, wherein the anatomical information includes identifying a small radius bend within the anatomy and wherein the controller is further configured to actuate selected ones of the stiffening elements to reduce the curvature of the flexible body around the small radius bend.

7. The medical system of any of claims 1-6, wherein the shape sensor includes at least one of a shape sensing fiber extending along the flexible body or a plurality of EM sensors extending along the flexible body.

8. The medical system of any one of claims 1-6, wherein the stiffening mechanism includes a longitudinal balloon array having a plurality of balloon portions and wherein each of the stiffening elements is one of the plurality of balloon portions.

9. The medical system of claim 8, wherein the flexible body includes a coil with a plurality of adjacent windings and wherein each of the balloon portions are configured to extend between the adjacent windings with the application of pressure.

10. The medical system of claim 9, wherein the controller is further configured to selectively apply pressure to each of the balloon portions to urge apart adjacent windings to shape the flexible body.

11. The medical system of any one of claims 1-6, further comprising a steering mechanism configured to control the distal end portion of the flexible body, wherein the steering mechanism includes a plurality of pull wires and wherein the controller is further configured to adjust tension in the pull wires along with selective activation of the stiffening elements to hold the portion of the flexible body in a pose determined from the shape sensor data.

12. The medical system of any one of claims 1-6, wherein the plurality of stiffening elements includes a plurality of nitinol actuators, the flexible body includes a wall structure, and the plurality of nitinol actuators are embedded in the wall structure.

13. The medical system of claim 12, wherein the plurality of nitinol actuators are distributed circumferentially within the wall structure.

14. A flexible elongate device comprising:

a flexible body with a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends, the flexible body having sufficient flexibility to form a pose;

a support structure coupled with the flexible body, the support structure including a plurality of sub-elements arranged in series, wherein at least a portion of the sub-elements are configured to spread apart when the flexible body flexes into the pose; and

a stiffening mechanism having at least one stiffening element extending along at least a portion of the flexible body and configured for actuation independent of the support structure, wherein actuation of the at least one stiffening element stiffens the support structure to hold at least a portion of the pose of the flexible body;

wherein the at least one stiffening element includes a compression feature configured to engage the support structure.

15. The flexible elongate device of claim 14, wherein the support structure includes a coil and the sub-elements include windings of the coil.

16. The flexible elongate device of claim 14, wherein the support structure includes a spine.

17. The flexible elongate device of any one of claims 14-16, wherein the stiffening mechanism includes an inflatable system.

18. The flexible elongate device of claim 17, wherein the inflatable system includes a balloon configured to extend in between the sub-elements.

19. The flexible elongate device of claim 18, wherein the balloon is configured to extend in between the sub-elements due to the application of a vacuum pressure causing the balloon to collapse into an exterior of the support structure and in between the sub-elements.

20. The flexible elongate device of claim 18, wherein the balloon is configured to extend in between the sub-elements due to the application of an inflation pressure causing the balloon to expand into an interior defined within the support structure and in between the sub-elements.

21. The flexible elongate device of claim 17, wherein the inflatable system includes a plurality of balloon portions.

22. The flexible elongate device of claim 21, wherein the plurality of balloon portions are selectively inflatable to hold the at least the portion of the pose.

23. The flexible elongate device of claim 21, wherein the plurality of balloon portions are positioned between the sub elements.

24. The flexible elongate device of claim 21, wherein the plurality of balloon portions spiral between the sub elements.

25. The flexible elongate device of claim 21, further comprising a plurality of control elements extending along the flexible body and configured to exert tension on the flexible body in conjunction with selective inflation of the balloon portions to further hold the at least the portion of the pose.

26. The flexible elongate device of any one of claims 14-16, further comprising:

a shape sensor configured to determine the pose of the flexible body; and

a controller, wherein the controller is connected in communication with the shape sensor and wherein the controller is configured to activate the stiffening mechanism to hold at least the portion of the pose of the flexible body.

27. A method of holding at least a portion of a pose of a flexible body, the method comprising engaging a stiffening element of a stiffening mechanism within a spacing between at least a pair of a plurality of sub-elements, wherein the plurality of sub-elements extend along the flexible body.

28. The method of claim 27, further comprising wherein engaging the stiffening element includes urging a portion of the stiffening element into the spacing between the at least the pair of the plurality of sub-elements.

29. The method of claim 28, wherein the urging of the portion of the stiffening element includes one of inflating or deflating the stiffening element.

30. The method of claim 27-29, further comprising actuating a plurality of pull wires extending within a wall structure of the flexible body including adjusting tension in the plurality of pull wires while selectively activating the stiffening elements to hold the pose of the flexible body.

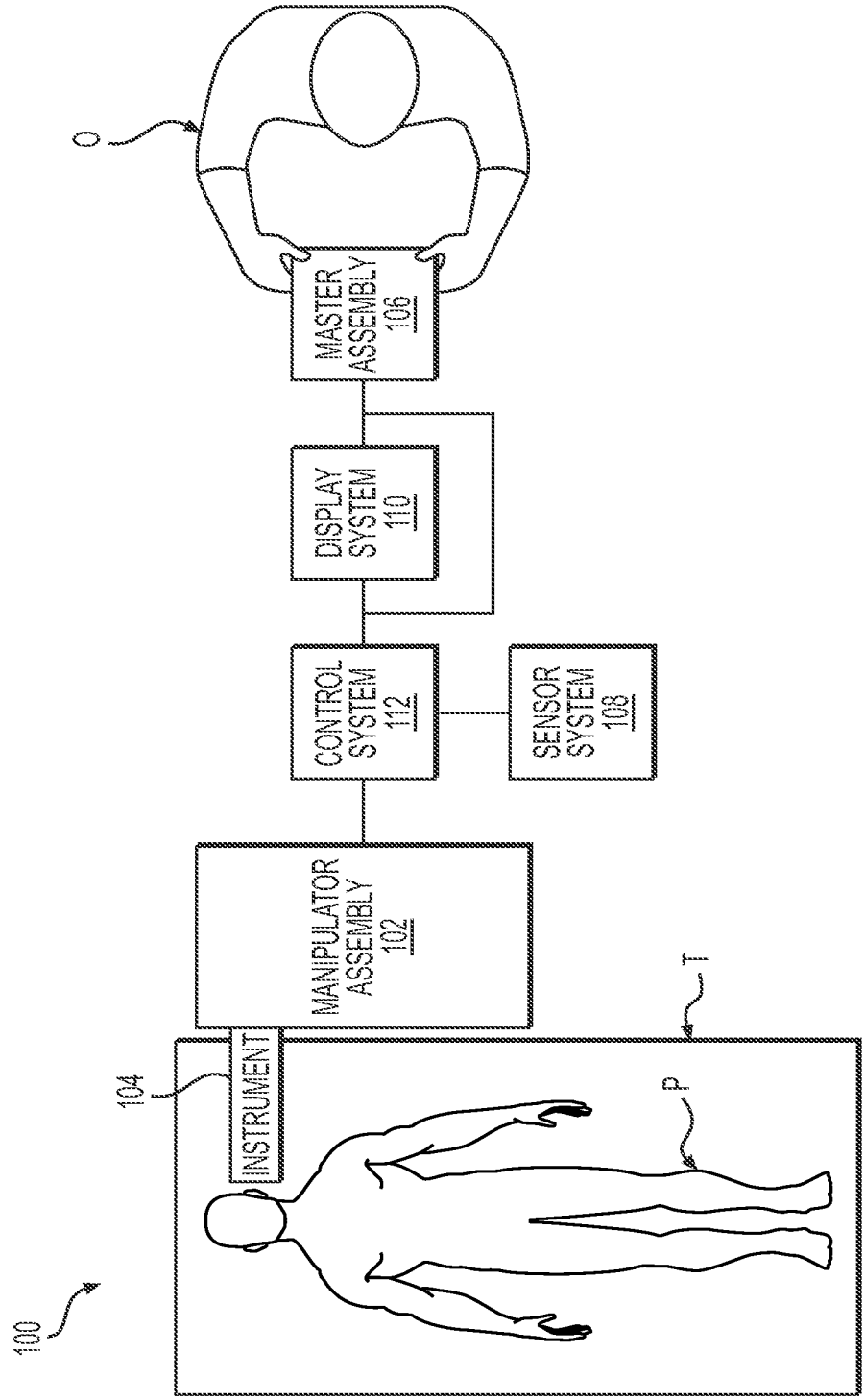

O
MASTER ASSEMBLY 106
DISPLAY SYSTEM 110
CONTROL SYSTEM 112
SENSOR SYSTEM 108
MANIPULATOR ASSEMBLY 102
INSTRUMENT
104
T
P
100

FIG. 1

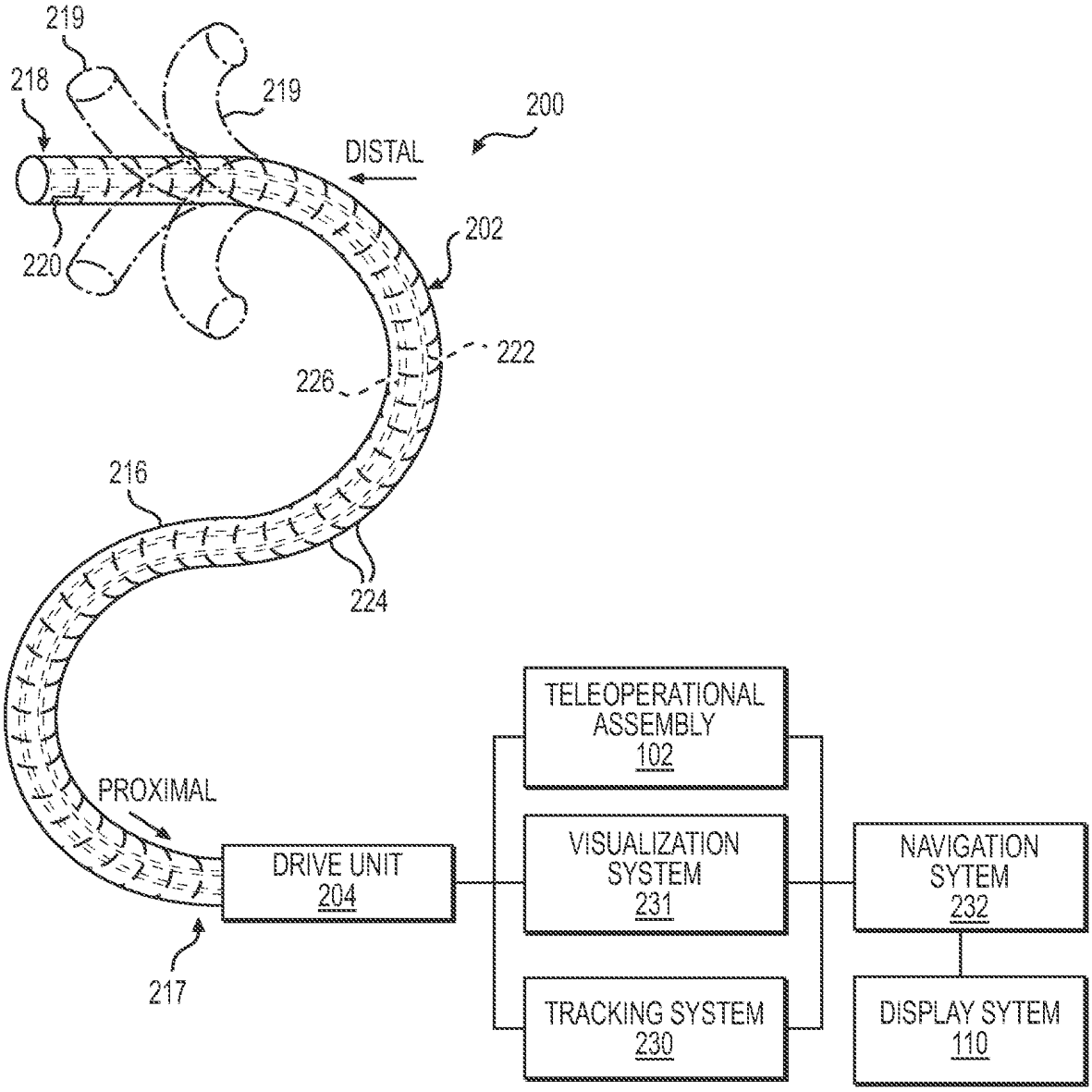

219
218
219
200
DISTAL
202
220
222
226
216
224
PROXIMAL
DRIVE UNIT
204
217
TELEOPERATIONAL ASSEMBLY
102
VISUALIZATION SYSTEM
231
TRACKING SYSTEM
230
NAVIGATION SYTEM
232
DISPLAY SYTEM
110

FIG. 2A

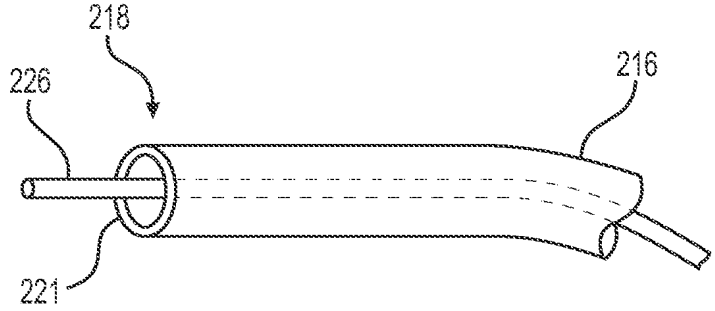

218
226
216
221

FIG. 2B

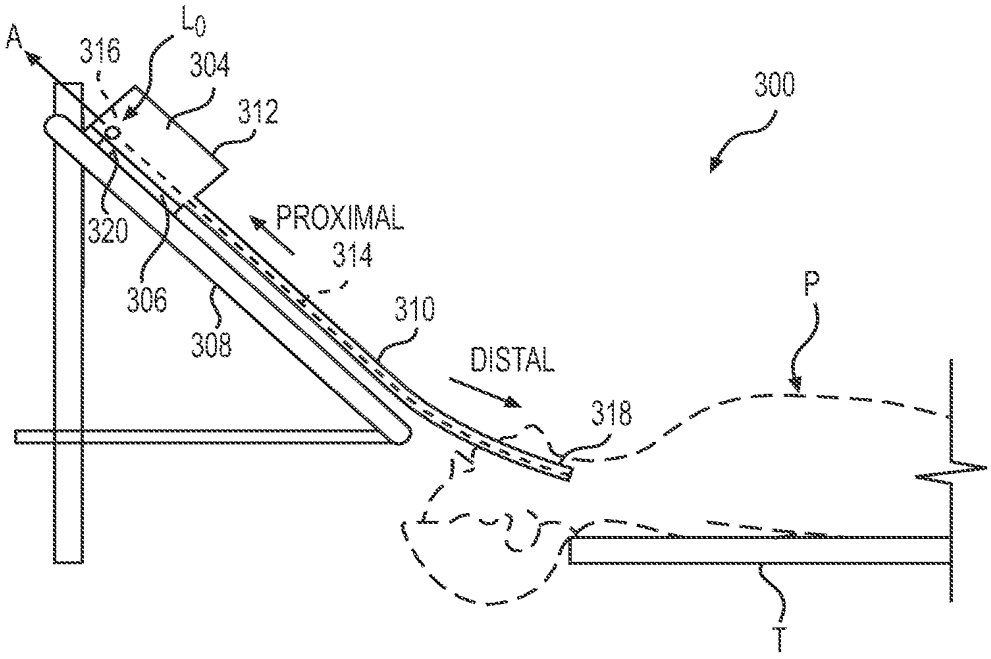

A
316
L_0
304
312
300
PROXIMAL
320
314
306
310
P
308
DISTAL
318
T

FIG. 3A

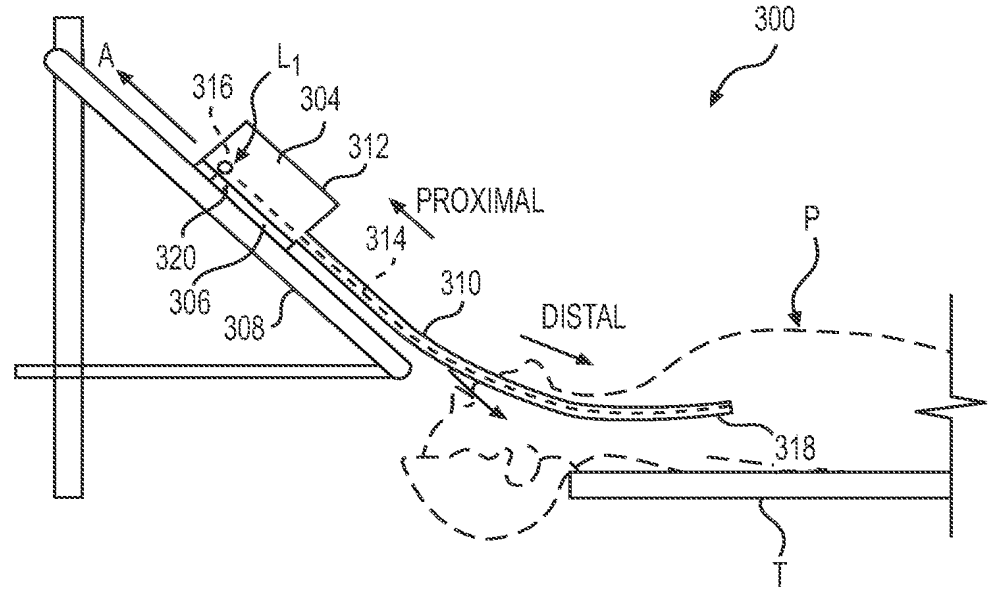

300
A
L_1
316
304
312
PROXIMAL
320
314
P
306
310
308
DISTAL
318
T

FIG. 3B

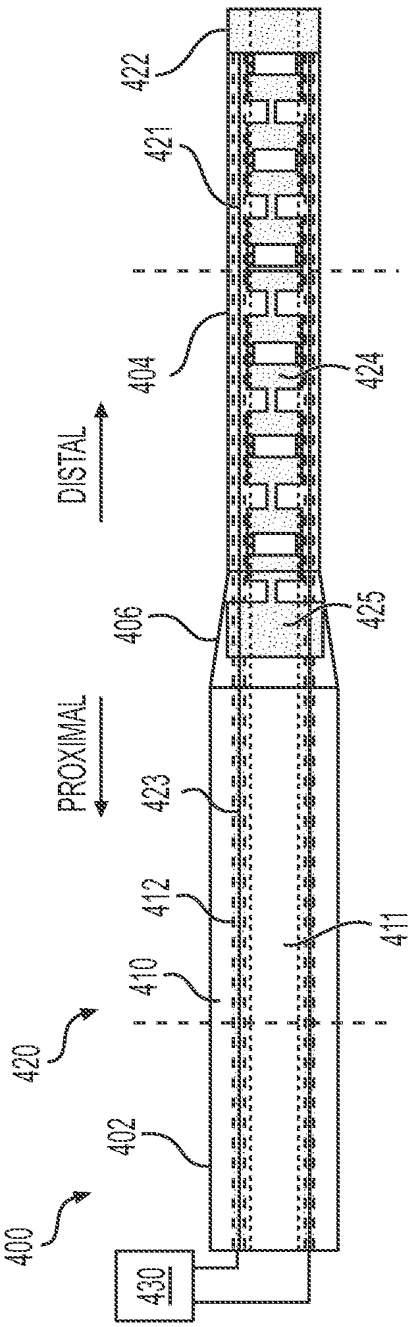


FIG. 4A

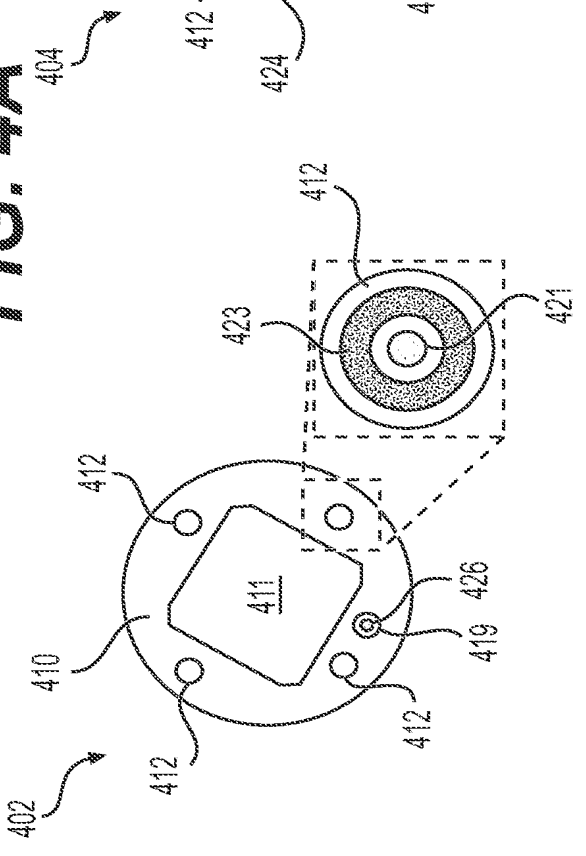


FIG. 4B

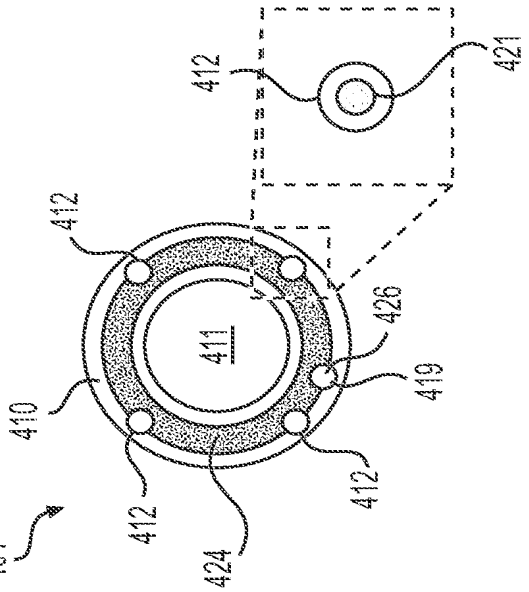


FIG. 4C

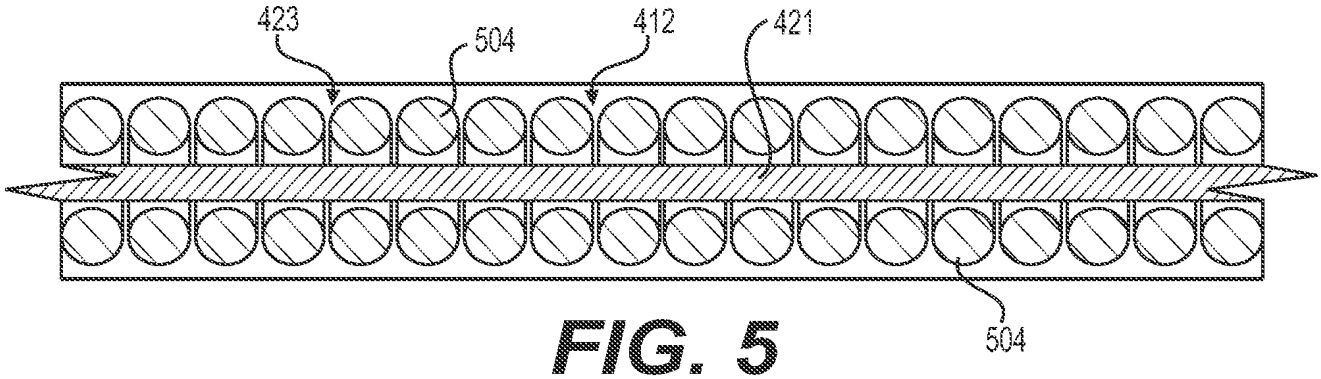


FIG. 5

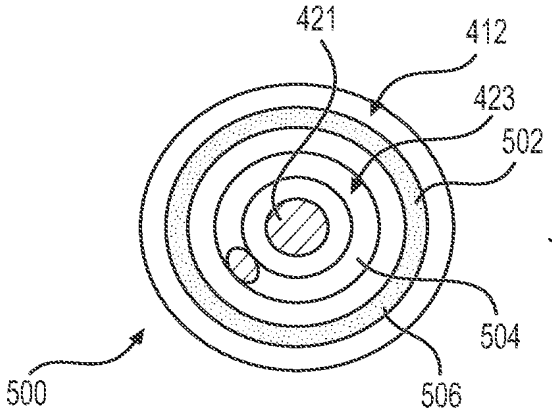


FIG. 6A

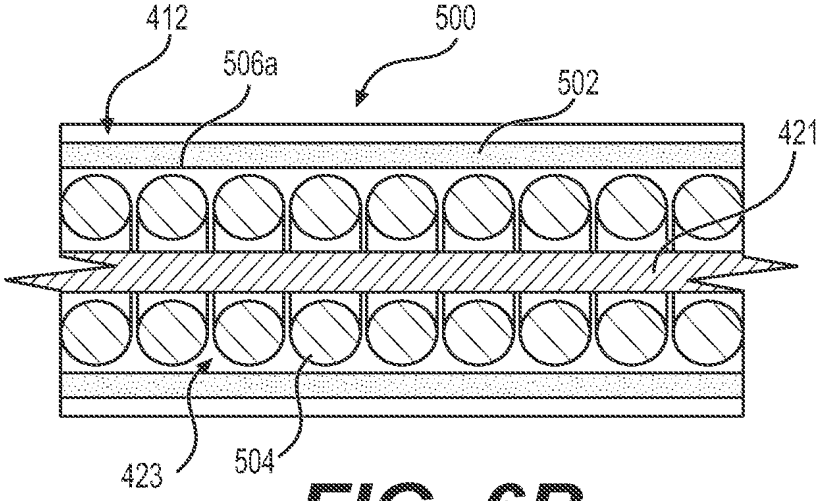


FIG. 6B

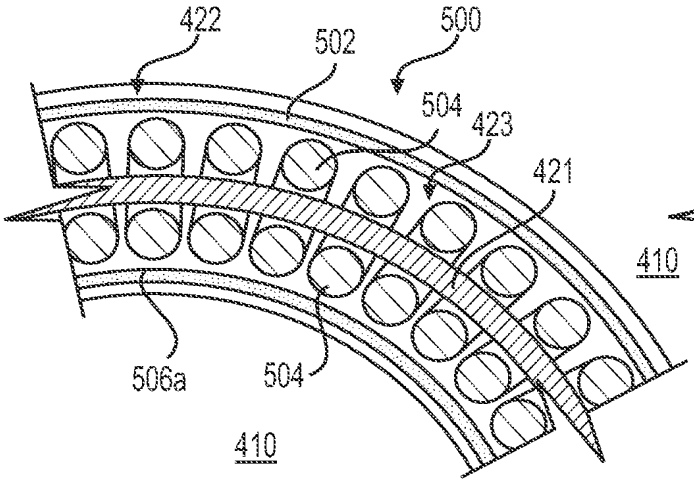


FIG. 6C

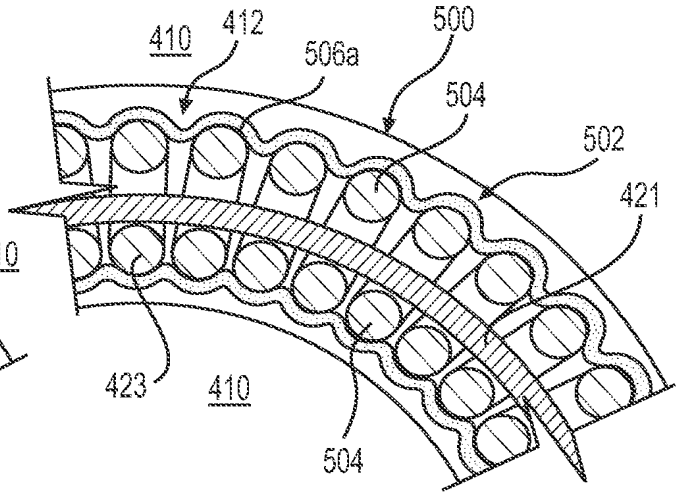


FIG. 6D

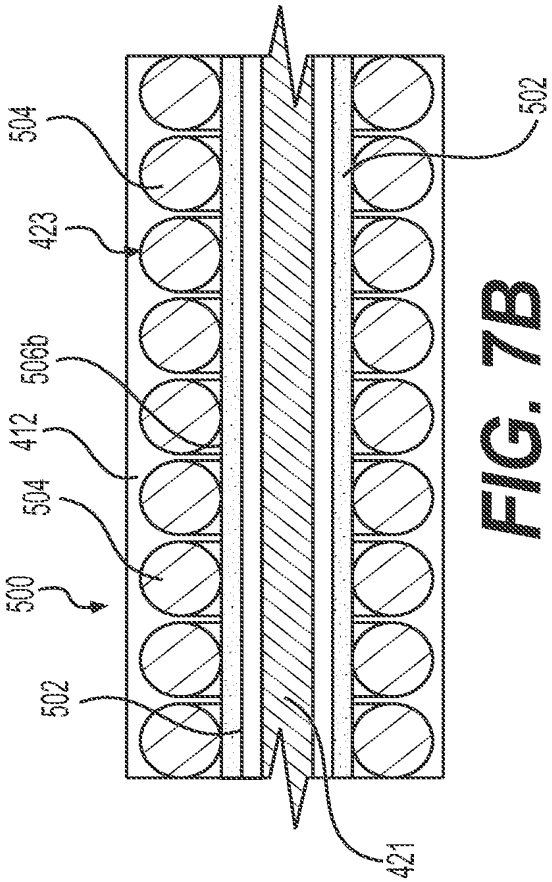


FIG. 7B

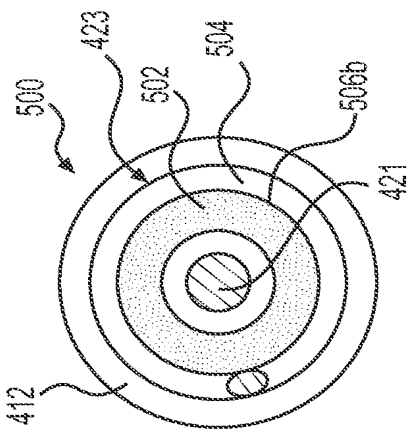


FIG. 7A

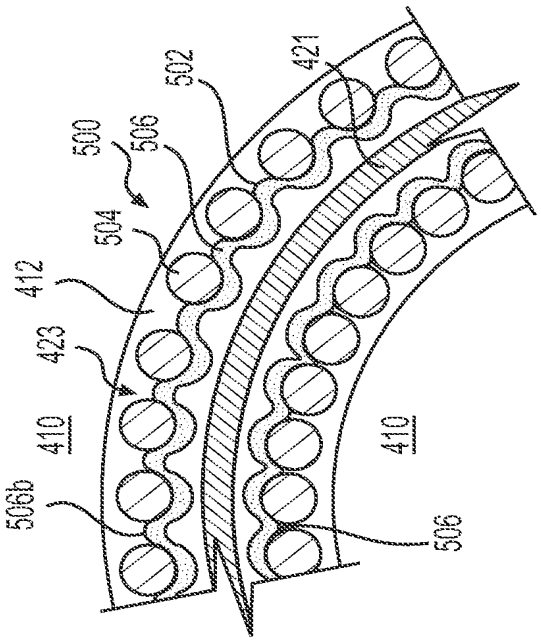


FIG. 7D

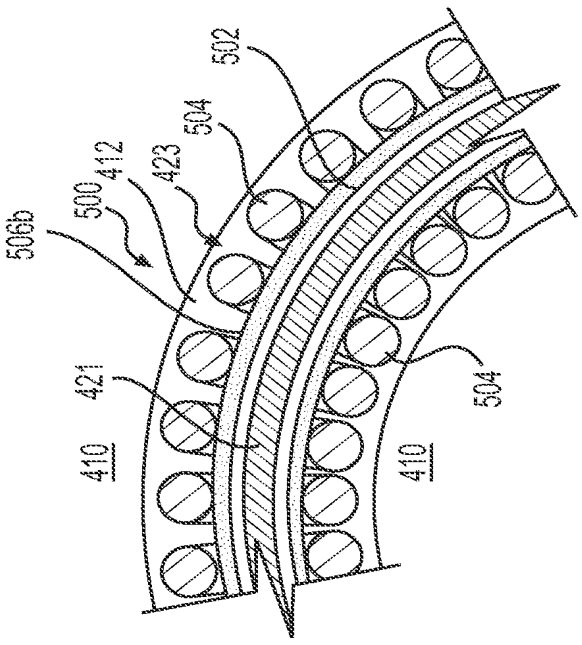


FIG. 7C

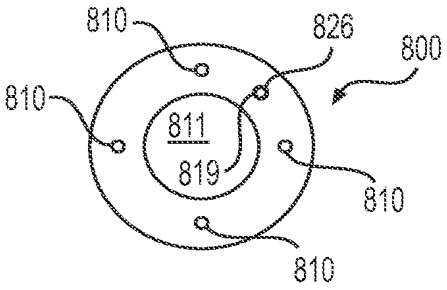


FIG. 8A

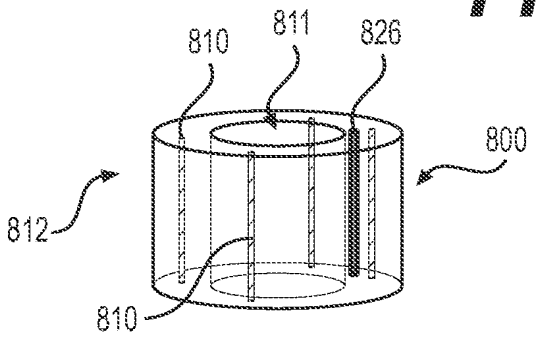


FIG. 8B

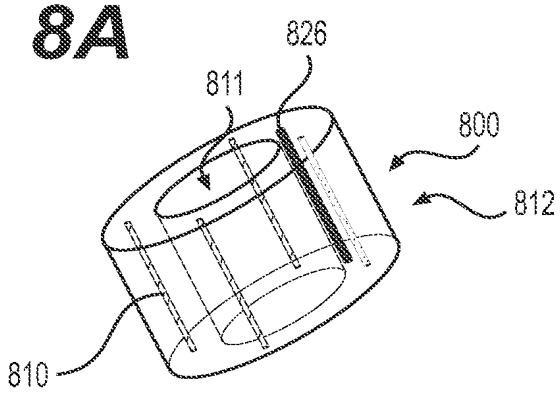


FIG. 8C

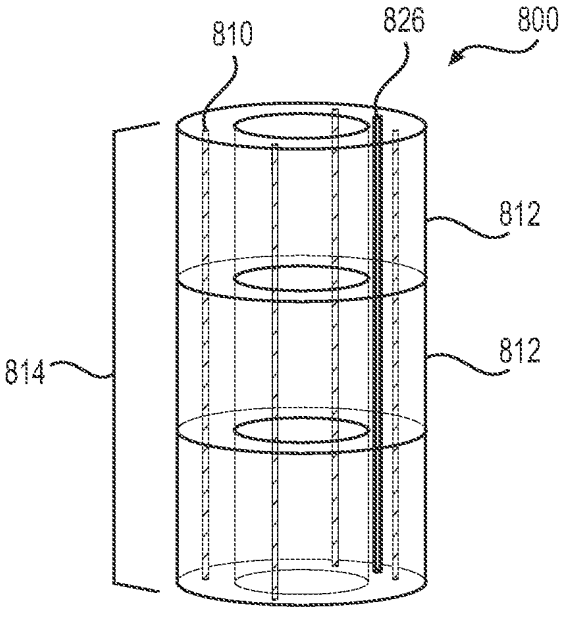


FIG. 8D

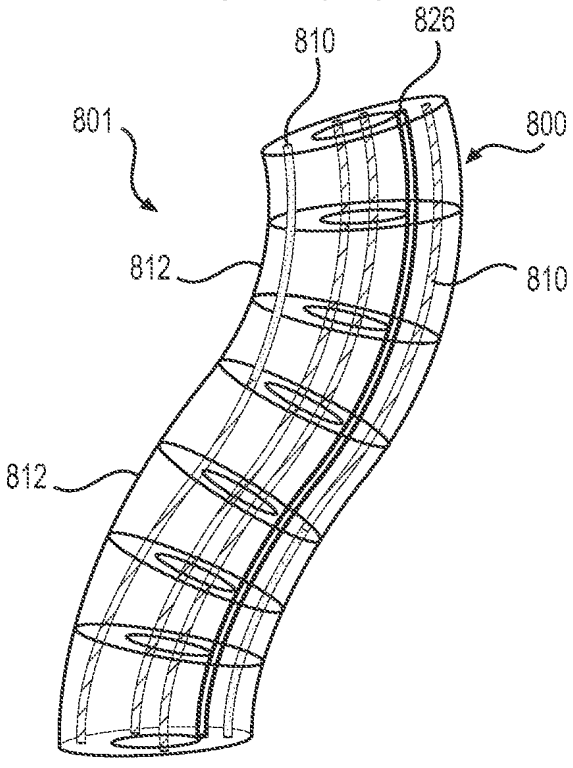


FIG. 8E

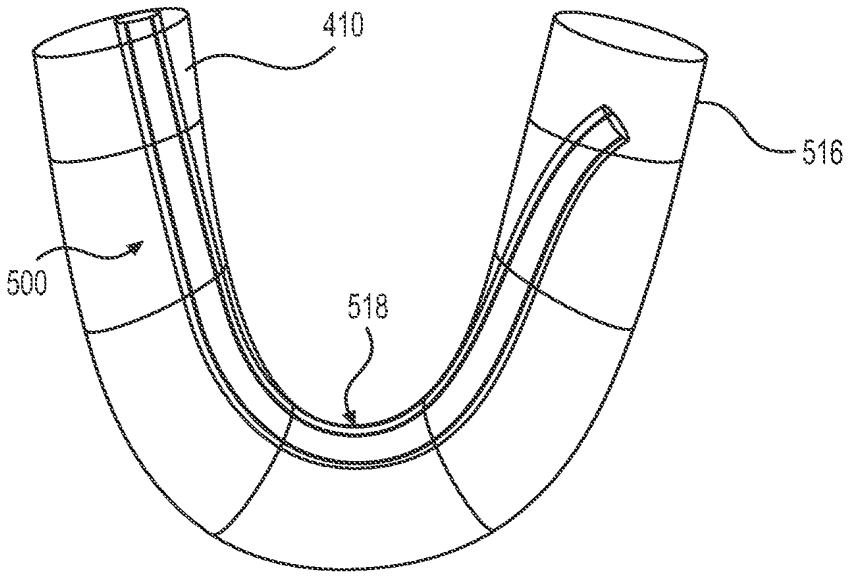


FIG. 9A

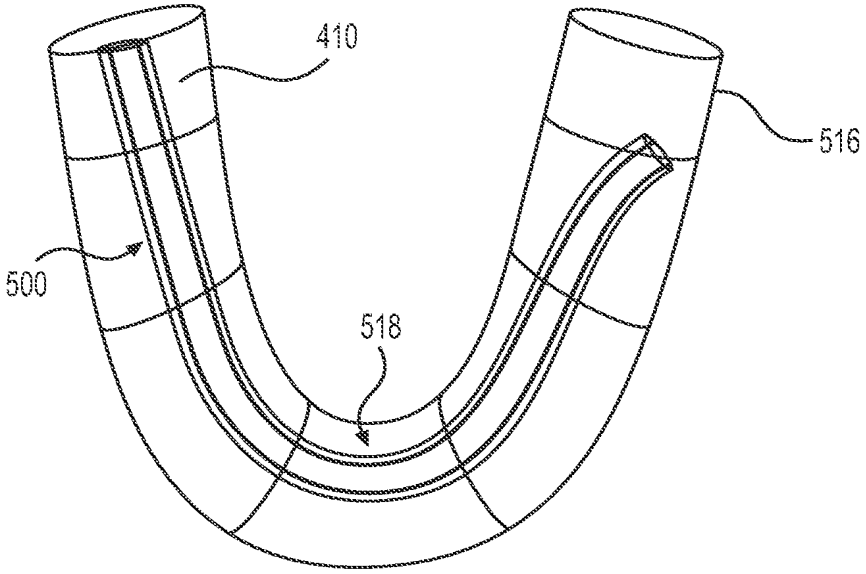


FIG. 9B

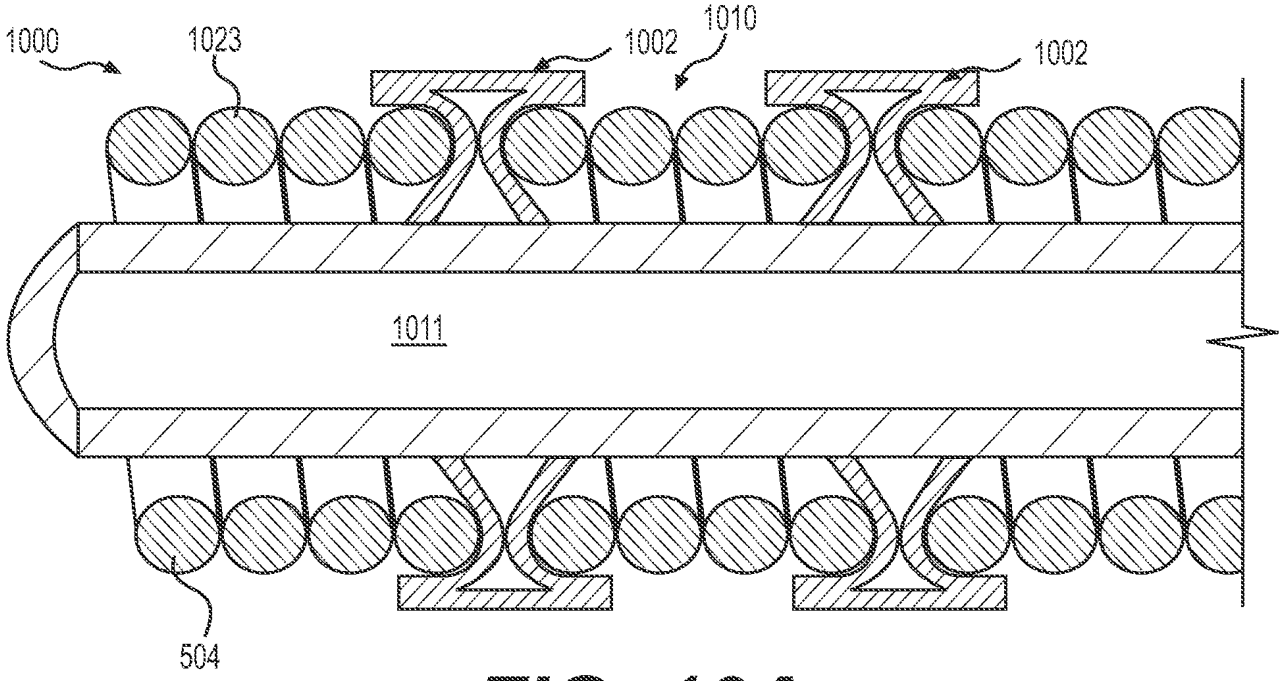


FIG. 10A

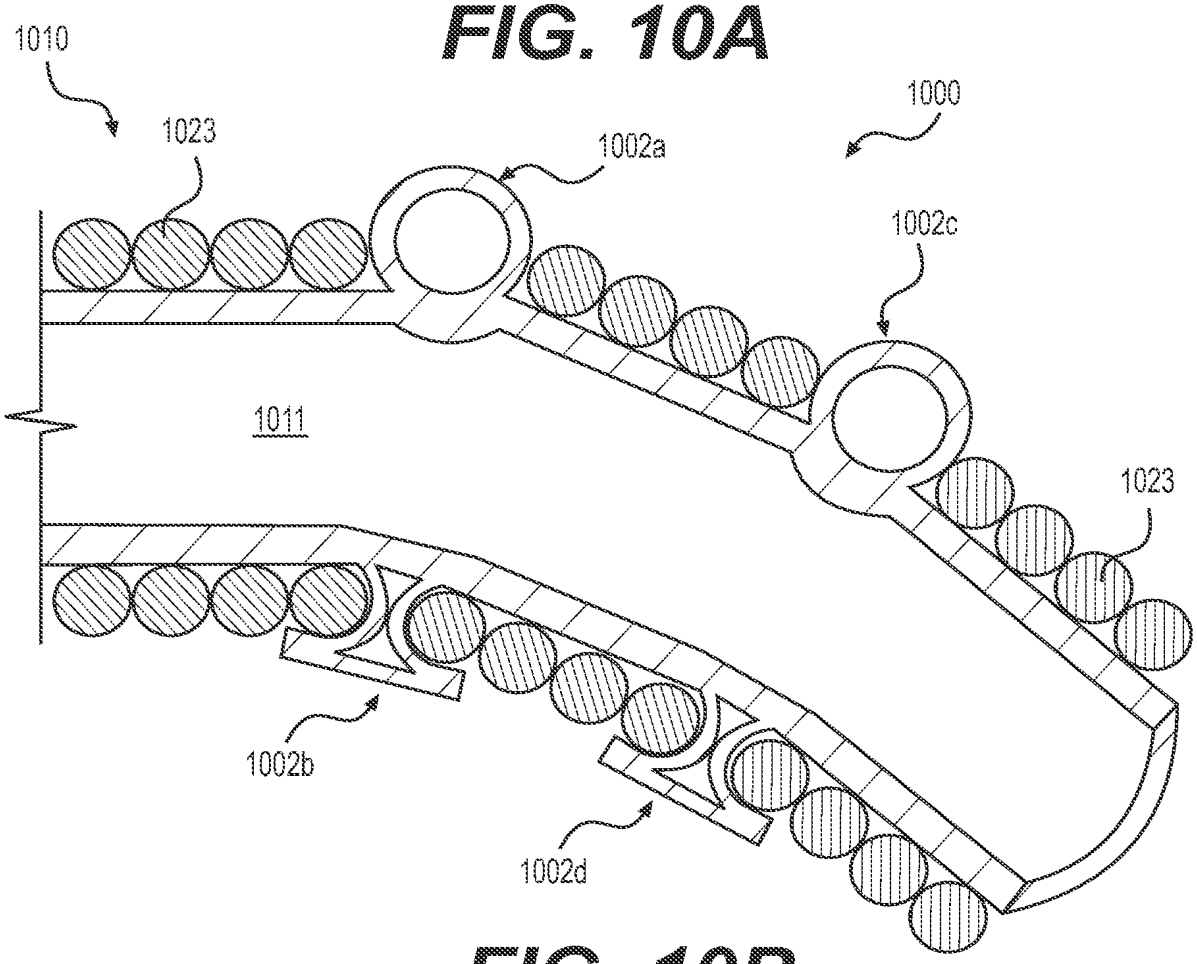


FIG. 10B

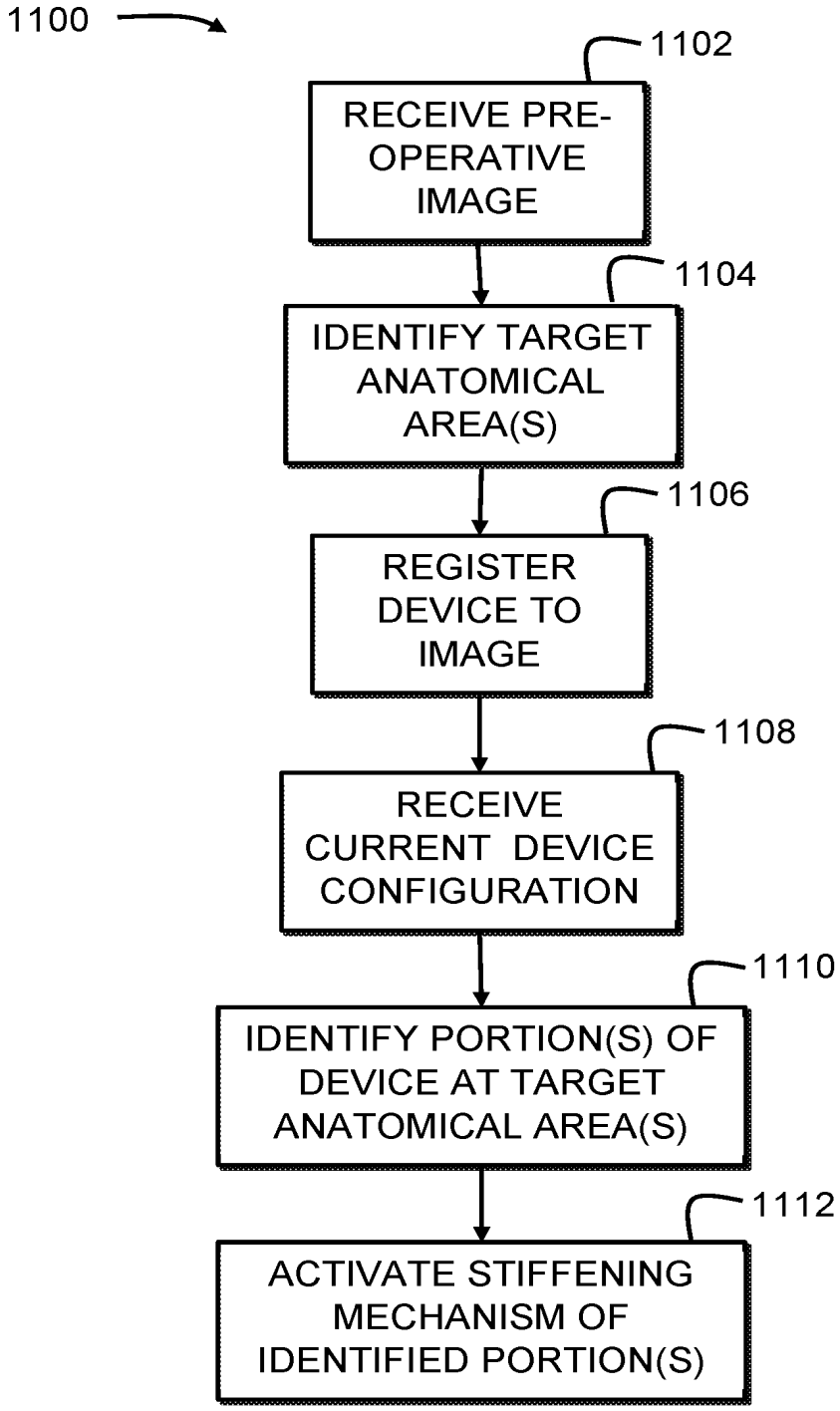

1100
1102
RECEIVE PRE-OPERATIVE IMAGE
1104
IDENTIFY TARGET ANATOMICAL AREA(S)
1106
REGISTER DEVICE TO IMAGE
1108
RECEIVE CURRENT DEVICE CONFIGURATION
1110
IDENTIFY PORTION(S) OF DEVICE AT TARGET ANATOMICAL AREA(S)
1112
ACTIVATE STIFFENING MECHANISM OF IDENTIFIED PORTION(S)

FIG. 11

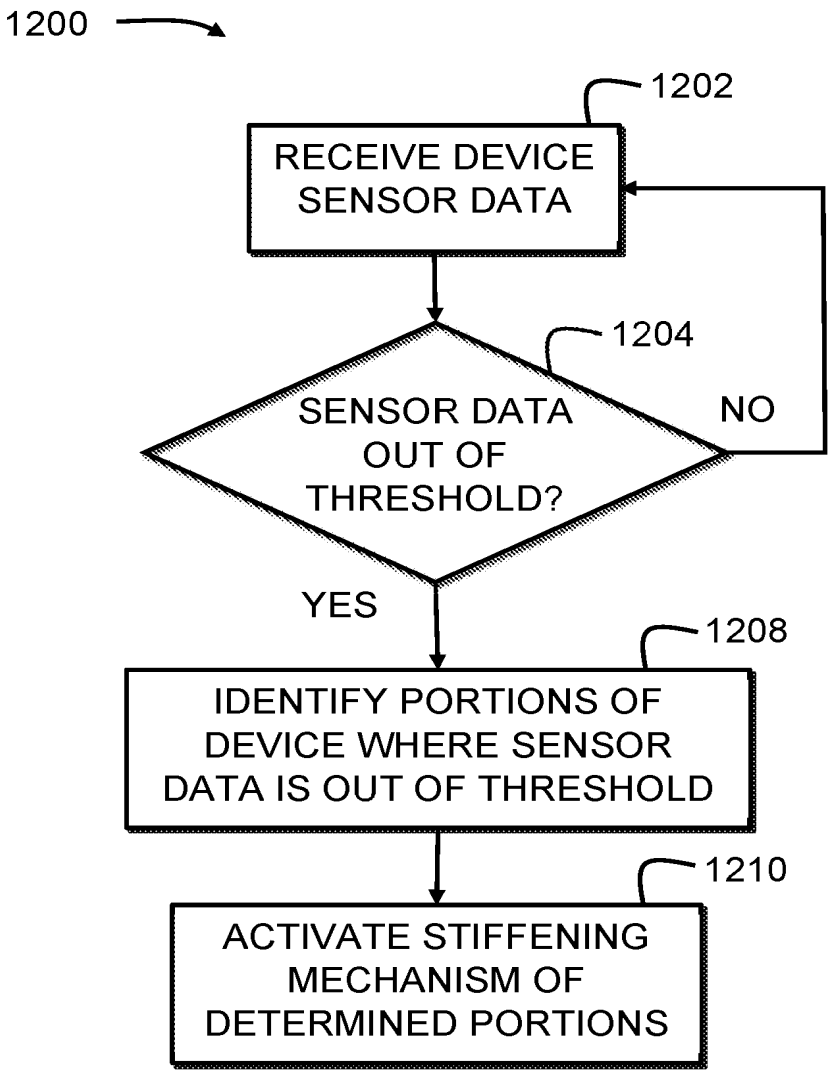

1200
1202
RECEIVE DEVICE SENSOR DATA
1204
SENSOR DATA OUT OF THRESHOLD?
NO
YES
1208
IDENTIFY PORTIONS OF DEVICE WHERE SENSOR DATA IS OUT OF THRESHOLD
1210
ACTIVATE STIFFENING MECHANISM OF DETERMINED PORTIONS

FIG. 12

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/037954

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B1/00 A61B1/005 A61B1/018 A61B1/267 A61M25/01
ADD. A61B17/00 A61B34/20 G02B23/24

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 G02B A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016/160586 A1 (BARRISH MARK D [US]) 6 October 2016 (2016-10-06) paragraphs [0003], [0007], [0025], [0053], [0055], [0081], [0180], [0185] paragraphs [0194], [0195], [0307] figures 1, 1-1, 3, 4A, 4B	1,7-30
X	US 2013/096385 A1 (FENECH CAROLYN M [US] ET AL) 18 April 2013 (2013-04-18) paragraphs [0024], [0025], [0033], [0036], [0039] figures 1, 3A	1-5,7
X	WO 2018/005928 A1 (INTUITIVE SURGICAL OPERATIONS [US]) 4 January 2018 (2018-01-04) paragraphs [0044], [0063] - [0065], [0078]	1,4,6

☐ 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
17 September 2019	30/09/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Hemb, Björn

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/037954

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2016160586 A1	06-10-2016	AU 2016243508 A1	12-10-2017
		CA 2980745 A1	06-10-2016
		CN 107835703 A	23-03-2018
		CN 107835704 A	23-03-2018
		CN 107921236 A	17-04-2018
		EP 3274038 A1	31-01-2018
		EP 3274039 A1	31-01-2018
		EP 3274040 A1	31-01-2018
		JP 2018514350 A	07-06-2018
		US 2016279388 A1	29-09-2016
		US 2017021132 A1	26-01-2017
		US 2017021143 A1	26-01-2017
		WO 2016160586 A1	06-10-2016
		WO 2016160587 A1	06-10-2016
		WO 2016160589 A1	06-10-2016
US 2013096385 A1	18-04-2013	NONE	
WO 2018005928 A1	04-01-2018	CN 109310287 A	05-02-2019
		EP 3478149 A1	08-05-2019
		US 2019231449 A1	01-08-2019
		WO 2018005928 A1	04-01-2018

(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 103764049 A
(43)申请公布日 2014.04.30

(21)申请号 201280036998.X
(22)申请日 2012.07.25
(30)优先权数据
13/191,306 2011.07.26 US
13/543,657 2012.07.06 US
(85)PCT国际申请进入国家阶段日
2014.01.24
(86)PCT国际申请的申请数据
PCT/US2012/048158 2012.07.25
(87)PCT国际申请的公布数据
WO2013/016435 EN 2013.01.31
(71)申请人 迈克尔·P·马克思
地址 美国加利福尼亚州
申请人 莱克·奎
(72)发明人 迈克尔·P·马克思 莱克·奎
(74)专利代理机构 上海专利商标事务所有限公司 31100
代理人 张兰英
(51)Int.Cl.
A61B 17/22(2006.01)
A61M 25/00(2006.01)

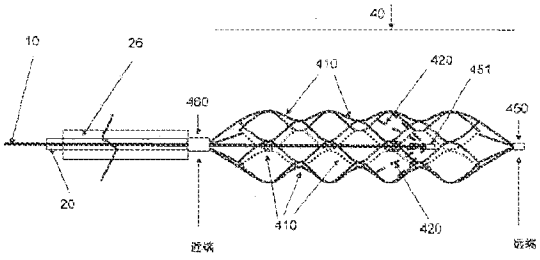
权利要求书4页 说明书29页 附图58页

(54)发明名称

血管内血栓切除装置及其使用方法

(57)摘要

提供一种用于加大或恢复体腔内流量的装置和方法。该装置和方法可通过从血管内去除凝块和/或重新打开血管来治疗像中风的病症。该装置可具有可扩张隔室，该可扩张隔室包括可重构元件和支承元件。支承元件可调节可重构元件的径向力和构造，由此允许从血管有效地去除凝块和/或重新打开血管，而对血管的损伤最少或没有损伤。或者，该装置可具有接合隔室，该接合隔室包括远侧接合元件和近侧接合元件。血管内的凝块可接合到远侧接合元件和近侧接合元件内和/或之间。可调节接合元件中的一个或两个的位置以及接合元件之间的间距以确保与凝块或闭塞物的接合。



CN 103764049 A

1. 一种用于体腔的装置，所述装置包括：

推送管件和可扩张隔室；

其中，所述可扩张隔室包括：

控制元件，所述控制元件包括近端和远端；

可重构元件，所述可重构元件与支承元件和所述控制元件相关联；以及

支承元件，所述支承元件与所述控制元件和所述可重构元件相关联，其中，所述支承元件构造成调节所述可重构元件的径向力和构造。

2. 如权利要求 1 所述的装置，其特征在于，所述控制元件包括线材、线缆或编织物。

3. 如权利要求 1 所述的装置，其特征在于，所述可重构元件和 / 或所述支承元件包括多个线材。

4. 如权利要求 3 所述的装置，其特征在于，所述可重构元件能自扩张到松弛的可扩张状态，以形成隔室或筐状物。

5. 如权利要求 4 所述的装置，其特征在于，所述可重构元件包括多个单元，且单元的尺寸和形成所述单元的线材的厚度在所述可重构元件内变化。

6. 如权利要求 1 所述的装置，其特征在于，所述支承元件呈支杆的形式，所述支杆由与所述可重构元件相同的材料制成，并且自动连接到所述可重构元件。

7. 如权利要求 1 所述的装置，其特征在于，所述支承元件呈丝网或编织物的形式。

8. 如权利要求 1 所述的装置，其特征在于，所述推送管件连接到所述可扩张隔室。

9. 如权利要求 1 所述的装置，其特征在于，所述控制元件被所述推送管件围绕，并能在所述推送管件内自由运动。

10. 如权利要求 1 所述的装置，其特征在于，所述支承元件包括第一构造和第二构造，所述支承元件和所述控制元件之间的角度在所述第一构造下比在所述第二构造下小。

11. 如权利要求 1 所述的装置，其特征在于，所述支承元件包括第一构造和第二构造，所述第一构造具有比所述第二构造的外直径小的外直径。

12. 如权利要求 10 和 11 所述的装置，其特征在于，所述控制元件向远侧方向突出使所述支承元件过渡到所述第一构造，因而，所述可重构元件的径向力减小。

13. 如权利要求 10 和 11 所述的装置，其特征在于，所述控制元件向近侧方向突出使所述支承元件过渡到所述第二构造，因而，所述可重构元件的径向力增大。

14. 如权利要求 1 所述的装置，其特征在于，所述装置构造成去除阻塞血管的闭塞物 / 凝块、打开血管的阻塞部段和 / 或增大血管内的流量。

15. 如权利要求 1 所述的装置，其特征在于，所述可重构元件的远端连结从而形成端部闭合的可重构元件，或者不连结从而形成端部敞开的可重构元件。

16. 如权利要求 1 所述的装置，其特征在于，所述可重构元件的各侧连结从而形成各侧闭合的可重构元件，或者不连结从而形成各侧敞开的可重构元件。

17. 如权利要求 1 所述的装置，其特征在于，所述支承元件包括多个线材，且所述线材能在所述近端和远端之间延伸，并且基本上被所述可重构元件围绕。

18. 如权利要求 1 所述的装置，其特征在于，所述可重构元件和所述支承元件呈丝网的形式，所述丝网能在所述近端和远端之间延伸，且所述支承元件基本上被所述可重构元件围绕，由此形成双层的可重构元件或可扩张隔室。

19. 如权利要求 1 所述的装置，其特征在于，所述可重构元件包括大致平行对准的多个直线形线材和呈大致圆形的多个线材，且所述支承元件包括与所述可重构元件和所述控制元件相关联的至少两个线材，由此形成伞形的可扩张隔室。

20. 如权利要求 1 所述的装置，其特征在于，所述可重构元件的远端和所述支承元件的远端不连接，并且独立运动。

21. 如权利要求 1 所述的装置，其特征在于，非创伤性柔性线圈附连到所述可重构元件的所述远侧末端。

22. 如权利要求 1 所述的装置，其特征在于，所述装置包括远侧可扩张结构和近侧可扩张结构。

23. 如权利要求 22 所述的装置，其特征在于，所述第一可扩张结构包括可重构元件、控制元件以及可选地支承元件。

24. 如权利要求 22 所述的装置，其特征在于，所述第二可扩张结构包括可重构元件和可选地封闭元件。

25. 如权利要求 22 所述的装置，其特征在于，所述远侧可扩张结构和所述近侧可扩张结构之间的间距可调。

26. 一种去除存在于血管的第一位置的闭塞物 / 凝块的方法，所述方法包括：

将如权利要求 1 所述的装置引入所述血管；

将所述装置定位在所述血管的所述第一位置；

通过调节所述装置的可重构元件的径向力和 / 或构造而与所述闭塞物 / 凝块接合；以及

从所述第一位置去除所述闭塞物 / 凝块。

27. 如权利要求 26 所述的方法，其特征在于，去除所述闭塞物 / 凝块还包括选自如下组中的一个或多个：

使所述闭塞物 / 凝块至少部分地与所述装置接合；

将所述闭塞物 / 凝块拆解成小尺寸碎屑，并收集所述碎屑中的至少一部分；以及

使所述血管的区域扩张。

28. 如权利要求 26 所述的方法，其特征在于，所述方法构造成应用于治疗中风。

29. 一种增大血管内流量的方法，所述方法包括：

将如权利要求 1 所述的装置引入所述血管；

将所述装置定位在大约所述血管的需要增大流量的第一位置；以及

调节所述装置的可重构元件的径向力和 / 或构造以使所述第一位置的区域扩张。

30. 一种去除存在于血管的第一位置的闭塞物 / 凝块的方法，所述方法包括：

将如权利要求 1 所述的装置引入所述血管；

将所述装置定位在大约所述血管的所述第一位置；

通过所述控制元件的近侧运动使与所述可重构元件相关联的支承元件延伸来支持所述可重构元件的扩张状态；

通过所述控制元件的近侧运动使与所述可重构元件相关联的支承元件延伸来进一步支持所述可重构元件的更扩张状态；

用于处于扩张状态的所述可重构元件 / 可扩张隔室来抓取所述闭塞物 / 凝块；

通过使所述控制元件向远侧运动来使所述可重构元件的构造向更松弛状态变化；以及

从所述第一位置去除所述闭塞物 / 凝块。

31. 一种去除存在于血管的第一位置的闭塞物 / 凝块的方法，所述方法包括：

将如权利要求 22 所述的装置引入所述血管；

将所述装置定位在所述血管的位置远侧；

向近侧拉动推送管件，以抓取处于扩张状态的两个可扩张结构之间的闭塞物 / 凝块；

通过所述控制元件的近侧运动使与所述可重构元件相关联的支承元件延伸来支持所述可重构元件的扩张状态；

用近侧可扩张结构来抓取所述闭塞物 / 凝块；

用远侧可扩张结构来捕获闭塞物 / 凝块碎屑；

在拉动所述控制元件时可选地收回所述装置以增大所述可扩张结构的径向力，并进一步支持所述可扩张结构的扩张状态；以及

从所述第一位置去除所述闭塞物 / 凝块。

32. 一种用于体腔的装置，所述装置包括：

微型导管，所述微型导管包括近端和远端；

管件隔室；

中心线；以及

接合隔室，

其中，所述接合隔室包括：

近侧接合元件；以及

远侧接合元件，

其中，所述远侧接合元件是与所述中心线相关联的可扩张元件，且所述近侧接合元件和所述远侧接合元件之间的间距可调。

33. 如权利要求 32 所述的装置，其特征在于，所述远侧接合元件包括形成支架的多个线材或支杆。

34. 如权利要求 32 所述的装置，其特征在于，所述远侧接合元件与延伸到所述装置的近端的中心线固定，由此，所述远侧接合元件在体腔内的位置由所述中心线的运动来控制。

35. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件是包括多个线材或支杆的可扩张元件，并能扩张成漏斗状或锥形结构。

36. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件与所述中心线相关联，并沿所述中心线运动。

37. 如权利要求 36 所述的装置，其特征在于，所述近侧接合元件与延伸到所述装置的近端的管件隔室固定，由此，所述近侧接合元件在体腔内的位置由所述管件隔室的运动来控制。

38. 如权利要求 36 所述的装置，其特征在于，所述近侧接合元件不与所述管件隔室固定，并构造成沿所述中心线自由运动。

39. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件位于所述微型导管的远端处。

40. 如权利要求 39 所述的装置，其特征在于，所述近侧接合元件不是所述微型导管的

一体部分，而是固定在所述微型导管的所述远端处。

41. 如权利要求 39 所述的装置，其特征在于，所述近侧接合元件是可膨胀或接合元件。

42. 如权利要求 39 所述的装置，其特征在于，所述近侧接合元件是微型导管的一体部分。

43. 如权利要求 42 所述的装置，其特征在于，所述近侧接合元件包括所述微型导管的所述远端的构造成根据施加于所述微型导管的所述远端的压力来改变形状的部分。

44. 如权利要求 42 所述的装置，其特征在于，所述近侧接合元件包括所述微型导管的所述远端的包括微型导管末端的部分和覆盖所述微型导管末端的薄管件层，其中，所述近侧接合元件的至少一部分构造成在移除所述薄管件层时改变形状。

45. 如权利要求 32 所述的装置，其特征在于，所述管件隔室包括推送管件和连接管件。

46. 如权利要求 32 所述的装置，其特征在于，所述管件隔室由一件具有可变刚度的管件制成，因而，所述管件隔室的远端是软的和柔性的，因此，所述装置能通过曲折的解剖体，同时所述管件隔室的近端刚硬到加强所述装置的可推送性。

47. 如权利要求 32 所述的装置，其特征在于，所述中心线包括线材、线缆或编织物。

48. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件和所述远侧接合元件之间的间距约在 0 到 50 毫米的范围内可调。

49. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件包括面向所述远侧接合元件的远端，所述近侧接合元件的所述远端被弯曲、倒圆或弄成圆滑。

50. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件包括面向所述远侧接合元件的远端，所述近侧接合元件的所述远端构造成不与所述体腔的表面直接接触。

51. 一种从体腔内的第一位置去除闭塞物的至少一部分的方法，所述方法包括：

将如权利要求 32 所述的装置引入所述体腔内；

将所述装置定位在大约所述第一位置；

使所述闭塞物的至少一部分与所述接合元件接合；以及

从所述第一位置去除接合的闭塞物。

52. 如权利要求 51 所述的方法，其特征在于，所述接合包括：

调节所述近侧接合元件和所述远侧接合元件中的一个或两个的位置以使所述闭塞物的至少一部分与所述近侧接合元件和 / 或所述远侧接合元件接合。

53. 如权利要求 51 所述的方法，其特征在于，所述接合包括：

调节所述近侧接合元件和所述远侧接合元件之间的间距以使所述闭塞物的至少一部分接合到所述近侧接合元件和所述远侧接合元件之间。

54. 如权利要求 51 所述的方法，其特征在于，所述方法还包括：

在接合之后，锁定所述近侧接合元件和所述远侧接合元件中的一个或两个的位置。

55. 如权利要求 51 所述的方法，其特征在于，在所述接合时，所述闭塞物的至少一部分与选自如下组的任何部件接合：所述体腔的表面、所述微型导管、所述管件隔室、所述近侧接合元件、所述远侧接合元件及其任何组合。

血管内血栓切除装置及其使用方法

[0001] 发明背景

技术领域

[0002] 本发明总地涉及用于诸如人体血管之类的体腔内的装置及其使用方法。

[0003] 相关技术的说明

[0004] 会至少部分地由于血管的阻塞或闭塞或凝块而造成多种病症。这种病症的熟知示例包括但不限于是中风。其它这种病症包括心肌梗塞、下肢缺血、血管移植物和旁路的闭塞或凝块以及静脉血栓。

[0005] 中风经常被称为“脑部侵袭”。这由于脑部供血紊乱经常会造成脑部功能的快速和明显丧失。由此，运动无力、语言的使用、视觉和许多其它生物功能会暂时地或不可逆地受到影响。中风是出血性的(由于出血)或者缺血性的(由于供血不足)。大部分中风是缺血性的。估计每年在美国发生约 700000 起缺血性中风。缺血性中风的大多数起因包括在供给脑部的血管中形成血栓(结块)或者从诸如心脏的另一源至供给脑部的血管的栓塞物。有时，在脑部中有预先存在的血管狭窄之处形成血栓，通常形成动脉粥样硬化疾病。

[0006] 急性缺血性中风的治疗集中于尽可能快地重新建立至脑部的血流。治疗包括使用诸如组织纤溶酶原激活剂(tPA)、血栓溶解剂(降凝块药)之类的药物。最近，食品与药品管理局已许可诸如 Merci 血栓切除装置(加利福尼亚州山景城的集中医药公司(Concentric Medical)) 以及 Penumbra 吸入血栓切除导管(加利福尼亚州阿拉米达的派母巴公司(Penumbra, Inc.)) 以及 Solitaire 血栓切除装置(加利福尼亚州欧文的 ev3 神经血管公司(Neurovascular))的装置用于急性中风的血栓切除。这些装置不总是能实现完全再通。有时，它们根本不能打开血管或者仅可部分地打开血管。它们工作起来还耗时，在重新打开血管之前需要装置多次进入颅内循环。此外，它们会弄碎凝块，并使得凝块的某些部分会在脑循环中运动到更远侧。需要具有以更快速方式执行的具有高完全再通率以及完全或部分凝块捕获功能的装置。

发明内容

[0007] 根据本发明的一方面，提供用于体腔内的装置。该装置可包括推送管件和可扩张隔室。根据一些实施例，可扩张隔室可包括包含近端和远端的控制元件、可重构元件和支承元件，该可重构元件可与支承元件和控制元件相关联，支承元件可与控制元件和可重构元件相关联。根据一些其它实施例，支承元件可构造成调节可重构元件的径向力和构造。

[0008] 在前述装置中，控制元件在至少一些实施例中可包括线材、线缆、或编织物。在一些其它实施例中，可重构元件和 / 或所述支承元件可包括多个线材。在又一些其它实施例中，可重构元件能自扩张到松弛的可扩张状态，以形成隔室或筐状物。在另一些其它实施例中，可重构元件包括多个单元，且单元的尺寸和形成所述单元的线材或支杆的尺寸可在可重构元件内变化。

[0009] 在一些实施例中，前述装置的支承元件呈支杆的形式，该支杆由与可重构元件相

同的材料制成，并且自动连接到可重构元件。在一些其它实施例下，支承元件可以呈丝网或编织物的形式。在一些替代实施例中，推送管件可连接到可扩张隔室。在又一些其它实施例下，控制元件可被推送管件围绕，并能在推送管件内自由运动。

[0010] 在一些其它实施例中，前述装置的支承元件可包括第一构造和第二构造，支承元件和控制元件之间的角度在所述第一构造比在第二构造下小。在某些实施例中，支承元件可包括第一构造和第二构造，所述第一构造的外直径比第二构造的外直径小。

[0011] 根据又一些其它实施例，控制元件向远侧方向突出使支承元件过渡到第一构造，因而，可重构元件的径向力或构造可减小。在一些替代实施例中，控制元件向近侧方向突出可使支承元件过渡到第二构造，因而，可重构元件的径向力或构造可增大。在某些方面，该装置可构造成去除阻塞血管的闭塞物 / 凝块、打开血管的阻塞部段和 / 或增大血管内的流量。

[0012] 根据某些方面，可重构元件的远端可连结从而形成端部闭合的可重构元件，或者不连结从而形成端部敞开的可重构元件。在一些实施例中，可重构元件的各侧可连结从而形成各侧闭合的可重构元件，或者不连结从而形成各侧敞开的可重构元件。在某些实施例中，支承元件包括多个线材，且这些线材能在所述近端和远端之间延伸，并且基本上被可重构元件围绕。

[0013] 在一些其它方面，前述装置的可重构元件和支承元件呈丝网的形式，该丝网能在近端和远端之间延伸，且支承元件基本上被可重构元件围绕，由此形成双层的可重构元件或可扩张隔室。在一些实施例中，可重构元件可包括大致平行对准的多个直线形线材和呈大致圆形的多个线材，且支承元件包括与可重构元件和控制元件相关联的至少两个线材，由此形成伞形的可扩张隔室。

[0014] 根据又一些其它方面，可重构元件的远端和支承元件的远端不连接，并且能独立运动。在某些实施例中，非创伤性线圈可附连到可重构元件的远侧末端。

[0015] 根据又一些其它方面，该装置包括远侧可扩张结构和近侧可扩张结构。在一些实施例中，第一可扩张结构包括可重构元件、控制元件和可选地支承元件。在一些其它实施例中，第二可扩张结构包括可重构元件和可选地封闭元件。在某些实施例中，远侧和近侧可扩张结构之间的间距可调。

[0016] 根据又一些其它方面，提供了一种在血管的第一位置去除闭塞物 / 凝块的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内，将装置定位在血管的第一位置，通过调节装置的可重构元件的径向力和 / 或构造面与闭塞物 / 凝块接合；以及从第一位置去除闭塞物 / 凝块。在一些实施例中，去除闭塞物 / 凝块还包括选择如下的一个或多个：使闭塞物 / 凝块至少部分地与装置接合，将闭塞物 / 凝块拆解成小尺寸碎屑，并收集碎屑中的至少一部分；以及使血管的区域扩张。在一些其它实施例中，该方法可构造成应用于治疗中风。

[0017] 根据又一些其它方面，提供一种增大血管内流量的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内，将装置定位在血管的需要增大流量的第一位置附近；以及调节装置的可重构元件的径向力和 / 或构造以使第一位置的区域扩张。

[0018] 根据又一些其它方面，提供了一种在血管的第一位置去除闭塞物 / 凝块的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内，将装置定位在血管的第一位

置附近，通过控制元件的近侧运动使与可重构元件相关联的支承元件延伸来支持可重构元件的扩张状态，通过控制元件的近侧运动使与可重构元件相关联的支承元件延伸来进一步支持可重构元件的更扩张状态，用处于扩张状态的可重构元件 / 可扩张隔室来抓取闭塞物 / 凝块，通过使控制元件向远侧运动来使可重构元件的构造向松弛状态变化，以及从第一位置去除闭塞物 / 凝块。

[0019] 根据又一些其它方面，提供了一种在血管的第一位置去除闭塞物 / 凝块的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内，将装置定位在血管的位置远侧；向近侧拉动推送管件，以抓取处于扩张状态的两个可扩张结构之间的闭塞物 / 凝块，通过控制元件的近侧运动使与可重构元件相关联的支承元件延伸来支持可重构元件的扩张状态，用近侧可扩张结构来抓取闭塞物 / 凝块，用远侧可扩张结构来捕获闭塞物 / 凝块碎屑；在拉动控制元件时可选地收回装置以增大可扩张结构的径向力，并进一步支持可扩张结构的扩张状态，以及从第一位置去除闭塞物 / 凝块。

[0020] 根据本发明的又一方面，提供用于体腔内的装置。该装置可包括微型导管，该微型导管包括近端和远端、管件隔室、中心线以及接合隔室。接合隔室可包括近侧接合元件和远侧接合元件。远侧接合元件是与中心线相关联的可扩张元件，且近侧接合元件和远侧接合元件之间的间距可调。

[0021] 在一些实施例中，前述装置的远侧接合元件可包括形成支架的多个线材或支杆。远侧接合元件可相对于延伸到装置近端的中心线固定，由此，远侧接合元件在体腔内的位置由中心线的运动来控制。

[0022] 在一些其它实施例中，前述装置的近侧接合元件可以是包括多个线材或支杆的可扩张元件，并能扩张成漏斗状或锥形结构。近侧接合元件可与中心线相关联，并沿中心线运动。在一些替代实施例中，近侧接合元件相对于延伸到装置近端的管件隔室固定，由此，近侧接合元件在体腔内的位置由管件隔室的运动来控制。在又一些替代实施例中，近侧接合元件可以相对于管件隔室不固定，并构造成沿中心线自由运动。

[0023] 在又一些替代实施例中，近侧接合元件可位于微型导管的远端处。在某些实施例中，近侧接合元件不是微型导管的一体部分，而是固定在微型导管的远端处。

[0024] 在又一些其它实施例中，近侧接合元件可以是可膨胀或接合元件。在某些实施例中，近侧接合元件可以是微型导管的一体部分。

[0025] 在又一些其它实施例中，前述装置的近侧接合元件可包括微型导管的远端的构造成根据施加于微型导管远端的压力来改变形状的部分。在某些实施例中，近侧接合元件包括微型导管的远端的包括微型导管末端的部分和覆盖微型导管末端的薄管件层，其中，近侧接合元件的至少一部分构造成在移除薄管件层时改变形状。

[0026] 在又一些其它实施例中，任何前述装置的管件隔室可包括推送管件和连接管件。

[0027] 在又一些其它实施例中，装置的管件隔室可由一件具有可变刚度的管件制成，因而，管件隔室的远端是软和柔性的，因此，装置能通过曲折的解剖体，同时管件隔室的近端刚硬到加强装置的可推送性。

[0028] 在又一些其它实施例中，任何装置的中心线可包括线材、线缆或编织物。近侧接合元件和远侧接合元件之间的间距在约 0 到 50 毫米的范围内可调。

[0029] 在又一些其它实施例中，近侧接合元件可包括面向所述远侧接合元件的远端，近

侧接合元件的所述远端被弯曲、倒圆或弄成圆滑。在替代实施例中，装置的近侧接合元件包括面向远侧接合元件的远端，近侧接合元件的远端构造成不与体腔的表面直接接触。

[0030] 根据本发明的另一方面，提供一种从体腔内的第一位置去除闭塞物的至少一部分的方法。该方法可包括将前述装置引入体腔内，将装置定位在第一位置附近；使闭塞物的至少一部分与接合元件接合；以及从第一位置去除接合的闭塞物。

[0031] 在一些实施例中，该方法的接合步骤可包括调节近侧接合元件和所述远侧接合元件中的一个或两个的位置，以使闭塞物的至少一部分与近侧接合元件和/或远侧接合元件接合。在一些其它实施例中，该方法的接合步骤可包括调节近侧接合元件和远侧接合元件中的一个或两个的位置，以使闭塞物的至少一部分接合到近侧接合元件和远侧接合元件之间。

[0032] 在一些其它实施例中，该方法还可包括在接合之后锁定近侧接合元件和远侧接合元件中的一个或两个的位置。在某些实施例中，在前述方法的接合步骤中，闭塞物的至少一部分与选择如下组的任何部件接合：体腔的表面、微型导管、管件隔室、近侧接合元件、远侧接合元件及其任何组合。

附图说明

[0033] 图 1 示出根据本发明的一些实施例的装置的非限制性说明性示例。

[0034] 图 2A-F 示出根据本发明的一些实施例的装置的特别是当该装置位于体腔内时的另一非限制性说明性示例，并示出根据本发明的一些实施例的用于从血管去除闭塞物/凝块和/或使血管扩张的机构的一些非限制性示例。

[0035] 图 3A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0036] 图 4A-C 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0037] 图 5A-C 示出根据本发明的一些实施例的又一非限制性说明性装置。

[0038] 图 6A-C 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0039] 图 7A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0040] 图 8A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0041] 图 9A-E 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0042] 图 10A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0043] 图 11 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0044] 图 12A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0045] 图 13 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0046] 图 14A-D 示出根据本发明的一些实施例的制成装置的过程的非限制性说明性示例。

[0047] 图 15 示出根据本发明的一些实施例的包括装置的设备的非限制性说明性示例。

[0048] 图 16 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0049] 图 17A-B 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0050] 图 18 示出根据本发明的一些实施例的包括装置的设备的非限制性说明性示例。

[0051] 图 19A-H 示出根据本发明的一些实施例的去除血闭塞物/血凝块或者使血管扩张的方式的一些非限制性说明性示例。

[0052] 图 20A, A', B 和 C 示出根据本发明的装置的非限制性说明性示例。图 20A 示出装置的打开状态，图 20B 示出装置的闭合状态(远侧接合元件和近侧接合元件之间)，而图 20C 示出具有远侧接合元件的端部闭合的远侧末端的装置。图 20A' 示出近侧接合元件由管件构成的实施例。

[0053] 图 21A-C 示出根据本发明的用于从体腔去除闭塞物或一部分闭塞物的方法的非限制性说明性示例。

[0054] 图 22A-D 示出根据本发明的用于从体腔去除闭塞物或一部分闭塞物的方法的又一非限制性说明性示例。

[0055] 图 23A-F 示出根据本发明的用于从体腔去除闭塞物的方法的一些其它非限制性说明性实施例。

[0056] 图 24 示出根据本发明的系统的非限制性说明性实施例。

[0057] 图 25 示出根据本发明的系统的又一非限制性说明性实施例。

[0058] 图 26A-B 示出根据本发明的装置的另一非限制性说明性实施例。图 26A 示出装置的打开状态，而图 26B 示出装置的闭合状态。

[0059] 图 27A-C 示出根据本发明的用于从体腔去除闭塞物或一部分闭塞物的方法的非限制性说明性示例。

[0060] 图 28 示出根据本发明的系统的另一非限制性说明性实施例。

[0061] 图 29 示出根据本发明的系统的另一非限制性说明性实施例。

[0062] 图 30A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 30A 示出装置的打开状态，而图 30B 示出装置的闭合状态。

[0063] 图 31A-C 示出根据本发明的用于从体腔去除闭塞物的方法的又一非限制性说明性实施例。

[0064] 图 32A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 32A 示出装置的打开状态，而图 32B 示出装置的闭合状态，在该闭合状态下，闭塞物与装置接合。

[0065] 图 33A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 33A 示出装置的打开状态，而图 33B 示出装置的闭合状态，在该闭合状态下，闭塞物与装置接合。

[0066] 图 34A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 34A 示出装置的打开状态，而图 34B 示出装置的闭合状态，在该闭合状态下，闭塞物与装置接合。

[0067] 图 35 示出根据本发明的装置的又一非限制性说明性实施例。特别是，附图示出装置的近侧部的替代实施例。

[0068] 图 36A-C 示出根据本发明的装置的又一非限制性说明性实施例。特别是，附图示出微型导管包括可转变成不同形状的末端的实施例。

[0069] 图 37A-D 示出根据本发明的特别是使用图 36 中所示的装置从体腔去除闭塞物的方法的非限制性说明性实施例。

[0070] 图 38A-D 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0071] 图 39A-B 示出根据本发明的装置的另一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0072] 图 40A-B 示出根据本发明的装置的另一非限制性说明性实施例，在该实施例中，

微型导管在其大约远端处包括可转变末端。

[0073] 图 41A-C 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0074] 图 42A-B 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0075] 图 43A-B 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0076] 图 44A-B 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0077] 图 45A-B 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0078] < 用于在附图中标示主要部件的附图标记 >

[0079] 1: 体腔表面

[0080] 5: 引导线

[0081] 10: 控制元件 / 中心线

[0082] 20: 推送管件

[0083] 21: 内推送管件

[0084] 22: 中间推送管件

[0085] 23: 外推送管件

[0086] 24: 远侧推送管件

[0087] 25: 近侧推送管件

[0088] 26: 引导器套管

[0089] 30: 微型导管

[0090] 31: 连接管件

[0091] 35: 微型导管毂

[0092] 40: 可扩张隔室

[0093] 41: 近侧元件连接件

[0094] 42: 近侧元件连结介质

[0095] 43: 外部近侧元件连接件

[0096] 50: 腔体表面

[0097] 60: 闭塞物 / 凝块

[0098] 65: 近侧接合元件

[0099] 70: 近侧元件标记

[0100] 80: 远侧元件连接件

[0101] 81: 远侧元件连结介质

[0102] 82: 外部远侧元件连接件

[0103] 90: 远侧接合元件

[0104] 100: 远侧元件标记

[0105] 120: 远侧部件控制手柄

[0106] 130：接头

[0107] 140：近侧部件的远侧连接件

[0108] 150：近侧部件的连接线

[0109] 160：近侧部件的段连接件

[0110] 170：可膨胀或可扩张元件

[0111] 180：注射通道

[0112] 190：注射器

[0113] 195：注射液体

[0114] 200：可转变的微型导管远侧末端

[0115] 210：外套管

[0116] 220：线材

[0117] 230：通道

[0118] 410：可重构元件

[0119] 420：支承元件

[0120] 425：封闭元件

[0121] 430：连接件

[0122] 431：外部连接件

[0123] 432：内部连接件

[0124] 440：标记

[0125] 450：远端连接件

[0126] 451：支承元件远侧连接件

[0127] 452：支承元件外部远侧连接件

[0128] 453：支承元件内部远侧连接件

[0129] 455：近侧可扩张结构的连接件

[0130] 460：近端连接件

[0131] 461：外部近端连接件

[0132] 462：内部近端连接件

[0133] 463：连接件连结介质(粘合剂、焊料等)

[0134] 470：调节管

[0135] 471：滑动管

[0136] 475：长内管

[0137] 480：高峰位置

[0138] 490：控制元件手柄管件

[0139] 520：连接线 / 抗拉伸线

[0140] 540：线圈

[0141] 550：远侧可扩张结构 / 远侧结构

[0142] 560：近侧可扩张结构 / 近侧结构

[0143] 570：连结介质

[0144] 580：推送管件连接点

[0145] 495：远侧柔性线圈

具体实施方式

[0146] 本发明总地涉及用于诸如血管的体腔内的装置及其使用方法。在一些实施例中，装置可定位在体腔内，以使内腔扩开和/或从内腔去除闭塞物/凝块。尽管装置位于体腔需要治疗的部分内，但操作者可操纵该装置以使内腔扩张和/或与闭塞物/凝块接合。

[0147] 本发明的一些方面提供构造成治疗血管内病症、包括但不限于是中风的装置和方法。在一些实施例中，装置和方法构造成通过从血管去除闭塞物/凝块和/或使具有一定潜在狭窄的血管重新打开以在血管内恢复血流来治疗与缺血性中风相关的病症。

[0148] 血管的非限制性示例可包括动脉、静脉和起到循环系统的部件作用的手术植入的移植物和旁路。

[0149] 术语“闭塞物”或“凝块”一般包括部分或完全阻碍血管内腔的任何物质。闭塞物/凝块减缓或阻碍了流经内腔的流动(例如，血流或任何其它生物流体)。闭塞物/凝块的示例可包括存在于血管以及脂肪或外来物体内的血闭塞物/血凝块和动脉粥样硬化斑块。

[0150] 术语“中风”一般包括部分地由于扰乱对脑部供血而引起的病症。扰乱可由血液的阻塞(例如，缺血性中风)和/或出血(例如，出血性中风)引起。特别是，缺血性中风会由于血管的部分或基本上闭塞/结块而引起。缺血性病症的治疗可应用于在脑部以及诸如心脏的其它组织内存在的血管。由此，本申请中公开的装置和方法不限于用于任何特定器官，而是可应用于需要使内腔扩开或去除闭塞物/凝块以恢复血流的任何人体血管。此外，根据本发明的装置和方法可用于治疗会造成除了局部缺血外的其它病症的静脉闭塞物/凝块。

[0151] 通过导管将该装置引入血管内。“导管”一般包括能插入体腔内的管状结构，由此允许将装置和/或化学物质给送到需要进行治疗的人体区域。术语“微型导管”可指构造成在诸如血管的相对较小的体腔内给送的导管。

[0152] 术语“管件”一般是指可包括用于保持和/或传导被包含的物体的中空空间(例如，圆筒形)的诸如导管的管状物体。管件可由各种材料制成，诸如金属、塑料、玻璃或其任何组合。

[0153] 术语“线材”一般是指拉成柔性细线或细杆的金属或非金属物体。线材的长度和厚度可从纳米级大幅变化到米级。

[0154] 术语“支架”一般是指暂时或永久地放置于例如血管、通道或管道的体腔内以治愈或解除障碍物的管状支承件。支架可由一个或多个线材构成。在一些情况下，支架可以呈支杆的形式，支杆一般是指形成框架的一部分并设计成抗压缩的杆或条。在一些其它情况下，支架可以呈线网或丝网的形式。

[0155] 此外，可以在不影响本发明范围的情况下进行对于本领域技术人员来说显然的许多不同变化和改型，以适当地用于特定治疗病症。因此，不仅在本申请中公开的示例、而且这种显然的变化和改型也应包含在本发明的范围内。

[0156] 本发明的一个方面与用于血管的装置有关，该装置包括可重构元件、支承元件、控制元件、推送管件等。控制元件、可重构元件和支承元件形成可扩张隔室。

[0157] 血管的尺寸可从较小动脉和静脉中的约 0.03 英寸(约 1 毫米)的直径大幅变化到主动脉中的约 1.0 英寸(约 25 毫米)的直径。由此，在一些实施例中，装置的直径可从塌缩

状态下的约 0.01 英寸(约 0.25 毫米)到扩张状态下的 1.0 英寸(约 25 毫米)。

[0158] 在一些实施例中,控制元件可包括线材、编织物或线缆,并构造成控制可扩张隔室的构造。各种材料可用于制造控制元件,控制元件包括金属和非金属材料。用于控制元件的金属材料的一些非限制性示例可包括镍、钛、不锈钢、钴、铬和前述的任何合金,诸如是镍钛诺(NiTi)、不锈钢或钴铬合金。此外,具有控制元件的期望特性的任何聚合物或塑料可用于生产该控制元件。聚合物包括但不限于聚酰亚胺、PEEK (聚醚醚酮)、尼龙、PTFE (聚四氟乙烯)、PET (聚对苯二甲酸乙二醇酯)、聚丙烯等。包括但不限于 PTFE 涂覆的不锈钢或 PTFE 涂覆的 NiTi 的聚合物涂覆的金属也可用作控制元件;控制元件还可由复合材料制成,诸如,NiTi 或不锈钢上的 PTFE 或 FEP (氟化乙烯丙烯)管件等。

[0159] 控制元件的直径可从约 0.001 英寸到约 0.10 英寸。

[0160] 术语"可扩张隔室"一般包括能插入体腔内的结构,以通过打开血管或去除闭塞物/凝块使阻塞的血管再通或者消除局部流动收缩。可重构元件是形成可扩张隔室的一个部件。在一些实施例中,可重构元件可包括由管件或板材构成的支杆(参见图 3 中示例)。在一些其它实施例中,可重构元件可包括能形成为网的多个线材(参见图 4 中示例)。在一些其它实施例中,可重构元件的多个线材可对准在一起并形成管状形状(参见图 11 中示例)。可重构元件可由金属材料制成。用于可重构元件的这种金属材料的一些非限制性示例包括镍钛 (NiTi) 合金、不锈钢、钛及其合金、以及钴铬 (CoCr) 合金等。或者,具有可重构元件的期望特性的任何聚合物或塑料可用作生产该可重构元件的材料。在其它替代示例中,可使用两种或更多种不同材料来构造可重构元件。

[0161] 在一些实施例中,用于可重构元件的支杆的直径可从约 0.0005 英寸变化到 0.1 英寸(12.5μm 到 2500μm)。在一些其它实施例中,用于可重构元件的线材的直径可从约 0.0005 英寸变化到 0.1 英寸(12.5μm 到 2500μm)。可重构元件大致柔性并具有弹性或超弹性特性。因此,可重构元件的构造可重构。可重构元件通常包括至少三种不同的构造,它们被称为"塌缩(即,轴向延伸、折叠或闭合)"构造、"松弛(即,未折叠或打开)"构造以及"扩张(即,径向延伸或径向扩张)"构造。可重构元件的完全塌缩构造一般表示可重构元件的外半径变为最小而其轴向长度最大的状态。当装置位于其引导器套管或微型导管内时,可重构元件处于其塌缩构造。当将可重构元件从微型导管或引导器套管推出时,并且如果没有压缩力,即没有任何约束,可重构元件处于其松弛状态。可重构元件的扩张构造一般表示可重构元件的外半径进一步扩张的状态。可重构元件的构造可通过控制元件或支承元件控制从其塌缩状态或松弛状态到扩张状态。外直径可随可重构元件的构造变化而变化,并且在塌缩构造下可从约 0.01 英寸变化到 0.5 英寸(0.25mm 到 12.5mm)。扩张构造直径的范围从约 0.04 英寸到 1.0 英寸(1.0mm 到 25mm)。可重构元件的轴向长度还可随其构造变化而变化。在某些实施例中,可重构元件的轴向长度可在其变得塌缩时增大。相反,可重构元件的轴向长度可在其变得扩张时缩短。可重构元件的轴向长度的范围可从约 0.1 英寸到 3 英寸(2.5mm 到 75mm)。

[0162] 根据本发明的一些实施例,支承元件包括多个线材或支杆。支承元件的多个线材或支杆可呈大致直线形状或大致非直线形状。在某些实施例中,支承元件呈丝网形式。在其它实施例中,支承元件呈编织物形式。在其它实施例中,支承元件呈通过激光切割由管制成的有孔管状形式。在其它实施例中,支承元件连同可重构元件呈通过激光切割或光蚀刻

工艺制成的有孔板形式。支承元件一般构造成调节可重构元件的构造，由此提供对可重构元件的径向扩张程度的精密控制。装置的这种精密控制机构在许多方面是有益的。在将装置递送并释放到选定的治疗部位之后，看起来似乎自扩张可重构元件的半径和／或径向力可小于对于该应用所期望的半径和／或径向力。在这种情况下，支承元件可向内腔进一步提供径向力／压力。可期望有时增加或减少装置施加于周围组织或闭塞物／凝块的径向力大小。在这种情况下，可动态控制可重构元件的构造，以提供根据本发明的装置的较大范围的径向力。该装置还可在递送、移除和／或操作该装置的同时减少对血管造成不必要的冲击或损伤或将其减到最少。在一些实施例中，当递送该装置时，在装置在血管内释放并可扩张到大于内腔直径时，它会向内腔提供不期望的压力和／或冲击。在这种情况下，可通过在必要时控制元件和支承元件的运动来减小可重构元件的直径和径向力。在其它情况下，当移除装置时，径向力会太大，并且在拉回通过血管时可能会引起损伤。相似地，可通过控制元件和支承元件的运动来减小可重构元件的直径和径向力。

[0163] 本发明的又一方面与用于血管的装置有关，该装置包括微型导管、中心线、管件部件和接合部件／隔室。接合部件／隔室可包括近侧接合元件和远侧接合元件。在一些实施例中，远侧接合元件可与中心线相关联。近侧和远侧接合元件中的一个或两个可以是接合元件。在某些实施例中，远侧和近侧接合元件之间的间距可调。远侧和近侧接合元件之间的间距可在至少一些实施例中约从 0mm 调节到 50mm。在某些实施例中，远侧和近侧接合元件之间的间距可调节为约 0mm, 5mm, 10mm, 15mm, 20mm, 25mm, 30mm, 35mm, 40mm, 45mm 和 50mm 以及它们之间的任何范围。在替代实施例中，远侧和近侧接合元件之间的间距可调节到大于 50 毫米。

[0164] 在一些实施例中，可将装置引入血管。血管的尺寸可从较小的动脉和静脉中的约 0.03 英寸(约 1 毫米)的直径大幅变化到较大动脉中的约 1.0 英寸(约 25 毫米)。由此，在一些实施例中，装置的直径可从约 0.01 英寸(约 0.25 毫米)到 1.0 英寸(约 25 毫米)。同样，当接合隔室打开(或扩张)或闭合(或塌缩)时，在操作过程中单个装置的直径可以改变。

[0165] 在一些实施例中，装置还包括中心线。中心线可穿过管件部件，并自由地运动通过管件部件。在某些实施例中，中心线与接合隔室相关联。更具体地，中心线可与远侧接合元件和近侧接合元件相关联。相关联一般是指两个物体之间的任何类型的连接。相关联包括固定，因此，当两个物体相关联时，一个物体的运动将受到另一物体的阻碍。换言之，一旦两个物体以固定方式相关联，则两个物体的运动将同步。然而，相关联不一定表示一个物体固定到另一个。由此，当两个物体相关联但不在固定状态下时，一个物体相对于另一物体的运动不受到阻碍。因此，在至少一些实施例中，均与中心线相关联的远侧接合元件和近侧接合元件可沿中心线自由运动。

[0166] 根据某些实施例，中心线与远侧接合元件固定或连结。在一些情况下，远侧接合元件的近端可连结到中心线的远端。中心线和远侧接合元件之间的关联(即，连接)可通过诸如焊接、胶粘或夹住之类的各种方式完成。在一些实施例中，中心线和远侧接合元件之间的接头被远侧元件连接件所覆盖。或者，将不提供覆盖物来围绕连接的控制线和远侧接合元件。

[0167] 在一些实施例中，中心线可包括线材、编织物或绳缆或呈线材、编织物或线缆的形式。各种材料可用于制造中心线，这些材料包括金属和非金属材料。用于中心线的金属材

料的一些非限制性示例可包括镍、钛、不锈钢、钴、铬以及前述任何合金，诸如镍钛诺(NiTi)或钴铬合金。此外，具有呈中心线的期望特性的任何聚合物或塑料可用于生产中心线。聚合物包括但不限于是聚酰亚胺、PEEK（聚醚醚酮）、尼龙、PTFE（聚四氟乙烯）、PET（聚对苯二甲酸乙二酯）、聚丙烯等。包括但不限于 PTFE 涂覆的不锈钢或 PTFE 涂覆的 NiTi 的聚合物涂覆的金属也可用作中心线。还可施加亲水涂层。可部分地施加这种涂层，以减小中心线和管件隔室之间的摩擦。中心线也可由复合材料制成，诸如 NiTi 线上的 PTFE 或 FEP(氟化乙烯丙烯)管件或者不锈钢上的 PTFE 或 FEP 管件等。中心线的直径范围可从约 0.001 英寸到 0.25 英寸。在某些实施例中，中心线的直径可以约为 0.001, 0.002, 0.003, 0.004, 0.005, 0.006, 0.007, 0.008, 0.009, 0.011, 0.012, 0.013, 0.014, 0.015, 0.016, 0.017, 0.018, 0.019, 0.020, 0.021, 0.022, 0.023, 0.024 和 0.025 英寸。或者，中心线的直径可大于 0.025 英寸。

[0168] 术语“接合隔室”一般包括这样的结构，即，该结构可压缩成小直径并插入体腔内，并且在释放压缩时扩张到较大直径，以通过打开血管或去除闭塞物的至少一部分来使阻塞的血管再通或者消除局部流动收缩。接合隔室可包括远侧接合元件和近侧接合元件。远侧接合元件和近侧接合元件在至少一些实施例中可以是编织结构。它们还可通过激光切割的海波管或者光蚀刻的板材来制成。会需要热处理使它们处于期望形状，例如锥形或圆柱形形状。

[0169] 在一些实施例中，接合元件可包括由管件或板材制成的支架。在一些其它实施例中，接合元件可包括能形成为网的多个线材。在一些情形下，远侧接合元件的远端可如图 20C 中可见那样是闭合的。或者，远侧接合元件的远端可保持打开，如图 20A 中可见那样。

[0170] 远侧接合元件可由金属材料制成。用于远侧接合元件的这种金属材料的一些非限制性示例包括镍钛(NiTi)合金、不锈钢、钛及其合金以及钴铬(CoCr)合金。或者，可使用具有针对远侧接合元件的期望特性的任何聚合物或塑料。在一些实施例中，远侧接合元件由柔性材料制成。在其它替代示例中，远侧接合元件能使用诸如聚合物涂覆的金属材料的两种或更多种不同材料来制成。

[0171] 在一些实施例中，远侧接合元件的直径可从约 1 毫米变化到其扩张状态下的约 8 毫米。在某些实施例中，处于其扩张状态的远侧接合元件的直径可以约为 1mm, 2mm, 3mm, 4mm, 5mm, 6mm, 7mm 和 8mm 或它们之间任何范围。在一些其它实施例中，远侧接合元件的长度可从约 10mm 变化到 40mm。在某些实施例中，远侧接合元件的长度可约为 10mm, 15mm, 20mm, 25mm, 30mm, 35mm 和 40mm 或者任何它们之间的范围。此外，在替代实施例中，远侧接合元件的长度可大于 40mm。

[0172] 远侧接合元件一般是柔性的，并且具有弹性或超弹性特性。由此，远侧接合元件的形状可变化。远侧接合元件通常包括至少两种不同的构造，这些构造被称为“塌缩(即，折叠或闭合)”构造以及“松弛(即，未折叠或打开)”构造。远侧接合元件的塌缩构造一般表示远侧接合元件的外半径变为最小的状态。当远侧接合元件位于微型导管内时，远侧接合元件处于其塌缩构造。当将远侧接合元件推出微型导管时且如果没有约束远侧接合元件的压缩力，远侧接合元件处于其松弛状态。在一些实施例中，远侧接合元件可包括可自扩张的支架。由此，一旦将支架推出微型导管或者撤回微型导管从而使支架留在微型导管远侧，则支架不受约束，并且它将自行扩张。由于远侧接合元件的柔性特性，可通过向微型导管轻轻拉

动或者推动远侧接合元件而将远侧接合元件容易地放置于微型导管内。

[0173] 根据本发明的一些实施例，近侧接合元件可包括由管件或板材制成的一个或多个线材。在一些其它实施例中，近侧接合元件可包括能如图 20 中所示形成为筐状形状的一个或多个线材。或者，近侧接合元件能制造成许多形状或形式。例如，近侧接合元件的可面向体腔表面的远端可进行修改，以减少对体腔表面的任何损伤。由此，使近侧接合元件的远端基本上平滑，以使得即使与近侧接合元件直接接触，体腔也保持很大程度上不受损。同样，近侧接合元件的远端将例如如图 30 中所示那样弯曲，因而，尖锐的端部将不与体表面直接接触。此外，近侧接合元件的形状或形式可在操作过程中变化。因此，在某些实施例中，近侧接合元件的远端、更具体来说是远侧末端可构造成在操作过程中移除。例如，如图 32-34 中所示，近侧接合元件的远侧末端直接(例如，图 33 和 34)或间接地(例如经由如图 32 中所示的连接线)连接到连接件。借助这些构造，近侧接合元件的远侧末端将通过连接件的运动而移动离开体腔。更具体来说，当远侧元件的近侧连接件连同凝块向近侧运动时，它可向近侧拉动近侧接合元件的远侧末端，并将近侧元件折叠成期望的筐形，其中末端为圆形或非创伤性的。因此，至少在一些实施例中，由于与体腔表面(例如，血管)直接接触而产生的损伤体腔的风险将大幅降低。这些末端特征还在需要时在内腔中向前推动近侧接合元件，并且不损伤体腔表面。

[0174] 在一些实施例中，近侧接合元件构造成大幅改善凝块接合和收回效率。例如，如图 3 中所示那样，当使用根据一些实施例的装置时，闭塞物可设置在近侧和远侧接合元件之间。该设计具有通过用两个独立的接合元件保持闭塞物或凝块来牢固接合闭塞物或凝块的改善的能力。

[0175] 近侧接合元件可由金属材料制成。用于近侧接合元件的这种金属材料的一些非限制性示例包括镍钛(NiTi)合金、不锈钢、钛及其合金以及钴铬(CoCr)合金。或者，可使用具有针对近侧接合元件的期望特性的任何聚合物或塑料。在一些实施例中，近侧接合元件由柔性材料制成。在其它替代示例中，近侧接合元件能使用两种或更多种不同材料来制成，如图 34 中所示。

[0176] 在一些实施例中，近侧接合元件的直径可从约 1 毫米变化到其扩张状态下的约 8 毫米。在某些实施例中，处于其扩张状态的近侧接合元件的直径可以约为 1mm, 2mm, 3mm, 4mm, 5mm, 6mm, 7mm 和 8mm 或任何它们之间的范围。在一些其它实施例中，近侧接合元件的长度可从约 2mm 变化到 40mm。在某些实施例中，近侧接合元件的长度可约为 2mm, 5mm, 7mm, 10mm, 12mm, 15mm, 17mm, 20mm, 22mm, 25mm, 27mm, 30mm, 32mm35mm, 37mm, 40mm 或任何它们之间的范围。此外，在替代实施例中，近侧接合元件的长度可大于 40mm。

[0177] 近侧接合元件一般是柔性的，并且具有弹性或超弹性特性。由此，近侧接合元件的形状可变化。近侧接合元件通常包括至少两种不同的构造，这些构造被称为“塌缩(即，折叠或闭合)”构造以及“松弛(即，未折叠或打开)”构造。近侧接合元件的塌缩构造一般表示近侧接合元件的外半径变为最小的状态。当近侧接合元件位于微型导管内时，近侧接合元件处于其塌缩构造。

[0178] 当近侧接合元件不在微型导管内并且不受约束时，近侧接合元件处于其松弛构造。

[0179] 在一些实施例中，近侧接合元件由弹性或超弹性材料制成，并由此自扩张。由于其

柔性特性，可通过向微型导管轻轻拉动会推动近侧接合元件而将近侧接合元件容易地放置于微型导管内。在其它替代实施例中，近侧接合元件可具有多于两种的不同状态。例如，如图 32-34 中所示那样，近侧接合元可构造成在操作过程中改变其形状，并且由此将呈完全塌缩和完全松弛状态之间的许多不同状态。

[0180] 在一些实施例中，可将一种或多种标记加到装置。这种标记可包括不透辐射材料，这些材料有助于监测装置在体内的位置和 / 或运动。不透辐射标记的一些非限制性示例可包括金、金合金、CoCr 合金、铂或铂合金。标记也可呈不透辐射涂层的形式。标记可加到装置中的任何位置。在一些实施例中，可将一种或多种标记加到远侧接合元件处，因此，将确定远侧接合元件在体内的位置。在一些其它实施例中，可将一种或多种标记加到近侧接合元件处，因而将确定近侧接合元件在体内的位置。在又一些其它实施例中，远侧和近侧接合元件均包含标记。远侧和近侧接合元件中的每个内的标记可以是相同或不同材料。或者，可将一种或多种标记加到中心线和 / 或管件隔室。在一些实施例中，标记可以约为 0.10 到 4mm 长，而直径约为 0.001 到 0.030 英寸。然而，任何尺度（例如，长度、直径、尺寸和质量）和标记的形状方面的任何变型是合适的。

[0181] 在一些实施例中，装置可包括管件隔室。管件隔室可包括多个管件元件。这种管件元件可包括推送管件和连接管件。推送管件还可在至少一些实施例中包括内推送管件、中间推送管件、外推送管件。同样在替代实施例中，推送管件可包括远侧推送管件和近侧推送管件。各种材料可用于制造管件元件，它们包括金属和非金属材料。在一些实施例中，远侧推送管件和 / 或外推送管件可由诸如 PTFE 或 PET 的光滑和柔性聚合物制成。中间和近侧推送管件可由镍钛诺超弹性材料、不锈钢、CoCr 合金、钛合金或聚合物（诸如，聚酰亚胺、PEEL 等）制成。管件元件中的一个或多个也可涂覆有诸如 PTFE 涂层、亲水涂层等的润滑材料。管件元件也可由复合材料制成，诸如镍钛诺线材上的 PTFE 或 FEP（氟化乙烯丙烯）管件或者不锈钢上的 PTFE 或 FEP 管件等。

[0182] 中心线可呈线材、编织物或管件的形式。用于中心线的金属材料的一些非限制性示例可包括镍、钛、不锈钢、钴、铬以及前述任何合金，诸如镍钛诺（NiTi）或钴铬合金。此外，具有呈中心线的期望特性的任何聚合物或塑料可用于生产中心线。聚合物包括但不限于是聚酰亚胺、PEEK（聚醚醚酮）、尼龙、PTFE（聚四氟乙烯）、PET（聚对苯二甲酸乙二酯）、聚丙烯等。包括但不限于 PTFE 涂覆的不锈钢或 PTFE 涂覆的 NiTi 的聚合物涂覆的金属也可用作中心线。还可施加亲水涂层。

[0183] 在一些实施例中，推送管件和连接管件的直径可约为 0.001 到 0.050 英寸。在其它实施例中，推送管件和连接管件的直径可小于 0.001 英寸或者超过 0.050 英寸。在又一些其他实施例中，装置可包括推送管件，而没有连接管件。

[0184] 为了说明的目的，在以下附图中提供根据本发明的装置的一些非限制性和说明性示例。尽管为了说明的目的文中仅描述了少数示例性应用，但也可进行对于本领域普通技术人员来说显然的许多不同改型和修改，而不影响本发明的范围。因此，不仅在本申请中公开的示例、而且明显的改型和修改也应包含在本发明的范围内。

[0185] 参见图 1，示出包括可重构元件（410）、支承元件（420）、控制元件（10）和推送管件（20）的装置。可扩张隔室（40）可存在于引导器套管（26）内。

[0186] 在临床手术过程中，可将该装置经由引导器套管（26）推入微型导管（30）内，并且

进一步推到损伤部位，如图 2 中所示。可重构元件（410）可连接到推送管件（20），在此情况下是中空薄管。支承元件可与控制元件相关联。控制元件（10）的至少一部分可由推送管件（20）围绕，并且控制元件（10）可自由地滑动通过推送管件（20）。由此，控制元件（10）和推送管件（20）的运动可不受彼此的限制，并且分别可沿装置的轴向轴线自由滑动，如图 3B 和 4B 中所示。可借助引导线将微型导管放置于闭塞物 / 凝块位置处。推送管件可用于将装置推入微型导管。然后，在治疗过程中可将该装置的可扩张隔室推出微型导管。可通过向近侧或远侧拉动或推动控制元件来调节可重构元件的径向力和直径。

[0187] 图 2 示出从血管去除闭塞物 / 凝块所需步骤。由此，内腔表面（50）可代表血管壁。在一些实施例中，可将该装置递送到存在有闭塞物 / 凝块（60）的内腔区域（50）。在递送过程中，借助引导线（5），微型导管的远侧末端可行进到阻塞部位，并穿过闭塞物 / 凝块（60），如图 2A 中所示。血管造影导引可用于确定微型导管相对于血管和闭塞物 / 凝块的位置。

[0188] 在移除引导线（5）之后，可将收回装置引入微型导管（30）内。可将可扩张隔室（40）推过微型导管（30）直到可扩张隔室（40）的远端到达微型导管的远端为止（图 2B）。如图 2C 中所示，当推送管件（20）保持稳定时，可通过向近侧拉动微型导管（30）来略撤回微型导管（30）。可扩张隔室（40）暴露于闭塞物 / 凝块（60），并部分地打开，如图 2D 中所示。操作者可调节可重构元件（410）的构造，即可重构元件的径向力、直径和轴向长度，以允许可重构元件（410）使闭塞物 / 凝块（60）裂开或与闭塞物 / 凝块（60）接合、破坏闭塞物 / 凝块（60）的至少一部分和 / 或使血管内腔扩张。可重构元件构造的这种调节可至少通过向远侧或近侧拉动或推动控制元件（10）来实现，如图 2E 中所示。在闭塞物 / 凝块（60）与可扩张隔室（40）接合之后，可从血管收回装置连同微型导管（30），如图 2F 中所示。

[0189] 或者，可先将微型导管放置到超出闭塞物 / 凝块，可扩张部件可在闭塞物 / 凝块远侧打开。在操纵并调节可重构元件的直径和径向力之后，可向近侧拉动该装置，而闭塞物 / 凝块可被可扩张隔室捕获并被拉出血管。

[0190] 尽管图 2 的实施例示出从内腔的阻塞部位基本上去除闭塞物 / 凝块，但可使用诸如破坏闭塞物 / 凝块的至少一部分的替代治疗。闭塞物 / 凝块经常是基本上软的，并且能以相对微小的冲击来使其断开。在这种情况下，可重构元件可将闭塞物 / 凝块部分地分裂成更小的部分。用装置收集并从主体去除各片阻塞材料。如果在可重构元件在血管内径向扩张时可重构元件的线材或支杆切过闭塞物 / 凝块（例如，血凝块），则当它扩张到血管的全直径时，闭塞物 / 凝块的各部分变得包含到可扩张隔室内或与可扩张隔室接合。通过将可重构元件部分地拉到微型导管末端内来使可重构元件略塌缩，可重构元件各单元的线材 / 支杆之间的开口将变得更小。这会将闭塞物 / 凝块保持在可扩张隔室内。支承元件还可有助于将闭塞物 / 凝块保持在可扩张隔室内。然后，可从血管拉出包含闭塞物 / 凝块的各部分的整个装置。在其它替代实施例中，该装置可使内腔扩开 / 扩张成在内腔的阻塞部位处重新形成流动。闭塞物 / 凝块也可以不用软到足以允许装置与闭塞物 / 凝块基本上接合。在这种情况下，可重构元件的构造可控制成与闭塞物 / 凝块的至少一部分接合，并使其运动。当可重构元件的直径进一步打开时，它的线材或支杆将推抵于闭塞物 / 凝块。当向近侧拉动时，可重构元件和闭塞物 / 凝块之间的摩擦会引起闭塞物 / 凝块从血管壁脱开并被去除。

[0191] 图 3 和 4 示出根据本发明的一些实施例的装置。该装置包括推送管件（20），该推送管件（20）与可重构元件（410）的近端连接件（460）连接。推送管件以及控制元件基本上

是长的。在一些实施例中，推送管件以及控制元件可长到足以使操作者经由推送管件以及控制元件从体外控制收回装置。在一些实施例中，推送管件以及控制元件可延伸约 100cm, 110cm, 120cm, 130cm, 140cm, 150cm, 160cm, 170cm, 175cm, 180cm, 185cm, 190cm 或 200cm。如果必要，这些线材可延伸超过 200 厘米。

[0192] 可重构元件（410）可包括至少两个端部，即远端和近端。可重构元件（410）的远端一般是指在近端之前进入人体的端部。可重构元件（410）的近端一般是指使可重构元件（410）与推送管件（20）相关联的端部。

[0193] 在一些实施例中，可重构元件（410）的远端闭合，这意味着可重构元件的线材或支杆（410）的远端借助例如熔化焊接、焊料焊接或胶粘、在使用或不使用连接件（430 或 450）的情况下保持在一起。在一些实施例中，控制元件（10）的远端和支承元件（420）的远端可借助例如熔化焊接、焊料焊接或胶粘等、在使用或不使用连接件（451）的情况下保持在一起。或者，远端连接件（451）可用于联接控制元件（10）的远端和支承元件（420）的远端。在可重构元件（410）的近端处有外侧近端连接件（461）和内侧近端连接件（462），这两个近端连接件都是如图 3B-8B 中所示的管状结构。可重构元件（410）的近侧线材或支杆端部可置于外侧近端连接件（461）和内侧近端连接件（462）之间，并且通过上述手段固定在位。控制元件（10）可通过内侧近端连接件（462）的内腔，以使它能在内侧近端连接件（462）内自由滑动。

[0194] 该装置还包括支承元件（420），该支承元件（420）可与可重构元件的线材 / 支杆（410）以及控制元件（10）相关联。支承元件（420）可经由连接件（430 和 / 或 451）与控制元件（10）相关联，例如如图 7 中所示。在一些实施例中，支承元件（420）以基本上固定不动的方式与控制元件（10）的远端相关联。由此，当向近侧拉动控制元件（10）时，可向近侧拉动支承元件（420）的远端。支承元件（420）可如图 3 和 4 中所示附连到可重构元件（410）。在该实施例中，附连到可重构元件（410）的支承元件端部可向外运动，从而使可重构元件（410）扩大（如图 3C 和 4C 中所示）。这将增大可重构元件的径向力。在其它实施例中，支承元件（420）由与如图 3 和 14 中所示的可重构元件（410）相同的材料制成。由此，无须连结这两个部件。在此实施例中，向近侧拉动控制元件（10）将使支承元件（420）与控制元件（10）之间的角度 α （图 3C）扩大，从而使可重构元件（410）变大（如图 3D 中所示）。这将增大可重构元件的径向力。

[0195] 如图 3B 和 4B 中所示，控制元件（10）可存在于近侧内连接件（462）的内腔内，并自由地滑动通过连接件（460）。在一些实施例中，可将标记（440）加到装置，例如，支承元件（420）在标记处与线材 / 支杆（410）相关联。这种标记可包括不透辐射材料，该材料有助于看到 / 监测装置在人体内的位置和 / 或运动。不透辐射标记的一些非限制性示例可包括金和 / 或铂。如果期望，可在支承元件（420）和可重构元件（410）的线材 / 支杆、控制元件或支承元件（420）的任何部分之间的一些附连点处加入标记。例如，可将标记施加于可重构元件的大约远端和 / 或近端处，或者涂覆到线材和 / 或连接件的任何部分上。还可通过使用 CoCr 合金作为可重构元件、控制元件和 / 或支承元件来实现装置的不透辐射特性。

[0196] 能以多种形式来构造支承元件。图 3、13 和 14 中所示的具体示例是内在结构，即，支承元件和可重构元件由管件或平板的一件材料制成。由此，不需要它们之间的附加连结 / 粘合。

[0197] 图 4 包括呈大致线性线材形式的多个支承元件。用于制造支承元件的材料是金属或非金属材料。用于支承元件的一些非限制性材料包括但不限于是镍、钛、NiTi、不锈钢、钴铬和前述任何合金。通过控制元件和支承元件的运动可控制可重构元件的构造。在使微型导管穿过闭塞物 / 凝块之后，可将该装置递送到微型导管内。当该装置从微型导管脱开时(参见例如图 2)，它可露出并与闭塞物 / 凝块接合。

[0198] 在一些实施例中，可重构元件一旦离开微型导管，则可以自扩张，并且可通过向远侧或近侧拉动或推动控制元件还可进一步改变可重构元件的构造。通过控制元件和支承元件可进一步控制可重构元件的径向力。如果自扩张隔室构造成扩张到大于血管直径，该自扩张过程会向壁施加过大的力。这会造成对血管伤害，从而造成撕裂或穿孔。由此，有益的是能以精密的方式控制可重构元件的构造(包括可重构元件的径向力、尺寸和形状)以实现安全和有效的治疗。此外，在可重构元件实现其标称自扩张直径之后，可重构元件需要进一步扩张，或可重构元件的径向力需要进一步增大。例如，会需要加强可重构元件的径向力以与闭塞物 / 凝块基本上接合、切过闭塞物 / 凝块和 / 或移动闭塞物 / 凝块。因此，所期待的是，需要在治疗过程中动态改变可重构元件的构造。根据本发明的至少一些实施例的装置设计成提供可重构元件的这种动态控制。

[0199] 或者，可重构元件可以不是自扩张的，并由此需要控制可重构元件的完全打开和闭合。在这种情况下，当可扩张隔室从微型导管脱开以治疗内腔中的病症时，可以向近侧略拉动控制元件，以使可重构元件可轴向扩张。类似于自扩张的可重构元件，该非自扩张的可重构元件的进一步扩张或塌缩将通过附连到支承元件的控制元件的运动来控制。

[0200] 在一些实施例中，装置包括至少两个机构来控制可重构元件的构造。首先，由支承元件提供控制。支承元件一般由控制元件控制。在控制元件进行远侧运动时，支承元件也变得沿轴向轴线延伸。当控制元件向近侧缩回时，支承元件将径向扩张，这将向可重构元件提供进一步支承压力。当控制元件更向近侧运动时，支承元件将变得更扩张，由此控制元件和支承元件之间的角度(图 3 和 4 中的 α)将增大。角度 α 的范围可以在约 0 度到 90 度之间。此外，将通过控制元件的运动来控制可重构元件的构造(例如，可重构元件的总体形状、轴向长度和外直径)。控制元件的向远侧运动将使可重构元件转换到其塌缩状态，即，可重构元件轴向延伸且其外直径缩小，同时轴向长度增加。控制元件的向近侧运动将使可重构元件的构造向其扩张状态转换，即，可重构元件变得径向扩张。由此，可重构元件的轴向长度可缩小，而外直径增加。可重构元件向其扩张状态的这种转换将加强可重构元件的径向力。

[0201] 连接件可以是诸如不锈钢(SS)、铂、金、镍钛诺管件的金属海波管件，诸如聚酰亚胺管件的塑料管件，或者可以是由不锈钢、铂合金、金或 CoCr 合金线材等构成的一段线圈。当使用诸如金、铂等的透辐射材料时，连接件也可用作标记。

[0202] 在一些实施例中，将在血管内控制可重构元件的构造，以从内腔去除闭塞物 / 凝块和 / 或使内腔扩张。一旦闭塞物 / 凝块与可重构元件接合，则该装置从内腔撤回并最终从人体撤出。当从内腔撤回装置时，与闭塞物 / 凝块接合的可扩张隔室可部分地撤回到微型导管内或留在微型导管远侧。具有闭塞物 / 凝块的可扩张隔室和微型导管可同时拉回到具有较大内直径的引导导管内。可使用荧光检查法来确定微型导管、引导导管和可扩张隔室之间的相对位置。

[0203] 图 5 和 6 中提供该装置的替代实施例。在该特定实施例中，支承元件（420）包括如图 5 中所示的多个线材或如图 6 中所示的编织结构。支承元件（420）从可重构元件或线材 / 支杆（410）的近端延伸，并止于可重构元件（410）的远端（在图 5-7 中标记为“*”）之前，由此形成双层可扩张隔室。支承元件（420）的远端可与控制元件（10）的远侧末端固定。

[0204] 如图 5B 和 6B 中所示，可通过近侧连接件（460）来使可重构元件（410）与支承元件（420）相关联。近侧连接件可包括至少两个隔室，即，外近侧连接件（461）和内近侧连接件（462）。可重构元件线材的近端和支承元件的近端用粘合剂、熔化焊接、焊料焊接来固定（463），或通过近侧外部连接件和内部连接件之间的机械连接来固定。在一些其它实施例中，这些内近侧连接件和外近侧连接件可以是管状或线圈结构，并且控制元件可自由地滑动通过内部连接件。

[0205] 在上述装置中，当控制元件（10）向近侧撤回时，它会引起支承元件（420）扩张，从而向可重构元件线材 / 支杆提供支承，这导致可重构元件（410）的直径的扩大和径向力的扩大。

[0206] 图 7 中提供该装置的又一替代实施例。在该特定示例中，支承元件（420）构造成包括两个高峰（plateau）位置（480），在这两个位置，支承元件（420）可向可重构元件线材 / 支杆（410）提供最大的支承强度。支承元件（420）可形成为如图 7 中可见的正弦形状。支承元件的远端固定到控制元件（10）。可重构元件和支承元件的近端都如图 7B 中所示固定到近侧连接件。如图 7C 中所示，支承元件的中间（薄）部段经由中间外部和内部管件连接件连接，而控制元件在近侧和中间连接件（430）内自由运动。

[0207] 在支承元件内具有两个或更多个高峰的一个优点是能在较佳位置选择性地加强径向力。如图 7 中容易可见，可重构元件（410）在两个高峰位置（480）处从支承元件（420）获得最大的支承强度，并且当它远离高峰时支承强度将减小。由此，如果期望，装置可向内腔区域提供较大范围的径向力。此外，支承元件的数目也可从两个变化到更多个，这些支承元件可周向分布在控制元件（10）周围，以使装置的径向力和 / 或外部形状和密度变化。

[0208] 图 8 中提供该装置的又一替代实施例。在该特定示例中，控制元件（10）延伸通过支承元件（420）的远端，并到达可重构元件（410）的远端。如图 8C 中可见，支承元件的远端可沿控制元件自由地滑动。支承元件（420）可在支承元件（420）的远端处例如经由连接件（451）与控制元件（10）相关联。连接件 450 由支承性远侧内部连接件（453）和支承性远侧外部连接件（452）构成，从而在它们之间连结支承元件的远端。控制元件（10）可在内部连接件的内腔中滑动。当向近侧拉动控制元件（10）时，可重构元件的连接件（450）和支承元件的远端（451）之间的距离变短。当两个连接件彼此接触时，支承元件将扩张，从而压抵于可重构元件，并且产生附加的径向力，如图 8D 中可见那样。图 8 的该特定实施例的一个益处是支承元件的远端（451）和可重构元件的远端（450）轴向对准，从而在向近侧拉动控制元件时避免支承元件末端倾斜。当该装置缩回到微型导管内时，还可避免对可重构元件（410）和支承元件（420）之间的线材轴向长度的限制。

[0209] 图 9 中提供该装置的又一替代实施例。在该特定示例中，支承元件（420）包括至少两个高峰位置（480）。此外，支承元件（420）的远端可以不是在装置的远端附近基本上固定不动的。因此，支承元件（420）可在支承元件的远端处例如经由连接件（430）与控制元件（10）相关联。这些连接件（430）可构造成沿控制元件自由滑动。连接件（430）的结构还由

内部连接件和外部连接件构成，以确保控制元件能自由地运动通过连接件。由此，当向近侧拉动控制元件时，可重构元件的远端连接件（450）可运动到更靠近于支承元件的远端。当两个连接件彼此接触时，支承元件将扩张，并且将推抵于可重构元件（410），从而如图 9E 中可见那样产生附加的径向力。

[0210] 图 9 的该特定装置可提供至少三个益处。支承元件包括多于一个高峰位置，高峰位置可允许在较佳位置处选择性地加强径向力。由此，如果期望，装置可向内腔区域提供较大范围的径向力。此外，类似于图 8 的装置，支承元件的远端和支承元件的远端通过控制元件轴向对准，从而在向近侧拉动控制元件时避免末端倾斜。当装置缩回到微型导管内时，还可避免对可重构元件（410）和支承元件（420）之间的线材轴向长度的约束。

[0211] 根据本发明的一些实施例，可将调节管用于所有所述设计中的装置。如图 10 中可见，调节管（470）可在支承元件的近端和远端之间放置于控制元件上。调节管可选择性地沿控制元件自由滑动。当在装置中存在调节管时，调节管可防止连接件（451 或 430）太接近于可扩张隔室的近端。由此，具有调节管（470）的装置可防止可重构元件的过度轴向扩张。当将装置拉回到引导器套管或微型导管内时，管件还可防止或减少控制元件与支承元件的支杆 / 线材之间的摩擦。

[0212] 图 11 中提供该装置的又一替代实施例。在该特定伞形装置中，可重构元件（410）可包括多个线材，并如图中可见那样形成管状结构。也可包括多个线材的支承元件可用于改变可重构元件的构造。支承元件（420）可与控制元件（10）以及可重构元件（410）相关联，且关联位置中的至少一些可联接有标记（440）。支承元件（420）以及可重构元件（410）能以基本上固定不动的方式与控制元件（10）相关联。支承元件（420）的所有线材可经由连接件（430）与控制元件（10）相关联。连接件（430）固定到控制元件。因此，向近侧拉动控制元件（10）或向远侧推动控制元件（10）还可相应地作用于其它线材（即，可重构元件和支承元件）。

[0213] 图 12 中示出前述装置的一些非限制性和说明性改型。在图 12A 和 12B 中所示的装置中，可重构元件（410）包括沿装置的轴向轴线对准的八个大致直线形线材。该装置还包括分布在装置的近端和远端之间的两组支承元件（420）。每组支承元件（420）可包括四个线材以操纵装置的径向力。或者，图 12C 的装置包括可重构元件（410）和支承元件（420），可重构元件（410）包括轴向对准的六个大致直线形线材，而支承元件（420）包括在同一组内的三个线材。此外，诸如使用一组或两组支承元件以及使用多于二组支承元件的任何进一步和其它改型可应用于该装置。此外，如果期望，可重构元件和支承元件可呈类似于图 7 中可见的丝网（编织物）的形式。

[0214] 在图 13 中示出根据本发明的另一实施例。在该特定示例中，可重构元件单元的尺寸和支杆的尺寸或线材的直径可在单个装置内变化。从可重构元件的近端到远端，该单元可从大尺寸变为小尺寸，或者反之，且支杆尺寸可从厚支杆变成薄支杆，或反之。在该图中所示的装置中，可重构元件（410）在区域 A 中比在区域 B 中具有一般更大的单元，或者反之。此外，支杆尺寸或线材直径可在区域 A 中比区域 B 更厚，或者反之。这些实施例的优点可包括如下中的至少一个或多个：

[0215] 1）较大近侧单元尺寸可具有较小的线材密度，这在增加径向力时会增加每个支杆施加的力和压力。这会使可重构元件（线材或支杆）能更容易地切过闭塞物 / 凝块或使其裂

开。闭塞物/凝块也可由于较宽的开口更容易地落入可扩张隔室内。小尺寸的远侧单元用于捕获和保持从可扩张隔室的近端裂开的闭塞物/凝块碎屑，因此碎屑将不会从装置逸出而行进到下游。

[0216] 2) 可重构元件的支杆尺寸也可从近端变化到远端，其中，近端处的支杆较宽/厚，而远端处支杆较薄。大又牢固的近端支杆将具有较大刚度，并可更容易地切割闭塞物/凝块。由于远端处加大数目的单元，远端处的支杆尺寸需要薄，以使装置能在其压缩状态下保持较小轮廓，从而能装入微型导管内。

[0217] 由此，应用中所示的示例不应认为限制本发明的范围，而是可以在不影响本发明范围的情况下进行对于本领域技术人员来说显然的许多不同修改和改型。因此，不仅在本申请中公开的示例、而且明显的修改和变型也应包含在本发明的范围内。

[0218] 可通过本领域中已知的多种技术来制造根据本发明的一些实施例的装置。例如，可重构元件和支承元件可由某件材料通过激光切割海波管制成。通过激光器切割之后的海波管可热固成可重构元件和支承元件的期望的形状和尺寸，这些可重构元件和支承元件能如图 13 中所示进一步组装到装置内。

[0219] 或者，可重构元件/支杆和支承元件/支杆可由相同薄型板通过激光切割或光蚀刻制成，如图 14A 中可见。该部件可热固成可重构部件和支承部件的期望形状和尺寸。这些部件可进一步组装到装置内。可重构元件的各侧可使用粘合剂、熔化焊接、焊料焊接和机械连结等方式来连结以形成各侧闭合的可扩张隔室(参见图 14B)或者简单地敞开作为各侧敞开的可扩张隔室(图 14C)。

[0220] 可重构元件的远端可以是闭合端部(线材或支杆端部连结，图 14B 和 14C 中所示)或者可以是开口端部(即，线材或支杆端部未连结，如图 14D 中所示)。

[0221] 海波管和金属板可由选自以下的一种或多种制成：镍钛(NiTi)合金、不锈钢、钛(及其合金)和钴铬(CoCr)合金等。

[0222] 加工海波管或薄板的上述技术的许多实施例的一个优点是可避免多个线材(例如，可重构元件和支承元件之间)的相关联(或连结)，因此，装置轮廓(尺寸)可较小。这些实施例与编织线材结构相比有利，因为可重构元件的支杆均连接到每个单元或窗的角部处。在不增加装置的轮廓的情况下，可通过单元形状和结构设计来控制径向力。

[0223] 本发明的一些实施例涉及设计成将可扩张隔室放置于对象的血管结构内的装置。对象可以是需要治疗、诸如去除血液堵塞物/血凝块和/或恢复体内的血流的患者。在图 15 和 18 中示出装置的示例性非限制性实施例。根据一些方面，在推送管件(20)和可扩张隔室(40)之间有线圈部段(540)。该线圈部段可被认为是推送管件的一部分。线圈(540)的功能可使装置的远侧部段柔性，因此，装置可通过曲折的血管。为了进一步改善装置的可推送性，可将诸如 PTFE、PET 等的塑料管件加到线圈周围，或者在推送管件的远端处简单地替换线圈作为柔性推送部件。如果使用线圈，一个或多于两个的薄线材(520)可用于连接推送管件(20)和可扩张隔室(40)的连接件，以防止线圈(540)伸展。根据另一些方面，推送管件(20)可连接到线圈(540)。此外，控制元件(10)可在推送管件(20)的内腔以及可重构元件的近侧连接件(460)和线圈或柔性管部段内自由滑动。根据又一些其它方面，在装置的近端处，控制元件手柄管件(490)可加到并固定到控制元件(10)的近端。借助该特征，操作者可容易地抓取控制元件手柄管件(490)，以控制可重构元件的打开或闭合。部件之间的

所有连接可通过胶粘(粘合剂)、熔化焊接、焊料焊接等连结。参见图 15,柔性线圈(495)可加到可扩张隔室的远端,以使装置末端为非创伤性,从而避免戳到管腔。

[0224] 在图 16 和图 17 中示出其它替代实施例。在这些实施例中,该装置可包括两个结构,即远侧可扩张结构(550)和近侧可扩张结构(560)。对于图 16 中所示的装置,两个可扩张结构之间的距离可改变 / 调节,即,例如通过推动或拉动控制元件(10),远侧结构可向近侧结构拉动 / 滑动或者远离近侧结构推动 / 滑动。

[0225] 参照图 16,远侧结构(550)呈包括可重构元件(410)、支承元件(420)和控制元件在内的筐状物或可扩张隔室的形式。控制元件(10)的远侧末端可连接到支承元件(420),并可在滑动管(471)和推送管件(20)内自由移动。通过经由控制元件来调节支承元件,可调节远侧结构的半径和径向力。如本申请中其它地方所示,支承元件的调节可通过推动或拉动中心元件来实现。在一些其它实施例中,滑动管(471)的近端可固定到推送管件的远端。远侧结构(550)的远端可通过连接件(460)固定到滑动管的中间点。近侧结构可以是伞形部件(560)。近侧结构的近端可与包括外部连接件和内部连接件在内的连接件(455)相关联。连接件的内直径一般大于滑动管的外直径,以使滑动管能在连接件内自由地滑动。在闭塞物 / 凝块收回过程中,当使微型导管脱开时,近侧结构由于摩擦而由微型导管的末端保持。近侧结构可与远侧结构分开。当拉动推送管件时,远侧结构向近侧结构运动。可接合 / 抓取两个结构之间的闭塞物 / 凝块(图 19 中将进一步示出装置如何捕获闭塞物 / 凝块的详细机构)。如果向近侧拉动控制元件,则远侧结构可进一步扩张。滑动管(在连接件 460 和滑动管的末端之间)的段具有与图 10 中的调节管(470)相同的功能,即,阻止远侧结构如之前部分中所述那样过度扩张。标记(440)也可如需要地加到远侧和近侧结构的远侧末端。

[0226] 参见图 17A,近侧结构(560)是可扩张隔室,它由可重构元件(410)、支承元件(420)和控制元件(10)构成。该结构的近端可连结到外管(460)和内管(475)之间。控制元件(10)的远侧末端能连接到支承元件(450),并在近侧结构的远端处在内管(475)内以及在推送管件(20)内自由运动。通过经由控制元件来调节支承元件,可调节近侧结构的构造和径向力。远侧结构(550)呈包括可重构元件(410)和封闭元件(425)在内的筐状物或自扩张隔室的形式。在远侧结构的中间,封闭元件的末端可通过连接件(451)来连结,以形成闭合的隔室 / 结构。封闭元件的结构可以与前述支承元件的一样,但其功能仅仅是使隔室闭合。由于封闭元件的末端不连接到控制元件,所以不能调节结构(550)的构造和径向力。或者,也可在没有封闭元件的情况下形成远侧结构。远端可通过如图 17B 中所示使可重构元件(410)的远侧线材 / 支杆连结来闭合(451)。远侧结构(550)的近端可固定到控制元件的远侧末端。在收回过程中,远侧结构可捕获不能由近侧结构保持 / 包含的闭塞物 / 凝块碎屑。两个结构之间的空间还可用作在收回过程中包含闭塞物 / 凝块或闭塞物 / 凝块碎屑的室。

[0227] 从推送管件末端 / 近侧连接件延伸到近侧结构(560)的中间部分内的内管件(475)具有与图 10 中的调节管 470 相同的功能,即,如之前部分中所述那样防止远侧可扩张结构的过度扩张。

[0228] 在包括两个隔室的实施例中,可如申请中其它地方公开那样通过激光切割、光蚀刻或线材编织形成远侧部件和近侧部件。其它地方所述的各种材料可用于形成可重构元

件。在这种实施例中，近侧结构的强度 / 刚度或线材 / 支杆尺寸可与远侧结构不同。此外，远侧结构的尺寸（当它完全扩张时）可与近侧结构不同。

[0229] 在图 18 中示出使用图 16 中所示设计作为示例的构造成应用包括两个可扩张结构的实施例的装置。在此特定实施例中，在装置中采用远侧结构（550）和近侧结构（560）。在图 19 中示出使用根据图 18 的装置来收回闭塞物 / 凝块。图 19 中所示的机构仅仅示出各种应用，并表示为某些实施例的说明。如申请中其它地方所述，根据本申请的装置可用于收回或去除例如血管内的闭塞物 / 凝块。此外，装置可用于使内腔区域扩张和 / 或恢复血流，这可以需要或不需要收回闭塞物 / 凝块。

[0230] 在闭塞物 / 凝块（60）如图 19A 可见定位在血管（50）内的假设条件下，包括收回装置的微型导管（30）可行进和定位在闭塞物 / 凝块近侧或远侧附近。然后，使微型导管（30）脱开，以使收回装置暴露于闭塞物 / 凝块。在图 19 中所示的一些实施例中，闭塞物 / 凝块可通过如下机构接合和收回：

[0231] 闭塞物 / 凝块（60）可保持在近侧结构（560）与微型导管（30）的末端之间，并从原位置被去除（图 19B）。

[0232] 闭塞物 / 凝块（60）可保持在近侧结构（560）与远侧结构（550）之间，并从原位置被去除（图 19C）。

[0233] 闭塞物 / 凝块（60）可由近侧结构（560）保持 / 接合，并从原位置被去除（图 19D）。在一些情况下，闭塞物 / 凝块可接合到近侧结构和动脉壁之间，并借助闭塞物 / 凝块与装置之间的摩擦去除。

[0234] 闭塞物 / 凝块（60）可由远侧结构（550）保持 / 接合，并从原位置被去除（图 19E）。在一些情况下，闭塞物 / 凝块可接合到远侧结构和动脉壁之间，并借助摩擦去除。

[0235] 闭塞物 / 凝块（60）可由于近侧结构而裂开成碎屑。碎屑会落入远侧结构（550）或被远侧结构（550）捕获和 / 或留在近侧结构（560）和远侧结构（550）之间（图 19F），并从原位置被去除。

[0236] 闭塞物 / 凝块（60）可接合在各种位置 / 位点，并通过任何上述机构（图 19G）的组合去除，并且从原位置被去除。

[0237] 根据一些实施例，在闭塞物 / 凝块接合和 / 或收回过程中，能在任何时间拉回控制元件（10），以操纵收回装置的径向力和半径（即，尺寸），以确保闭塞物 / 凝块与装置接合，并且不滑离装置（图 19H）。

[0238] 图 20 示出根据本发明的一方面的装置。该装置可包括管件部件和接合隔室。管件部件可包括诸如推送管件（20）和连接管件（31）的多个管件元件。接合隔室可包括远侧接合元件（90）和近侧接合元件（65）。该装置还可包括中心线（10）。

[0239] 如图 20 中可见，在某些实施例中，远侧接合元件（90）和近侧接合元件 65 与中心线（10）相关联。在某些实施例中，远侧接合元件 90 可连接到（或固定到）中心线（10），且近侧接合元件（65）可连接到连接管件（31），该连接管件还可连接到推送管件（20）。中心线（10）可放置于连接管件 31 和推送管件（20）内，并自由运动通过连接管件以及推送管件。在一些实施例中，中心线（10）和推送管件（20）可延伸到装置的近端。

[0240] 在一些实施例中，可独立操纵中心线（10）和连接管件（31），由此允许单独控制远侧接合元件和近侧接合元件。更具体来说，远侧接合元件将通过连接到远侧接合元件的中

心线的运动来控制；而近侧接合元件将通过与近侧接合元件连接的连接管件或推送管件的运动来控制。在诸如图 20 中可见那样的某些实施例中，推送管件和连接管件彼此连接，由此，推送管件的运动可最终控制近侧接合元件。

[0241] 在某些实施例中，远侧接合元件可在其远端处具有开口端部（例如，参见图 20A）。或者，在某些其它实施例中，远侧元件可在其远端处具有闭合端部（例如，参见图 20C）。远侧接合元件（90）可连接到中心线（10）。远侧接合元件可通过例如焊接、胶粘或夹紧的各种手段在其大约近端处连接到中心线。

[0242] 在某些实施例中，中心线（10）和远侧接合元件（90）之间的连接置于远侧元件连接件（80）内。远侧元件连接件可呈较短管或线圈的形式，并放置于中心线（10）上。在一些实施例中，远侧元件连接件可包括外部远侧元件连接件（82）和 / 或远侧元件连结介质（81）。在这种实施例中，远侧接合元件的近端可放置于外部连接件和中心线之间。在一些情况下，远侧接合元件、连接件和中心线可通过诸如夹子、扣钩或紧固件之类的连结介质来连接，这些连结介质将远侧接合元件和中心线紧固或保持在一起。

[0243] 根据一些实施例，近侧接合元件可包括多个线材。或者，近侧接合元件可由管件例如通过激光切割技术来制成。因此，在某些实施例中，在近端处省去了一小段管件，并且在远端处切割或形成支承件，如图 20A' 中可见。在这种实施例中，是近侧接合元件的一体部分的位于近端处的管件段可用作近侧元件连接件。在替代实施例中，可将单独的近侧元件连接件加到装置，如图 20A 中可见。在一些实施例中，近侧元件连接件（41）可包括诸如连结介质（42）和外部近侧元件连接件（43）的多个元件。在这种实施例中，近侧接合元件的近端可置于内部近侧元件连接件处、外部近侧元件连接件处或外部近侧元件连接件和连接管件的末端之间。在一些实施例中，将近侧接合元件的近端置于内部近侧元件连接件内。在一些情况下，近侧接合元件的近端与连接件可使用诸如夹子、扣钩或紧固件之类的连结介质来连结，这些连结介质紧固或保持远侧接合元件、更具体是其近端。或者，近侧元件连接件可包括其内放置有近侧接合隔室的单层管件。

[0244] 当存在单独的近侧元件连接件（例如，图 20）时，近侧接合元件到近侧连接件的连接可通过诸如焊接或胶粘的各种手段来进行。或者，如上讨论的那样，近侧连接件可包括能紧固或保持近侧接合元件的连结介质。在任何情况下，近侧元件连接件围绕中心线，并且允许中心线在近侧元件连接件内作自由运动。

[0245] 在某些实施例中，装置包含连接到近侧接合元件的连接管件。在一些实施例中，连接管件可进一步连接到推送管件，例如如图 20 中所示。借助该构造，近侧接合元件永久地连接到推送管件。然而，或者，将近侧接合元件固定到推送管件是暂时的或者可逆的，因此，如果期望，则近侧接合元件、可选地连同近侧连接件能从推送管件脱开。作为另一替代方式，近侧接合元件和与其相关联的近侧元件连接件可以不固定到管件隔室处（参见，例如图 26）。替代地，它们能沿中心线自由滑动。

[0246] 根据本发明的一方面，远侧接合元件的位置可通过控制中心线来确定。例如，在图 20 中所示的实施例中，远侧接合元件与中心线连接。操作者能控制中心线的运动（例如，推入和推出），以将远侧接合元件定位在期望的位置。在某些实施例中，近侧接合元件可通过例如推送管件、连接管件或两者的管件元件的运动来定位。如图 20 中所示，在一些实施例中，近侧接合元件固定到管件元件的远端附近。由此，操作者可通过控制管件元件、即推送

管件和连接管件将近侧接合元件定位在期望位置。借助这些构造，能独立操纵两个接合元件。此外，这允许使两个接合元件之间的间距能变化。当用该装置来治疗患者时，装置的两个接合元件之间的间距能变化的这方面是有益的。该设计能通过将闭塞物或凝块保持在两个独立的接合元件之间来牢固地接合闭塞物或凝块。此外，通过调节每个接合元件的位置以及两者之间的距离，它可使保持的效率和精度最大化。

[0247] 在图 20B 中，示出图 20A 中所示的装置的不同状态。在该闭合位置，向近侧拉动中心线，由此向近侧接合元件拉动远侧接合元件，从而缩短两个接合元件之间的距离。

[0248] 图 21 示出从体腔(例如，血管)去除凝块或闭塞物的示例性实施例。在某些实施例中，装置可如下所述用于与凝块或闭塞物接合并从体腔去除凝块或闭塞物：

[0249] (A) 首先借助引导线的引导将微型导管(30)设置到在体腔内发生闭塞的区域。根据凝块或闭塞物的硬度、长度、位置和形状，微型导管可部分地穿过凝块(或闭塞物)或者到达凝块远侧。之后，管件隔室和接合部件可通过微型导管递送到闭塞物。在该技术中，近侧可扩张元件与远侧可扩张元件分离。当放置于装置内时，将近侧接合元件的末端放置于凝块或闭塞物后面 / 近侧。

[0250] (B) 将微型导管拉回以使接合部件和管件隔室的一部分脱开。理想地，近侧接合元件位于凝块近侧，而远侧接合元件位于凝块远侧，或者如果凝块相当长的话，位于凝块的近侧部的远侧。在一些实施例中，如图 21B 中可见那样，在此阶段，凝块将至少部分地由远侧接合元件保持或与其接合。

[0251] (C) 如果期望，操作者还可调节接合元件中的一个或两个的位置。例如，在保持推送管件以固定近侧接合元件时，操作者可向近侧拉动与远侧接合元件连接的中心线。然后，由于远侧接合元件与凝块之间的摩擦，凝块将向近侧运动。当这发生时，两个接合元件之间的距离缩短了，而凝块被抓取或接合在两个接合元件内和 / 或之间。如果操作者在拉动中心线和远侧接合元件时感觉到阻力，这表示凝块被接合在两个接合元件内和 / 或之间。然后，他或她能锁定远侧和近侧接合元件的位置，并从体腔(例如，动脉)拉出装置和被接合的凝块连同微型导管。在一些实施例中，通过置于装置上的标记(70)和 / 或(100)来识别装置的位置。

[0252] 在图 22 中，示出从体腔去除凝块或闭塞物的技术的替代实施例。该装置可如下所述用于与凝块或闭塞物接合并从体腔去除凝块或闭塞物：

[0253] (A) 微型导管(30)行进到在体腔内发生闭塞的区域。微型导管可在凝块或闭塞物的远端上前进。根据凝块或闭塞物的硬度、长度、位置和形状，微型导管可穿过凝块(或闭塞物)或者在基本上不干扰凝块的情况下经过凝块。在一些实施例中，一旦微型导管位于闭塞区域附近的位置，就将管件隔室和接合元件引入到微型导管内。在某些情况下，操作者可将微型导管和可扩张隔室放置于一旦脱开近侧接合元件就位于凝块近端的远侧的位置。如申请中其它地方阐释的，例如能使用装置中存在的标记来监测装置的位置。

[0254] (B) 使微型导管脱开，且接合隔室和管件隔室的一部分露出。

[0255] (C) 操作者还可进一步调节接合元件中的一个或两个的位置。例如，当保持中心线以及因此保持远侧接合元件稳定时，拉回近侧接合元件直至其远端刚经过凝块的近端。这可通过观察近侧接合元件的远端内的标记(70)来指示。近侧接合元件的远端在此位置打开。或者，如果期望，在保持近侧接合元件时，可调节远侧接合元件。此外，如果期望，可一

起调节近侧和远侧接合元件以确保与凝块的接合。

[0256] (D) 当通过固定推送管件来保持近侧接合元件稳定时，操作者可拉动连接到远侧接合元件的中心线。然后，由于远侧接合元件与凝块之间的摩擦，凝块可向近侧运动。两个接合元件之间的距离缩短了，且凝块被抓取或接合在两个接合元件内和 / 或之间。如果操作者在拉动中心线和远侧接合元件时感觉到阻力，这表示凝块被接合在两个部件内和 / 或之间。然后，他或她能锁定远侧和近侧接合元件的位置，并从体腔（例如，动脉）拉出装置和接合的凝块连同微型导管。在一些实施例中，通过置于装置上的标记（70）和 / 或（100）来识别装置和微型导管的位置。

[0257] 图 22 中所示的实施例的一些优点包括近侧接合元件能在脱开之后定位到凝块近侧，以在相对于凝块或闭塞物放置接合部件时确保相对较高的精度。由于可将近侧接合元件直接放置于凝块或闭塞物后面，当拉动远侧接合元件以使凝块向近侧运动时，凝块在接合到两个接合元件之间之前仅须行进非常短的距离。因此，与图 21 中所示的技术相比，凝块丢失的可能性降低。

[0258] 在图 23 中，表示出使用装置接合凝块的一些附加机构。如图 23 中所示，凝块可接合到管件元件和体腔表面（例如，动脉壁）之间（23A）、微型导管和近侧接合元件之间（23B）、近侧接合元件和动脉壁之间（23C）、远侧接合元件和动脉壁之间（23D）、近侧和远侧接合元件之间（23E）以及近侧接合元件和导管末端之间并且同时在两个接合元件之间（23F）。因此，显然可以在不脱离本发明的范围和精神的情况下对本申请中公开的装置和方法进行各种修改和应用。由此，当然本发明的范围包含这种变型和修改中的任一种。

[0259] 图 24 示出包括前述装置的系统的说明性实施例。在一些实施例中，中心线（10）可延伸到装置的近端，并连结到远侧部件手柄（120）。系统从远端到近端的长度可以约为 100 到 200 厘米。在一些实施例中，系统从远端到近端的长度可约为 100cm, 110cm, 120cm, 130cm, 140cm, 150cm, 160cm, 170cm, 180cm, 190cm 和 200cm。在一些其它实施例中，系统从远端到近端的长度可比 100 厘米短或者比 200 厘米长。在一些实施例中，系统可包括多个推送管件，诸如近侧推送管件（25）、中间推送管件（22）和远侧推送管件（24）。在一些其它实施例中，连接管件可连接到中间和近侧推送管件。可在系统的远端处，即如图 24 中所示借助远侧部件控制手柄和近侧推送管件由操作者来操作远侧和近侧接合元件。

[0260] 图 25 示出存在有远侧推送管件和近侧推送管件的系统的替代实施例。在连接管件顶上有远侧推送管件。在一些实施例中，推送管件中的至少一些部分是柔性的以确保装置能行进通过曲折路径。在其它实施例中，远侧推送管件中的至少一些部分可以是光滑和柔性的，因此，它还加强装置的可推送性。在某些实施例中，推送管件的近端可由刚硬 / 牢固的管件制成，以加强装置的可推送性。

[0261] 在装置需要拉回到微型导管内的情况下，每个接合元件可独立操作。例如，可先将近侧接合元件拉回到微型导管内，然后可通过拉动中心线将远侧部件拉入微型导管内，以避免两个元件（及其支杆）交叠。这将避免两个可扩张元件彼此交叠以及不能拉到微型导管内。在某些实施例中，一旦凝块被接合，两个接合元件的位置可锁定。在这种实施例中，两个接合元件的运动将同步，且将它们相继引入微型导管内。

[0262] 图 26 示出装置的替代实施例。特别是，近侧接合元件可以不与管件隔室连接。而是，与近侧元件连接件（41）相关联的近侧接合元件（65）可如图 26A 中可见那样沿中心线

10 自由滑动。在一些实施例中，近侧元件连接件（41）的内直径大于中心线（10）的外直径，因此，与近侧元件连接件（41）相关联的近侧接合元件（65）可在中心线（10）上自由滑动。此外，在至少一些实施例中连接管件是不需要的。图 26B 示出图 26A 中所示的实施例的闭合状态，其中，向近侧拉动中心线（10），由此，远侧接合元件 90 向近侧接合元件（65）运动。这将缩短两个接合元件之间的空间（或距离）。该特征将装使装置能如下图中所示与凝块接合。

[0263] 图 27 示出特别是使用图 26 中所示的装置从体腔（例如，血管）去除凝块或闭塞物的示例性实施例。在某些实施例中，装置可如下所述用于与凝块或闭塞物接合并从体腔去除凝块或闭塞物：

[0264] (A) 先借助引导线的引导使微型导管（30）行进到在体腔内发生闭塞的区域。微型导管可定位到在凝块或闭塞物近端的远侧。根据凝块或闭塞物的硬度、尺寸、位置和形状，微型导管可穿过凝块（或闭塞物）或者在基本上不干扰凝块的情况下经过凝块。之后，管件隔室和接合隔室可通过微型导管递送到闭塞物。近侧可扩张元件与远侧可扩张元件分开。当放置装置时，近侧接合元件的末端放置于凝块或闭塞物的近侧。

[0265] (B) 使微型导管脱开，且接合隔室和管件隔室的一部分露出。操作者可将装置调节成使近侧接合元件可位于凝块近侧，而远侧接合元件可位于凝块远侧，或者如果凝块相当长，则至少经过凝块的一部分。在一些实施例中，如图中可见，在此阶段，凝块将至少部分地由远侧接合元件保持。

[0266] (C) 操作者可进一步调节远侧接合元件的位置。例如，操作者可向近侧拉动与远侧接合元件连接的中心线。然后，由于远侧接合元件与凝块之间的摩擦，凝块将向近侧运动。两个接合元件之间的间距缩短。当凝块与近侧接合元件接触时，凝块可被抓取或接合到两个接合元件内和 / 或之间。同时，接合隔室和凝块进一步拉动到微型导管末端附近。为了确保接合，操作者可锁定远侧接合元件的位置并拉动装置。

[0267] 在某些实施例中，图 27 中所示的过程可如下进行：当进行图 26 中所示过程时，当装置脱开时，在微型导管内腔和近侧接合元件之间会有摩擦，并且近侧接合元件被拉离远侧接合元件。一旦两个元件离开微型导管，两个接合元件之间的间距可最大化或者基本上延长。操作者无须在展开之后调节两个接合元件的位置。操作者可通过与中心线连接的推送管件向近侧拉动远侧接合元件。因此，两个部件之间的距离将缩短以与凝块接合。在某些情形下，微型导管的末端可用于防止近侧接合元件向后运动。当操作者在向近侧拉动推送管件 / 中心线时感到阻力时，这可表示凝块被接合到两个接合元件内和 / 或之间，且近侧接合元件还被微型导管的末端止挡。此时，可锁定该装置并将其从体腔移除。因此，能容易地并以高效率去除凝块或闭塞物。

[0268] 图 28 示出包括图 26 中所示装置的系统的又一示例性实施例。或者，图 20 中所示的装置可用于图 28 的该系统中。在一些实施例中，近侧接合元件（65）位于中心线（10）周围，由此，它能在远侧接合元件 90 和推送管件（140）的远侧末端之间自由地滑动。此外，远侧接合元件 90 可连接到中心线（10）。中心线（10）可向近侧延伸。中心线 10 可与推送管件（例如，近侧推送管件 25、中间推送管件 22、内推送管件 21 和外推送管件 23）中的至少一个连结。因此，与图 24 中所示的实施例不同，中心线 10 不必延伸到装置的近端。而是，它可与管件元件中的任一个连接，并且与连接的管件一起被控制。在一些实施例中，外推送管

件(23)可以是柔性的且光滑的，并放置到接近于系统的远端，因而，它可允许装置通过体腔内的曲折路径。此外，在一些其它实施例中，薄内推送管件(21)可存在于系统中，而该内推送管件(21)可以是柔性的，但又能增加系统的可推送性。在又一些其它实施例中，具有一定柔性的中间推送管件(22)可存在于系统中。在又一些其它实施例中，相对刚硬的远侧推送管件(24)和/或近侧推送管件(25)可存在于该系统内，以使该系统的可推送性进一步提高。一个或多个推送管件可用粘合剂彼此连接，并还可与包括中心线(10)在内的其它部件连接。在又一些其它实施例中，具有可变刚度的单个推送管件可用于该装置中，以替代多个推送管件和连结部。该管件可通过将管件磨成不同壁厚或通过螺旋形切割来形成，以确保远端更柔性，而近端更刚硬。

[0269] 图 29 示出存在远侧推送管件和近侧推送管件的系统的替代实施例。在该实施例中，中心线(10)可以不延伸到系统的近端。类似于图 28 中所示的示例，中心线连接到管件元件中的一个或多个，并且通过连接的管件元件来控制。在连接管件顶上有远侧推送管件。在一些实施例中，远侧推送管件中的至少一些部分是柔性的，以确保装置能行进通过曲折路径。在其它实施例中，远侧推送管件中的至少一些部分可以是光滑和柔性的，因此，它还加强装置的可推送性。在某些实施例中，推送管件的近端可由刚硬/牢固的管件制成，以加强装置的可推送性。

[0270] 图 30A 示出装置的替代实施例。与图 20 中所示的实施例不同，该装置包括可推动和可拉动的近侧接合元件。然而，在该设计中修改了近侧接合元件的远侧末端。近侧接合元件的远端可如图 30 中所示向内弯曲或弄成圆滑，这可进一步确保末端对于动脉的内壁是无创伤性的。由此，可在动脉内腔中拉动和推动近侧接合元件，而损伤动脉壁的风险低得多。图 30B 示出图 30A 中所示的装置的靠拢状态，其中，近侧和远侧接合元件之间的距离最小化。

[0271] 图 31 示出特别是使用图 30 中所示的装置从体腔(例如，血管)去除凝块或闭塞物的示例性实施例。该图中所示的凝块收回机构很大程度上类似于图 21 和 22 中的收回机构。

[0272] 根据本发明的一些实施例的装置具有明显优点。例如，在操作过程中，如果凝块不位于两个接合元件内和/或之间，或者一个或两个接合元件位于凝块太远侧或太近侧，操作者可将接合元件中的一个或两个定位成确保接合。特别是，在图 31 中所示的实施例中，通过经由连接管件拉动或推动来将近侧接合元件调节到期望位置。由于近侧元件具有非创伤性圆形末端且能被向前推动以使凝块与远侧元件接合，该手术/技术可避免需要仅用远侧接合元件来拉动凝块一段距离，这可进一步降低在手术过程中丢失凝块的可能性。因此，这种装置可使用两个接合元件与凝块接合，并稳定凝块直至从体腔去除凝块。两个接合元件的这种独立控制允许在手术过程中非常精细地调节装置，因此，特别是在治疗中的精确定位是必要的情形下(例如，脑内中风治疗)十分有用。

[0273] 图 32A 示出装置的替代实施例。在该特定实施例中，近侧接合元件具有筐状特征。在该近侧接合元件(65)上没有相对尖锐的端部，因为近侧接合元件的远端通过近侧接合元件的连接线(150)连接到近侧接合元件的远侧连接件(140)。因此，当近侧接合元件被压缩时，其远端将向后运动并形成如图 32B 中所示的光滑远端。该光滑端部对于动脉内腔是无创伤性的。在至少一些实施例中，该近侧接合元件可在体腔内拉动和推动。在某些实施例中，近侧接合元件的远端比近侧接合元件的其它部分薄。因此，当凝块在两个接合元件内和

/ 或之间被拉动或推动时，近侧接合元件的远侧部会弯折或者翻转，如图 32B 中所示，因而，凝块被近侧接合元件接合将不会被近侧接合元件 65 和近侧接合元件的远侧连接件（140）之间的附加关联所阻碍。

[0274] 图 33A 示出装置的另一替代实施例。在该特定实施例中，近侧接合元件具有筐状特征。然而，与图 32 中所示的实施例不同，近侧接合元件 65 的远端与近侧部件的远侧连接件（140）直接连结。该装置还在近侧接合元件上具有不尖锐的端部，且由此还减少损伤体腔的任何风险。在该设计中，用于近侧接合元件的近侧部的材料可以与近侧接合元件的其它部分的材料相同或者不同。在某些实施例中，近侧接合元件的远侧部可由比近侧接合元件的其它部分相对柔性的元件构成。由此，当凝块抵靠于近侧接合元件被拉动时，近侧接合元件的远侧部会弯折或翻转，以使近侧接合元件可如图 33B 中所示与凝块更好接合。

[0275] 图 34A 示出装置的另一替代实施例。该装置还包括用于进一步确定装置的安全性的附加特征。该设计可包括具有筐状特征的近侧接合元件。将近侧元件的远侧部通过软的 / 柔性连接件（例如，段连接件 160）连结到近侧元件的近侧部，这些软的 / 柔性连接件允许弯折，而远侧部向后压缩。可例如通过控制与近侧接合元件相关联的管件隔室而拉动或推动近侧接合元件。在近侧接合元件中没有尖锐端部，因此，它对于动脉壁来说无创伤性。此外，在该设计中，近侧接合元件可由多于一种材料制成，材料中的一种比另一种软。因此，在与凝块接合时易于使近侧接合元件的至少远侧部弯折或翻转（参见图 34B）。

[0276] 图 35 示出装置的近侧部的又一替代实施例。该装置还包括用于进一步确定装置的安全性的附加特征。该设计包括具有圆形远侧端部的近侧接合元件，以形成对于血管更无创伤的末端。因此，可例如通过控制与近侧接合元件相关联的管件隔室而拉动或推动近侧接合元件。

[0277] 下图 36-45 提供用于接合（和去除）凝块的近侧元件位于微型导管的远侧末端或端部处的进一步的替代实施例。在一些实施例中，该接合元件可附连到微型导管的远侧末端处。在一些其它实施例中，微型导管本身的远侧末端或端部成形为并构造成起到近侧接合元件的作用。换言之，近侧接合元件是微型导管的一体部分。

[0278] 在一些实施例中，可单独地附连到微型导管或者是微型导管的一体部分的近侧接合元件可在收回过程中或需要时改变形状和 / 或尺寸。例如，在收回装置放置于期望位置，即完全或部分经过凝块之后，可将收回装置插入微型导管内。然后，可向近侧拉动微型导管以使装置脱开。当微型导管的远侧末端到达凝块的大约近端处时，将微型导管的远侧末端操纵成改变成打开 / 漏斗形状。当保持微型导管稳定时，收回装置可连同与收回装置的接合元件部分接合的凝块一起拉回，直至凝块基本上或完全接合（或捕获）在微型导管的远侧末端（即，近侧接合元件）与收回装置的接合元件（即，远侧接合元件）之间。通过将收回装置和微型导管锁定到装置的近端处，可从例如动脉的内腔拉出装置和微型导管连同被接合的凝块。

[0279] 在微型导管的远侧末端提供近侧接合元件的某些实施例中，它可简化收回装置的设计以及由此其制造过程。代替两个单独的接合元件，例如如图 20 的实施例中所示，收回装置可仅需一个接合元件，即远侧接合元件，而起到近侧接合元件作用的另一元件可由微型导管来提供。

[0280] 图 36 示出诸如囊体的可膨胀或接合元件附连到微型导管的远端 / 远侧末端处的

装置的实施例。可扩张或接合元件(170)的形状和尺寸可通过其膨胀和收缩来控制。根据一些实施例,可扩张或接合元件(170)可例如通过用注射器 190 将液体(195)(例如,盐水溶液)注入可扩张或接合元件(170)内来膨胀,以形成期望的形状。在某些实施例中,将注入的液体通过注射通道 180 传递到可扩张或接合元件(170)。可扩张或接合元件(170)在膨胀后的形状和尺寸可变化。例如,当将预形成的囊体附连到微型导管的远侧末端时,它在膨胀时可成形为任何预形成的形状,例如漏斗状形状,如图 36B 中可见那样。或者,如图 36C 中可见,当膨胀时可仅增加可扩张或接合元件(170)的表面面积。由微型导管提供的可变形的近侧接合元件可单独地或者与其它元件(例如,体腔表面、微型导管、管件隔室、近侧接合元件、远侧接合元件及其任何组合)组合并以高效率与凝块接合(例如,参见图 33 和 37)。

[0281] 图 37 示出使用图 36 的装置来接合和去除凝块的机构。在收回过程中,操作者可将微型导管(30)插入体腔(例如,动脉)内直至远侧末端进入或通过凝块(60)。收回装置可与微型导管一起或者一旦微型导管在位则通过微型导管递送到闭塞物位置。在某些实施例中,可推动收回装置直至其接合元件 90 可如图 37A 中可见那样通过凝块的至少一部分。当保持收回装置稳定时,操作者可向后(即,向近侧)拉动微型导管,直至微型导管的远侧末端位于凝块的大约近端处,并且使收回装置的接合元件 90 露出,并扩张到其松弛或打开状态(图 37B)。因此,凝块可位于远侧接合元件 90 和微型导管的远侧末端(即,近侧接合元件 170)之间。然后,操作者可使微型导管 170 的可变形的远侧末端扩张,以将末端在凝块的近端处变形为漏斗形状(图 37C)。当保持微型导管稳定时,操作者可向后拉动远侧接合元件 90,因而,凝块可向后运动,并且接合到远侧接合元件 90 与微型导管的远侧末端(170)之间。然后,操作者可固定微型导管和收回装置,并且将它们拉出动脉,这使得能去除凝块。

[0282] 图 38 示出微型导管的远侧末端形成接合元件、更具体是近侧接合元件的装置的另一实施例。在该特定实施例中,例如通过激光切割来切割微型导管(200)的远侧末端,因而,在收回过程中,它能在被凝块(60)和 / 或远侧接合元件 90 压缩时转变成漏斗形状。在某些实施例中,在到达微型导管远侧末端的到底端之前结束切割过程,因而,微型导管的远侧末端仍是闭合的。

[0283] 图 39 示出微型导管的远侧末端(200)经受螺旋形切割的实施例的又一替代方案。类似于图 38 的装置,在收回过程中,当被压缩时,微型导管的远侧末端将成形为例如漏斗形状(图 39B)。在某些实施例中,在到达微型导管远侧末端的到底端之前结束切割过程,因而,微型导管的远侧末端仍是闭合的。

[0284] 图 40 示出微型导管的远侧末端形成为编织结构的又一实施例。或者,如申请中其它地方所述,单独的编织结构可附连到微型导管的远侧末端处。附连到微型导管处或形成于微型导管内的编织结构(200)可以是具有或不具有塑料涂层的金属编织物。在与远侧接合元件 90 一起与凝块接合时,编织结构(200)将被压缩和成形为例如漏斗形状,因而,凝块保持在远侧接合元件 90 和编织结构(200)之间。

[0285] 图 41 示出微型导管的远侧末端切割到到底端的又一实施例。因此,如图中可见,微型导管的远侧末端的该到底端并不闭合。在用远侧接合部件 90 向后拉动凝块时,微型导管的末端压缩成例如漏斗形状(沙嘴),并且凝块保持在收回装置的远侧接合部件 90 和微型导管(200)的远侧末端之间。图 41B 和 C 示出微型导管的开口末端的两个不同形状。

[0286] 在某些实施例中,近侧接合元件可包括微型导管的远端的包括微型导管末端的一

部分和覆盖微型导管末端的一层薄管件。在一些实施例中，近侧接合元件的至少一部分构造成在移除一层薄管件时改变形状。在图 42 中示出这种实施例的示例。图 42 示出一装置，在该装置中，外套管层施加于微型导管。在某些实施例中，用作接合元件的微型导管的远侧末端可包括预成形结构或形状记忆结构。外套管（210）可保持微型导管的远侧末端（200），因此，它能在接合之前通过凝块。当将微型导管向近侧拉到凝块时，通过向近侧拉动外套管而使末端打开到其预成形，例如漏斗形状。或者，形状记忆材料可用于微型导管的远侧末端（200），因而，它能在从外套管露出时形成一定形状。

[0287] 图 43 示出线材用于在微型导管的远侧末端处提供一定形状的装置的又一实施例。图 43B 中所示的该设计示出具有嵌入到末端内的例如弹性线材的线材（220）的微型导管的远侧末端（200），以确保末端将在被拉出外套管（210）之后扩张到其预设定的形状。

[0288] 图 44 示出装置的另一实施例。在该特定实施例中，预成形漏斗末端结构（切片的）放置于微型导管的末端处，且微型导管的末端通过线材（220）保持，这些线材延伸通过微型导管壁的内通道（230）内的内腔。线材可保持微型导管的末端平直或未折叠，直到在接合之前该末端通过凝块。当通过向近侧拉动线材而将微型导管向近侧拉到凝块时，末端打开到其预成形、例如漏斗形状。

[0289] 图 45 示出编织结构和外套管被一起采用的装置的又一实施例。将预成形编织结构放置于微型导管的远侧末端，一层外套管保持末端平直，因此，能在接合之前循环前进到达或通过凝块。当通过向近侧拉动外套管而将微型导管定位到凝块近侧时，编织物末端打开到其预成形、例如漏斗形状。

[0290] 尽管文中描述了各种方面和实施例，但其它方面和实施例将对于本领域技术人员来说是显然的。文中公开的各种方面和实施例是出于说明的目的，并且不意在限制，由下述权利要求书表示实际范围和精神。

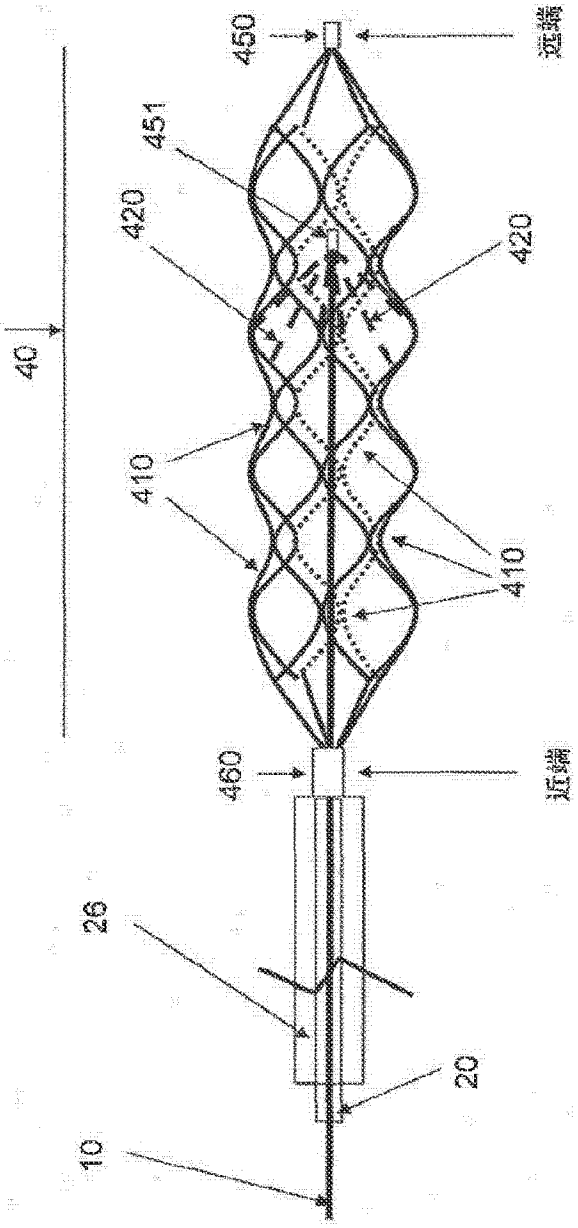


图 1

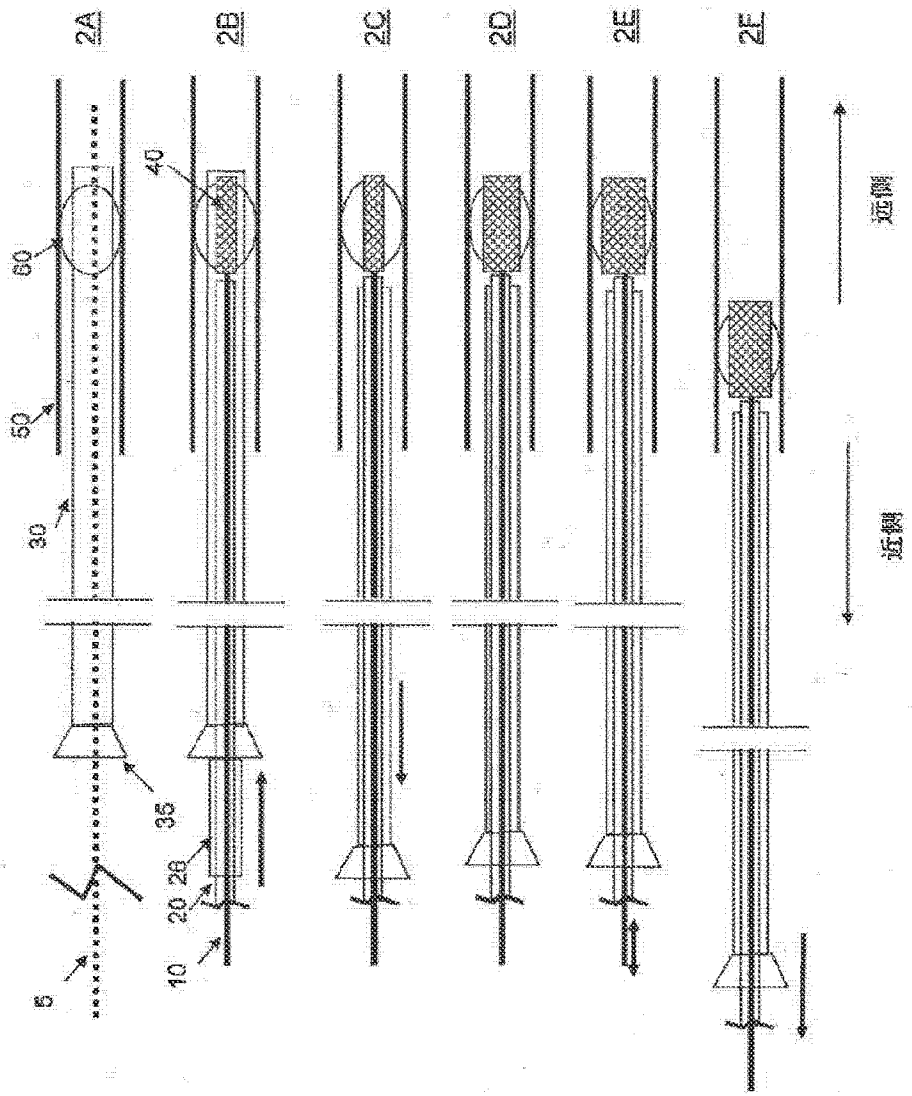


图 2A-F

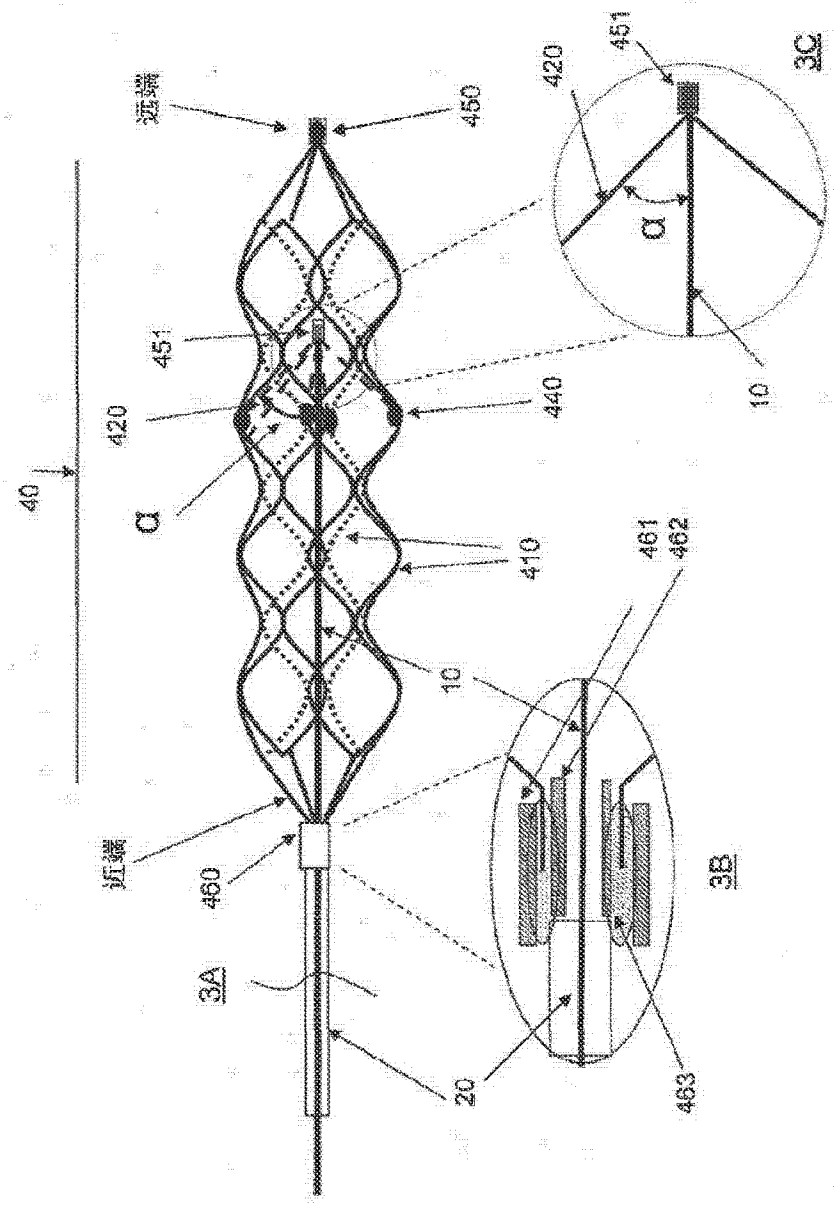

远端
450
420
451
3C
α
10
451
420
440
40
α
410
461
462
10
近端
460
3B
3A
20
463

图 3A-C

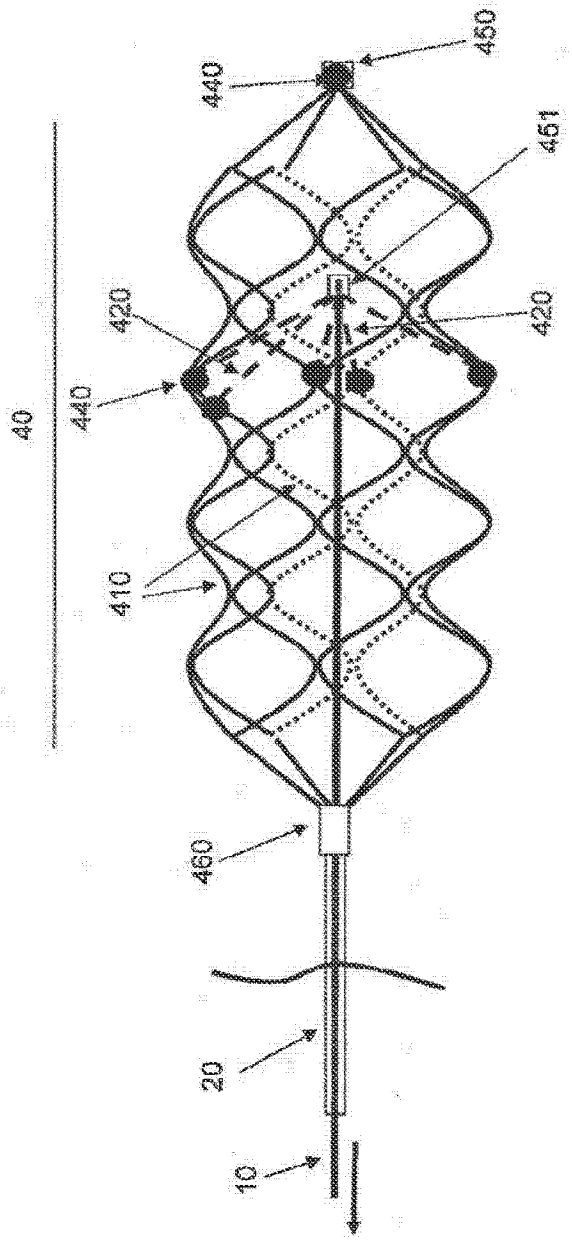


图 3D

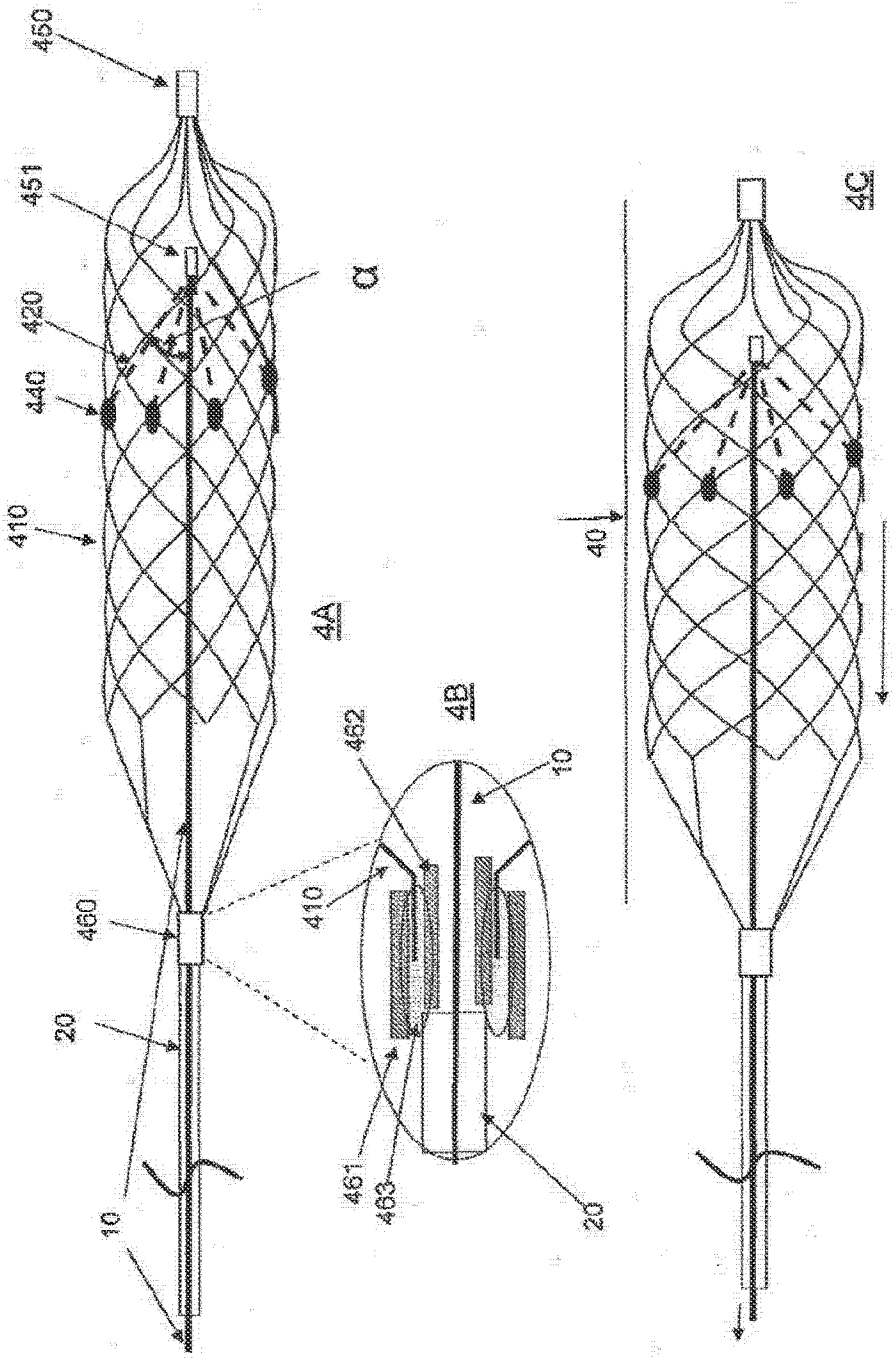


图 4A-C

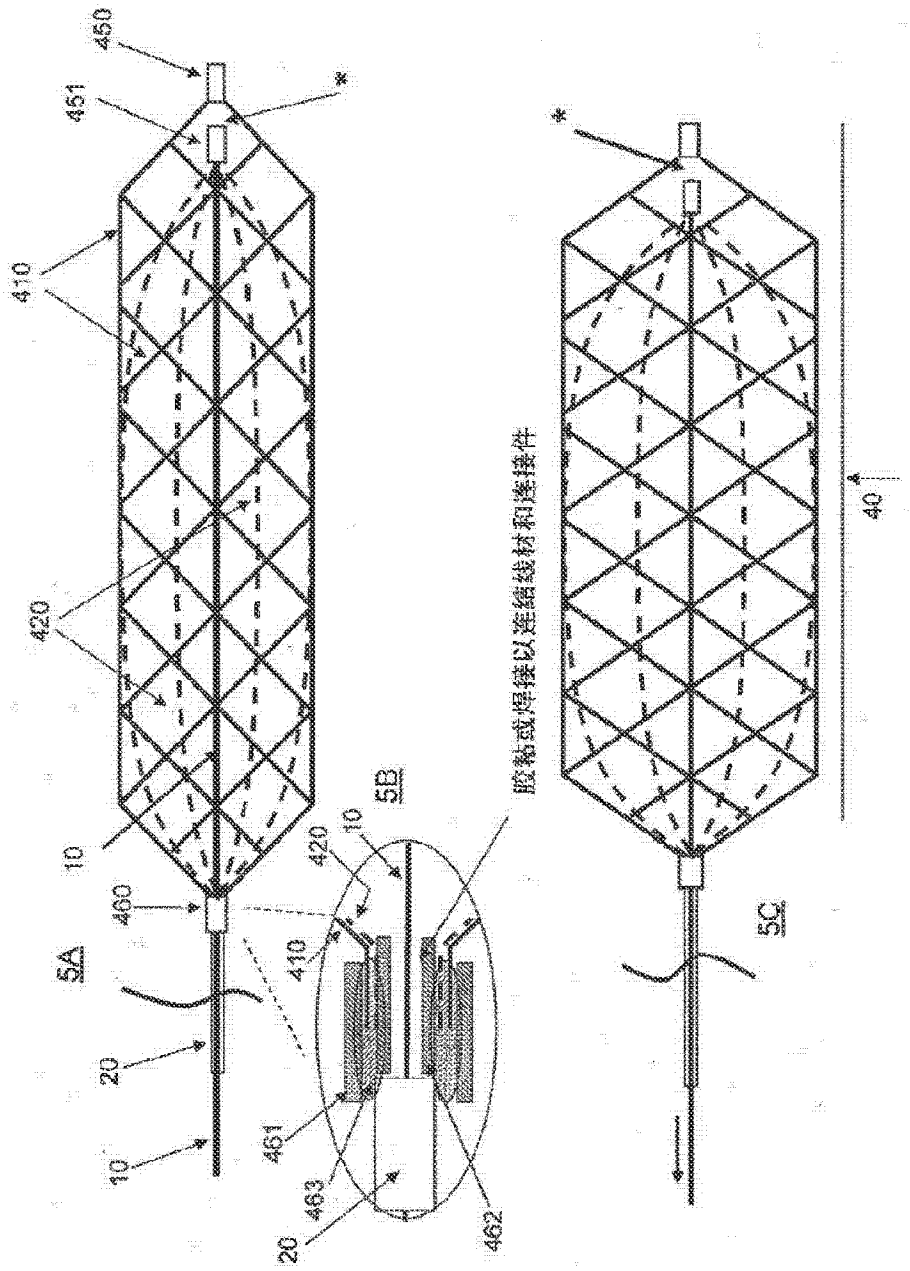

450
451
*
410
420
10
460
5A
20
10
461
463
20
462
5B
420
10
410
胶粘或焊接以连结线材和连接件
*
40
5C

图 5A-C

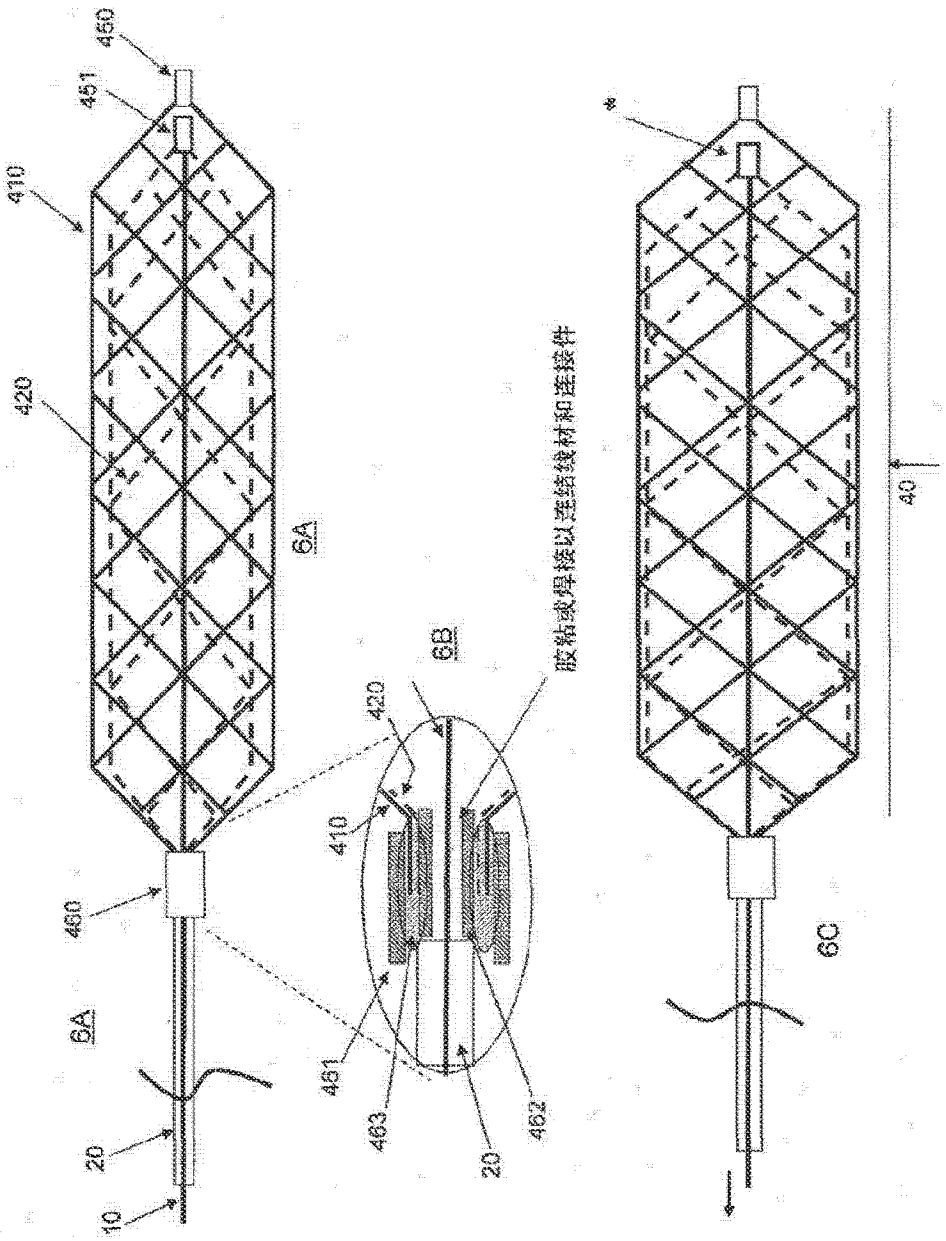

460
451
410
420
6A
460
6A
20
10
6B
420
410
461
463
462
20
胶粘或焊接以连结线材和连接件
*
40
6C

图 6A-C

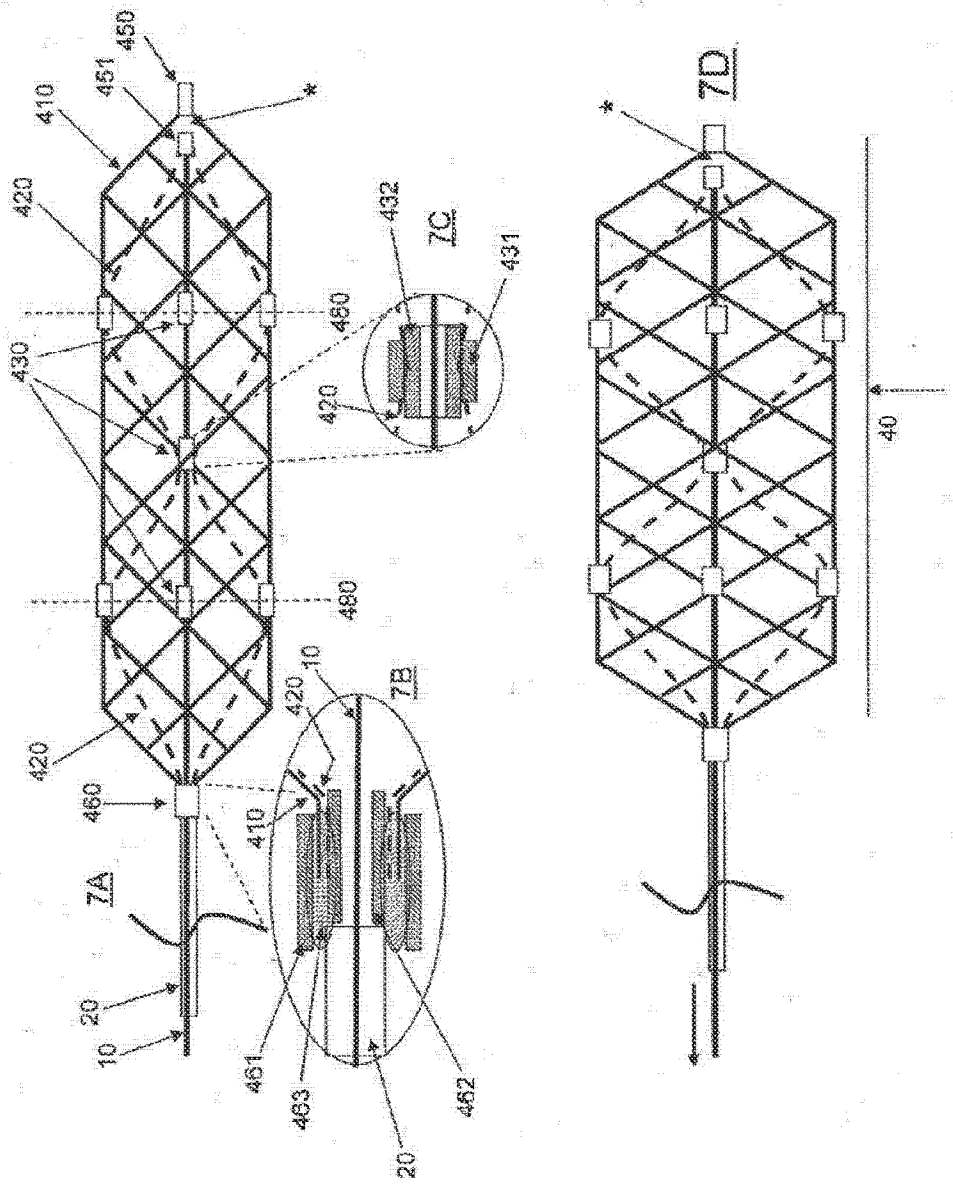

450
451
410
420
430
480
460
ZA
20
10
ZB
461
463
462
ZC
432
431
7D
40

图 7A-D

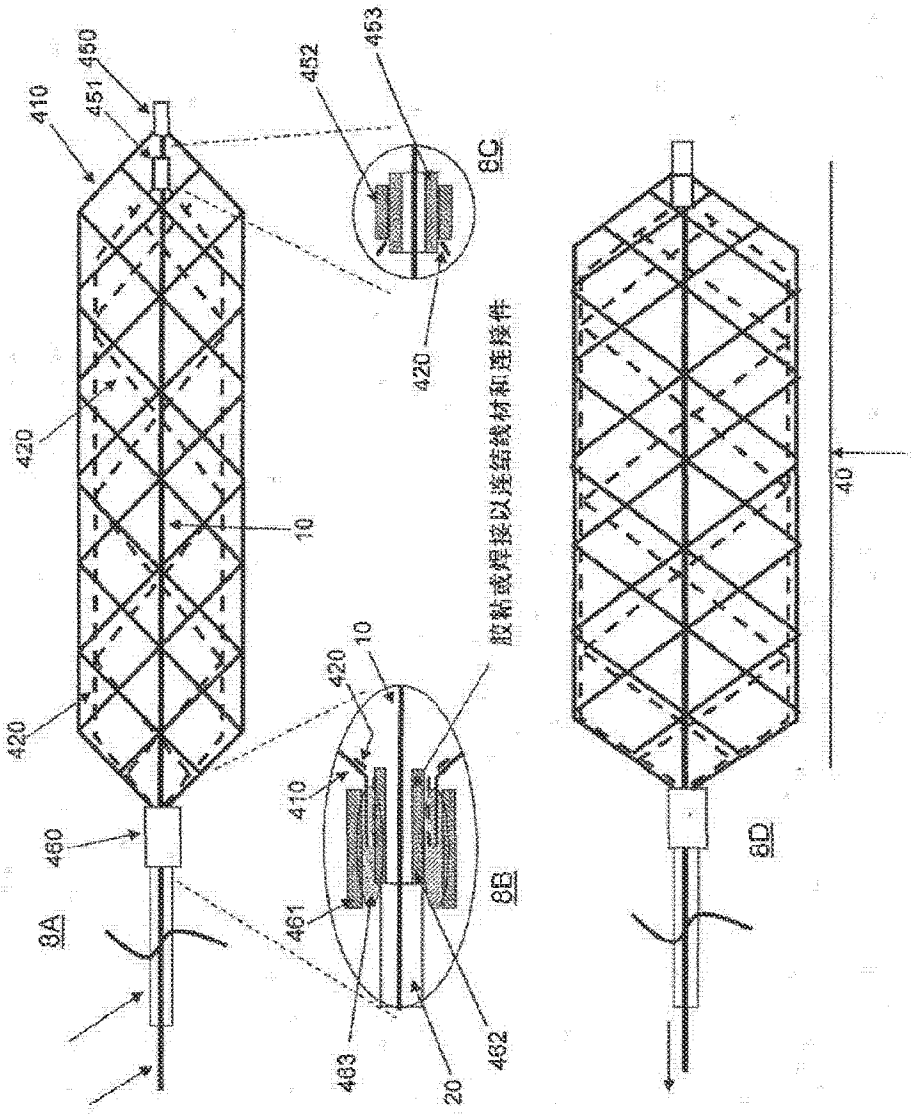

410
451
450
452
453
8C
420
420
10
420
420
10
410
460
461
8A
8B
463
20
462
胶粘或焊接以连结线材和连接件
8D
40

图 8A-D

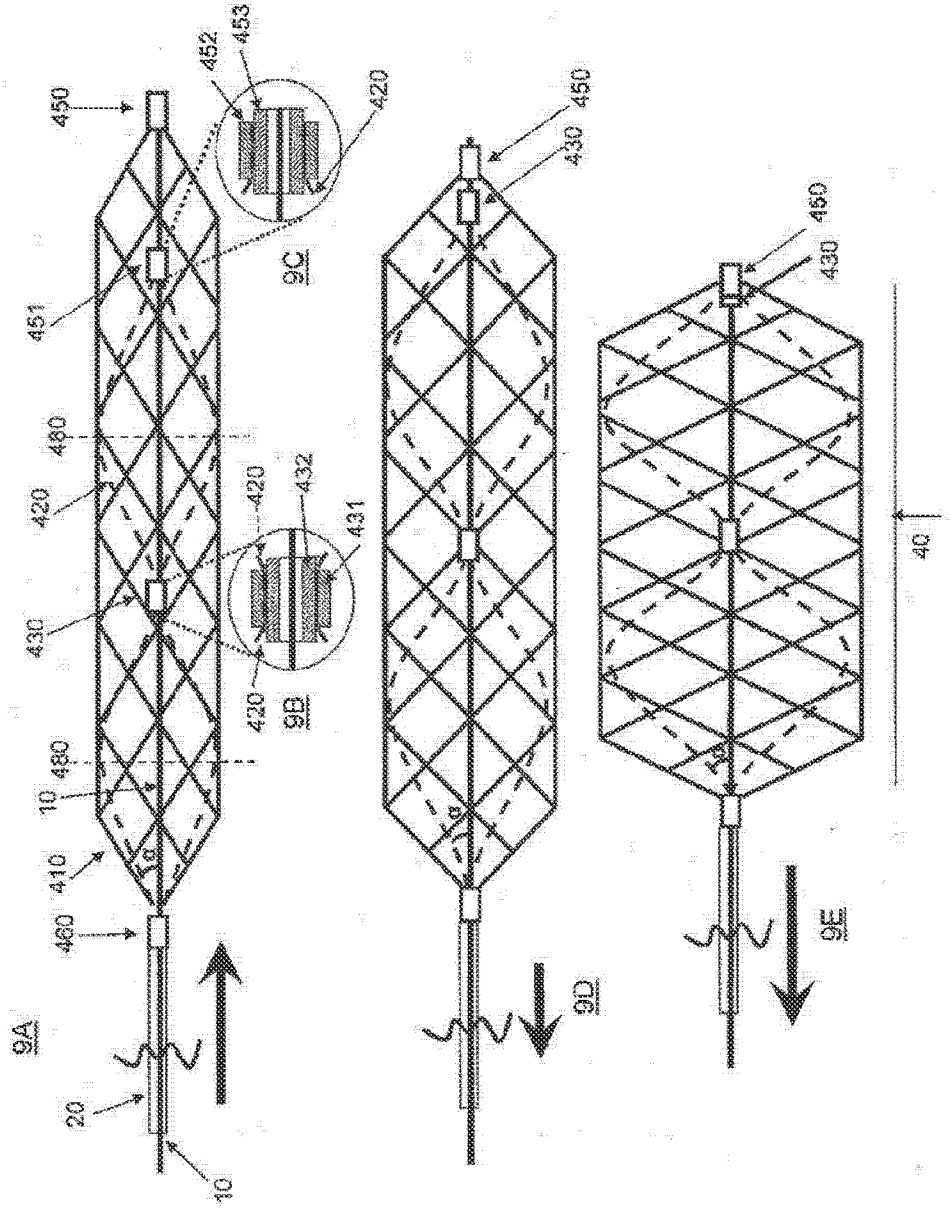

450
452
453
420
9C
451
460
420
420
432
431
430
9B
420
480
10
410
460
9A
20
10
450
430
9D
460
430
40
9E

图 9A-E

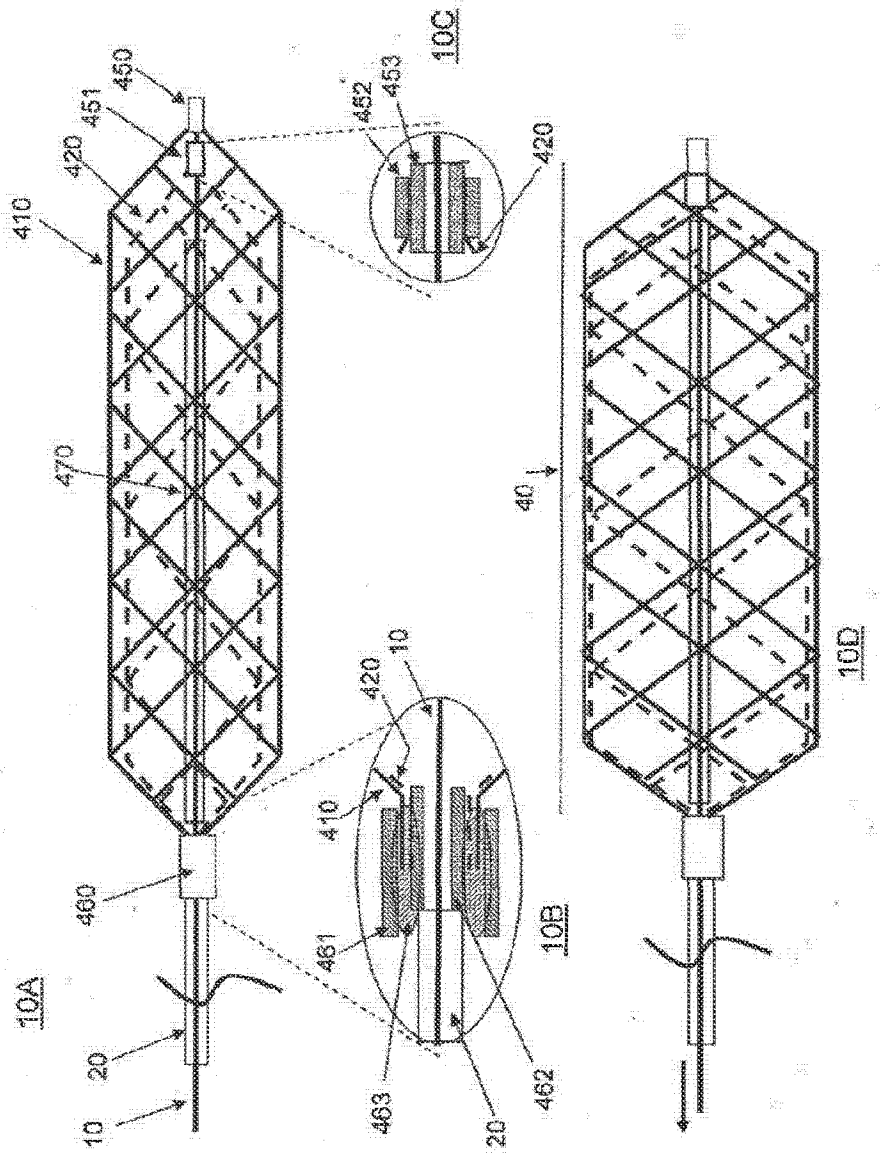

10C
450
451
420
410
452
453
420
470
40
10D
420
10
410
460
461
10B
10A
20
10
463
462
20

图 10A-D

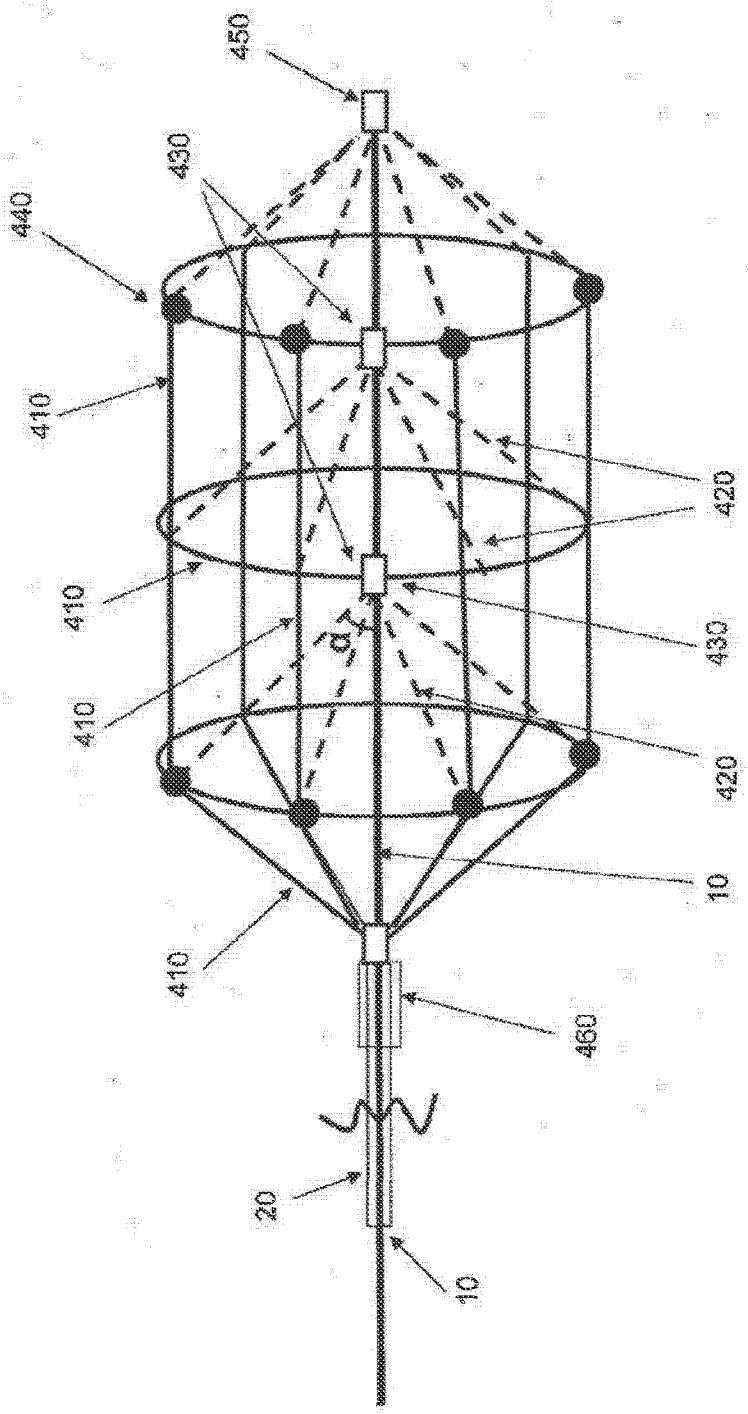


图 11

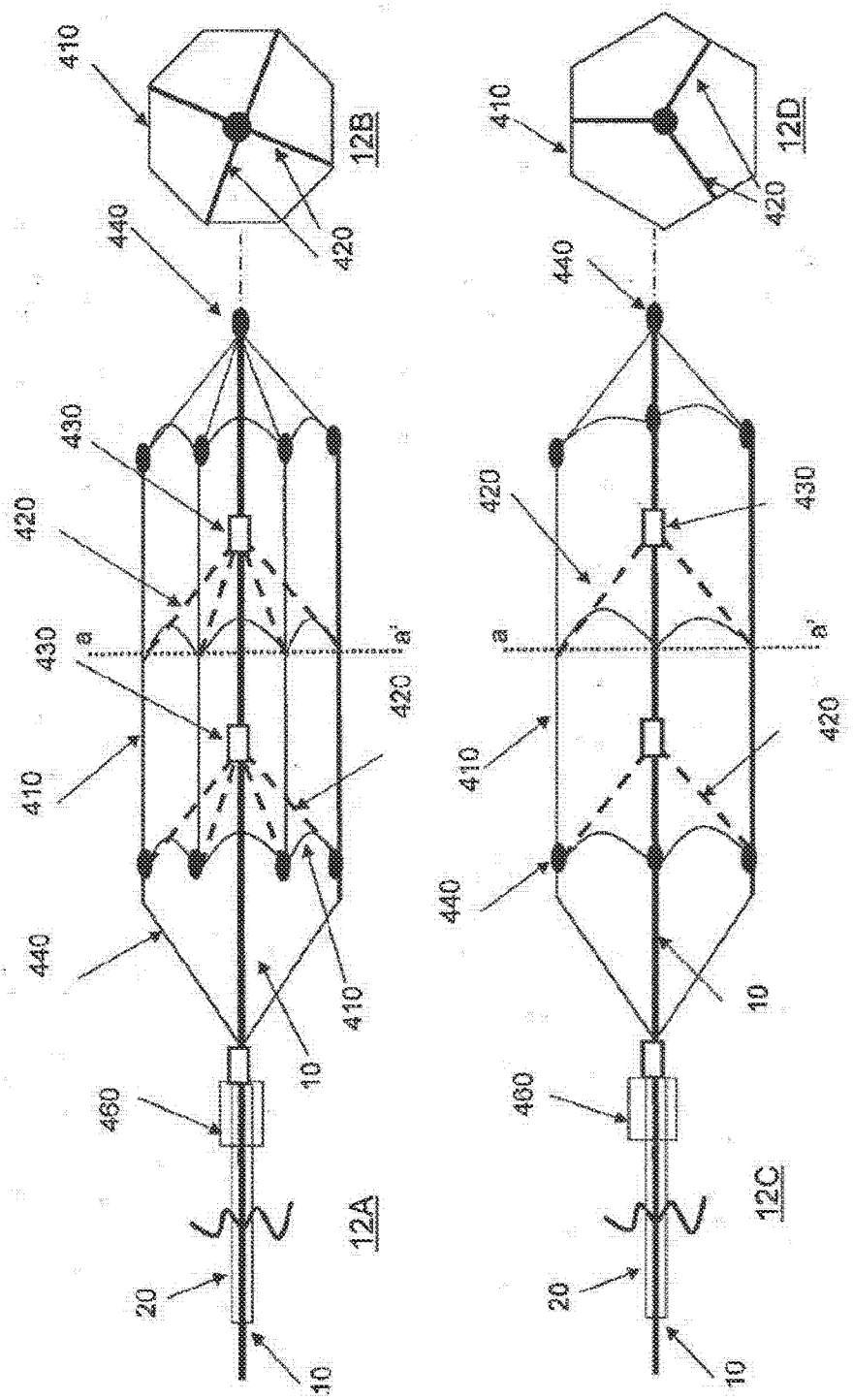

410
420
12B
440
430
420
a
a'
430
420
410
440
410
10
460
12A
20
10
410
420
12D
440
420
430
a
a'
420
410
440
10
460
12C
20
10

图 12A-D

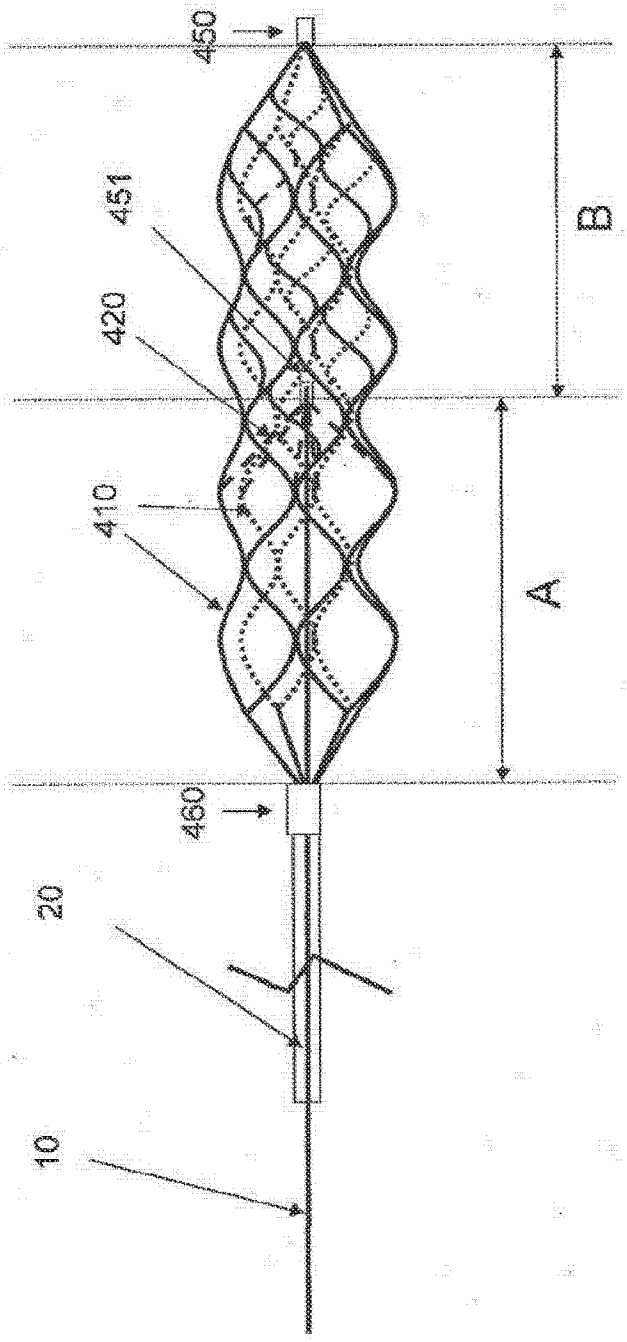
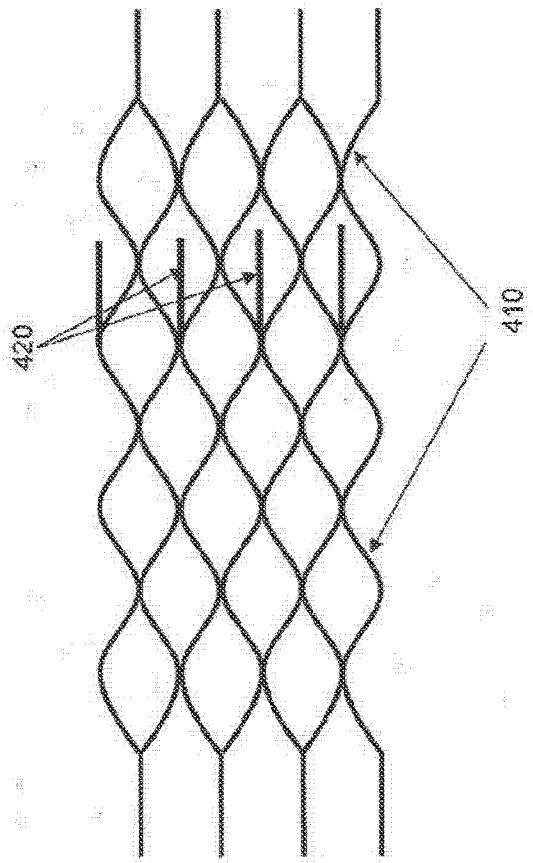


图 13



14A

图 14A

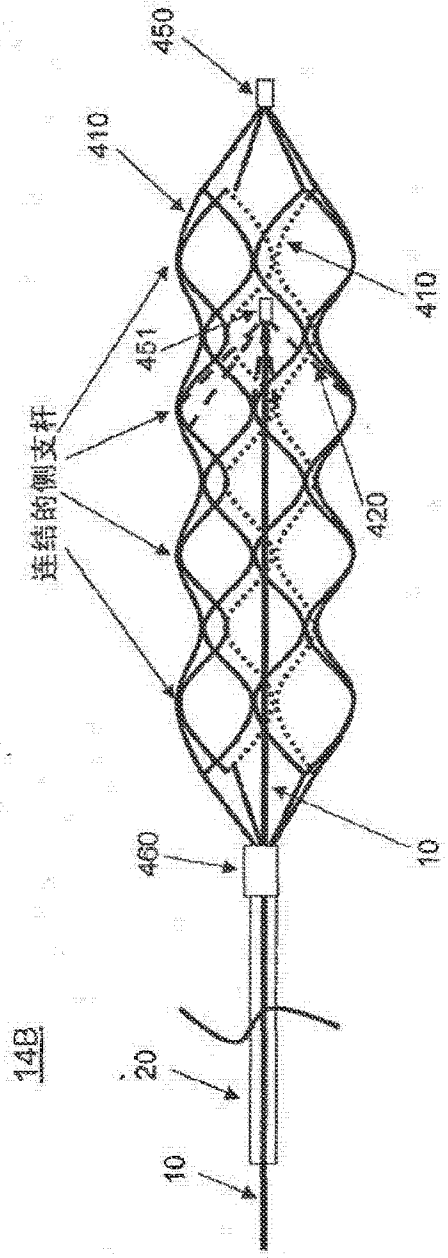


图 14B

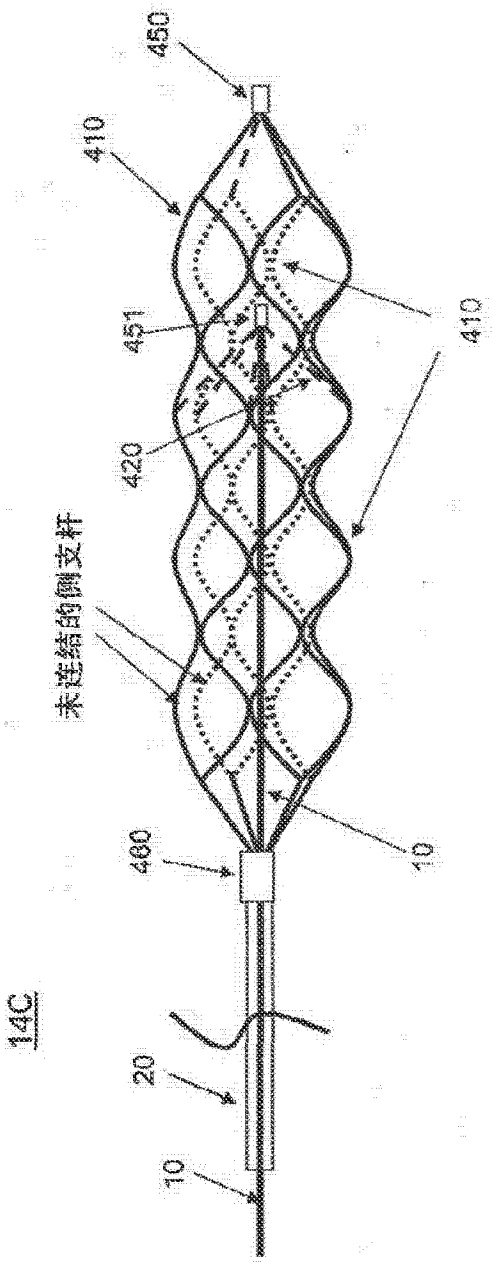


图 14C

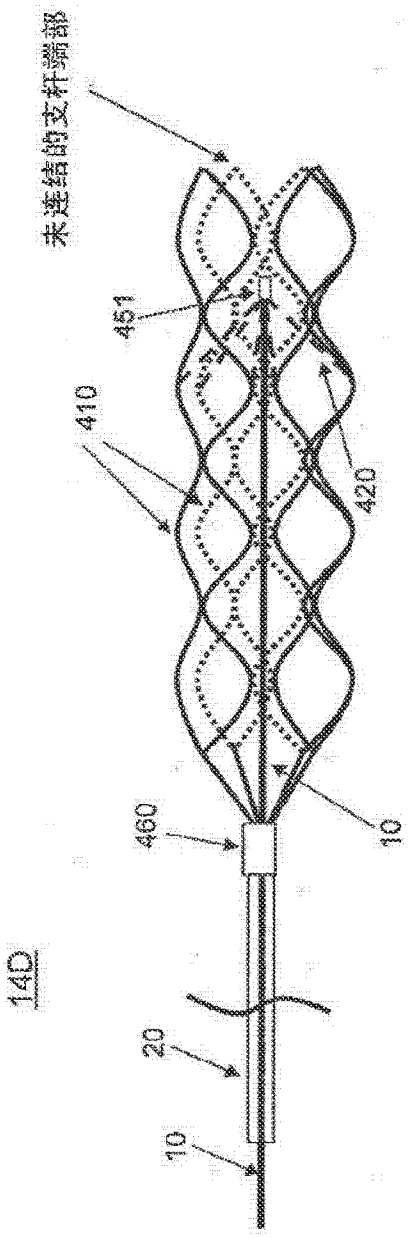


图 14D

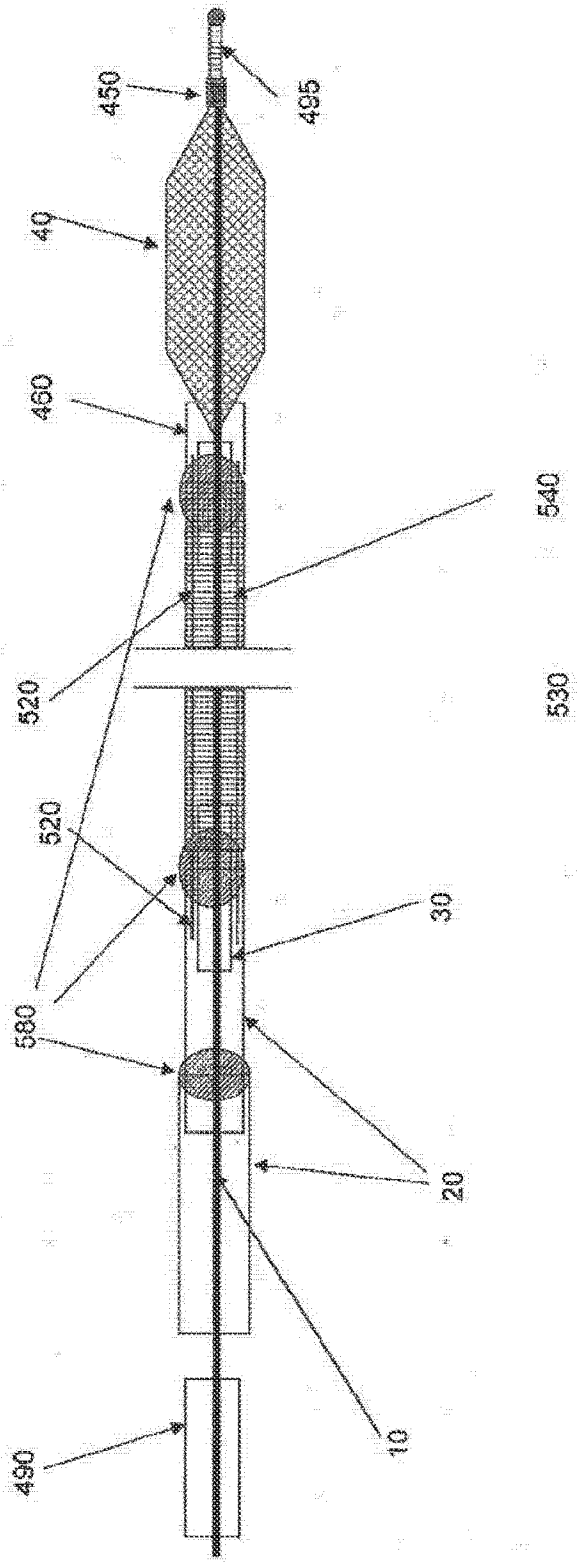


图 15

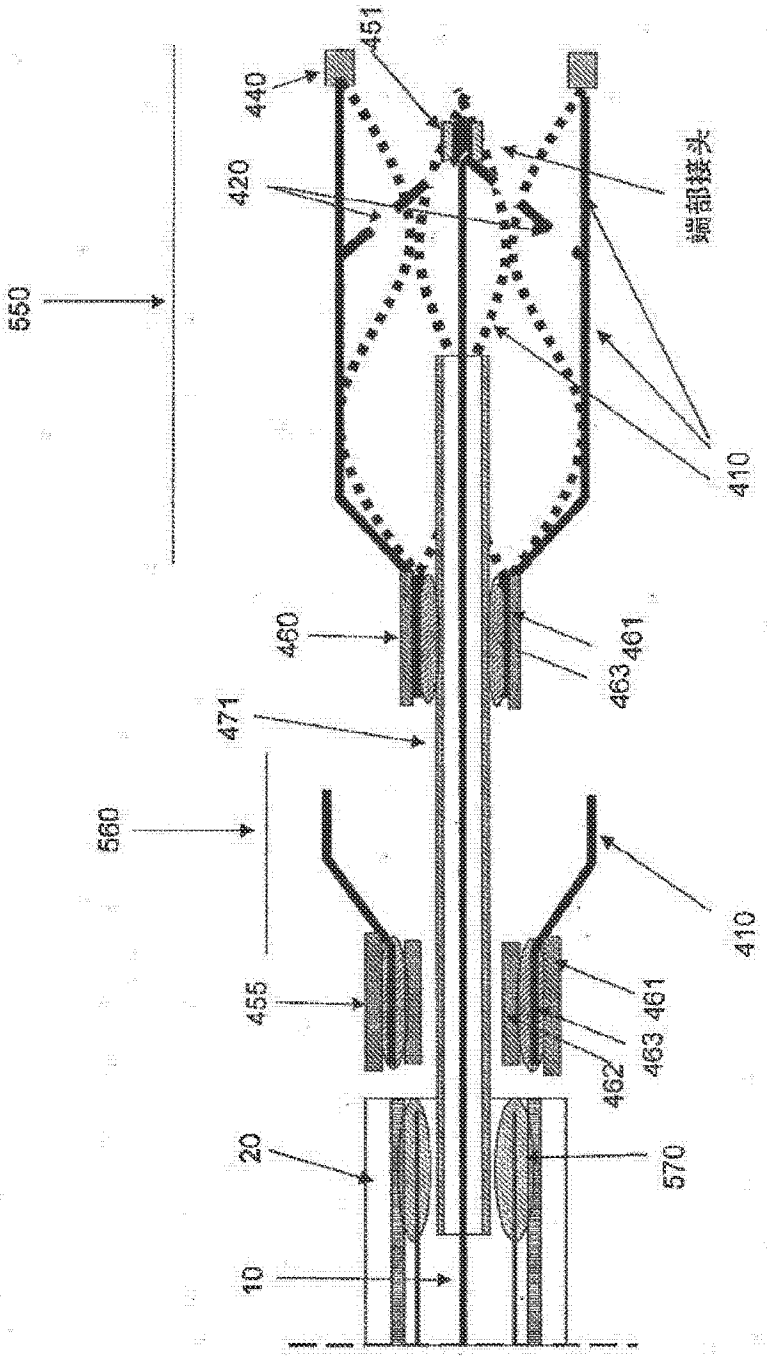

451
440
420
端部接头
550
410
460
461
463
471
560
410
455
461
463
462
20
570
10

图 16

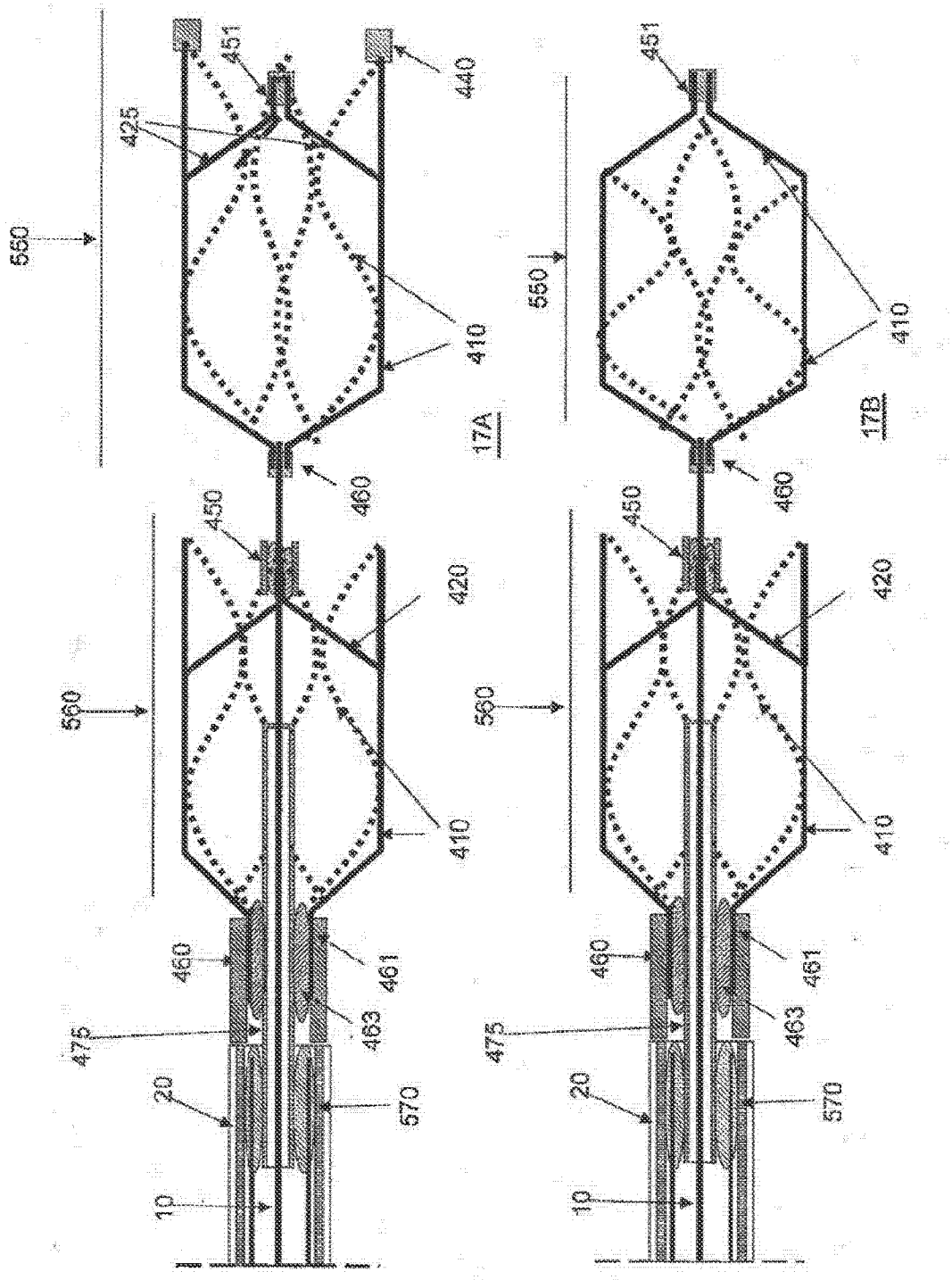


图 17A-B

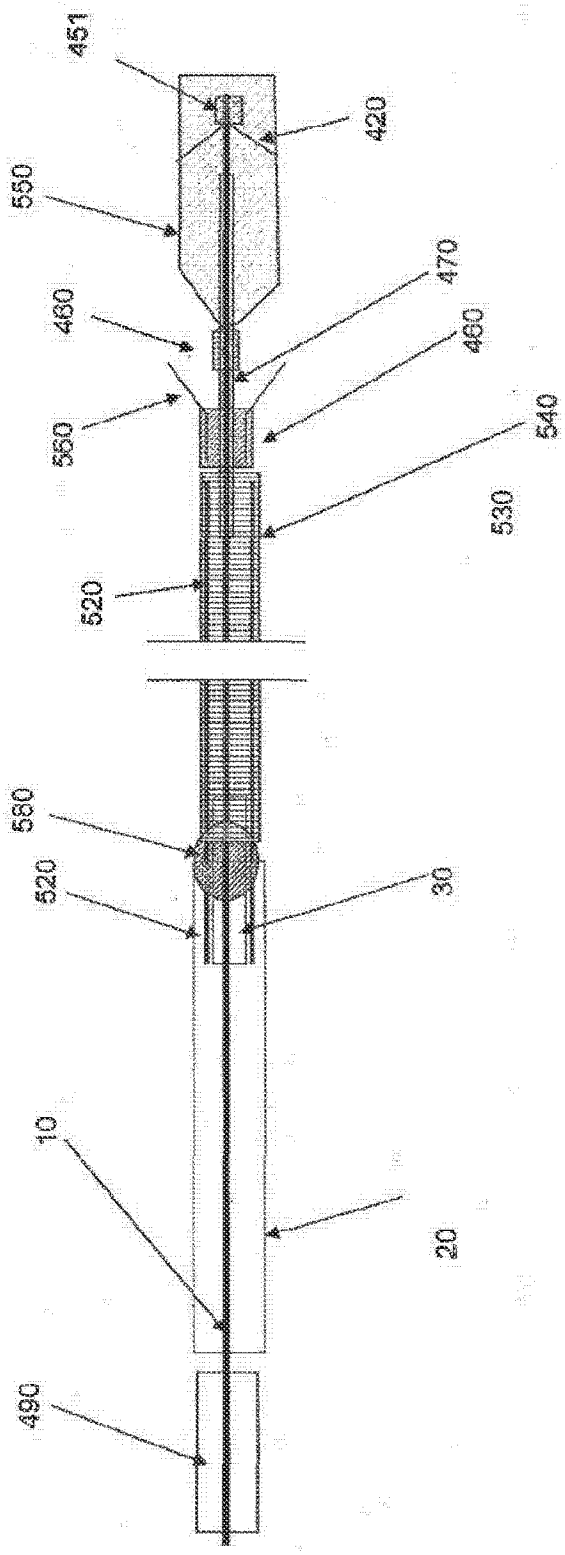


图 18

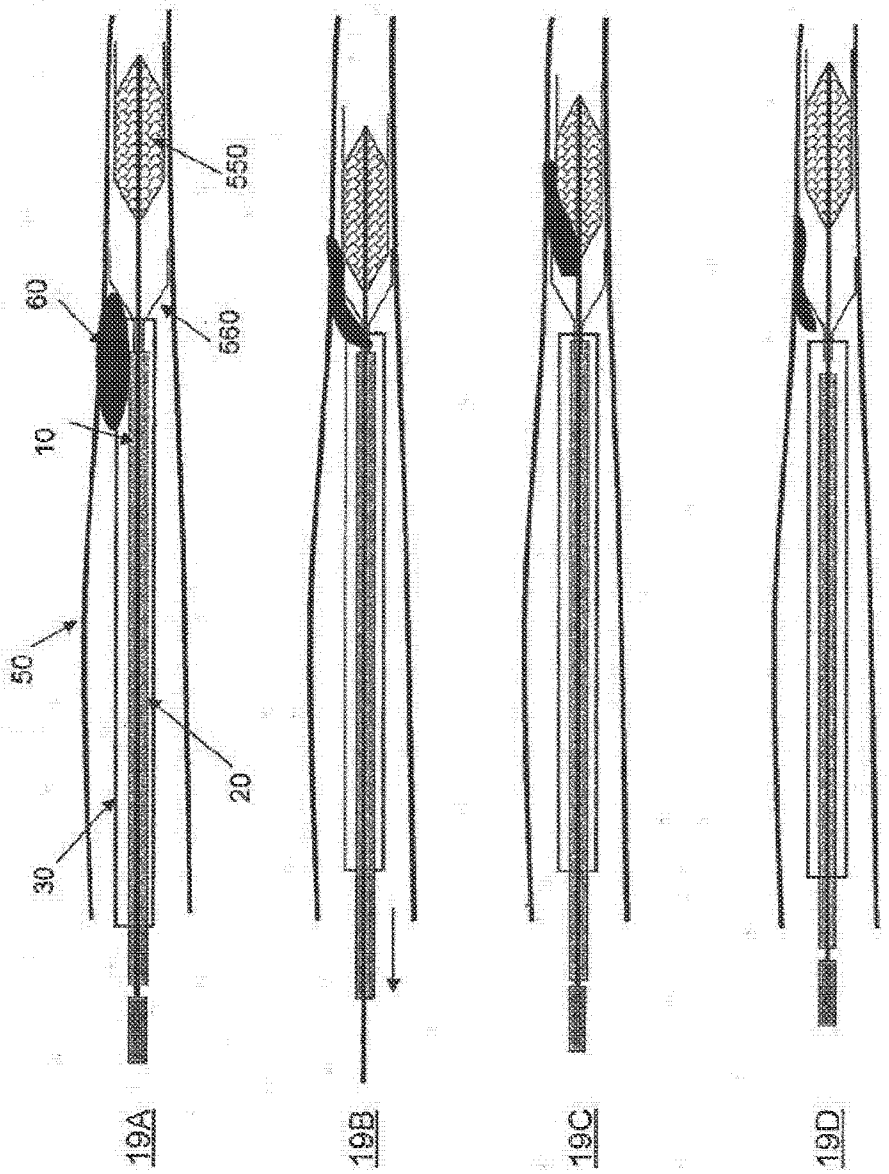


图 19A-D

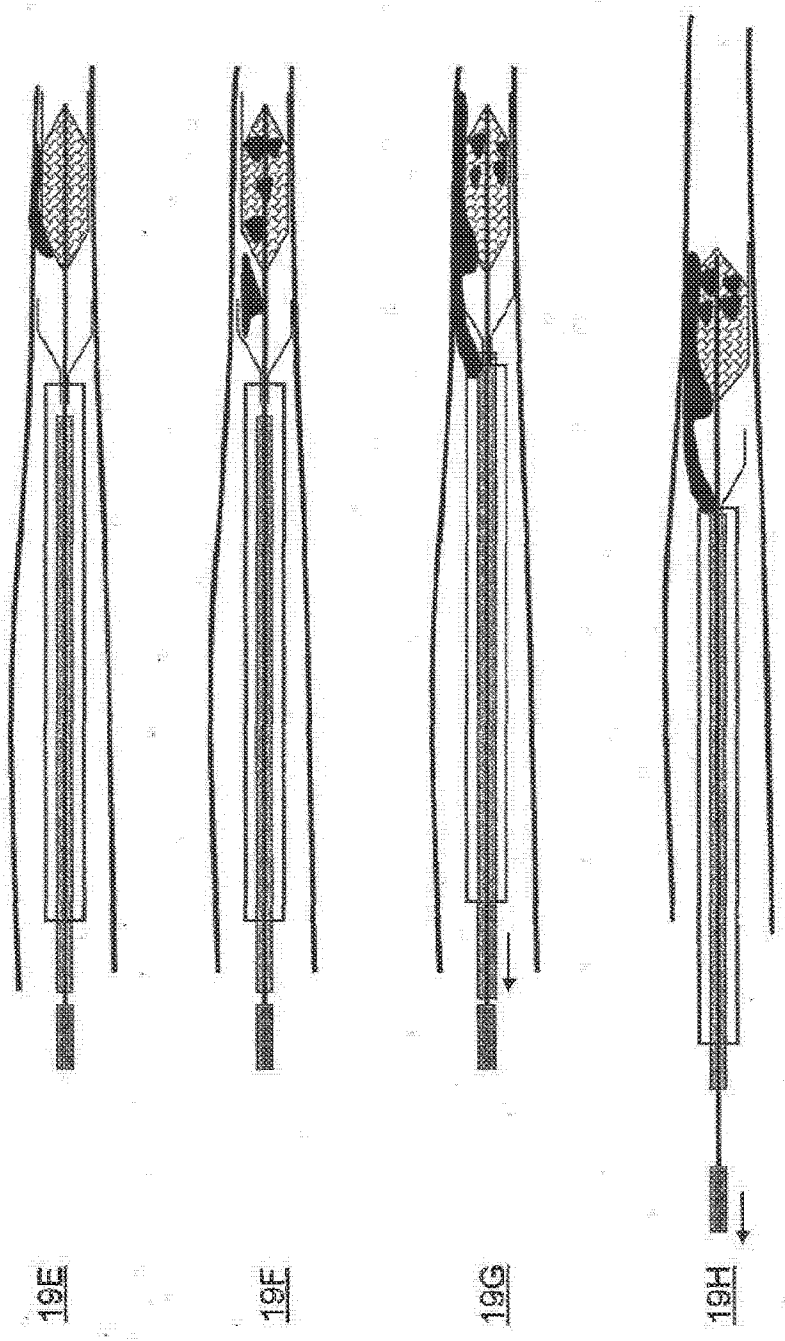


图 19E-H

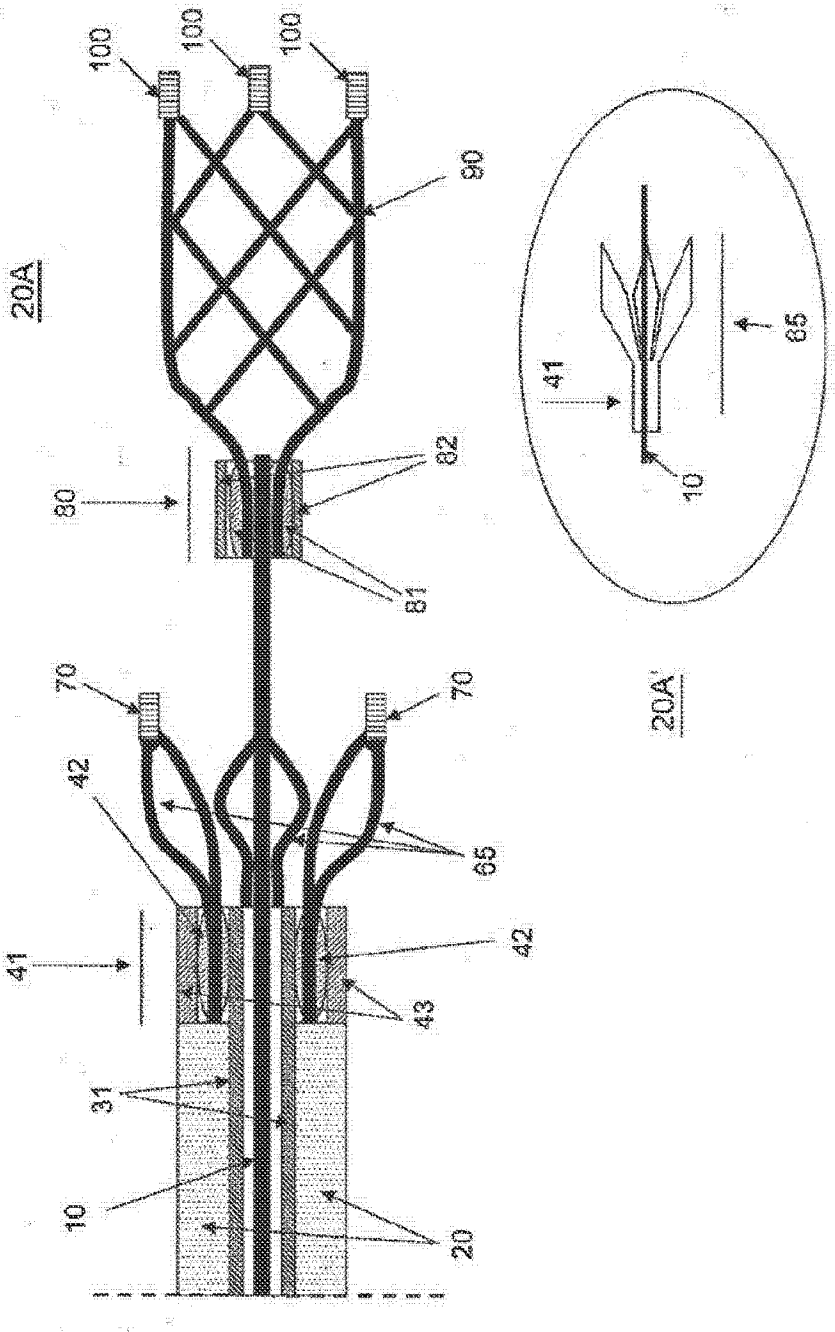


图 20A-A'

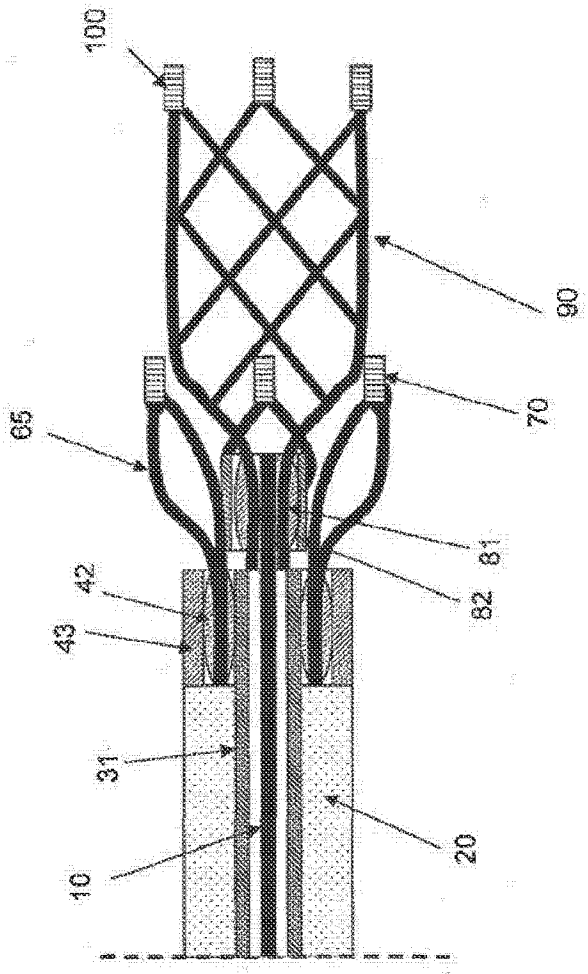


图 20B

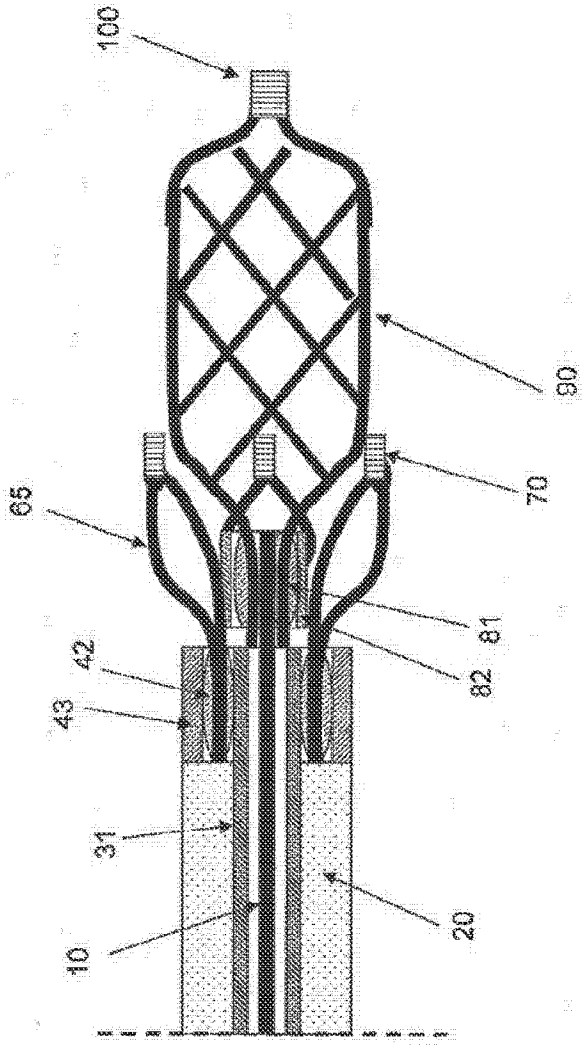


图 20C

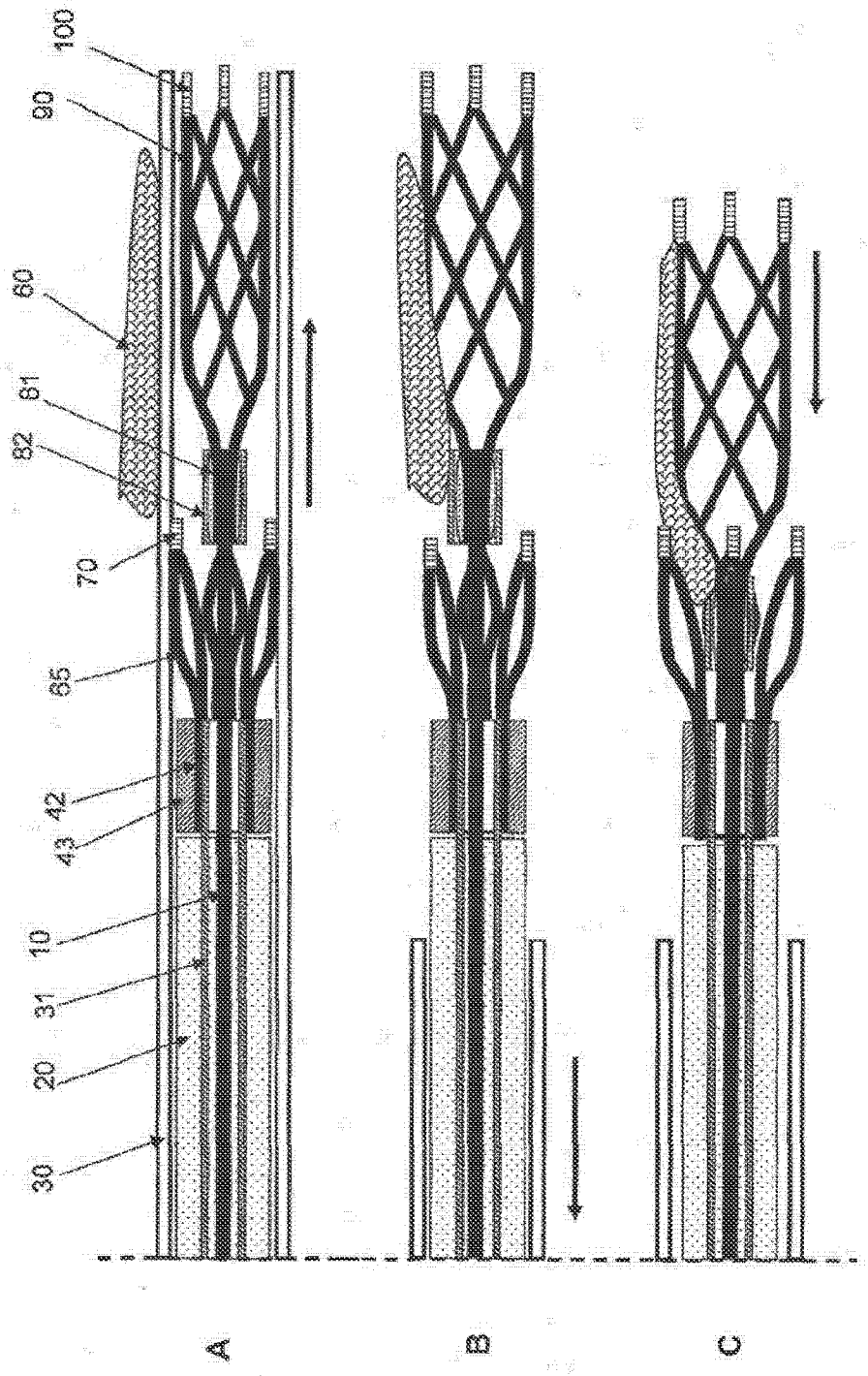


图 21A-C

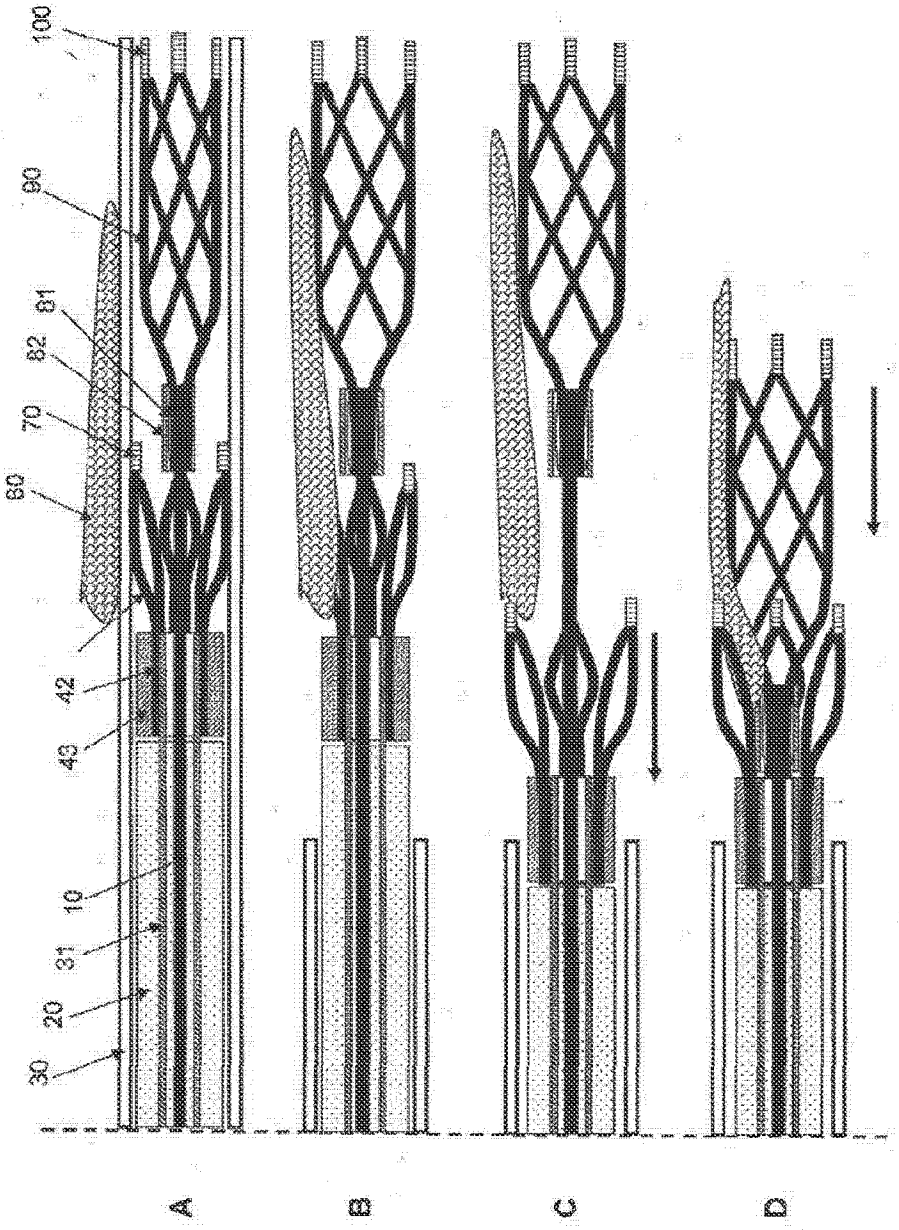


图 22A-D

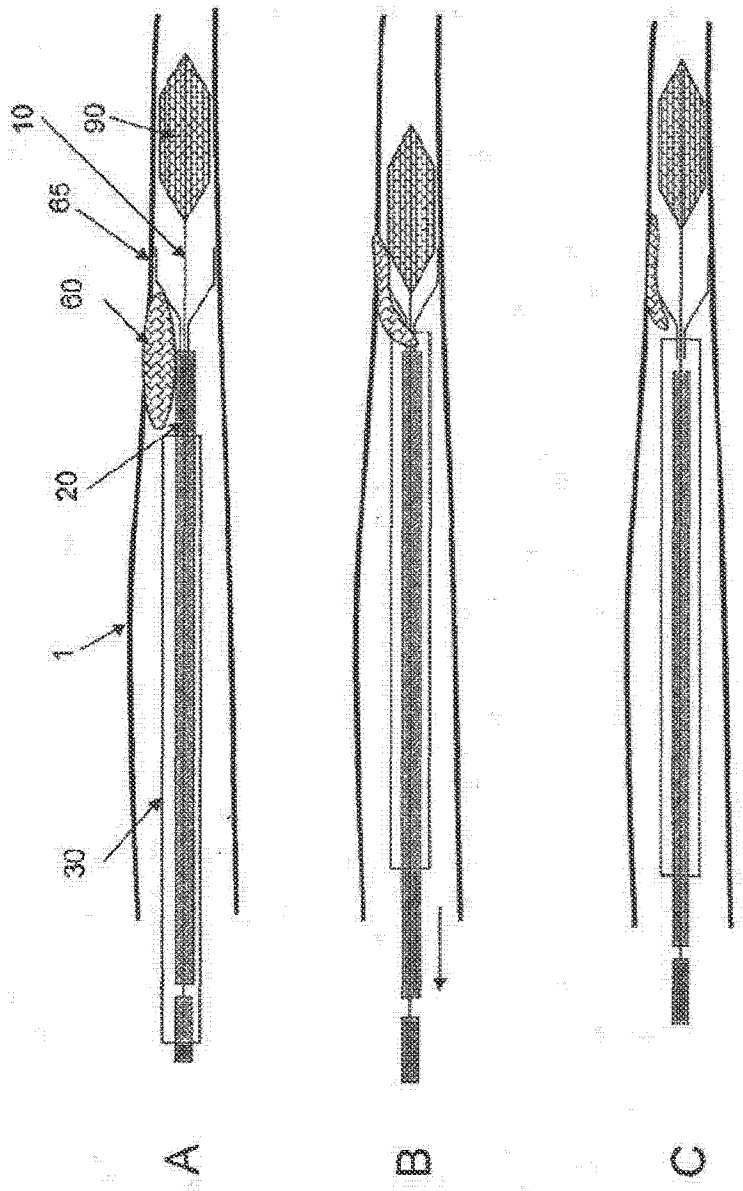


图 23A-C

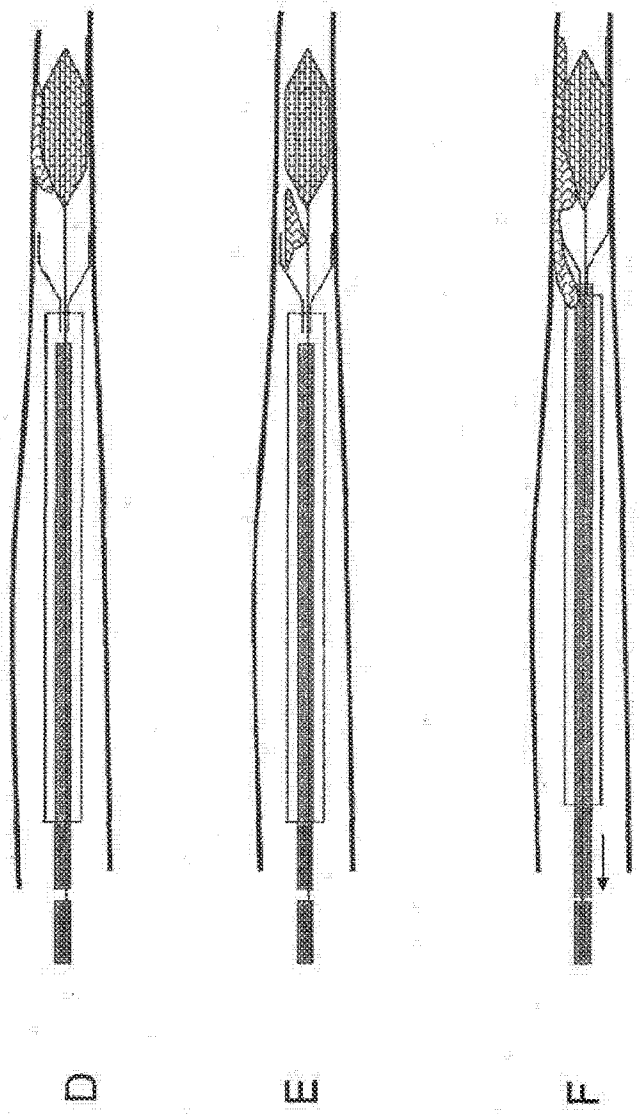


图 23D-F

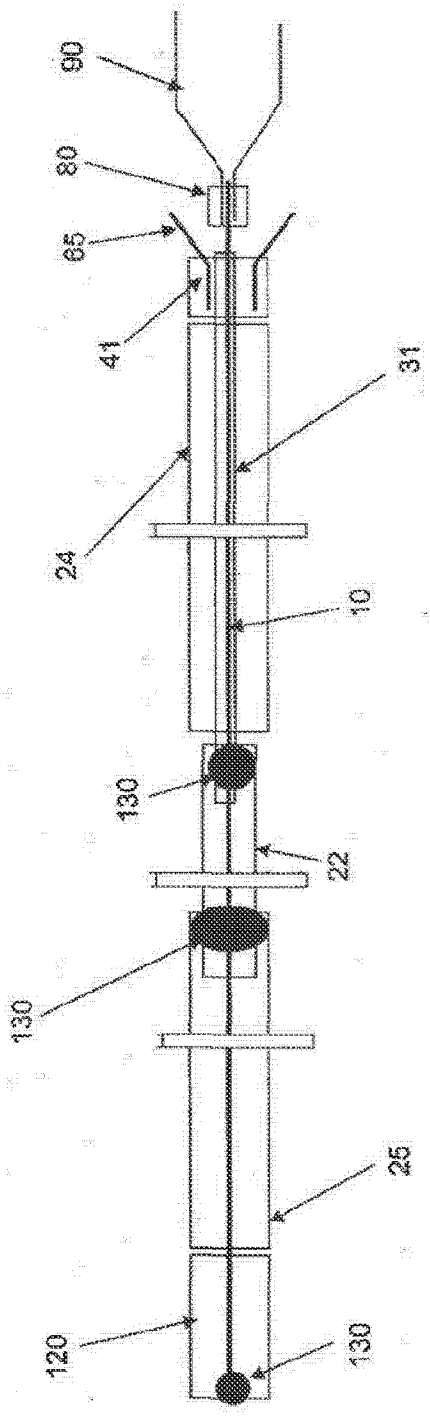


图 24

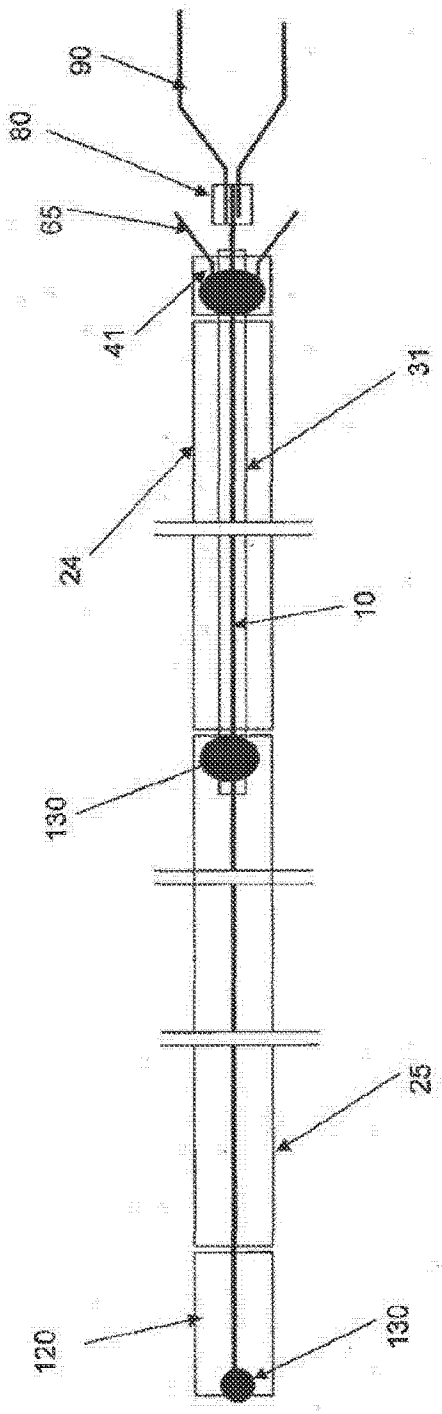


图 25

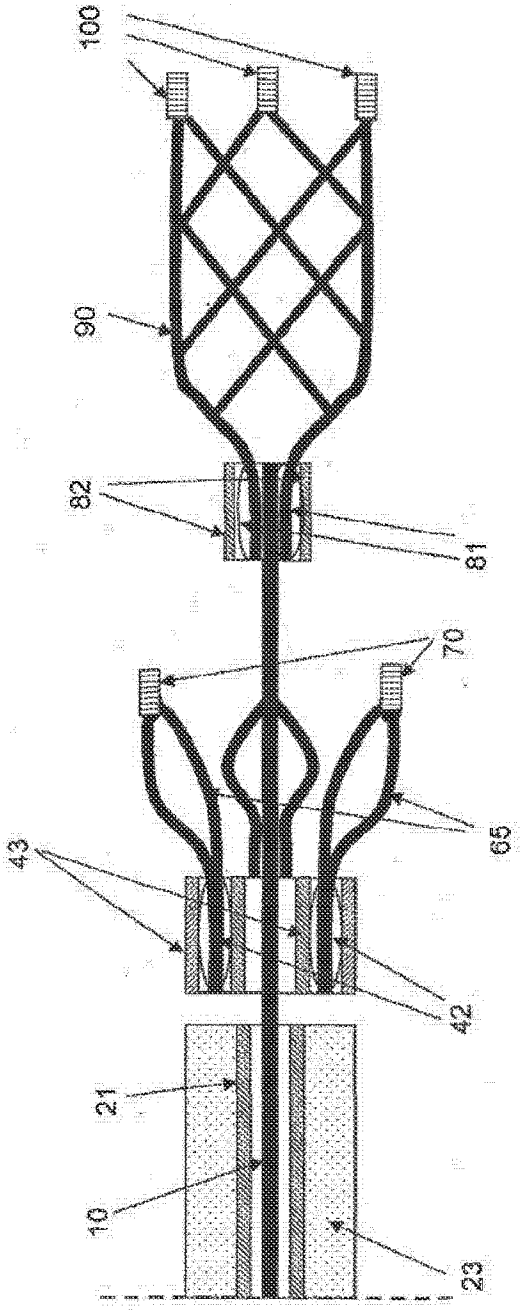


图 26A

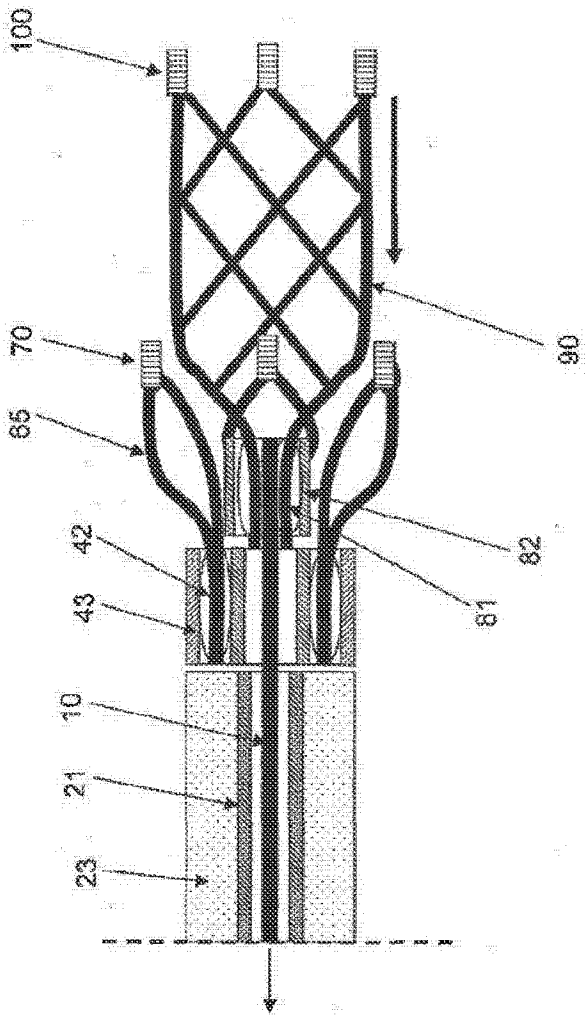


图 26B

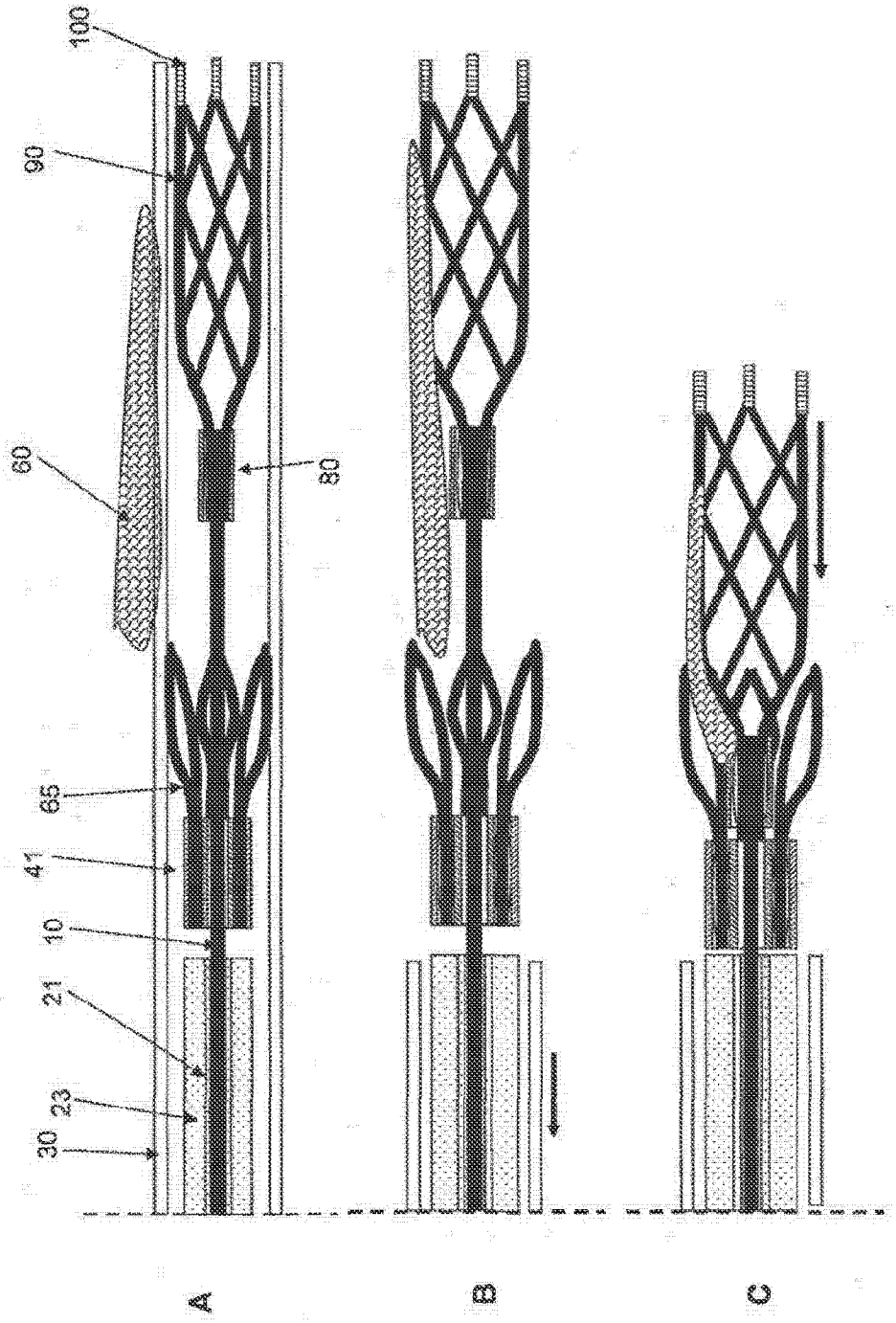


图 27A-C

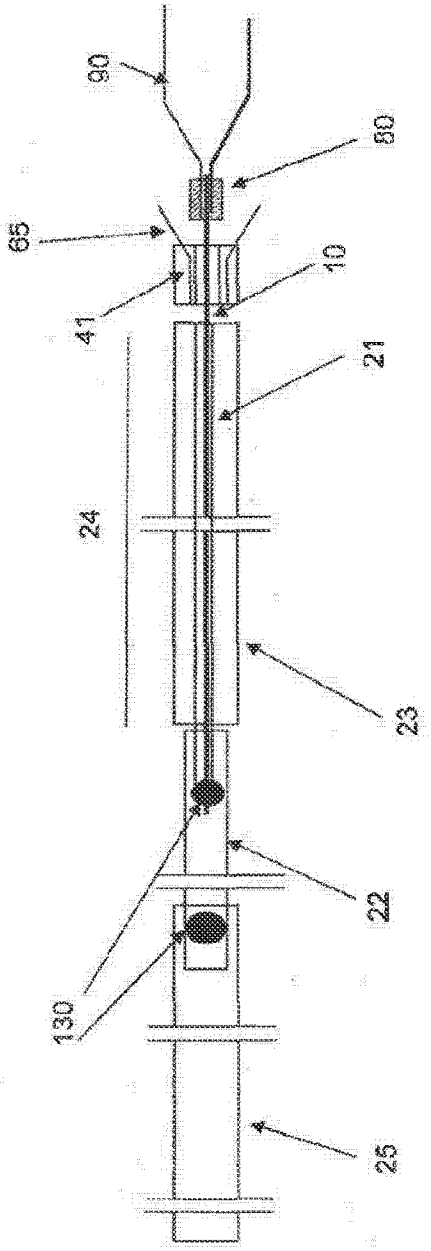


图 28

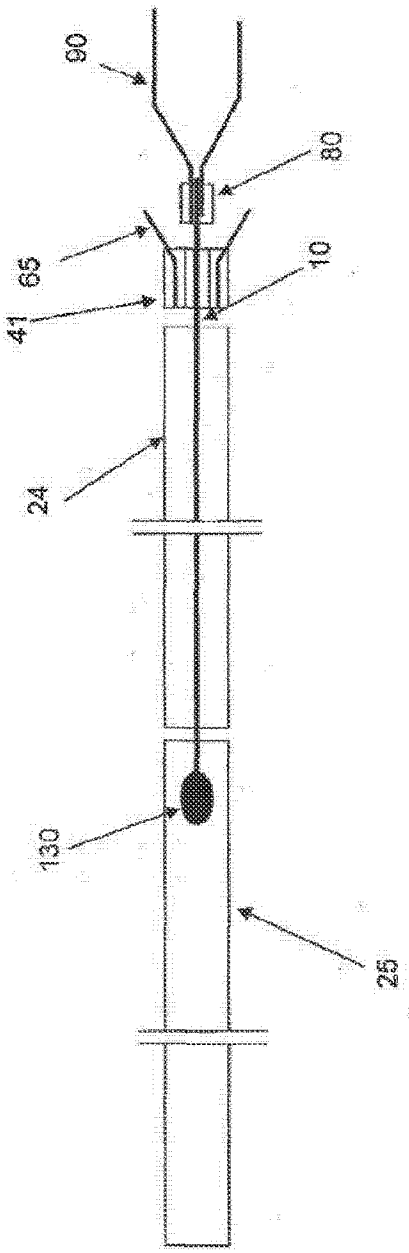


图 29

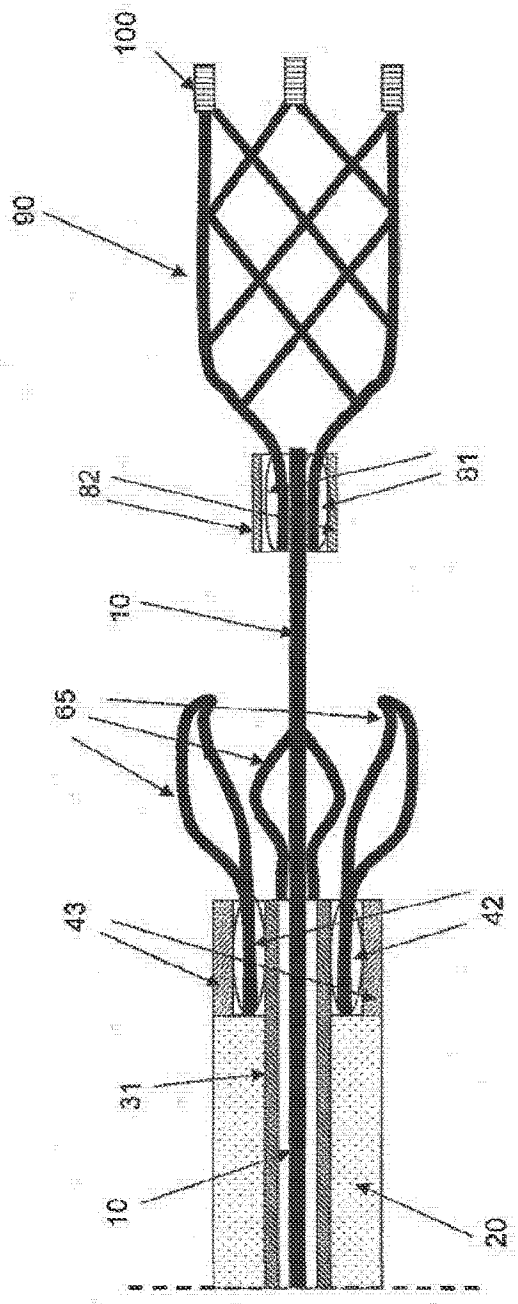


图 30A

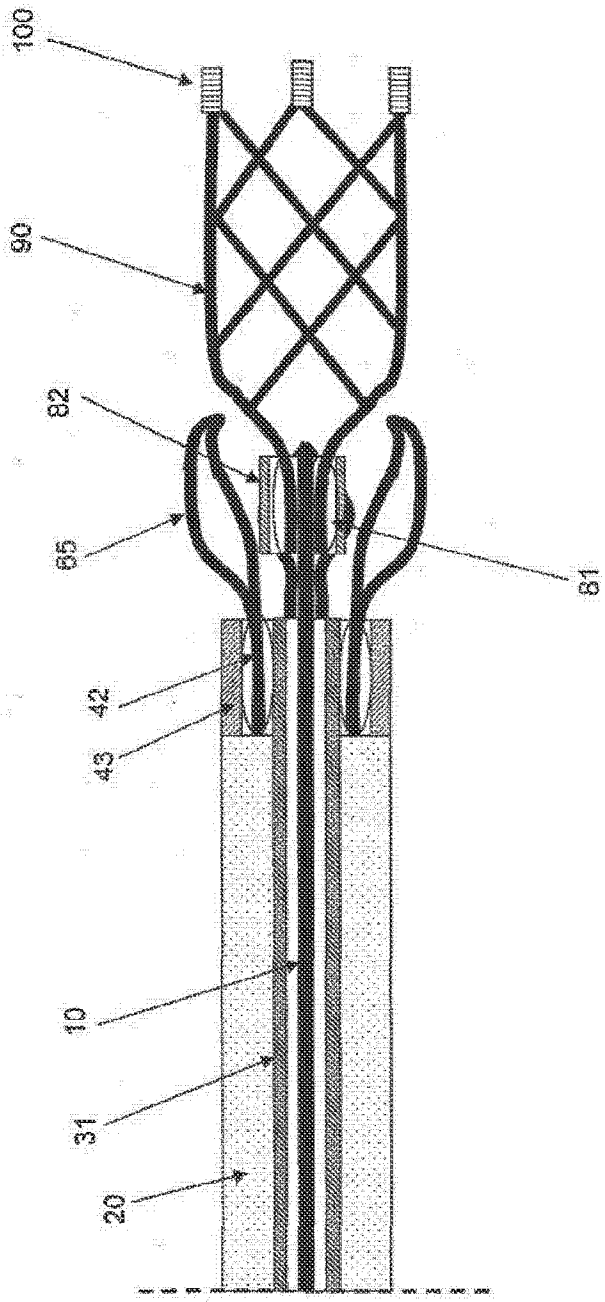


图 30B

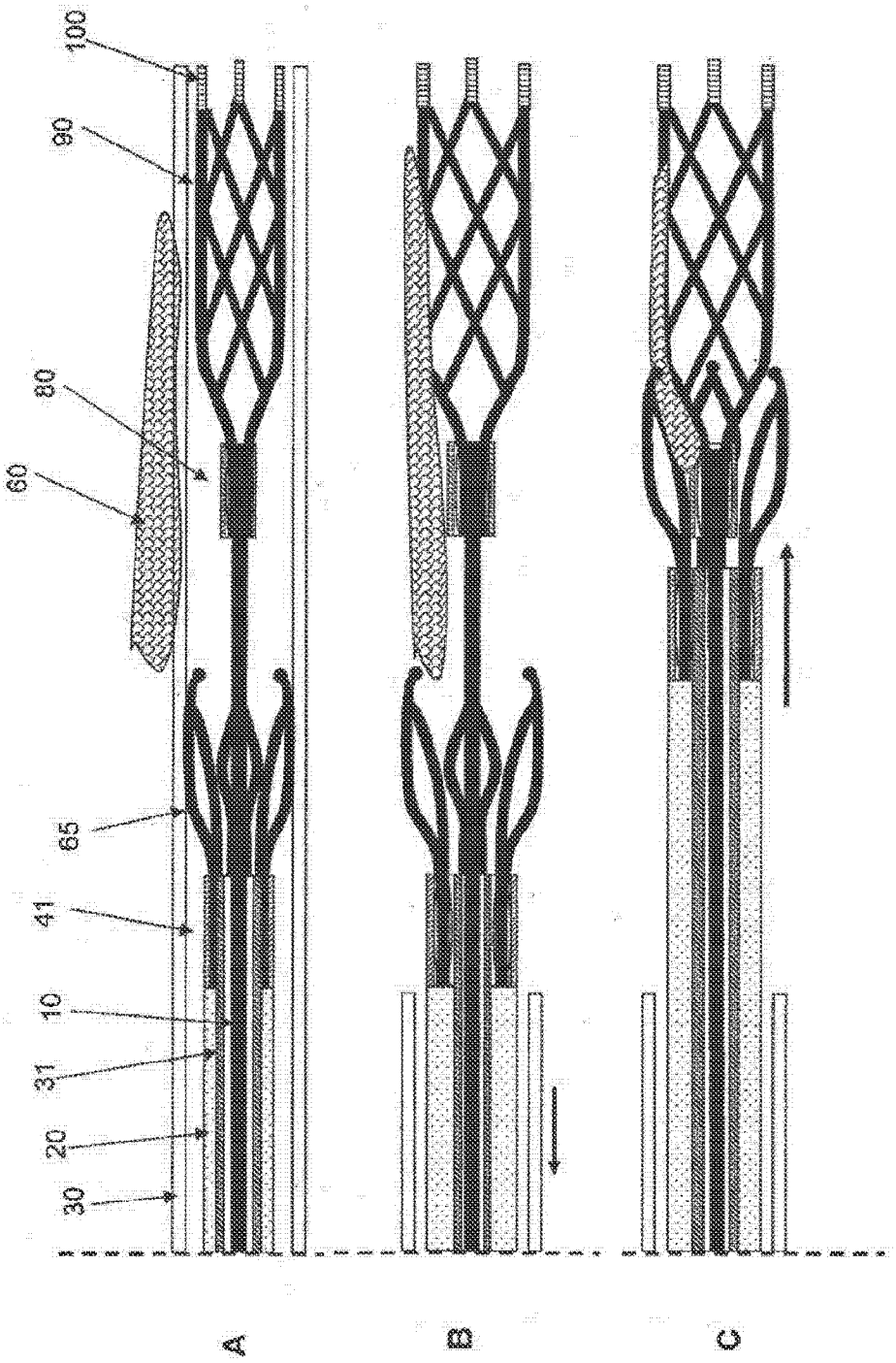


图 31A-C

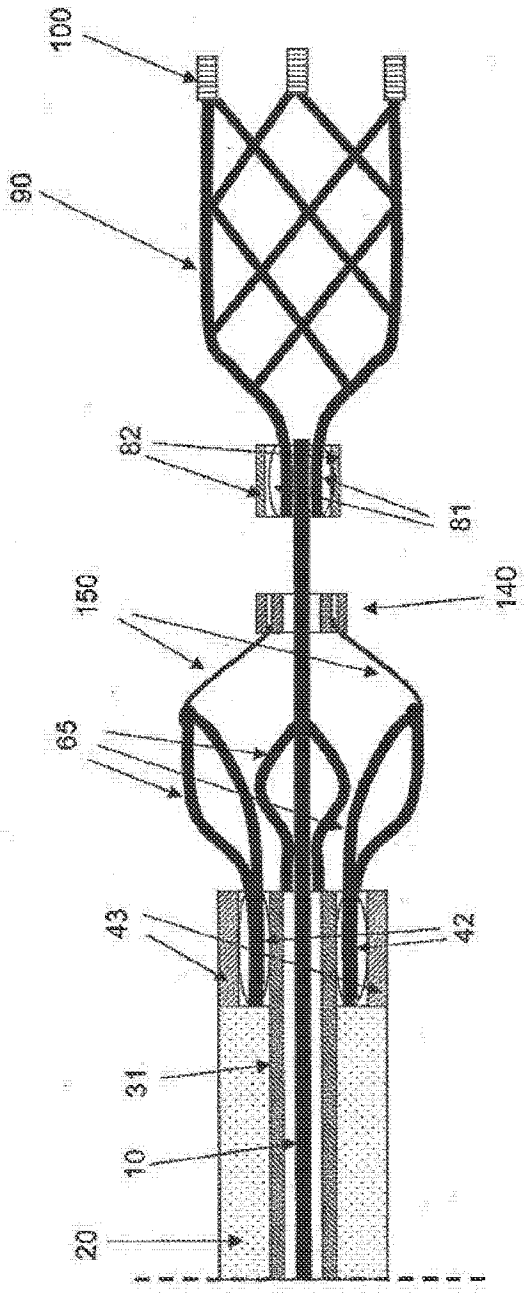


图 32A

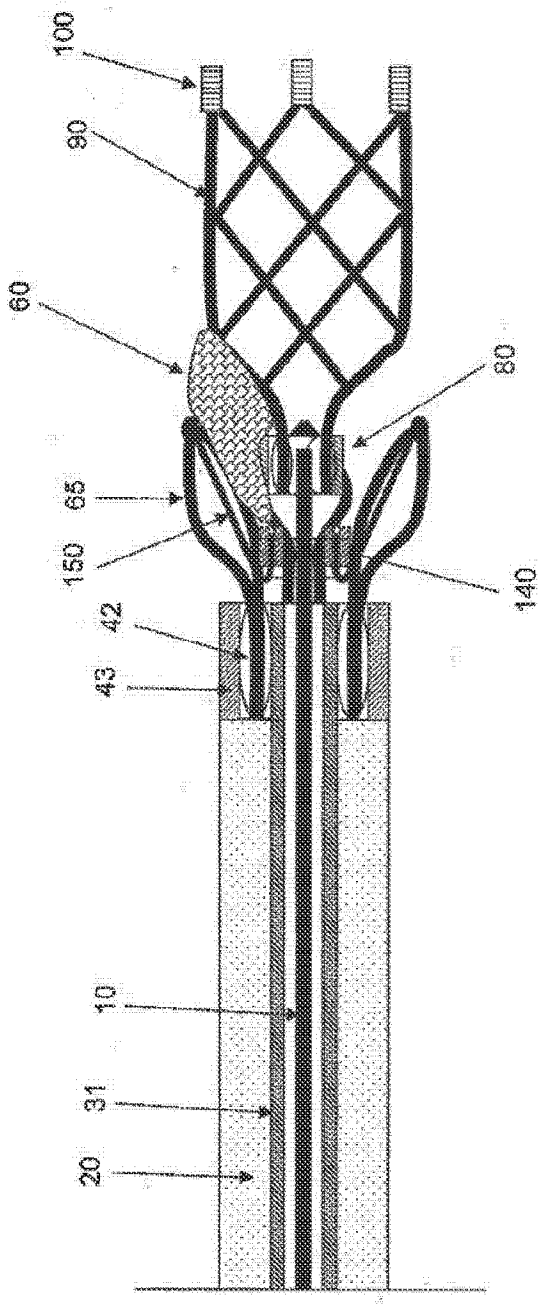


图 32B

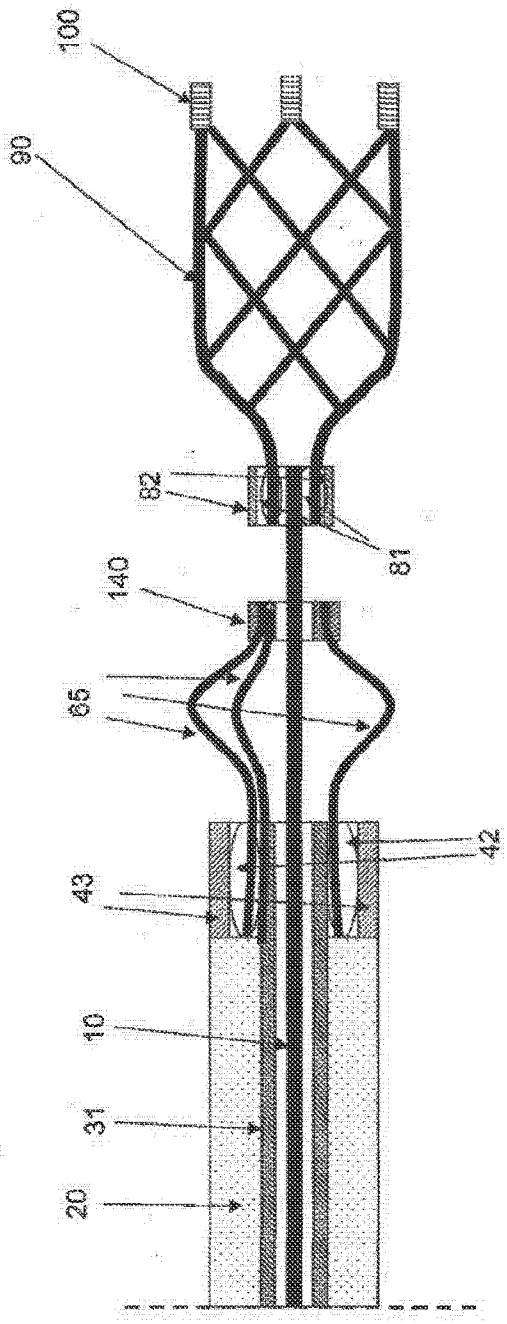


图 33A

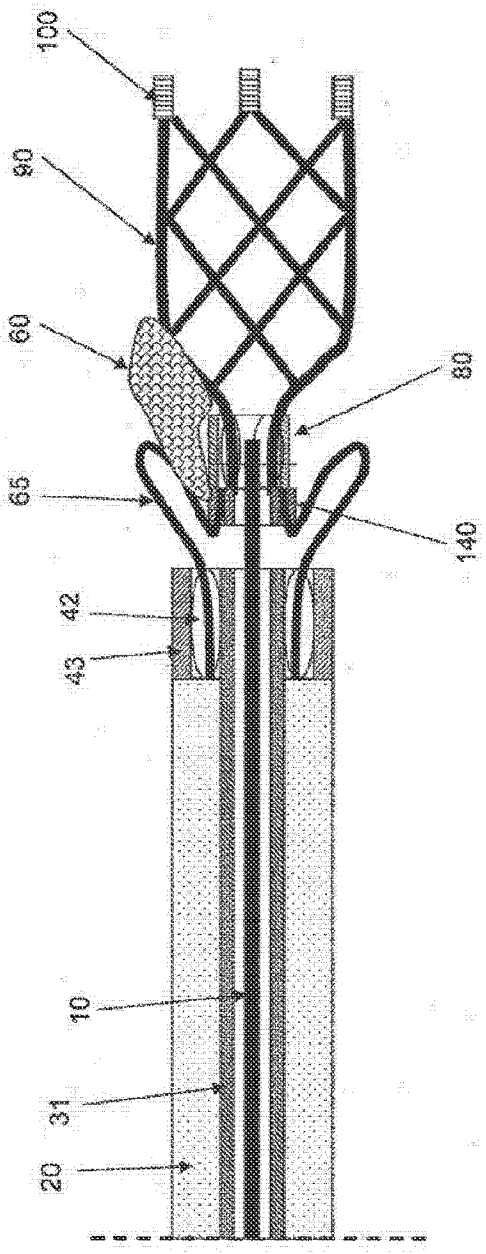


图 33B

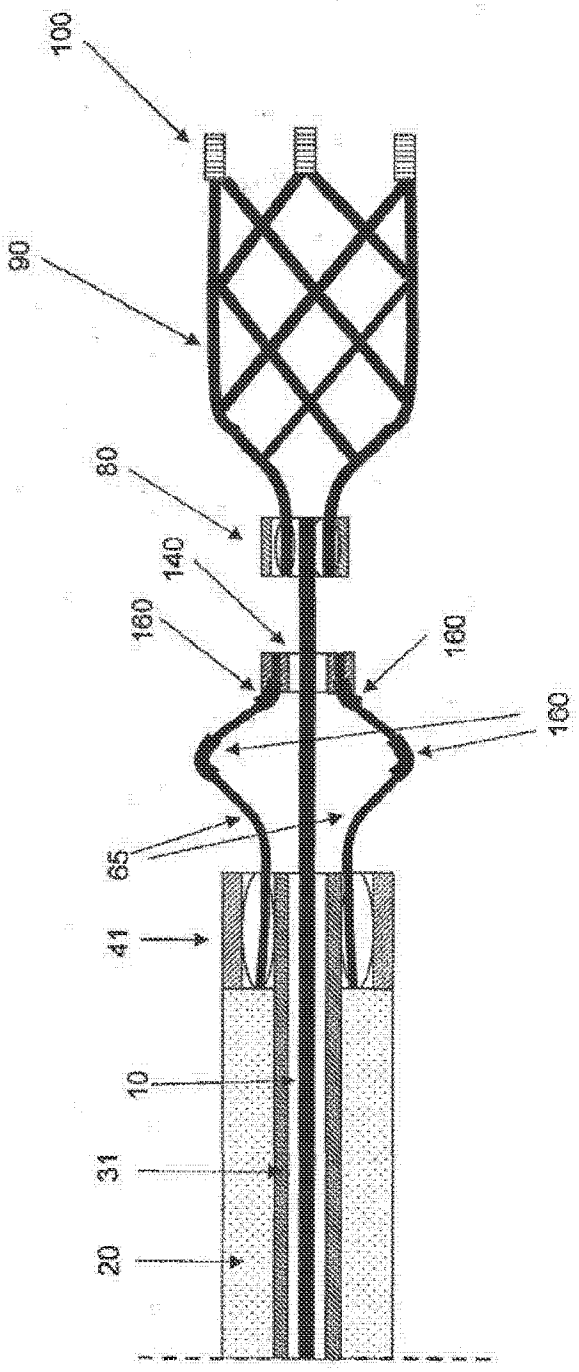


图 34A

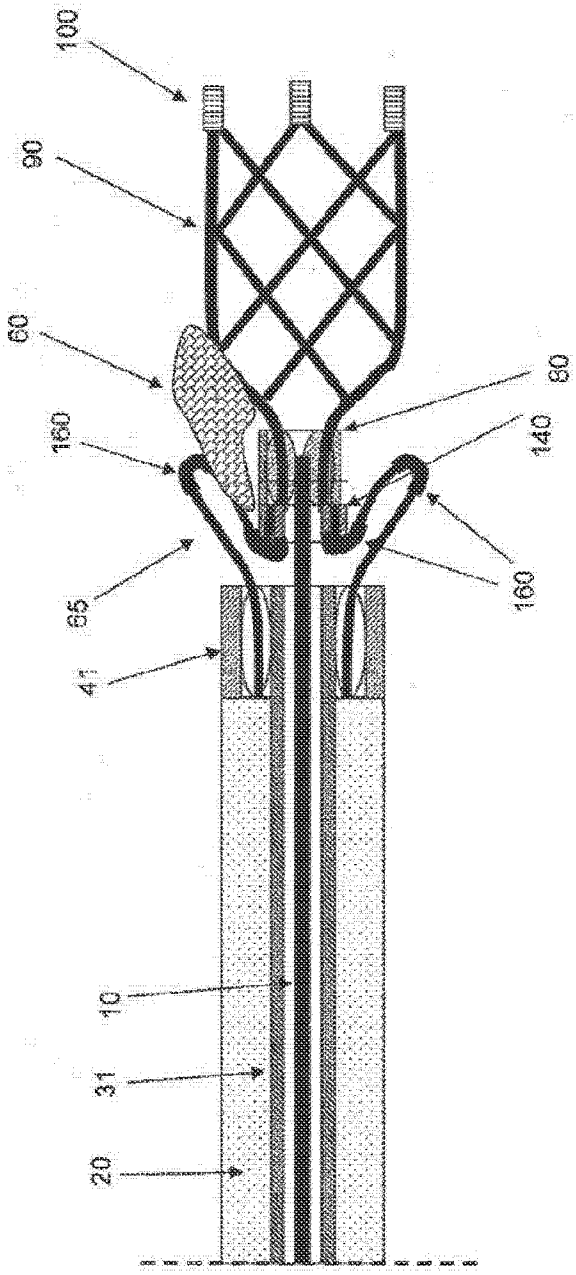


图 34B

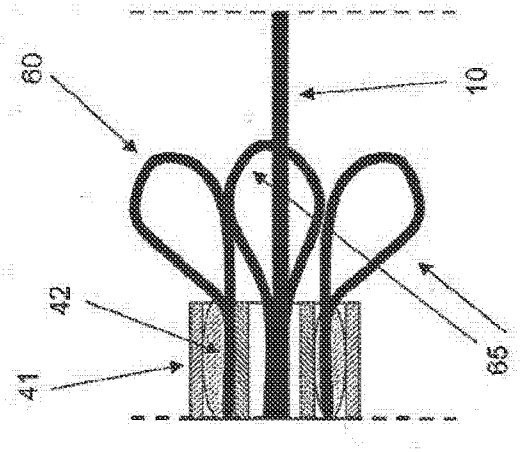


图 35

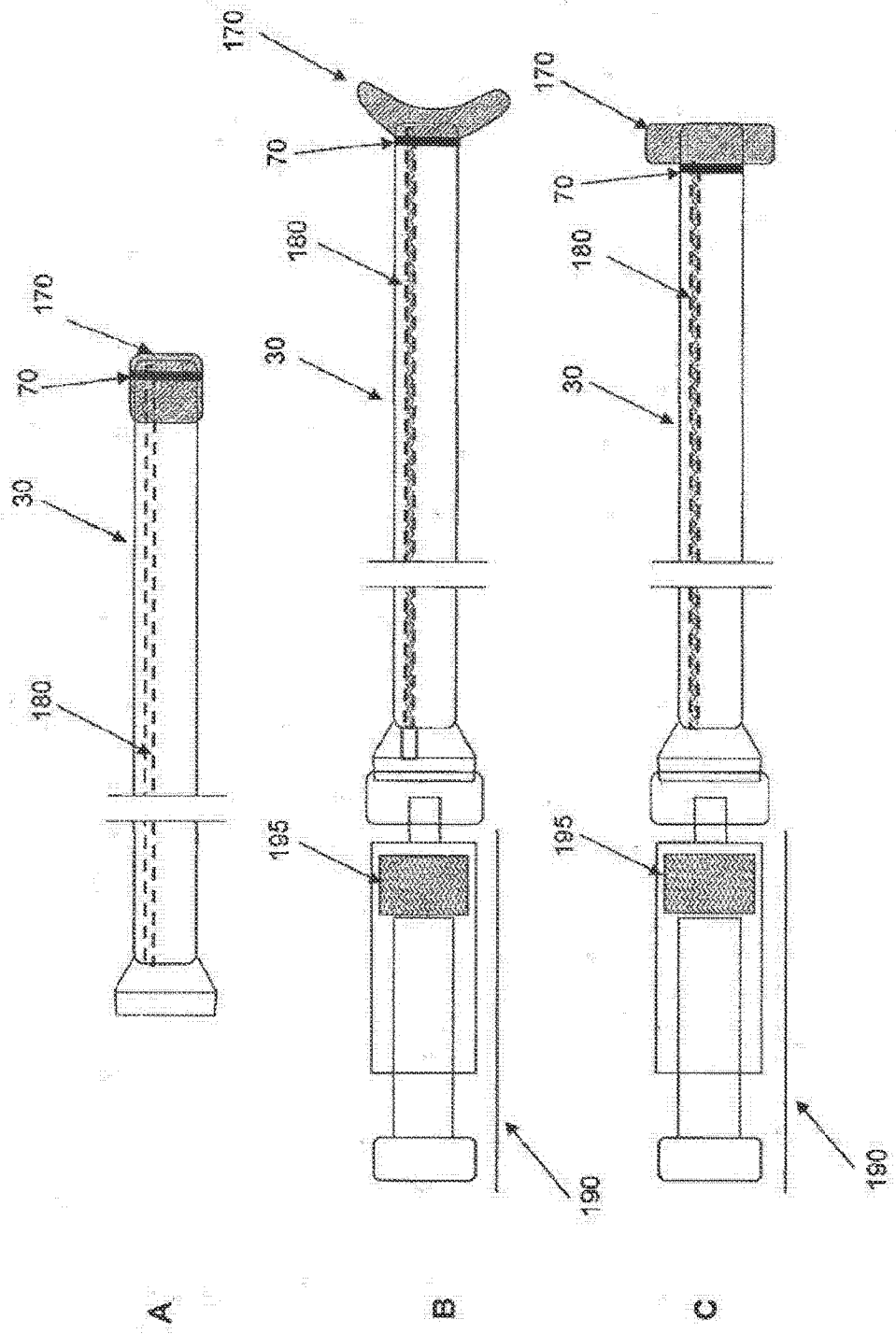


图 36A-C

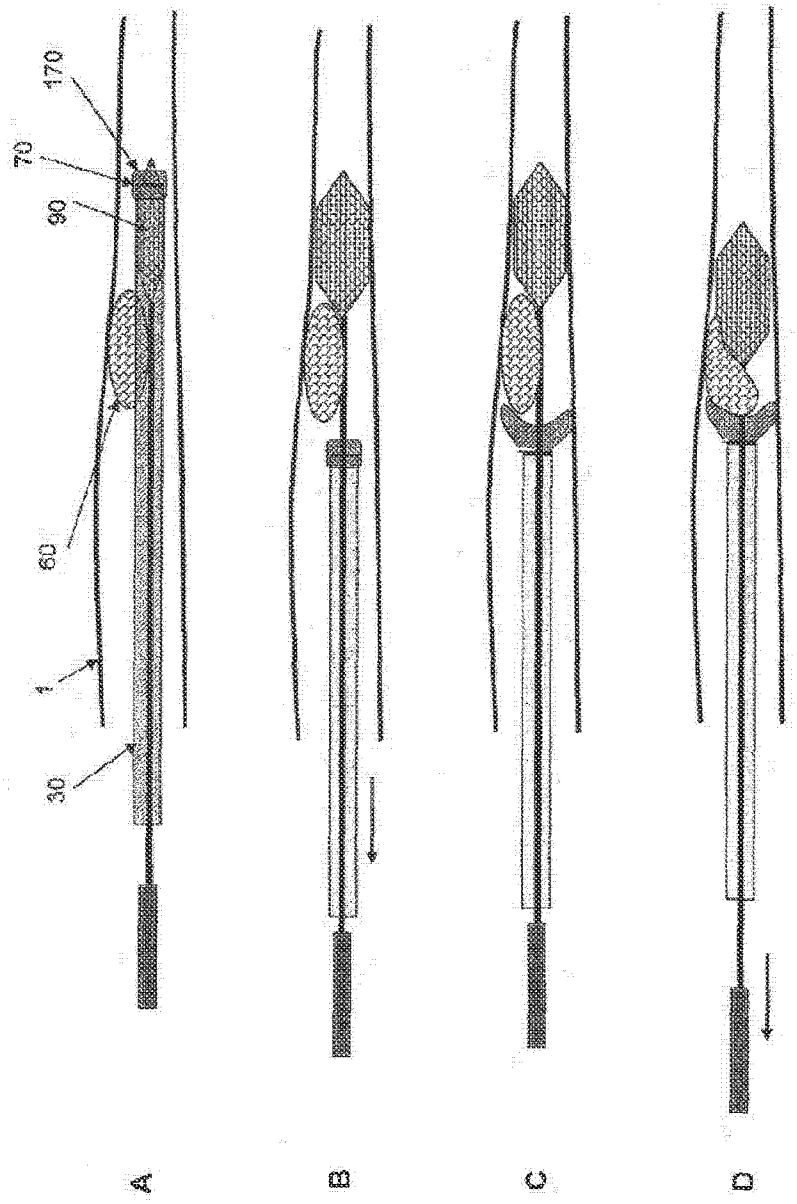


图 37A-D

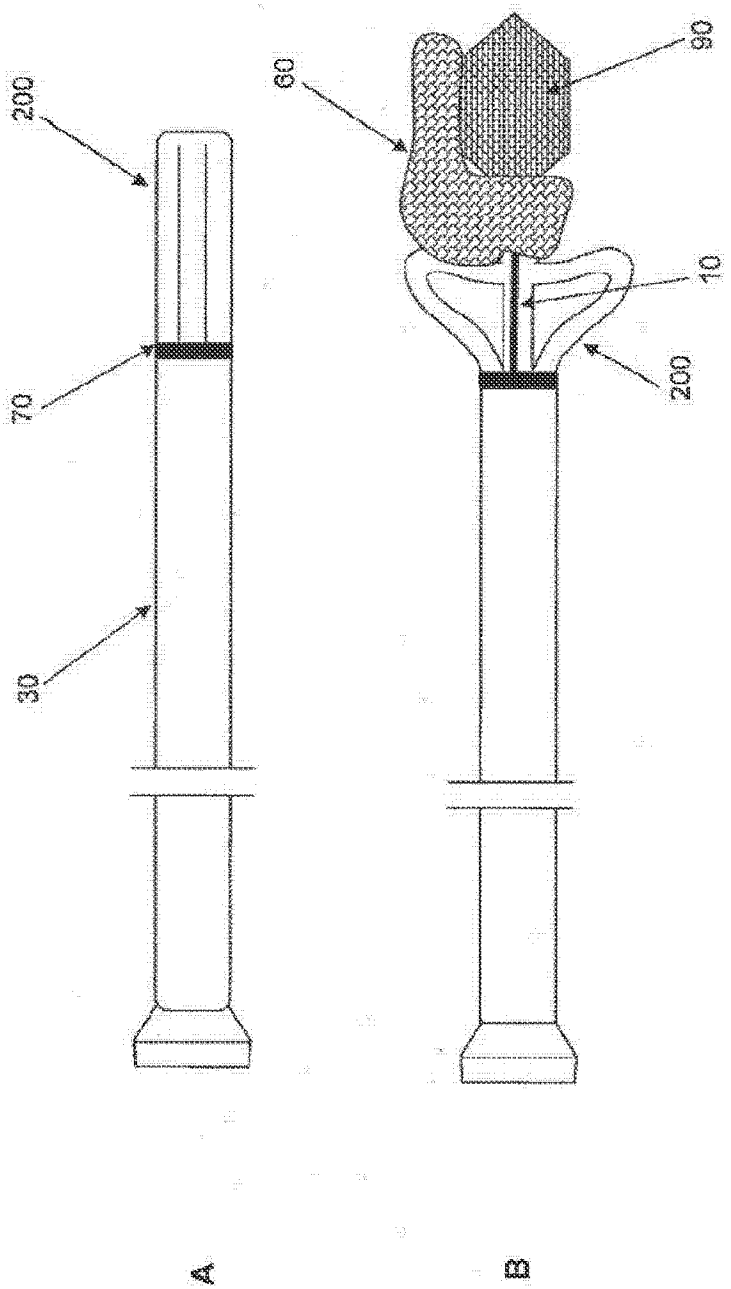


图 38A-B

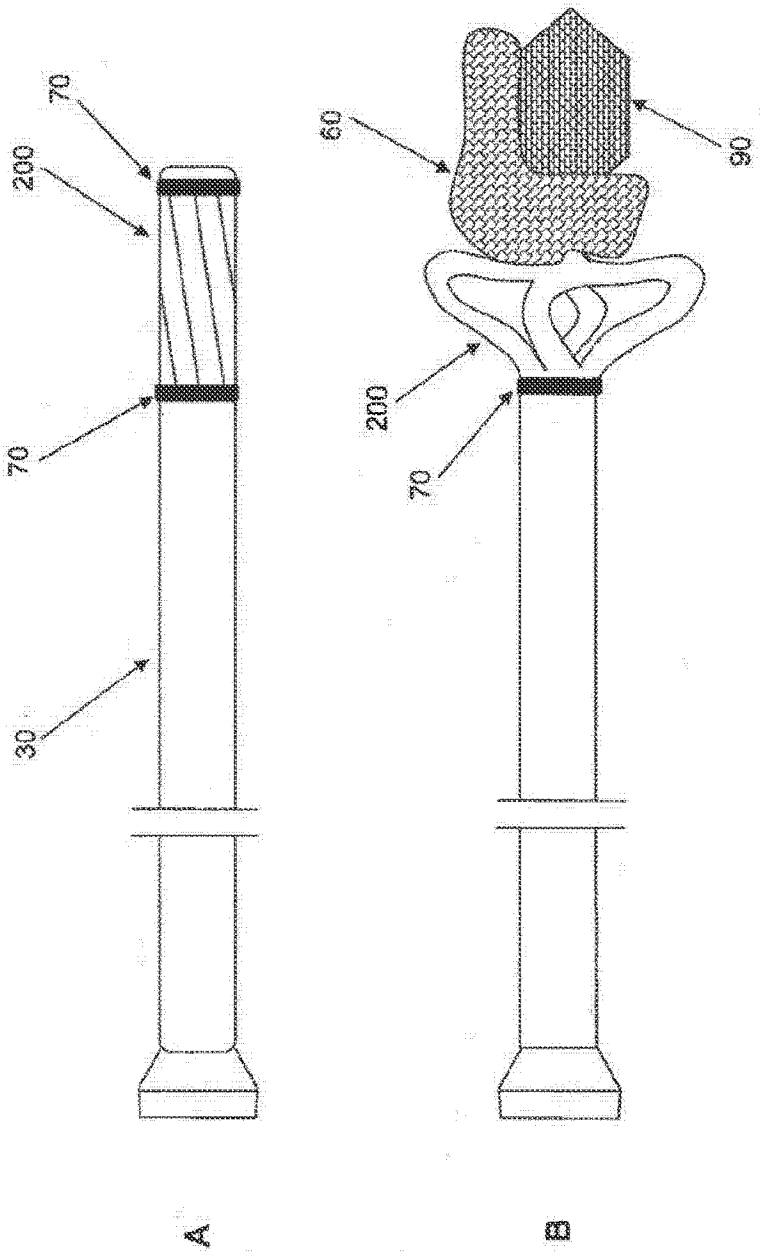


图 39A-B

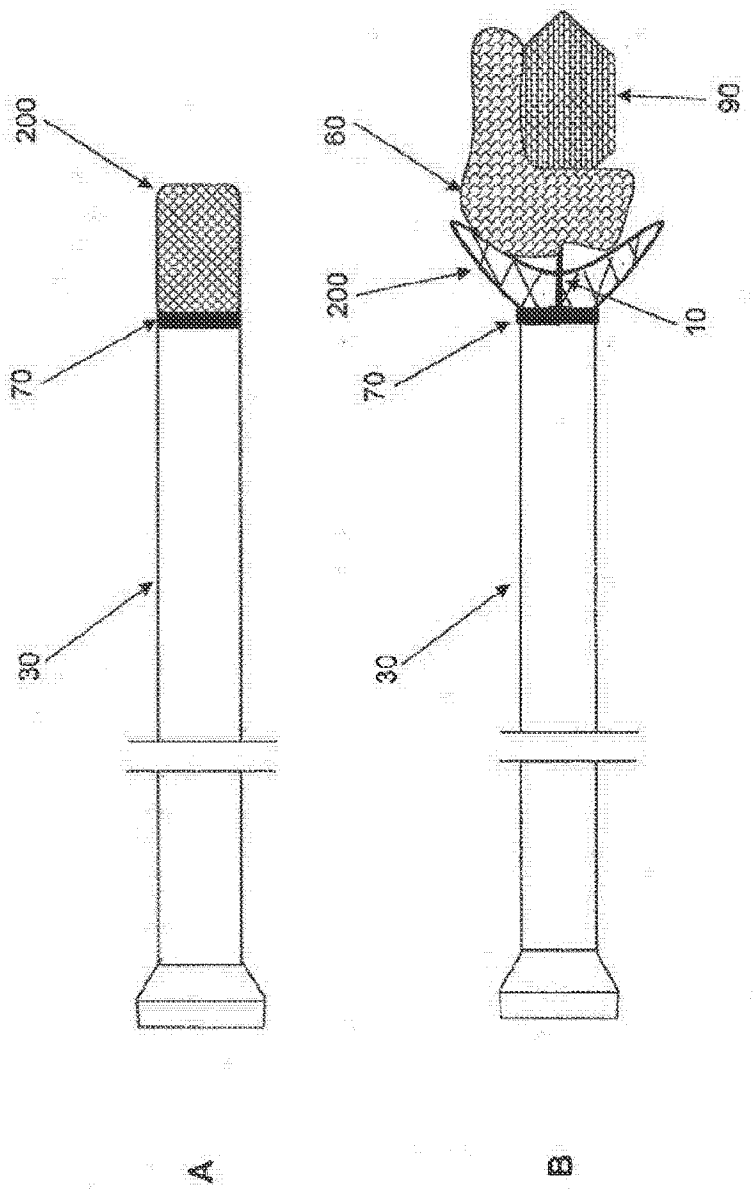


图 40A-B

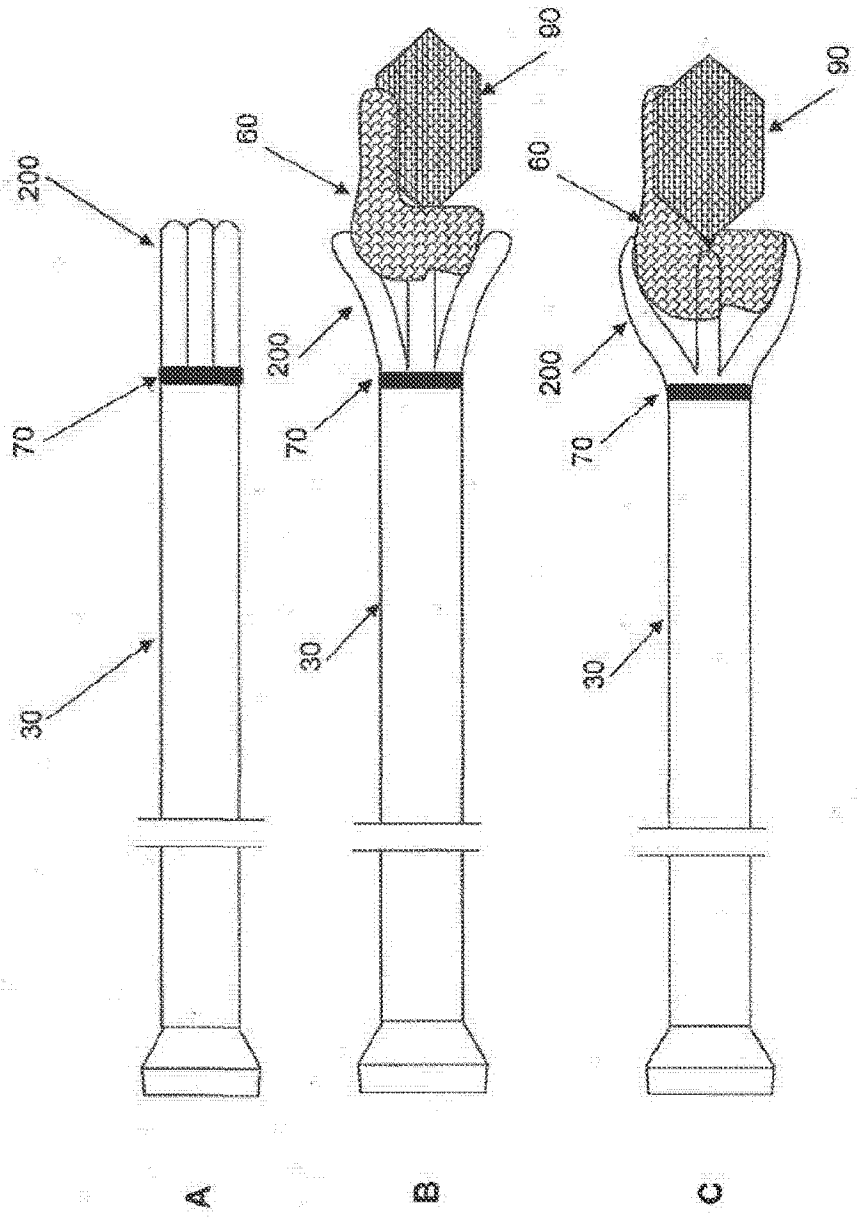


图 41A-C

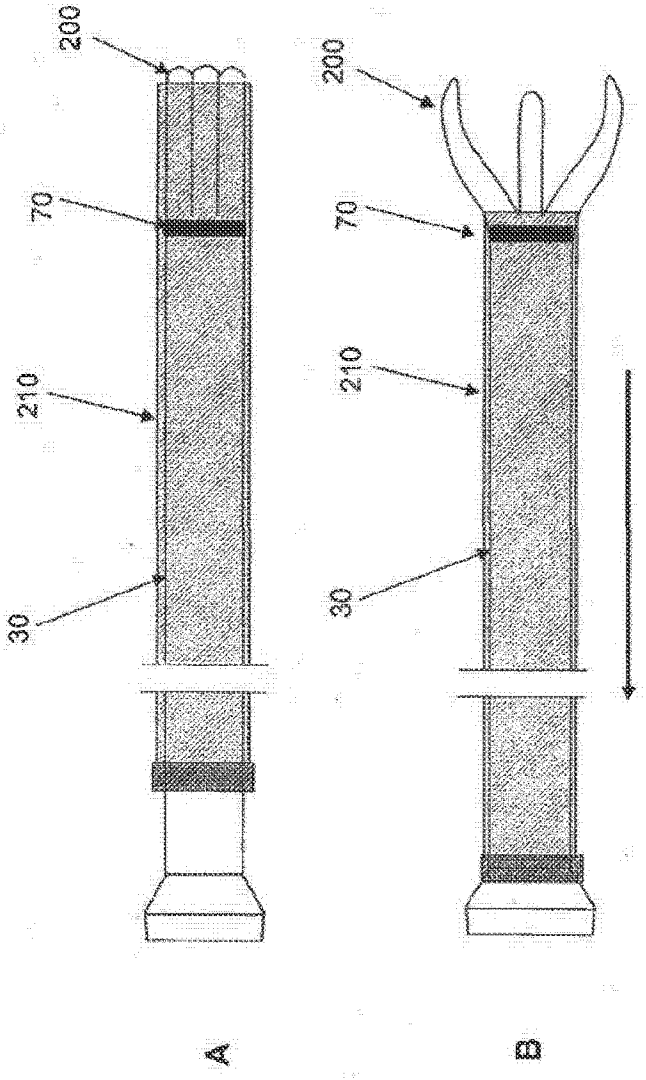


图 42A-B

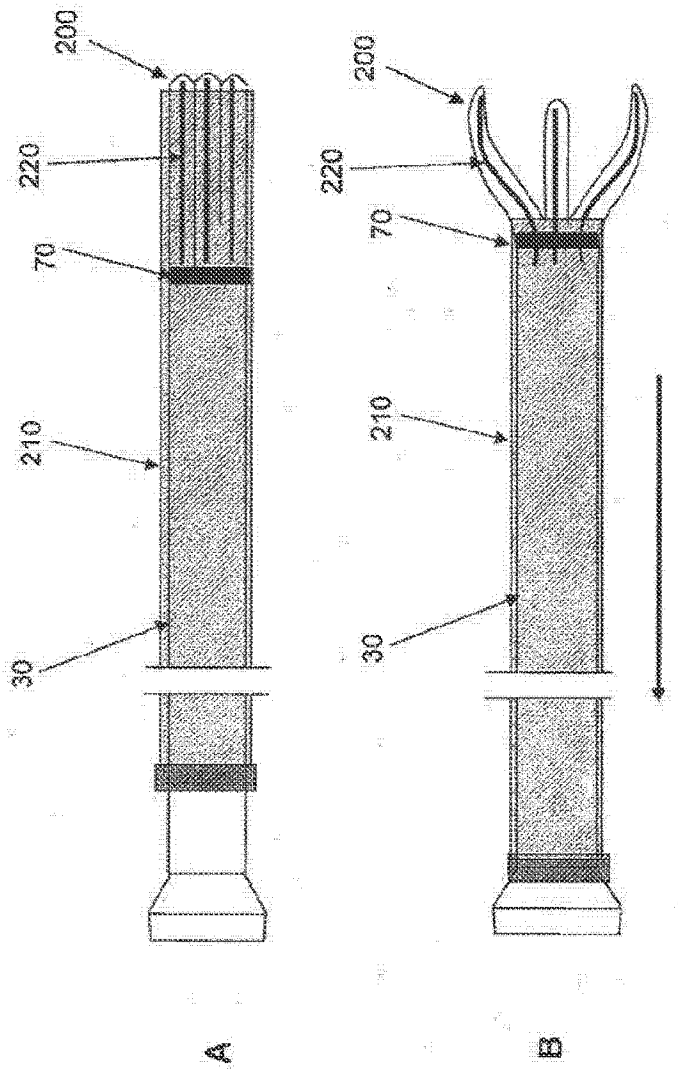


图 43A-B

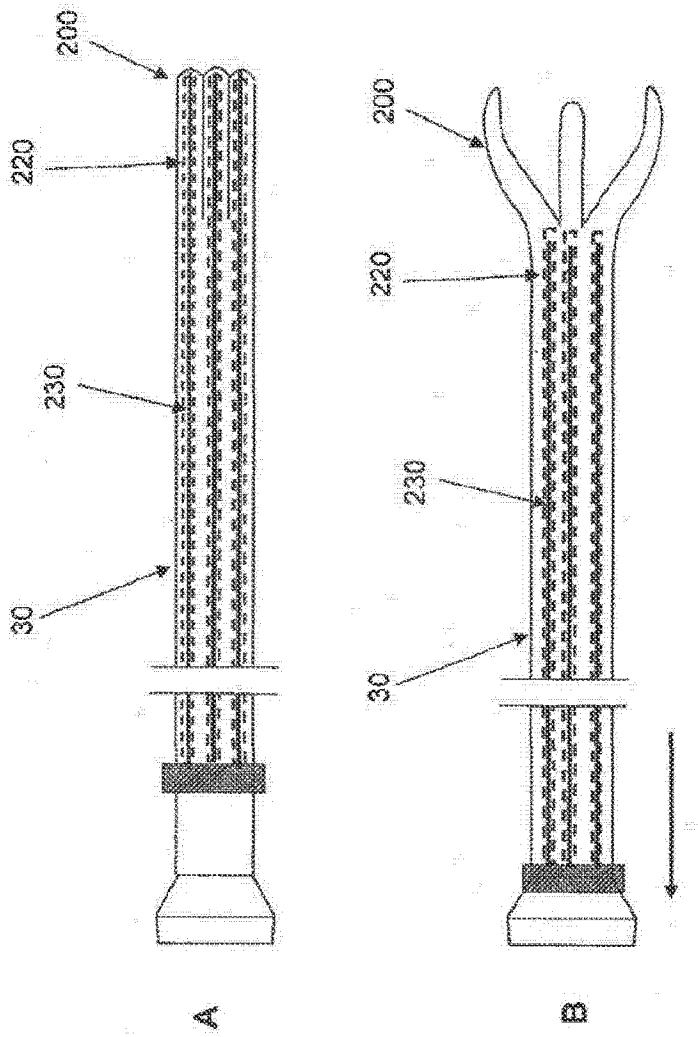


图 44A-B

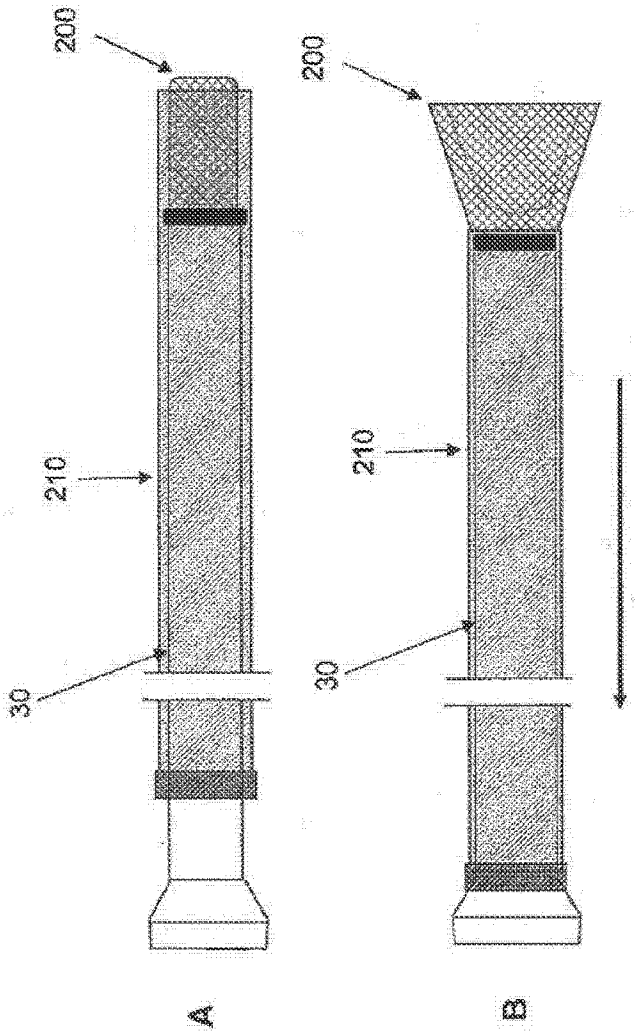


图 45A-B

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 September 2010 (10.09.2010)

PCT

(10) International Publication Number
WO 2010/102307 A1

(51) International Patent Classification:
A61M 29/00 (2006.01)

(21) International Application Number:
PCT/US2010/026571

(22) International Filing Date:
8 March 2010 (08.03.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/158,324 6 March 2009 (06.03.2009) US
61/171,419 21 April 2009 (21.04.2009) US

(71) Applicant *(for all designated States except US)*: **LAZARUS EFFECT, INC.** [US/US]; 767 El Solyo Heights Drive, Felton, California 95018 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MARTIN, Brian B.** [US/US]; 767 El Solyo Heights Drive, Felton, California 95018 (US).

(74) Agents: **BAGADE, Sanjay S.** et al.; Levine Bagade Han LLP, 2400 Geng Road, Suite 120, Palo Alto, California 94303 (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, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, 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, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, 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**: RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

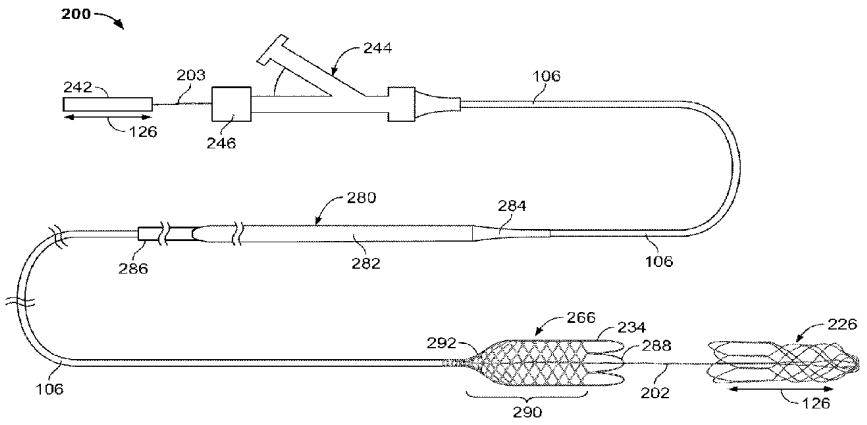


FIG. 15

(57) **Abstract**: The devices and methods described herein relate to improved structures for removing obstructions from body lumens. Such devices have applicability in through-out the body, including clearing of blockages within the vasculature, by recanalizing or removing the obstruction within the body lumen.

WO 2010/102307 A1

RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

RELATED APPLICATIONS

[0001] This application is a non-provisional of U.S. Provisional application No. 61/158,324 filed March 6, 2009 and a non-provisional of Provisional application No. 61/171,419 filed April 21, 2009, the contents of which are incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The devices described herein are intended to retrieve obstructions from the body. In a first variation, the devices are constructed in wire form where the wires diverge from a main bundle to form a variety of shapes that form a composite device. The benefit of such a diverging wire construction is that the composite complex device can be of a "joint-less" construction. Such devices have applicability through out the body, including clearing of blockages within body lumens, such as the vasculature, by providing a capturing portion that can envelop the obstruction to address the frictional resistance between the obstruction and body lumen prior to attempting to translate and/or mobilize the obstruction within the body lumen. In addition, the devices described below include features that prevent unwanted and premature mobilization of the obstruction when removing the obstruction through tortuous anatomy.

BACKGROUND OF THE INVENTION

[0003] Many medical device applications require advancement of device in a reduced profile to a remote site within the body, where on reaching a target site the device assumes or is deployed into a relatively larger profile. Applications in the cerebral vasculature are one such example of medical procedures where a catheter advances from a remote part of the body (typically a leg) through the vasculature and into the cerebral region of the vasculature to deploy a device. Accordingly, the deployed devices must be capable of achieving a larger profile while being able to fit within a small catheter or microcatheter. In addition, the degree to which a physician is limited in accessing remote regions of the cerebral vasculature is directly related to the limited ability of the device to constrain into a reduced profile for delivery.

[0004] Treatment of ischemic stroke is one such area where a need remains to deliver a device in a reduced profile and deploy the device to ultimately remove a blockage in an artery leading to the brain. Left untreated, the blockage causes a lack of supply of oxygen and nutrients to the brain tissue. The brain relies on its arteries to supply oxygenated blood from the heart and lungs. The blood returning from the brain carries carbon dioxide and cellular waste. Blockages that interfere with this supply eventually cause the brain tissue to stop functioning. If the disruption in supply occurs for a sufficient amount of time, the continued lack of nutrients and oxygen causes irreversible cell death (infarction). Accordingly, immediate medical treatment of an ischemic stroke is critical for the recovery of a patient.

[0005] Naturally, areas outside of ischemic stroke applications can also benefit from improved devices. Such improved devices can assume a profile for ultimate delivery to remote regions of the body and can remove obstructions. There also remains a need for devices and systems that can safely remove the obstruction from the body once they are secured within the device at the target site. Furthermore, there remains a need for such devices that are able to safely removed once deployed distally to the obstructions in the even that the obstructions is unable to be retrieved.

[0006] Furthermore, the techniques for treating strokes described herein can be combined with stenting as well as the delivery of clot dissolving substances.

[0007] The use of stents to treat ischemic stroke is becoming more common. Typically, a physician places an unexpanded stent across a clot and then expands the stent to compress the clot and partially open the vessel. Once the vessel is at least partially open, clot dissolving fluids, such as t-PA or urokinase, can be deployed through a microcathter to further dissolve the clot. However, these fluids generally take a long time to dissolve clot (sometimes up to several hours). Thus, the use of these fluids has not been terribly effective at dissolving clot in vessels where a complete blockage occurs. The use of a stent allows immediate flow to the vessel, the fluid can then be administered over several hours to dissolve the clot. Once the clot dissolves, the stent can either be left in place (i.e., a permanent stent), or removed (i.e., a temporary stent).

[0008] However, once blood flow is restored, a portion of the clot dissolving substance is dispersed downstream of the clot via blood flow. This minimizes the contact time and amount between the fluid and the clot thereby decreasing the efficiency of the stent and fluid treatment.

[0009] The methods, devices and systems, address the problems described above.

SUMMARY OF THE INVENTION

[0010] The examples discussed herein show the inventive device in a form that is suitable to retrieve obstructions or clots within the vasculature. The term obstructions may include blood clot, plaque, cholesterol, thrombus, naturally occurring foreign bodies (i.e., a part of the body that is lodged within the lumen), a non-naturally occurring foreign body (i.e., a portion of a medical device or other non-naturally occurring substance lodged within the lumen.) However, the devices are not limited to such applications and can apply to any number of medical applications where elimination or reduction of the number of connection points is desired.

[0011] One variation of the device includes a medical device for removing an obstruction from a blood vessel, the medical device comprises a main bundle comprising a group of wires having a first end and a second end, a capturing portion formed by the group of wires and having a translating surface adjacent to a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, where the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface, the translating surface, and open proximal end about the main bundle; and where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than a capturing surface axial strength, wherein application of a tensile force on the main bundle causes axial compression of the capturing surface without causing axial compression and deformation of the translating surface sufficient to deform the translating surface as the capturing portion engages the obstruction.

[0012] The medical device can include a capturing surface that is configured to generate a spring force against the translating surface when a proximal force applied

by the main bundle of wires compresses the capturing surface against the translating surface when encountering resistance from the obstruction, where the capturing surface is configured to have a sufficient axial stiffness to direct the spring force and proximal force to the open proximal end as the open proximal end engages the obstruction where the capturing surface is also sufficiently flexible to conform to a shape of the vessel.

[0013] In another variation, the capturing section is configured so that when the open proximal end of the translating section engages resistance equal to or greater than a threshold force, proximal movement of the leading wire inverts the capturing section within the translating section and reduces a size of the capturing section to enable the capturing section to re-enter a catheter.

[0014] In those variation of the device that are navigated in tortuous anatomy (such as the cerebral vasculature), the device can include a main bundle joined to a proximal bundle, where the proximal bundle comprises a stiffness greater than the main bundle and where the main bundle extends for at least a predetermined range from the permeable distal end to allow navigation of a distal portion of the medical device within the cerebral vasculature.

[0015] Another variation of the device includes a retrieval device for removing an obstruction from a body lumen, the system comprising at least one leading wire; a retrieval body comprising a translating section adjacent to a capturing section, the translating section having an open proximal end and the capturing section having a permeable distal end, where the leading wire is extends to a portion of the capturing section to permit articulation of the open proximal end relative to the leading wire; and where the translating section and capturing section are configured so that a translating section axial strength is greater than a capturing section axial strength, wherein application of a tensile force on the leading wire causes axial compression of the capturing surface without causing axial deformation of the translating surface when the retrieval body engages the obstruction.

[0016] Variations of the retrieval system can also include a sheath having a hub located at a proximal end, a proximal capture portion affixed to a distal end of the sheath, at least one leading wire extending through the sheath, where a distal section

of the leading wire comprises a distal stiffness and where a proximal section of the leading wire comprises a proximal stiffness, where the proximal stiffness is greater than the distal stiffness, a distal capturing portion at the distal end of the leading wire, the distal capturing portion being axially moveable relative to the proximal capture portion, and an insertion tool slidably located over the sheath, the insertion tool comprising a gripping region affixed to a rigid section, where compression of the gripping portion creates a frictional fit between the insertion tool such that when the insertion tool is coupled to the catheter, compression of the gripping portion and axial movement of the insertion tool advances the sheath within the catheter.

[0017] In one variation of the devices described herein, the device comprises a main bundle or group of wires that diverge to form a device having various shapes but few or no connections points or joints (where fabrication of such a construction is referred to as "jointless"). Clearly, the inventive devices described herein are not limited to such a jointless construction. Additional variation includes one or more leading wires that are attached to a capturing portion as described below.

[0018] In another variation, the device includes a main bundle comprising one or a group of wires. The device also includes a capturing portion formed by the wires or wire of the main bundle. The capturing portion includes a cavity or space that is able to surround the obstruction. Accordingly, the capturing portion includes an open proximal end, a permeable distal end, and a capturing surface extending therebetween. The permeable distal end should be sufficiently permeable to allow blood to flow but have sufficient surface area to prevent escape of the obstruction or to prevent particles such as pieces of clot or emboli that would otherwise cause a complication if such pieces migrate through the body. In some variations of the device, the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface and open proximal end about the main bundle. Although some closing of the open proximal end can occur, it will not be sufficient to interfere with the obstruction as the capturing portion moves over the obstruction. In some variations, the permeable end may be the distal end or be towards the distal end (meaning anywhere past a proximal end). The terms

distal and proximal are relative to the physician (e.g., the distal end is the farthest end from the catheter/physician).

[0019] The devices of the present invention typically include a main bundle from which the wires extend. In most case, the main bundle extends for a length sufficient to withdraw the device from a body of a patient. Accordingly, in such cases, the main bundle shall extend through the length of a catheter. In alternate constructions, the main bundle may be affixed to a single wire or member. In such cases, a main bundle does not extend from the capturing portion to the exterior of the patient. Instead, a single wire extends to the operator interface of the device where the wire is affixed to a main bundle.

[0020] Devices of the present invention can incorporate any number of wires of different characteristics including, but not limited to, materials, shapes, sizes and/or diameters. Clearly, the number of permutations of device configurations is significant. Providing devices with such a composite construction allows for the manipulation of the device's properties to suite the intended application.

[0021] In an additional variation, the surface of the capturing portion can include a wire frame structure, a mesh, a single wound wire, a film, a membrane, a polymer covering, and a plurality of crossing wires or a heterogeneous mixing of these. In additional variations, a section of the capturing portion can include wires, while another section of the capturing portion can include a film. Clearly, any number of permutations is within the scope of this disclosure. In any case, the capturing surface should prevent the obstruction from escaping as the device is removed from the body. Clearly, the capturing surface can comprise any number of shapes or configurations.

[0022] As noted herein, the joint-less construction improves the flexibility and strength of the device by eliminating joints, connection points, or other attachment points. In addition, the joint-less construction improves the ability of the device to be delivered through a small microcatheter. As a result, the device and microcatheter are able to access remote regions of the vasculature.

[0023] The devices may be fabricated to be self-expanding upon deployment from a catheter. Alternatively, the devices can be constructed from shape-memory alloys

such that they automatically deploy upon reaching a pre-determined transition temperature.

[0024] The devices of the present invention may also include features to prevent migration of the obstruction as the capturing portion encapsulates the obstruction. For example, a proximal foot (such as region of increased surface area) can be located on or in the catheter. In another variation, an additional capture portion is located on the catheter where the proximal end of this capture is a mesh, a single wound wire, a film, a membrane, a polymer covering, or a plurality of crossing wires affixed to or in the catheter. Accordingly, the capturing portions both envelope or surrounds the obstruction as they are moved together. As noted below, additional variations may allow for temporarily locking of the two capturing portions together for increase effectiveness in removing the obstruction from the body.

[0025] The capturing portions disclosed herein can include mechanical features that assist in removal of the obstruction. These features can be hooks, fibers, barb, or any such structure. Any portion of the capturing portion or even the device can have such hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. It will be important that such features prevent the obstruction from sliding proximally but do not hinder the ability of the practitioner to remove the device from the body.

[0026] The operation of the devices and method described herein secure the obstruction, overcome the friction forces acting on the obstruction, and then remove the obstruction from the anatomy without losing or fractionating the obstruction. In a first variation, the inventive method includes advancing a catheter distal to the obstruction, deploying a first capturing portion distal of the obstruction, where the first capturing portion comprises a translating surface and a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, and at least one leading wire affixed to the capturing surface and extending through the capturing portion and through the catheter, where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than that of a capturing surface axial strength, proximally moving the leading wire to compress the capturing surface without compressing the translating

surface such that the translating surface gradually advances over the obstruction, and removing the obstruction and first capturing portion from the blood vessel

[0027] Additional variations of the method include (1) passing a catheter distally to the obstruction by passing either through the obstruction and/or between the obstruction and the vascular wall; (2) deploying a first capturing portion distally to the obstruction and the catheter is withdrawn proximal to the obstruction; (3) the capturing portion is then translated over the obstruction by withdrawing the main bundle. Since the main bundle is affixed to a distal end of the capturing portion, misalignment between the bundle and the capturing portion does not cause distortion of the open proximal end. Since the open proximal end remains expanded against the lumen wall, the capturing portion can then be advanced over the obstruction.

[0028] The method and systems may also include the use of an additional capturing portion having an open distal end. This configuration allows the first capturing portion and second capturing portion to envelop or ensnare the obstruction from both the proximal and distal sides. Additional variations even allow for temporarily locking the two capturing portions together. Such a feature increases the ability to remove the obstruction from the body

[0029] It should be noted that reference to surrounding, capturing or securing the obstruction includes partially and/or fully surrounding, engulfing, encapsulating, and/or securing the obstruction. In any case, a portion of the device engages the obstruction prior to translation of the obstruction within the lumen.

[0030] It should be noted that in some variations of the invention, all or some of the device can be designed to increase their ability to adhere to the obstruction. For example, the wires may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to "weld" to the obstruction. Application of energy to the device can allow the surrounding portion to deform into the obstruction and "embed" within the obstruction. Alternatively, the device can impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. In another variation, a negative charge could be applied to further build thrombus and nest the device for better pulling force. The wires can be made stickier by use of a hydrophilic substance(s), or by chemicals that would generate a chemical bond to the surface of

the obstruction. Alternatively, the filaments may reduce the temperature of the obstruction to congeal or adhere to the obstruction.

[0031] Additional variations of the invention include a reentry device for withdrawing an object into a distal end of a sheath, the reentry device comprising a elongate member having a distal portion and a lumen extending therethrough, a plurality of first tines arranged circumferentially at the distal portion, the plurality of first tines each having a distal end forming a first discontinuous funnel where the distal end of each first tine is spaced from the distal end of an adjacent first tine, wherein the first discontinuous funnel is collapsible upon withdrawal into the distal end of the sheath, a second funnel spaced proximal to the first funnel, where the second funnel is collapsible upon withdrawal into the distal end of the sheath, and wherein a distal perimeter of the first discontinuous funnel shape is distal to a distal perimeter of the second funnel.

[0032] Another variation of a device as described herein includes methods and devices for recanalizing a blood vessel having an obstruction. The obstructions can vary from fully blocking flow to partially blocking flow in the blood vessel. In addition, the devices and methods can only recanalize the blood vessel or can also remove the obstruction.

[0033] In one example, the device includes a distal capturing portion having an open proximal end and a fluidly permeable distal end, the distal capturing portion having a translating surface adjacent to the open proximal end and a distal capturing surface adjacent the fluidly permeable distal end; a proximal capturing portion having an open distal end and a fluidly permeable proximal end, the proximal capturing portion having a medial surface between the open distal end the fluidly permeable proximal end, where the medial surface comprises a stent-type structure that is configured to expand to compress the obstruction when deployed therein; and a main bundle comprising a group of wires having a first end and a second end extending through the proximal capturing portion to the distal capturing portion, where the main bundle is moveable relative to the proximal capturing portion such that proximal movement of the main bundle decreases a distance between the open ends of the distal capturing portion and proximal capturing portion.

[0034] The device can optionally include a proximal capturing portion configured to include at a plurality of fluid delivery ports on a surface proximal capturing portion allowing fluid to be delivered from a perimeter of the proximal capturing portion.

[0035] In some variations, the devices described herein can include at least one filament forming the proximal capturing portion, the filament including at least one fluid delivery passage extending therethrough and in fluid communication with the fluid delivery ports.

[0036] The medial surfaces of the proximal capturing portion can comprise stent-like structures. For example, they can include mesh patterns or braided structures.

[0037] Another variation of a method for recanalizing a blood vessel having an obstruction includes inserting an expandable structure within the obstruction, where the expandable structure comprises at least one fluid delivery port adjacent to an exterior surface of the expandable structure; expanding the expandable structure within the obstruction; and delivering a substance through the fluid delivery port such that the substance begins to dissolve the obstruction.

[0038] One variation of the method includes the use of an expandable structure that is fabricated from at least one tubular element, the tubular element comprising a fluid delivery passage extending through at least a portion of the tubular element, where the fluid delivery passage terminates in at least one of the fluid delivery ports.

[0039] In another variation, the expandable structure comprises a stent portion and a fluid delivery tube or membrane located within the stent portion, where expanding the expandable structure comprises expanding the stent portion and where delivering the substance comprises delivering the substance through at least one delivery port located in the fluid delivery membrane.

[0040] The method can also include withdrawing the proximal capturing portion proximally to the obstruction and then surrounding the obstruction with the distal capturing portion and the proximal capturing portion to capture the obstruction.

[0041] The method can also include using the distal capturing portion to assist in compressing the obstruction by withdrawing the distal capturing portion against the expandable structure when the expandable structure is located in the obstruction to cause the expandable structure to increase a radial force to the obstruction.

[0042] In another variation, the expandable structure comprises a distal capturing portion having a fluid permeable distal end and a proximal stent section, where the proximal stent section comprises a plurality of high density stent sections and a plurality of low density of stent sections, where expanding the expandable structure comprises expanding the proximal stent section into the obstruction.

[0043] Another variation of the present invention also includes a method of recanalizing a blood vessel having an obstruction by advancing a microcathter distal to the obstruction; deploying a distal capturing portion distally of the obstruction; positioning a proximal capturing portion within the obstruction, where the proximal capturing portion is sized to have a greater length than a length of the obstruction and where proximal capturing portion expands to compress a portion of the obstruction against the vessel; moving the proximal capturing portion toward to the obstruction; securing the obstruction by moving the distal capturing portion and the proximal capturing portion together; and removing the obstruction from the blood vessel.

[0044] As noted herein, the methods can include a capturing portion structure (sometimes referred to as a medial surface) that comprises a stent portion having a fluid permeable proximal end. The stent portion can comprise a structure that expands against an obstruction to assist in recanalizing the vessel.

[0045] In one variation, withdrawing the proximal capturing portion comprises resheathing at least a section of the proximal capturing portion within a microcatheter during withdrawal of the proximal capturing portion. A segment of the proximal capturing portion can be deployed from the microcatheter proximal to the obstruction such that the partially deployed segment functions as a proximal basket.

[0046] Any variation of the methods described herein can optionally include delivering a substance to the obstruction where the substance is configured to dissolve the obstruction. In such cases the delivering the substance to the obstruction can comprise delivering the substance through the microcatheter or delivering the substance through a surface of the proximal capturing portion.

[0047] The present disclosure also includes methods of recanalizing a blood vessel having an obstruction by advancing a catheter distal to the obstruction; deploying a first capturing portion distally of the obstruction, where the first capturing portion

comprises a permeable distal end, an open proximal end, a capture surface extending therebetween, and at least one leading wire extending through the capturing portion and through the catheter; positioning a second capturing portion within the obstruction, the second capturing portion having an open distal end and a fluidly permeable proximal end, and a medial surface extending therebetween, such that the second capturing portion compresses a portion of the obstruction against the blood vessel; withdrawing the second capturing portion proximal to the obstruction; capturing the obstruction between the first and second capturing portions by moving the first capturing portion over the obstruction by pulling on the leading wire to apply a force to the capturing portion at a location distal to the open proximal end of the first capturing portion; and removing the obstruction from the blood vessel.

[0048] The present disclosure also include a method of removing an obstruction from a blood vessel using a stent structure having high density section and low density section. For example, a variation of the method can include inserting an expandable structure within the obstruction, where the expandable structure comprises a distal capturing portion having an open proximal end and a fluid permeable distal end, and a proximal stent section, where the proximal stent section comprises a plurality of high density stent sections and a plurality of low density of stent sections, where the high density stent sections comprise a high surface area of a mesh, or a woven pattern; and expanding the expandable structure within the obstruction such that one or more high density stent sections engage the obstruction. In an additional variation, the expanded expandable structure can be withdrawn or reciprocated within the vessel to break the obstruction free or shear portions of the obstruction.

[0049] Additional devices and methods for treating ischemic stroke are discussed in commonly assigned U.S. Patent application nos.: 11/671,450 filed February 5, 2007; 11/684,521 filed March 9, 2007; 11/684,535 filed March 9, 2007; 11/684,541 filed March 9, 2007; 11/684,546 filed March 9, 2007; 11/684,982 filed March 12, 2007, 11/736,526 filed April 17, 2007, 11/736,537 filed April 17, 2007, and 11/825,975 filed September 10, 2007; the entirety of each of which is incorporated by reference. The principles of the invention as discussed herein may be applied to the above referenced cases to produce devices useful in treating ischemic stroke. In other words, the wire-

shaped construction of devices according to present invention may assume the shapes disclosed in the above-referenced cases when such a combination is not inconsistent with the features described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0050] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.

[0051] Fig. 1A illustrates an example of a device according to the present invention when used in a system for removing obstructions from body lumens.

[0052] Fig. 1B illustrates a first example of an obstruction removal medical device.

[0053] Fig. 1C illustrates the obstruction removal device articulating relative to leading wires (or a main bundle) without deforming an open end of the capturing portion.

[0054] Figs. 2A to 2E show a capturing portion for use with systems described herein where the capturing portion has sections of varying axial strengths. Such features can optionally be designed to provide a spring force when a section of the capturing portion is compressed and/or staged inversion of the capturing portion so that it can be removed through an immovable obstruction.

[0055] Fig. 3A illustrates a first variation of the device having a joint-less construction of a capturing portion that articulates about a main bundle of wires.

[0056] Figs. 3B to 3H illustrate various constructions of capturing portions for use in the present invention.

[0057] Fig. 4A illustrates a variation of a capturing portion having a main bundle that extends beyond a certain distance to provide a device having an extremely flexible distal region and a relatively stiff proximal region with a strong joint region that will be sufficiently spaced from tortuous anatomy during use of the device.

[0058] Fig. 4B illustrates a main bundle having a curved or shaped portion.

[0059] Figs. 4C to 4E illustrate wires of different constructions within a main bundle.

[0060] Fig. 5A illustrates am example of a proximal foot located on a catheter of the present system.

[0061] Fig. 5B illustrates a distal and a proximal capturing portion located on a system under the present invention.

[0062] Figs. 5C to 5E illustrate an overview of a variation of a delivery system employing a proximal and distal capturing portion.

[0063] Figs. 5F illustrates compression or collapsing of a proximal capturing portion about an obstruction prior to translation of the obstruction in the vessel.

[0064] Figs. 6A to 6B illustrate an example of traversing an obstruction with a sheath to deploy a distal capturing portion.

[0065] Figs. 7A to 7C illustrates a condition where a section of the capturing portion deflects to provide a spring force that gradually drives a traversing section along the obstruction.

[0066] Figs. 7D to 7G illustrate staged inversion of the distal capturing portion to allow removal of the device from an immovable clot.

[0067] Fig. 8A illustrates closure of the proximal opening of a capturing portion without the benefit of articulation of the capturing portion about a leading wire.

[0068] Fig. 8B illustrates, conceptually, one benefit of articulation of a capturing portion about a leading wire or main bundle of wires.

[0069] Figs. 8C to 8D illustrate a proximal capturing portion and a distal capturing portion approaching an obstruction.

[0070] 8F illustrates a device after securing an obstruction between proximal and distal capturing sections.

[0071] Fig. 9 illustrates a main bundle as including an increased surface area or medial foot that is used to dislodge or loosen the obstruction from a wall of the body passage.

[0072] Fig. 10 illustrates a variation of a proximal and distal end of a retrieval device.

[0073] Figs. 11A to 11C illustrate a variation of a funnel catheter useful for retrieving objects from vessels or body lumens.

[0074] Fig. 12A shows an example of a retrieval device getting caught on a guide sheath.

[0075] Figs. 12B to 12C provide illustrative examples of funnel catheter used for removal of an obstruction.

[0076] Fig. 13A to 13G illustrates another variation of a funnel catheter using a mesh or layer of material to form a funnel.

[0077] Figs. 14A to 14D illustrate additional concepts to prevent or minimize flaring of the distal capture portion so that it may be withdrawn into a guide sheath.

[0078] Figs. 15A illustrates another variation of a distal basket and a proximal capturing portions where the proximal capturing portion comprises a stent-like structure.

[0079] Figs. 16A to 16E show a retrieval device that uses a proximal capture portion that is configured to be deployed against an obstruction within a vessel or other lumen.

[0080] Figs. 17A to 17C illustrate a variation of a working portion of an obstruction removal device having a distal capturing portion affixed to a proximal section comprising one or more high density sections interconnected with one or more low density sections.

[0081] Figs. 18A to 18H illustrate variations of capture portion that are configured to deliver a substance at a perimeter of the device so that the substance can be deployed closely to the obstruction.

DETAILED DESCRIPTION

[0082] It is understood that the examples below discuss uses in the cerebral vasculature (namely the arteries). However, unless specifically noted, variations of the device and method are not limited to use in the cerebral vasculature. Instead, the invention may have applicability in various parts of the body. Moreover, the invention may be used in various procedures where the benefits of the method and/or device are desired.

[0083] Fig. 1A illustrates a system **10** for removing obstructions from body lumens as described herein. In the illustrated example, this variation of the system **10** is suited for removal of an obstruction in the cerebral vasculature. Typically, the system **10** includes a catheter **12** microcatheter, sheath, guide-catheter, or simple tube/sheath configuration for delivery of the obstruction removal device to the target anatomy. The catheter should be sufficient to deliver the device as discussed below. The catheter **12** may optionally include an inflatable balloon **18** for temporarily blocking blood flow or for expanding the vessel to release the obstruction.

[0084] It is noted that any number of catheters or microcatheters maybe used to locate the catheter/microcatheter **12** carrying the obstruction removal device **200** at the desired target site. Such techniques are well understood standard interventional catheterization techniques. Furthermore, the catheter **12** may be coupled to auxiliary or support components **14**, **16** (e.g., energy controllers, power supplies, actuators for movement of the device(s), vacuum sources, inflation sources, sources for therapeutic substances, pressure monitoring, flow monitoring, various bio-chemical sensors, bio-chemical substance, etc.) Again, such components are within the scope of the system **10** described herein.

[0085] In addition, devices of the present invention may be packaged in kits including the components discussed above along with guiding catheters, various devices that assist in the stabilization or removal of the obstruction (e.g., proximal-assist devices that holds the proximal end of the obstruction in place preventing it from straying during removal or assisting in the removal of the obstruction), balloon-tipped guide catheters, dilators, etc.

[0086] Fig. 1B illustrates a first example of an obstruction removal medical device according to the features described herein. As shown, the device **200** generally includes capturing portion **226** comprising a translating section/surface **222** and a capturing section/surface **224**. In the illustrated variation, the translating section **222** shown comprises a wire framework. However, any number of configurations is within the scope of this disclosure. In many variations of the device, the translating section **222** provides a low friction surface so that it translates over the obstruction without significantly moving the obstruction. This permits the capturing portion **226** to envelop or surround the obstruction prior to attempting to move the obstruction within the body lumen. As noted herein, the translating section **222** attempts to reduce the outward radial force applied by the obstruction against the wall of the lumen during movement of the obstruction within the lumen.

[0087] Fig. 1B illustrates a distal section of the capturing portion **226** that serves as a capturing section/surface **232**. The capturing section **232** has an increased frictional surface (in this variation illustrated by the crossing **204** wires) so that it can capture and ultimately remove the obstruction. The frictional surface of the capturing section

232 can also be described as an increased coverage density. In essence, as the frictional surface of capturing section 232 coverage density increases, there is a greater "device" surface area to interact with the obstruction. In some variations the capturing section 232 increases in frictional surface between the translating section 234 and the end of the device 200.

[0088] As shown, the device 200 includes a main bundle 202 comprising a group of individual leading wires 204. In this variation, the bundle of leading wires 204 is surrounded by a coil or coiled wire 205. The coiled wire 205 can comprise a single leading wire that joins the device 202. Alternatively, the coiled wire 205 can extend terminate or wrap back prior to forming the capture portion 226. Moreover, the coiled wire 205 can extend throughout a length the main bundle 202, or along one or more segments of the main bundle 202.

[0089] While the example shows the group consisting of four individual leading wires 204, the bundle 202 can have any number of leading wires. In various examples 2, 4, or 8 wires were used to construct the device. In certain variations, the number of wires in the main bundle loop around from the capturing portion. For example, if 2 leading wires are used to construct the device, then when constructing the main bundle 202 2 wires are set to extend distally towards the capturing portion, where the 2 wires are then shaped to form the capturing portion. Eventually, the wires then loop back to extend proximally away from the capturing portion. Therefore, the 2 wires are doubled in the main bundle to create 4 separate wires in the main bundle.

[0090] The individual wires 204 themselves may be comprised of a number of different "micro" filaments, wires, or a single type of wire. Variations of the wires 204 are discussed in detail below; however, the wires 204 can be strands, filaments, or any similar structure that is able to be joined to form the device. The bundle 202 may be braided, wrapped, twisted, or joined in any manner such that they do not separate or become unbundled except where desired. For example, wires in any section of the device 200 can be bonded together (e.g., with epoxy, a polymeric coating, weld, solder, and/or adhesive, etc.) to prevent the wires from separating during deformation of the device as it deploys or removes the obstruction. In addition, the main bundle 202 can incorporate any number of features to assist in orienting the device 200 within

the body passage. For example, the main bundle **202** can include a pre-set bend that would bias the capturing portion **226** in a desired orientation upon deployment as discussed below.

[0091] As also discussed below, variations of the present device **200** include capturing portions **226** where the translating section **234** provides a greater axial strength than an axial strength of the capturing section **232**. The axial strength (e.g., column strength) determines whether the respective section of the capturing portion **226** compresses when the device **200** encounters resistance from an object and as a proximal or pulling force is applied through the main bundle or leading wire **202**. In use, the translating section **234** resists axial compression and deformation so that it can locate about the obstruction. While the nature of moving the translating section will place the structure in a state of compression, there will be no visible deformation or deflection that prevents the translating section from advancing across an obstruction.

[0092] There are a number of approaches to adjust the axial strength of a capturing section **232** as well as the entire structure. In a first example, the manner in which the leading wire is wound to form the respective surface **232**, **234** impact the respective axial strength. As shown, the traversing section **234** comprises a series of wrapped wires extending in an axial direction. This axial alignment causes the wires to oppose axial forces and thus increases the axial strength of the traversing section **234** relative to the capturing section **232**. In the latter section, the wires **232** extend in a helical direction about the section **232**. Thus there is less resistance to an axial load when compared to the traversing section **234**.

[0093] Alternatively, or in combination, additional techniques can produce a device **200** with a capturing portion **226** that has sections of varying axial strength. In one example, the wire diameter can be adjusted to produce the desired column strength. Generally, for a given construction, a larger diameter wire increases the column strength of the section. In addition, larger diameter leading wires can terminate at the translating section **234** to permit smaller diameter wires to form the capturing section **232**. In another example, the leading wire **204** composition can be selected to produce the desired axial strength. For example, drawn filled tube (DFT) wire has 30% platinum 70% nitenol. Decreasing the amount of platinum and increasing the nitenol

increases the wire strength and results in higher column strength. In yet another example, the respective section, or the entire capturing portion **226**, can be processed to produce the desired axial strength. For example, changing the annealing profile (e.g., temp, time) affects the wire strength, and therefore the axial strength.

[0094] Variations of devices **200** described herein can have capturing portions with alternate configurations than those shown in above. The capturing portion **226** can include constructional designs such as a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a film, a membrane, a polymer covering, , or a plurality of crossing wires. In variations of the device, the capturing portion **226** is sufficiently permeable to allow blood or other fluid flow therethrough. As noted above, capturing portion **226** may be any structure that covers, encapsulates, engulfs, and/or ensnares the obstruction either fully or partially. Accordingly, although the capturing portion **226** is illustrated as a filter/bag, the wires may diverge to form a coil, helical shape, other mesh structure, or any other structure that defines a space that can be translated over the obstruction to ultimately remove the obstruction **2**.

[0095] The capturing portion **226** can include an open proximal end **228**, a permeable distal end **230** and a capturing surface **232** located therebetween. The capturing surface **232** of the capturing portion **226** defines a volume, cavity, or space that is able to cover, encapsulate, envelop, engulf, ensnare and/or surround the obstruction. Generally, the term traversing wire or filament refers to the section of leading wire **204** that forms the traversing surface **238**. Generally, the traversing wires form the capturing surface **238** and then form the open proximal end **228**. As discussed herein and illustrated below, the open proximal end **228** expands within the lumen, typically to the lumen walls, so that the obstruction enters the open proximal end **228** as the bundle **202** (or leading wire) translates the device **200** proximally.

[0096] The permeable distal end **230** is typically sufficiently porous so that fluid or blood may flow through. However, the end **230** is sufficiently closed (or has an increased surface area) so that the obstruction should not escape through the distal end **230** of the device **200**. This construction typically causes the obstruction to become ensnared within the capturing portion **226** and prevented from passing through by the permeable distal end **230**.

[0097] As shown in Fig. 1C, an important feature of the present devices **200** is that the main bundle **202** and capturing portion **226** can articulate relative to one another without interfering with the size or profile of the open proximal end **228**. This feature is described more fully below. As shown, the main bundle **202** extends through the open proximal end **228** and through at least a the traversing section **234**capturing portion **226**.

[0098] Fig. 1C illustrates a condition where the main bundle **202** and capturing portion **226** articulate relative to one-another. Because the main bundle **202** joins the capturing section **232** at a distance from the open proximal end **228** movement of the main bundle **202** relative to an axis **236** of the capturing portion **226** does not reduce a profile of the open proximal end **228**. If the main bundle **202** were affixed or connected to the open proximal end **228**, then any movement of the bundle **202** away from the capturing portion's axis **236** would exert a force on the open end. This force, in turn, would cause the open end to narrow or deform. By doing so, the open end would not be able to uniformly expand against the lumen wall to capture the obstruction.

[0099] Turning now to the construction of the device **200**, as shown above, the main bundle or a leading wire **202** extends beyond the open proximal end **228** and forms the capturing portion. In one variation, the construction of the device relies on converging/diverging wires to form continuous shapes so that the device is completely joint or connection free. However, as noted herein, the leading wire or main bundle **202** can be affixed to a structure that forms the capturing portion via an attachment point, joint, or junction. In addition, the structures forming the capturing portion can be fabricated from such processes as laser cutting of tubes, etching, metal injection molding, or any other such process.

[00100] The devices of the present invention can also include additional features to aid in removal of obstructions. For example, as shown in Figs. 1B to 1C, the open proximal end **228** can include one or more petals or flanges **238** extending radially outward. The flanges **238** allow device **200** to have a flared structure at the open proximal end **228**. In one example, the capturing portion **226** can be slightly oversized relative to the body passage containing the obstruction or slightly larger than the

capturing portion. The flanges **238** provide an additional force against the wall of the passage to ensure that the device **200** is able to surround or encapsulate the obstruction. In yet another feature, in variations of a system having a proximal and distal capturing portion, the flanges can serve to lock the proximal and distal capturing portions together once they encapsulate or surround an obstruction. This feature minimizes the chance that the obstruction escapes from the capturing portions as the device and obstruction are removed from the body lumen.

[00101] In additional variations, the main bundle can diverge to form the capturing portion in multiple locations so long as the capturing portion's ability to articulate is not sacrificed. For example, the main bundle can diverge in several locations along the capturing surface (not shown).

[00102] Figs. 1B to 1C also shows an integrally formed reinforcement ring **240** located along the length of the capturing surface **232** (i.e., on the traversing wires). The reinforcement ring **240** can be a separate or discrete ring located on or in the capturing surface **232**. Alternatively, or in combination, the reinforcement ring **240** can be a ring shape that is integrally formed through arrangement of the wires **204** (as show in Figs. 1B to 1C). The reinforcement ring **240** assists in expanding the device when deployed in the body lumen and/or prevents the device (e.g., the open proximal end) from collapsing as the device moves within the lumen to secure the obstruction. The reinforcement ring **240** can comprise a single wire, or a twisted pair of wires. Alternatively, the rings do not need to extend entirely circumferentially around the capturing surface. Instead, a reinforcement portion may extend between adjacent traversing wires but does not necessarily extend around the circumference of the capturing section. As noted herein, reinforcement portions may extend between adjacent traversing wires in multiple locations.

[00103] Figs. 2A to 2E show several benefits of varying axial strengths of the different sections of a capture portion **226**. As shown in Fig. 2A, when the physician retrieves the capturing portion **226** by pulling on the leading wire or main bundle **202** (as shown by arrow **120**), the entire capturing portion **226** translates as shown by arrow **122**. However, when the device **200** encounters resistance (as schematically shown by force arrows **124**) the lesser axial strength of the capturing section **232** causes axial

deformation or compression of the capturing section **232** (as shown by Fig. 2B). In certain variations, the capturing section **232** can be constructed to function as spring such that deformation of the capturing section **232** stores energy. Accordingly, the physician can pull the main bundle **202** to build energy in the capturing section **232**, then relax the force on the main bundle **202**. The stored energy in the capturing section **232** gradually drives the open proximal end of the translating section **234** over or along the obstruction. The physician can apply this "pull and relax" technique repeatedly until the obstruction is sufficiently captured by the capturing portion **226**.

[00104] Fig. 2C shows an additional safety benefit given the varying axial strengths of the different sections of a capture portion **226**. In the event the capturing portion **226** encounters an excessive degree or threshold of force (as denoted by arrows **124**), the reduced axial strength of the capturing section **232** can invert within the translating section **234**. As shown, the permeable distal end **230** of the capturing section **232** inverts and is pulled by the main bundle **202** within the translating section **234** and reduces in size. As shown in Fig. 2D, continued pulling on the main bundle **202** causes eventual inversion of the translating section **234** so that the capturing section **232** extends through the translating section **234** and the permeable distal end **230** is now proximal to the translating section **234**. Continuing to apply move the main bundle **202** in a proximal direction **120** inverts the capturing portion **226** as shown in Fig. 2E. As shown, the translating section **234** is now distal to the capturing section **232**. This causes a reduction in the size of the capturing portion through inversion of the capturing portion **226**. This feature permits withdrawal of the capturing portion **226** within a delivery sheath **106** or through an immobile obstruction (as discussed below). As shown below, the ability to sequentially invert the capturing portion **226** and reduce its diameter enables retrieval of the device if deployed distal to atherosclerotic plaque or an immobile object where continued pulling against the object could cause damage or tearing of the body passage or vessel wall. It was found that retrieval devices that are not constructed with regions of varying axial strength, spring function, or staged inversion can often flatten or expand in diameter when attempting to retrieve the device though an immobile or stubborn obstruction.

[00105] Fig. 3A illustrates an additional variation of a capturing portions **226** according to the present disclosure. In Fig. 3A, the main bundle **202** and the group of wires **204** branch or diverge at the permeable distal end **230** to form the capturing portion **226**. In additional variations, the main bundle **202** can branch or diverge within a mid-portion of the capturing surface **232** rather than at the permeable distal end **230**. In such a case, the wires **204** form the capturing surface **232** first and ultimately branch to form the remainder of the capturing portion. In any case, by extending through the open proximal end **228**, the main bundle **202** is able to articulate relative to the capturing portion **226** without significantly reducing a profile of the open distal end **228**. As discussed above, the capturing surface **232** of these variations is fabricated (either through processing or wire construction) to have an axial strength that is lower than that of the traversing section **234**.

[00106] Fig. 3B illustrates a variation having an integrated reinforcement ring **240**. Typically, the reinforcement ring **240** provides radial strength to the capturing portion **226** to prevent collapse or deformation that would otherwise interfere with enveloping the obstruction. A reinforcement ring **240** may allow for use of wires that would otherwise provide unacceptable radial strength. For example, the reinforcement ring **240** may permit use of smaller diameter wires thereby allowing the device **200** to compress to a smaller diameter during delivery via a catheter.

[00107] In addition to the reinforcement ring **240**, Fig. 3B includes an open proximal end **228** having a number of petals/flanges **238**. In this variation, although the flanges **238** intersect one another, they are independently moveable.

[00108] Fig. 3C shows a variation of a device **200** where the capturing portion **226** includes flanges **238** that are interwoven or connected with adjacent flanges **238**. (Variations include bonding or otherwise joining the adjacent flanges together.) This feature provides the flanges **238** with a higher radial strength that reduces the likelihood that the flanges **238** bend or distort when moving in the body lumen or removing the obstruction.

[00109] Figs. 3D to 3E illustrate additional variations of devices having capturing portions **226** that have a basket type configuration. As shown, the capturing portions **226** and surface **232** comprise a denser mesh of traversing wires that ultimately lead to

the traversing section **234** that terminates in flanges **238** at the open proximal end **228**. In such variations, a first portion of the traversing surface **232**that is adjacent to the open proximal end has a low coverage density relative to the remaining portion of the capturing surface having a higher coverage density that eventually forms the permeable distal end **230**. This construction lowers the lowering frictional resistance of the first portion of the capturing surface when moving over or against the obstruction but allows the remaining portion of the capturing surface to encapsulate and secure the obstruction.

[00110] As shown in Fig. 3E, the wires diverge from the main bundle towards the distal end of the capturing portion **226** to form the permeable distal end **230**. The permeable distal end **230** can actually have the same configuration as the capturing surface **232**. In other words, the permeable distal end can simply be an extension of the capturing surface that extends over the distal end of the capturing portion.

[00111] Naturally, the divergence of the wires can occur over a length of the capturing portion **226** rather than immediately at the distal end. For example, as show in Fig. 3D, the wires diverge towards a mid-section of the capturing portion and ultimately form the permeable distal end **230**.

[00112] Fig. 3F illustrates a variation of a device **200** having multiple reinforcement rings **240**. As noted above, the reinforcement rings provide additional radial strength to the capturing portion **226** as the device **200** moves within the body lumen and prevents distortion of the capturing portion **226**. However, as noted above, the device will be fabricated to provide varying regions of axial strength to allow for either the spring effect or the staged inversion discussed above. In any case, the rings **240** do not need to extend around an entire circumference of a device, variations include any number of supports that extend between adjacent traversing wires.

[00113] Fig. 3G illustrates another variation of a device **200** having a leading wire **202** extending to a distal end **230** of a capturing portion **226**. In this variation the capturing portion **226** is fabricated from a stent-type structure. As noted above, it is within the scope of this disclosure to use any type of similar structure such as a laser cut tube, a chemically etched or photo etched tube, a polymer or metal injection molded structure, a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a

film, a membrane, a polymer covering, or a plurality of crossing wires as the capturing portion **226** so long as the device can be compressed to a small size for delivery and expand after traversing the obstruction. The illustrated variation also shows a covering **270** located on the distal end **230** of the capturing portion **226**. The length of the polymeric covering **270** can vary across the capturing portion **226** to prevent the obstruction from escaping as the device is translated over the obstruction. Furthermore, the covering **270** can be polymeric or a wire mesh. However, typically the covering has sufficient porosity to allow blood to flow through the device **200**. In this variation, the flanges **238** form the translating surface.

[00114] Fig. 3H illustrates another feature for use with system described herein. In this variation, the system includes a proximal capturing portion **260** located on an exterior of a delivery sheath **106**. The main bundle **202** extends through the sheath **106** to a distal capturing portion (not shown). As discussed below, the proximal capturing portion **260** can be similar to the distal capturing portions **226** described herein with the exception that the distal end **262** of the proximal capturing portion is open while the proximal end **264** of the proximal capturing portion is closed. Furthermore, the proximal capturing portion **260** articulates with respect to the sheath **106** much in the same manner as the distal capturing portion **226** articulates relative to the main bundle **202**. In this variation, the proximal end **264** of the proximal capturing portion **260** is tapered or has a smaller profile than the remaining proximal capturing portion **260**. Such a feature may be useful to improve the deliverability of the device to the intended site as well as to maneuver around any obstructions within the body passage. In addition, as noted below, the proximal capturing portion **260** can be compressed about the obstruction to improve the ability of the system to remove the obstruction. The construction of the proximal capturing portion **260** can optionally include variations having regions of differing axial strength, or sections capable of generating spring force. Typically, since the proximal capturing portion **260** is not advanced distal to the obstruction, the need for staged inversion is not necessary. Accordingly, any number of capturing designs can be incorporated for the proximal capturing portion.

[00115] In some variations, the leading wire can extend to the proximal end of the system for manipulation by the physician. However, it is often the case that the characteristics of the device must vary along its length. For example, when the device is intended for use in remote tortuous anatomy, the proximal section of the device is desirably stiffer (to advance the distal portion of the device to the target anatomy). However, the distal section of the device must have properties that make it suitable for the tortuous anatomy. In the case where devices are used in the cerebral vasculature, the distal section must be extremely flexible, while the proximal section should be stiff. In many cases, different material properties are required. A problem then arises in attempting to join different materials especially in the joining region.

[00116] Conventional joining methods include soldering, welding, gluing, thermal junctions, etc. These joining methods produce an area having an increase in the stiffness of the device. For example, if two wires are to be laser welded together, then the section where they are joined has an overlap which yields greater stiffness than the rest of the wire. This increased area of stiffness is often balanced against the strength of the joined segment. If the joined region is too long, the strength will be sufficient but the increase in stiffness often prevents navigation through the tortuous anatomy. IF the joined region is too short, then the device can navigate through the anatomy but the bond is weaker and a risk of failure increases.

[00117] Fig. 4A illustrates another variation of an improvement for use with the devices described herein especially for use in tortuous anatomy such as the cerebral vasculature. In this example, the capturing portion **226** is show with a number of leading wires **204** extending proximally. To provide the desired characteristics, the leading wires **204** are joined in region **196** to wires **198** having a structure that is suitable for the proximal anatomy (e.g., the wires are larger in diameter or stiffer). To enable use of the device **200** in the cerebral anatomy without compromising bond strength characteristics or flexibility of the device **200**, the leading wires extend a pre-determined region so that the bond region **196** is placed out of the tortuous anatomy. Since the cerebral vasculature is approximately 30 centimeters in length, the leading wires **204** can extend for a length **195** of at least a predetermined length so that it remains very flexible when navigating the cerebral vasculature or other tortuous

anatomy. In one example the length was 20 centimeters (but can be 30 or more centimeters). By deliberately extending the leading wires **204** by length **194**, the length of the bond region **196** can be chosen to accommodate the proximal anatomy (where a greater stiffness of the bond region **196** can be accommodated). The length of the bond region **196** can vary depending on the application (e.g., from 2 to20 cm for a device intended for cerebral the cerebral vasculature). However, the bond can extend along the entire proximal section of leading wire.

[00118] Fig. 4B illustrates an addition aspect of for use with devices described herein where the main bundle **202** has a curved or bend portion **252**. This pre-set shape assists in orienting the capturing portion **226** within the body passage since the bend will cause the device to bias against a wall of the body passage.

[00119] Fig. 4C and 4D show cross sectional views taken along the line A-A in Fig. 4B. As shown, the wire form construction described herein allows for a number of configurations depending on the particular application. For example, the individual wires **204** (as discussed herein) may themselves comprise a bundle of smaller wires or filaments. In addition, the wires can be selected from materials such as stainless steel, titanium, platinum, gold, iridium, tantalum, Nitinol, alloys, and/or polymeric strands. In addition, the wires used in a device may comprise a heterogeneous structure by using combinations of wires of different materials to produce a device having the particular desired properties. For example, one or more wires in the device may comprise a shape memory or superelastic alloy to impart predetermined shapes or resiliency to the device. In some variations, the mechanical properties of select wires can be altered. In such a case, the select wires can be treated to alter properties including: brittleness, ductility, elasticity, hardness, malleability, plasticity, strength, and toughness.

[00120] The device may include a number of radiopaque wires, such as gold and platinum for improved visibility under fluoroscopic imaging. In other words, any combination of materials may be incorporated into the device. In addition to the materials, the size of the wires may vary as needed. For example, the diameters of the wires may be the same or may vary as needed.

[0100] In addition, the individual wires may have cross-sectional shapes ranging from circular, oval, d-shaped, rectangular shape, etc. Fig. 4C illustrates one possible variation in which a number of circular wires **204** are included with a d-shaped wire 205. Moreover, the device is not limited to having wires having the same cross-sectional shape or size. Instead, the device can have wires having different cross-sectional shapes. For example, as shown in Fig. 4D, one or more wires **205** can have a different cross-sectional shape or size than a reminder of the wires **204**. Clearly, any number of variations is within the scope of this disclosure.

[0101] To illustrate one such example, a device can have 8-12 wires made of .003" round superelastic material (e.g., nitinol). The device may additionally have 2-4 wires made from .002" platinum for fluoroscopy. Of the 8-12 nitinol wires, 1-4 of these wires can be made of a larger diameter or different cross-section to increase the overall strength of the device. Finally, a couple of polymer fibers can be added where the fibers have a desired surface property for clot adherence, etc. Such a combination of wires provides a composite device with properties not conventionally possible in view of other formation means (such as laser cutting or etching the shape from a tube or joining materials with welds, etc.). Clearly, any number of permutations is possible given the principles of the invention.

[0102] In another example, the device may be fabricated from wires formed from a polymeric material or composite blend of polymeric materials. The polymeric composite can be selected such that it is very floppy until it is exposed to either the body fluids and or some other delivered activator that causes the polymer to further polymerize or stiffen for strength. Various coatings could protect the polymer from further polymerizing before the device is properly placed. The coatings could provide a specific duration for placement (e.g., 5 minutes) after which the covering degrades or is activated with an agent (that doesn't affect the surrounding tissues) allowing the device to increase in stiffness so that it doesn't stretch as the thrombus is pulled out. For example, shape memory polymers would allow the device to increase in stiffness.

[0103] In another variation, one or more of the wires used in the device may comprise a Drawn Filled Tube (DFT) such as those provided by Fort Wayne Metals, Fort Wayne, Indiana. As shown in Fig. 4E, such a DFT wire 252 comprises a first material

or shell 208 over a second material 210 having properties different from the outer shell. While a variety of materials can be used, one variation under the present devices includes a DFT wire having a superelastic (e.g., Nitinol) outer tube with a radiopaque material within the super-elastic outer shell. For example, the radiopaque material can include any commercially used radiopaque material, including but not limited to platinum, iridium, gold, tantalum, or similar alloy. One benefit of making a capturing portion from the DFT wire noted above, is that rather than having one or more markers over the capturing portion, the entire capturing portion can be fabricated from a super-elastic material while, at the same time, the super-elastic capturing portion is made radiopaque given the core of radiopaque material within the super-elastic shell. Clearly, any composite DFT wire 252 can be incorporated into the system and capturing portions described herein.

[0104] Fig. 5A shows a working end of a variation of a system **10** for removing an obstruction from a body lumen. In this variation, the system **10** includes a main bundle **202** and capturing portion **226** extending out of a micro-catheter or catheter **102**. The micro-catheter **102** can optionally include a proximal foot **256** that can slide axially over main bundle **202** and can be variably positioned in relation to the capturing portion **226**. The proximal foot **256** can include any number of configurations apart from the petal/flange **258** configuration (i.e., the foot can be a balloon, coil, shoulder, etc. where such structures simply replace the petals in Fig. 5A). In any case, the proximal foot **256** provides an increased surface area that provides an opposing force to the capturing portion **226**, where the opposing force aids the movement of the obstruction within the capturing portion **226**. Alternatively, the proximal foot stabilizes the obstruction and keeps the obstruction from moving with the capturing portion until the capturing portion envelops the obstruction.

[0105] The size of the proximal foot **256** can be adjusted depending on the target site anatomy. For example, a larger surface area can be employed if the target site is within a bifurcation of the body passage. The size of the proximal foot **256** can also be adjustable during the procedure. For example, in the case of a petal/flange **258** configuration, the petals **258** can assume a larger size to initially stabilize the

obstruction and then reduce in size to allow the obstruction to be completely engulfed by capturing section **226**.

[0106] The proximal foot **256** can extend from an interior of the catheter **102**, such as from within the internal lumen of the catheter, or from an additional lumen within a wall of the catheter. Alternatively, the proximal foot **256** can be permanently affixed to the catheter **102**. In such a case, a separate catheter (without a proximal foot) can be employed to traverse the obstruction for deployment of the device distally to the obstruction. Once the device is deployed, the catheters can be exchanged to provide the proximal foot. In an additional variation, the proximal foot **256** can be affixed to a delivery sheath (as described below) and be collapsed within the catheter, where advancement out of the catheter expands the proximal foot **256** so that it may function as described above.

[0107] In an additional variation, a proximal capturing portion (as shown in Fig. 3H) can be used with a foot **256** that is located about the main bundle **202**. Such a variation may or may not include a distal capturing portion. Accordingly, the construction of the proximal capturing portion (as described herein to include sections of varying axial strength) can be used to perform a push and relax technique (similar to that of the pull and relax technique described herein).

[0108] Fig. 5B illustrates another variation of the system **10** where the system includes a proximal capturing portion **260** located on an exterior of a delivery sheath **106**. Naturally, the proximal capturing portion **260** could also be affixed to an exterior of a micro-catheter. The proximal capturing portion **260** is similar to the capturing portions **226** described herein with the exception that the distal end **262** of the proximal capturing portion is open while the proximal end **264** of the proximal capturing portion is closed. The proximal capturing portion can also optionally be configured to have regions of varying axial strength, spring rate, and various other features associated with the distal capturing portion **226**. In the illustrated variation, the capturing portion **226** and main bundle **202** move relative to the proximal capturing portion **260** to capture an obstruction. Furthermore, the proximal capturing portion **260** articulates with respect to the sheath **106** much in the same manner as the distal capturing portion **226** articulates relative to the main bundle **202**. As shown, the

petals **238** on the open ends **228** and **262** can interact to nest once the capturing portions **226** and **260** are moved sufficiently close to one another. The outward force caused by the retained obstruction provides a frictional interaction between adjacent petals/flanges **238** to maintain the nesting.

[0109] Variations of the device include additional structures, such as springs, hooks, barbs, etc, to cause the open ends 228 and 262 to interlock. As noted above, a separate catheter can be used to initially deploy the capturing portion **226** beyond the obstruction. Although the capturing portions shown have the same configuration, the capturing portions **226** and **260** used in any given system do not have to match in size, shape, and configuration. For example, the proximal capturing portion can be impermeable to flow while the distal capturing portion allows flow. In another example, one basket may be undersized relative to the other to improve nesting.

[0110] In any case, the construction of the system **10** shown in Fig. 5B includes open ends **228** and **262** of capturing portions **226** and **260** that are unconnected. Accordingly, as the capturing portions **226** and **260** move towards one another as a result of the main bundle **202** translating relative to the delivery sheath **106** the open ends are free to articulate around the main bundle **202** and delivery sheath **106** respectively to remain expanded against the lumen wall.

[0111] Figs. 5C to 5E illustrate a variation of a system for delivery of the capturing portions **226** and **260**. Fig. 5C shows the proximal **260** capturing portion affixed to a delivery sheath **106**. In alternate variations, the proximal capturing portion **260** can be replaced with a proximal foot (not shown). As noted above, the main bundle or leading wires **202** extends through the delivery sheath **106** and connects to the distal capturing portion **226** beyond the opening **228** of the distal capturing portion **200**. The main bundle or leading wire **202** extends through the proximal capturing portion **260**. This allows the free ends of the capturing portions **228** and **262** to remain relatively unattached so that they can articulate and conform to the curvature of the vessels (as discussed below). The capturing portions **226** and **260**, main bundle **202** and delivery sheath **106** extend through a microcatheter **102**.

[0112] Fig. 5D illustrates a state of deployment after the microcatheter **102** traverses the obstruction (not shown). Once the microcatheter **102** is distal to the obstruction,

the distal capturing portion **226** deploys from the end of the microcatheter **102**. As noted herein, the capturing portions can self-expand or can expand upon actuation by the physician. In any case, the distal capturing portion **226** should be sufficiently collapsible to remain within the microcatheter **102** for deployment distal to an obstruction. To deploy the distal capturing portion **200** from the catheter **102**, the main bundle **202** can translate to push the distal capturing portion **226** to eject it from the catheter **102**. Alternatively, the microcatheter **102** can be withdrawn from the distal capturing portion **226**.

[0113] Fig. 5E illustrates the deployment state after the catheter **102** is withdrawn proximal to the obstruction (not shown) and after the proximal capture portion **260** is delivered from the microcatheter **102**. As noted above, the proximal capture portion **260** can be affixed to an exterior of the catheter, in which case the catheter may be either de-sheathed or exchanged. Alternatively, and as shown, the proximal capturing portion **260** is affixed to a delivery sheath **106** and is fabricated to collapse within the microcatheter for ultimate deployment, whereby translating the sheath **106** delivers the proximal portion **260** from the microcatheter.

[0114] Fig. 5F shows another aspect of the system **10** where the proximal end **264** of the proximal capturing portion **260** is collapsed or compressed about an obstruction **2** prior to translation of the obstruction **2** within the vessel. In this illustration, the proximal capturing portion **260** is compressible by advancing the catheter **102** over the closed proximal end **264** of the capturing portion **260**. In such a case, the proximal capturing portion **260** is slidable within and relative to the catheter **102.** Naturally, variations may include compressing the proximal end **264** during translation of the obstruction **2**. In either case, the proximal capturing portion **260** can be compressed in a number of different ways. For instance, the proximal basket can be compressed using a catheter **102**(as shown), or the delivery sheath **106**, or any other number of mechanisms (not illustrated).

[0115] As shown, the proximal end **264** can be compressed using a sheath **106** and/or catheter **102** However, other means of compressing may be employed (e.g., a loop structure, a tube over the sheath, a draw-string configuration, etc.) In use, once the distal capturing portion **226** is deployed distally to the obstruction **2** and the catheter

102 is withdrawn proximal to the obstruction **2**, the proximal capturing portion **260** is deployed. As the proximal capturing portion **260** partially (or totally) engulfs the obstruction **2**, the physician can collapse or compress the proximal capturing portion **260** to better secure the obstruction within the system **10**.

[0116] It is noted that any number of shapes, configurations, as well as any number of joined wires may be contemplated to form devices under the present disclosure. However, variations of the invention include selecting a number of wires to produce specific structural properties to the device. For example, the devices can have any number of wires where the limit is determined by the ability to produce a device of a sufficiently small size to access the area containing the obstruction. However, in some cases, it may be desired that wires are chosen to impart specified characteristics. For example, in the illustrated variation, the main bundle may comprise any number of wires that do not diverge to form subsequent shapes in the device. In other words, not all of the wires forming a section are required to diverge to form an adjacent section. Instead, these non-diverging wires may simply "loop" back away from the device. In an additional variation, one or more wires may diverge to form a particular portion of the capturing portion (e.g., the closed end, traversing wires, etc.). Then the wires can loop back to converge again with the main bundle.

[0117] Figs. 6A to 6E show one example of the deployment of a variation of a device according to the present invention about an obstruction in a vessel. The figures are intended to demonstrate the initial placement of the device immediately prior to removal of the obstruction.

[0118] Fig. 6A illustrates an obstruction **2** lodged within a body lumen or vessel **6**. In the case where the vessel is a cerebral artery, the obstruction may result in an ischemic stroke. Using standard interventional catheterization techniques, a microcatheter **102** and guidewire **104** traverse the obstruction. The microcatheter **102** may be advanced through the obstruction **2**. Alternatively, the microcatheter **102** may "push" aside the obstruction and is advanced around the obstruction. In any case, the microcatheter **102** travels from the near end **3** (or proximal side) of the obstruction **2** to the far end **4** (or distal side) of the obstruction **2**. It is noted that the catheter **102** may be centered

or off-center with respect to the obstruction **2**. Furthermore, the device may or may not be used with a guidewire to navigate to the site and traverse the obstruction.

[0119] Some variations of the device may be placed without an accompanying guidewire. Moreover, the structures discussed herein may be directly incorporated into a guidewire assembly where deployment may require a sheath or other covering to release the components from constraint.

[0120] Fig. 6B illustrates deployment of a capturing portion **226** and main bundle **202** of the device **200** from within the microcatheter **102** distal to the obstruction **2**. Accordingly, in most variations, the capturing portion **226** is designed to fit within the catheter **102** for delivery and expand upon deployment. Alternatively, the device may be actuated to assume the desired shape (e.g., upon reaching a transition temperature where one or more wires comprise a shape memory alloy). As shown, the capturing portion **226** includes a traversing section **234** and a capturing section **232**. In some procedures the traversing section **234** engulfs the obstruction **2** with little or no complication as the main bundle **202**, catheter **102**, or sheath **106** pulls the capturing portion **226** in a proximal direction.

[0121] However, as discussed above, there may be some procedures where the distal capturing portion **226** is deployed distal to an obstruction **2** that is deposited within the vessel or lumen such that a steady translation of the capturing portion **226** will not engulf the obstruction **2**. Figs. 7A to 7G illustrate some examples of such a situation. As shown in Fig. 7A, a sheath **106** might be able to traverse the obstruction **2** to deploy the distal capturing portion **226** in preparation for engulfing the obstruction **2**. Fig. 7B illustrates a condition where the traversing section **234** engages the obstruction **2** but is unable to easily or fully engulf the obstruction **2**. However, in those variations where the capturing portion **226** includes regions having different axial strength (as discussed above), continued pulling of the main bundle **202** in a proximal direction **120** causes the capturing section **234** to compress. When the capturing section **234** is constructed to function as spring, the deformation of the capturing section **232** stores energy from the proximal movement of the main bundle **202**. This storing of energy allows the physician to relax the pulling force **120** on the main bundle **202**. Fig. 7C shows a compressed capturing section **234**. The energy stored in the capturing section

232 gradually drives the open proximal end 228 of the translating section 234 over or along the obstruction 2. The physician can apply this "pull and relax" technique repeatedly until the obstruction is sufficiently captured by the capturing portion 226. In some variations, the capturing section 234 remains compressed as the obstruction 2 finally breaks loose and removed.

[0122] Fig. 7D represents the situation where a distal capturing portion distal to an object 2 that is significantly embedded within a vessel or body lumen. In such cases, the force required to remove the obstruction 2 may damage the vessel or lumen. Such obstructions include atherosclerotic plaque or other immobile objects. As shown, when the distal capturing portion 226 is pulled once the proximal force 120 reaches a threshold value (as determined by the construction of the capturing portion 226) the capturing portion 226 undergoes a staged inversion as the permeable end 230 enters the traversing section 232. In this variation, the permeable end 230 actually enters the obstruction 2. The construction of the capturing portion 226 prevents flattening or expanding in diameter, where such movements would prevent removal of the capturing portion. Again, if the force applied by the capturing portion 226 breaks the obstruction 2 free. The obstruction 2 can be removed even though a part of the capturing portion 226 is within the obstruction 2 as shown in Fig. 2D.

[0123] Fig. 7E shows advanced inversion of the capturing portion 226 as the capturing section 234 is now proximal to the traversing section 232. The traversing section 232 may be deformed upon inversion but will taper towards the capturing section 234 as the capturing section 234 passes through the obstruction 2 (typically via an opening that was previously created by advancement of a sheath 106 through or around the obstruction 2).

[0124] Fig. 7F shows the capturing portion 226 nearly passing through the obstruction 2 so that it may be removed from the body. As shown in Fig. 7G, the capturing portion 226 is now fully inverted and is in a state where it can re-enter a catheter for removal from the patient.

[0125] The construction described herein that allows for staged inversion of the capturing portion 2 provides a significant safety feature. A physician must undertake additional surgical intervention to remove any retrieval device that has become lodged

distally to an immobile obstruction. The ability of staged inversion allows the physician to invert and remove the capturing portion **226** if application of a predetermined or threshold force is exceeded by proximal displacement of the device. This feature reduces the need for additional surgical intervention to remove a retrieval device that would otherwise become lodged or separated as a result of excessive forces being applied.

[0126] Figs. 8A to 8B illustrate an additional benefit of affixing a leading wire or bundle of wires **202** beyond a proximal opening **228** of a capturing portion **226**. Fig. 5A illustrates a basket type structure **90** where a wire **202** is affixed to a proximal end **92**. As shown, as the leading wire **202** pulls the basket **90** through tortuous anatomy **6**, the force component pulling away from an axis of the device **90** causes the proximal open end **92** to constrict or reduce in size. As shown, as the proximal end **92** approaches the obstruction **2** the perimeter of the end is not placed against the walls of the body passage **6**. As a result, the constricted opening **92** places an increased axial force on the obstruction **2** as the basket **90** translates over the obstruction **2** (because the proximal end **92** pushes against the obstruction rather than sliding around it), making encapsulation of the obstruction more difficult and possible leading to vascular damage.

[0127] Fig. 8B shows a device **200** according to the principles disclosed herein. The leading wire **202** is affixed to the distal end **230** of the capturing portion **226**. As the main bundle 202 is pulled through the curved vascular path, the capturing portion **226** pivots or articulates about the bundle 202 and remains aligned with the axis of the vessel. As a result any misalignment between the leading wire **202** and an axis of the capturing portion **226** does not affect the open proximal end **228**. As noted above, some closing of the open proximal end may occur, though it will not be sufficient to interfere with the obstruction as the capturing portion moves over the obstruction. Such a configuration allows the perimeter of the open proximal end **228** to remain against the wall of the passage **6**. As shown, because the open proximal end **228** is not constricted, the open proximal end **228** is better suited to slide around the obstruction for eventual removal.

[0128] Fig. 8C shows withdrawal of the microcatheter **102** to the proximal side **3** of the obstruction **2** and deployment of a proximal capturing portion **260** (in alternate variations, a proximal foot can be used or the capturing portion **226** alone can be used). Again, the catheter **102** can be exchanged for a catheter **102** having a proximal capturing portion **260**. Alternatively, and as shown in the accompanying figures, the proximal capturing portion **260** can be affixed to a delivery sheath **106** that is fed through the microcatheter **102**.

[0129] As also shown in the figure, the main bundle **202** and capturing portions become misaligned due to the tortuousity of the anatomy. However, because the capturing portions **226** and **260** are able to pivot or articulate relative to the main bundle **202** and catheter **102** or sheath **106**, the open ends are able to remain against the lumen wall. In conventional devices where the open end is attached to either a wire or catheter, when the wire or catheter bends in the anatomy, the forces exerted on the open ends deform or distort the end to assume a reduced profile. Accordingly, the physician may have difficulty in removing an obstruction if the profile of the open end becomes reduced in size. Closing of the open end can also result in vascular damage if the physician applies too much force in translating the device.

[0130] Fig. 8D shows movement of the capturing portions **226** and **260** adjacent to the obstruction **2**. The proximal capturing portion **260** can remain stationary or may be advanced relative to the distal capturing portion **226**. Regardless, the physician is able to ensnare the obstruction **2** within the cavities defined by the capturing portions **226** and **260**. Fig. 8E illustrates the system as the two capturing portions are drawn together. For purposes of clarity, the obstruction is not shown. Upon sufficient advancement of the capturing portion **226** and proximal capturing portion **260** relative to one-another, flanges **238** on the respective open ends can interlock. This feature provides added safety in removing the device as the obstruction is encapsulated between the two nested portions.

[0131] Fig. 8F illustrates a device **200** after securing an obstruction between a proximal **260** and distal **226** capturing sections. As shown, the captured obstruction **2** is held between capturing portions **226** and **260** where the flanges **238** nest within one-another to "lock" the capturing portions together. In some variations of the device,

one of the capturing portions can be undersized relative to the other. This configuration allows for the undersized capturing portion to become further compressed as the devices are pulled together. The compression of the capturing surface then serves to further compress the obstruction **2** captured within the device.

[0132] The capturing portions described herein can include coverings or wrappings so long as the other features of the device are not impaired. Such coverings can be located on both capturing portions **226** and **260**, only one or more capturing portions. The covering can include a strand or fiber wrapped or woven about the section, a polymer film, or a dipped polymer coating such as silicone, urethane, etc. The coating on either capturing portion can be solid or porous. In the latter case, blood can continue to flow through the coating. In one variation, the proximal capturing portion **260** could employ a solid covering while the distal capturing portion **200** could include a porous covering. In such a case, blood or other fluid flow could be temporarily halted by the presence of the solid covering to assist in removal of the obstruction.

[0133] Fig. 9 illustrates a variation of the system where the main bundle **202** includes a medial foot **274**. The construction of the medial foot **274** can be similar to that of the proximal foot discussed above (e.g., wires looped into a petal configuration.) However, the medial foot includes a surface area or diameter larger than a diameter of the main bundle. In any case, the increased surface area of the medial foot **274** provides an increased resistance to the obstruction **2** as the distal capturing portion **200** and main bundle **202** are pulled in a proximal direction towards an obstruction **2**. The medial foot **274** engages the obstruction **2** to partially displace or loosen the obstruction from the walls of the body passage. The medial foot **274** can be slidably located on the main bundle such that after a threshold force, the medial foot moves within the distal capturing portion **200**. The main bundle **202** can include any number of medial feet **274**.

[0134] Although the illustrated variation shown above comprise open-ended, circular, looped or partial loop shape cross sectional areas, variations of the capturing portions can include any number of shapes. For example, such a shape can include a circle, an arcuate shape, a partial circular shape, a loop, an oval, a square, a rectangle, a polygon, an overlapping loop, a pair of semi-circles, etc.) The various shapes may be heat set to

be either self-expanding (i.e., superelastic) or the use of shape memory alloys can allow for the device to assume the particular shape upon reaching a desired transition temperature.

[0135] The exemplary shapes discussed above permit the shaped section to adjust in diameter in response to placement in varying diameters of body lumens. It is noted that a device may have different shaped sections on different ends of the device.

[0136] While many different shapes are contemplated to be within the scope of this disclosure, the shapes will depend upon the ultimate application of the device. As noted herein, the illustrated examples have particular applicability in retrieving obstructions from the vasculature. Accordingly, for these applications the shaped sections should form a shape so that they can expand against a vessel wall without causing trauma to the vessel. For example, upon release from the catheter, the shaped section can assume their resting shape and expand within the vessel. The resting shape can be constructed to have a size slightly greater than that of the vessel. Sizing the device relative to the target vessel may assist in placing the parts of the device against a vessel.

[0137] In an additional aspect, the shaped sections may be designed to have an unconstrained shape that is larger than the intended target vessel or simply different than a cross sectional profile of the intended vessel (i.e., not circular or tubular, but e.g., linear or other different shape). In such an example, as the shaped section is released from the delivery catheter, the shape section attempts to return to the unconstrained shape. In those variations where the unconstrained shape is different from the circular profile of the vessel, the leading wire assumes a shape that accommodates the vessel but is more rigid and stable since its unconstrained shape is entirely different from that of the vessel. In other words, the shaped section continually exerts an outward force on the vessel.

[0138] In yet another aspect, the shaped sections shown herein may not necessarily lie in the same plane. Instead, they can be axially spaced by an offset. One benefit of constructing the device to have non-planar shaped section is that the configuration might allow for delivery of the device through a smaller microcatheter because the

shaped sections do not interfere with one another when collapsed to fit within the microcatheter.

[0139] Another aspect applicable to all variations of the devices is to configure the devices (whether the traversing filament or the surrounding portion) for better adherence to the obstruction. One such mode includes the use of coatings that bond to certain clots (or other materials causing the obstruction.) For example, the wires may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the device secures about a clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction. Coatings may also be combined with the capturing portions or catheter to improve the ability of the device to encapsulate and remove the obstruction (e.g., a hydrophilic coating).

[0140] Such improvements may also be mechanical or structural. Any portion of the capturing portion can have hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. The hooks, fibers, or barbs **154** can be incorporated into any portion of the device. However, it will be important that such features do not hinder the ability of the practitioner to remove the device from the body.

[0141] In addition to additives, the device can be coupled to an RF or other power source (such as **14** or **16** in Fig. 1A), to allow current, ultrasound or RF energy to transmit through the device and induce clotting or cause additional coagulation of a clot or other the obstruction.

[0142] The methods described herein may also include treating the obstruction prior to attempting to remove the obstruction. Such a treatment can include applying a chemical or pharmaceutical agent with the goal of making the occlusion shrink or to make it more rigid for easier removal. Such agents include, but are not limited to chemotherapy drugs, or solutions, a mild formalin, or aldehyde solution.

[0143] As for other details of the present invention, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts that are commonly or logically employed. In addition, though the invention has been described in reference to several examples, optionally

incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention.

[0144] Fig. 10 illustrates one variation of a retrieval device **200** including a distal capture portion **226** coupled to one or more leading wires in the form of a main bundle **202**. The main bundle extends through a sheath **106** that includes a proximal capture portion **260**. The configuration of the retrieval device **200** can incorporate the proximal and distal capture portions discussed herein as well as various other configurations discussed in the commonly assigned patent applications noted above. In addition, the relative sizes of the various components shown in Fig. 10 and discussed below are for illustrative purposes only.

[0145] An end **264** of the proximal capture portion **260** is affixed to a distal end of the sheath **106**. However, as noted above, other variations are within the scope of the disclosure. The main bundle **202** can optionally terminate at a handle **242**. As noted above, in certain variations, the main bundle is joined to a stiffer wire or stiffer bundle of wires. This allows the device **200** to have a very flexible distal section with a relatively stiffer proximal section. Fig. 4A above, discusses placement of a joint at a location spaced from the distal section of the device so as to increase a bond strength but not impair the distal section's flexibility. In any case, the device **200** can have a proximal bundle **203** that comprises either the exposed wires or a covering/tube over the wires. In certain variations, the bundle or wire **202**, **203** can be encapsulated with a coating.

[0146] The proximal end of the sheath **106** includes a sheath handle **244**. As discussed herein, axial movement of the bundle **202** or proximal bundle **203** (typically at the handle **242**) results in movement **126**, or translation of the bundle within the sheath **106**. This action moves the distal capture portion **226** (as shown by arrows **126**). In certain variations, the device **200** is loaded into a microcatheter (not shown but discussed above) that is delivered to the site of the obstruction and crosses the obstruction.

[0147] In some variations, the sheath hub **244** includes one or more locking hubs **246**. Where actuation (either axial or rotational) of the locking hub **246** locks the main bundle **202** relative to the sheath handle **244** and sheath **106**. It follows that such

locking action also locks the distal capture portion **226** relative to the proximal capture portion **260**. A variety of methods can be employed to increase a frictional interference between the locking hub **246** and the proximal bundle **203**. As a result, when a physician determines a length of an obstruction, the physician can set a spacing between the capturing portions **226 260** by locking the proximal bundle **203** relative to the sheath hub **244**. Accordingly, the proximal bundle **203** can include any type of incremental markings to allow the physician to readily determine a spacing of the capturing portions. As illustrated, the sheath hub **244** can include additional injection ports to deliver fluid or other substances through the sheath **106**.

[0148] As noted above, the device **200** can be used with micro-catheter. In those variations it is important that the device **200** is loaded without damaging the distal bundle **202**, capture portions **226 260**, and/or sheath **106**. As a result, the device **200** can include an optional funnel **286** that reduces the proximal capture portion **260** (and /or the distal capture portion **226**) for loading within the microcatheter and/or sheath **106**.

[0149] Another variation of the device **200** includes an insertion tool **280** slidably affixed to the sheath **280**. Because variations of the device **200** can be extremely flexible, the insertion tool **280** can be used to provide column strength to the sheath **106**, bundle **202** or other components as the device **200** is pushed into the microcatheter. The insertion tool comprises a rigid section **282** and a frictional coupler **284**. The rigid section **282** has a column strength that supports the device **200** to prevent buckling. The frictional coupler **284** can be a flexible material that allows an operator to squeeze or grip the coupler **284** to create a temporary frictional interface between the loading tool **280** and the device **200** (typically the sheath **106**). Such an action allows axial advancement of the device **200** as the loading tool **280** is advanced into the microcatheter. Once the rigid section **282** is fully inserted into the microcatheter, the operator releases the frictional coupler **284** and can withdraw the loading tool **280** from the catheter without withdrawing the device **200**. The insertion tool **280** can also include an optional loading tube **286** slidably coupled to the rigid section **282**. When used, the funnel **286** can withdraw the proximal and distal capturing portion **226 260** within the loading tube **286**. The loading tube **286** then

couples to a microcatheter allowing the capturing portions to advance therein as the rigid section **282** and frictional coupler **284** advance the device **200** relative to the loading tube **286**.

[0150] Fig. 11A illustrates a funnel catheter **300** useful for retrieving objects from vessels or body lumens. Typically, when a physician captures an obstruction in various retrieval devices, the device and the obstruction are easily removed from the body by withdrawing the device and obstruction into a sheath, guide catheter or introducer ("guide catheter"). However, in some circumstances, a physician has difficulty withdrawing the obstruction loaded device within a sheath, guide catheter or introducer. Specifically, one or more components of the retrieval device might become caught on an edge of the guide catheter. The concern may still remain even when using a guide catheter having an increased diameter (such as when the retrieval device catches on one edge of the guide catheter tip). Moreover, large guide catheters are difficult to advance within various parts of the anatomy. As a result, the obstruction loaded device must travel further. Movement of the obstruction loaded device within the body creates the risk that the obstruction will detach or break apart and cause additional adverse consequences.

[0151] The funnel catheter **300** includes a first and second slotted funnels **330**, **340** located at the distal end of an inner shaft **302.** Each funnel **330 340** comprises a number of extensions or tines **332 342**. The inner shaft **302** can be cut to produce the first tines **332**. Alternatively, the first tines **332** can be affixed to a portion of the inner shaft **302**. The second slotted funnel **340** is offset in both a proximal and rotational position relative to the first slotted funnel **330**. The purpose of this dual offset is discussed in detail below. As shown, the second funnel **340** can be a slotted tube that is affixed over the inner shaft **302**. In an alternate variation, a plurality of second tines **342** can be located about the inner shaft **302** to form a second slotted funnel **340**. As shown in Fig. 11B, the tines **332 342** can be configured to expand outward (if not restrained) via use of a coil or other spring-type means. Alternatively, they can be actuated to expand outward. However, in most cases, the tines **332 342** can expand passively upon entry of the retrieval device **200**. The expansion of one or both funnels assists in receiving the retrieval device. In additional configurations, one or more

funnels can be designed so that they remain in a cylindrical shape rather than expand outwards (as shown in Fig. 11C). Variations of the funnel catheter **300** can include configurations having one or more funnels, or configurations where the tines spaced or adjacent (or a combination thereof).

[0152] Fig. 11C also illustrates the dual offset nature of the dual funnel catheter **300**. The first offset is a linear offset **316** such that the distal ends of the first tines **332** or funnel **330** extends beyond a distal end of the second tines **342** or second funnel **340**. The second offset comprises a rotational offset (denoted by rotational angle **A**). For example, the illustrated rotational offset **A** is 45 degrees. However, the rotational offset can vary depending on the particular application. In most variations, the rotational offset **A** will place the second tines **342** over the gaps or spaces between the first tines **332**. The number of tines can vary depending on the application. Variations of the funnel catheter can include discontinuous funnels with two or more tines.

[0153] Turning back to Fig. 11A, the funnel catheter **300** can optionally include any number of medical fittings or components. As shown, the catheter **300** includes a hemostasis valve or hub **306** at the proximal end. The hemostasis valve **306** can include a fluid side port **308** for delivery of fluid through the catheter **300**. The catheter **300** can also include one or more radiopaque markers **310** so that the location of the funnel or funnels **330 340** can be identified via non-invasive imaging (e.g., under fluoroscopy). The funnel catheter **300** can also optionally include one or more markers **312**. Such markers are useful to inform a physician (who is only able to view the proximal end of the device **300**) of the distance to the first or second funnel. As a result, the physician will be able to determine whether the funnels are advanced out of the guide catheter. Fig. 11A also shows the funnel catheter **300** as including a loading tool **314**. The loading tool **314** can be advanced over the funnels **330 340** to compress the funnel when loading into a guide catheter or other sheath.

[0154] Figs. 12A to 12C provide an illustrative example where use of a funnel catheter **300** aids in removal of an obstruction **2** loaded within a retrieval device **200**.

[0155] As shown in Fig. 12A, attempting to remove the obstruction **2** when engulfed in the retrieval device **200** creates a risk that one or more portions of the device **200** become caught on the guide sheath or access catheter **108**. In some cases, the

physician can simply engage the device **200** against the distal end of the guide sheath **108** and withdraw until the obstruction **6** and device **200** are located in an acceptable area of the body or withdrawn entirely from the body. For example, in certain situations, the obstruction **6** and device **200** can be withdrawn with the guide sheath **108** until all components reach a high flow, non-critical locations (e.g., the groin area). In the case of a clot, a clot dissolving substance (t-PA urokinase, etc.) can then be applied to dissolve and remove the clot. Alternatively, the physician can attempt to aspirate through the guide sheath **108** in an attempt to draw the entire retrieval device **200** and obstruction **2** within the guide sheath **108**. In yet another variation, the physician can advance fibers or guide wires out through the guide sheath **108**, then withdraw the obstruction **2**/retrieval device **200** and attempt to use the fibers or guide wires as a moveable surface to capture the device **200**. Furthermore, the physician can attempt to use a variety of existing devices (e.g., the FastCath provided by Genesis Medical Inc., the Merci Retriever provided by Concentric Medical Inc., or any commercially available snare or distal protection device) to remove the engulfed obstruction **2** from the body.

[0156] In some variations, the capturing portions discussed above can be constructed to improve their ability to be withdrawn into a guide sheath. For example, increasing the number of petals or flanges on the traversing sections increases the probability that the distal flanges nest within the proximal capturing portion. Alternatively, or in combination, the petals **238** on the distal capturing portion can be staggered in length or position to ease insertion into the proximal capturing portion. In another variation, the petals **238** shape or curvature can be adjusted so that they do not flare outward.

[0157] Fig. 12B shows a distal end of a funnel catheter **300** as it receives an obstruction **2** loaded retrieval device **200**. As shown, the tines **332** of the first funnel **330** receive the device **200**. The tines **332** minimize the likelihood that the device **200** becomes caught. The limited surface area of the tine **332** (combined with the rounded tines **332 342**) produces a tendency for the device **200** to deflect away from the tines as it is withdrawn into the funnels. The second funnel **340**(being rotationally offset from the first funnel **330** provides coverage over the spaces between the first tines **332** thereby assisting in nesting of the device **200** within the funnels. Ultimately, the

device **200** and obstruction **2** are withdrawn into a guide sheath **108** and removed from the body.

[0158] Figs. 12 C to 12D show additional variations of funnel catheter **300**. Fig. 12C shows a single funnel **330** having a plurality of tines **332**. Fig. 12D illustrates a dual funnel catheter **300** having a discontinuous first funnel **230** and a second funnel **346**. The second funnel **346** can be a continuous funnel so long as it is able to retract within the guide sheath **108**. As shown, the second funnel **346** can include a single slit **348** that allows the funnel to compress within the guide sheath **108**. In addition, the variation of Fig. 12D can be used without the first discontinuous funnel **330**. Accordingly, as the retrieval device **200** and clot **2** approach the funnel **346** and enters the funnel, further withdrawing the retrieval device **200** causes squeezing of the retrieval device **200** and obstruction **2**. In yet another variation, the funnel **346** can incorporate a drawstring to compress the funnel **346** once the retrieval device **200** and obstruction are located therein.

[0159] Fig. 13A to 13B illustrates another variation of a funnel catheter **350** suited to remove a retrieval device **200** from the body. As shown in Fig. 13A, the funnel catheter **350** includes a first shaft **352** and a second shaft **354** slidably located therein. A mesh **370** is fused to each shaft **352 354** at a distal location **362 364**. Accordingly, relative movement of the shafts **352 354** (either the first shaft **352** can be pushed or the second shaft **354** can be pulled) creates a funnel shape **372** as the mesh portion affixed to the second shaft **354** is inverted within the remainder of the mesh **370**. It is noted that in some variations of the system, the mesh funnel funnels are combined with the tine based funnels described above. Such that one funnel comprises the tines while the other comprises the mesh structure described herein.

[0160] In another variation, a third distally located capture portion (similar to a distal capture portion) can be used to draw the retrieval device within a guide sheath. In such a variation, the third capture portion can be a larger distal capture portion and when the retrieval device engulfs an obstruction, the third basket portion can be proximally withdrawn to capture the retrieval device and obstruction.

[0161] As illustrated in Fig. 13B, as the retrieval device **200** and obstruction **2** approach the funnel catheter **350**, the distal attachment points **362 364** of the shafts

352 354 are moved together to invert the mesh 370 and form a funnel 372. The retrieval device 200 can then be withdrawn into the funnel. This design allows for the retrieval device 200 to be fully withdrawn into the catheter 350 while the funnel 372 is expanded. Alternatively, the funnel 372 can be used to compress the retrieval device 200 and obstruction 2 prior to withdrawal into the catheter 350.

[0162] The mesh 370 can include any medically acceptable material such as a nitenol braid. Furthermore, the mesh allows for flow through the vessel or lumen while expanded. However, additional variations of the device can include a solid layer of material substituted for the mesh.

[0163] Figs. 13C to 13E illustrate another variation of a funnel catheter 350 suited to remove a retrieval device 200 from the body. As shown in Fig. 13C, the funnel catheter 350 includes a first shaft 352 and a second shaft 354 slidably located therein. A mesh 370 is joined only the rear shaft 354 at a distal location 362. The end of the mesh 370 is free at the distal end of the device 350. The mesh 370 is sized at a distal end 371 to neck down. Accordingly, as the distal shaft moves rearward, the mesh 370 is unsupported. The necked section 371 of the mesh allows for distal advancement of the device 200 through the neck portion 371. However, as shown by Fig. 13D, rearward movement of the device 200 causes engagement with the neck portion 371. Further rearward movement of the device 200 causes the unsupported mesh 370 to form a funnel shape 372 as shown in Fig. 13E. The funnel shape allows for the retrieval device 200 to be fully withdrawn into the catheter 350 while the funnel 372 is expanded. Alternatively, the funnel 372 can be used to compress the retrieval device 200 and obstruction 2 prior to withdrawal into the catheter 350. To compress the funnel, the device 200 can be advanced out of the funnel and away from the mesh 370. Next, the distal shaft 352 can be advanced through the neck portion 371 of the mesh 370 to receive the device 200. In another variation, the device 350 can include a single shaft 354 where the mesh 370 can extend beyond the shaft 354. The mesh can be heat set to assume a funnel shape upon the application of a current or as it reaches body temperature. In another variation, the mesh 370 can comprise a super-elastic material that assumes the shape shown in Fig. 13E when released from a constraining member.

[0164] Figs. 13F to 13G illustrate yet another variation a funnel catheter **350** suited to remove a retrieval device **200** from the body. In this variation, the funnel catheter **350** includes a single shaft **354** having a mesh **370** is fused to a distal location **364**. The mesh **370** is free at a proximal side. The mesh is also pre-formed to assume a funnel shape as shown in Fig. 13G. Accordingly, upon delivery the mesh **370** can be constrained (e.g., via a sheath, or other removable restraint). Once the restraint is removed, the mesh **370** expands to form a funnel **372**.

[0165] Figs. 14A to 14D illustrate additional concepts for use with various retrieval devices **200**. Fig. 14A illustrates a distal capturing portion **226** and a proximal capturing portion **260** where the proximal capturing portion includes a covering **212** (e.g., a polymeric covering or a wire or fiber wound about the flanges **238**). The covering **212** prevents the flanges **238** of the distal capturing portion **226** from flaring outside of the proximal capturing portion **260**.

[0166] Fig. 14B illustrates a variation of a reentry sleeve where tines **332** of the reentry sleeve **302** include protrusions **214** on an inner surface. The protrusions **214** cause the tines **332** to splay out as the retrieval device **200** is withdrawn within the tines **332**. As the reentry sleeve **302** is withdrawn in a guide catheter (as discussed above) the protrusions serve to compress the retrieval device **200** even further.

[0167] Fig. 14C and 14D illustrate variations of a wire or fiber **218** affixed to the flanges **238** of a distal capturing portion **226** to assist in compressing the flanges **238** prior to entry within a guide sheath. As shown in Fig. 14C the fiber **218** can be affixed to a suture ring **216**. As the fiber **218** is pulled, the suture ring **216** compresses the flanges **238** to prevent outward flaring. In Fig. 14D, one or more fibers **218** are affixed to one or more flanges **238**. Once the obstruction is captured, the fibers can be pulled to draw the flanges **238** closed.

[0168] Fig. 15 illustrates another variation of a retrieval device **200** including a distal capture portion **226** coupled to one or more leading wires in the form of a main bundle **202**. The main bundle extends through a sheath **106** that includes a proximal capture portion **266** is configured to expand when placed within or moved into an obstruction in a blood vessel. For example, the illustrated variation includes a translating portion **234** adjacent to an open distal end **288**. Next, the proximal capture portion **266**

includes a surface **290** adjacent to the translating portion **234** (or adjacent to the open distal end **288** if no translating portion is used). The surface **290** comprises a higher density than that of the translating portions described above. In some variations, the surface **290** can comprise a low-density surface but the device is otherwise configured to expand within an obstruction. As shown, the proximal surface **292** is fluid permeable to allow blood flow when the proximal capture portion **266** is deployed in a vessel.

[0169] The proximal capture portion **266** illustrated can comprise a construction similar to that of a stent-type device, where such a configuration permits the proximal capture portion **266** to be deployed against an obstruction in a manner similar to a stent deployment. As described below, application of the capture portion **266** within an obstruction allows for re-establishing blood flow, in the event the obstruction is a total occlusion. A therapeutic substance can then be delivered to the obstruction to assist in breaking down the obstruction. For example, the substance can be delivered through a microcatheter (not shown), delivery sheath **106** or by any fluid delivery mode described herein.

[0170] The configuration of the retrieval device **200** can incorporate the proximal and distal capture portions discussed herein as well as various other configurations discussed in the commonly assigned patent applications noted above. In addition, the relative sizes of the various components shown in Fig. 15 and discussed below are for illustrative purposes only.

[0171] An end **292** of the proximal capture portion **266** is affixed to a distal end of a sheath **106**. However, as noted above, other variations are within the scope of the disclosure. The main bundle **202** can optionally terminate at a handle **242**. As noted above, in certain variations, the main bundle is joined to a stiffer wire or stiffer bundle of wires. This allows the device **200** to have a very flexible distal section with a relatively stiffer proximal section. Fig. 4A above, discusses placement of a joint at a location spaced from the distal section of the device so as to increase a bond strength but not impair the distal section's flexibility. In any case, the device **200** can have a proximal bundle **203** that comprises either the exposed wires or a covering/tube over

the wires. In certain variations, the bundle or wire **202**, **203** can be encapsulated with a coating.

[0172] The proximal end of the sheath **106** includes a sheath handle **244**. As discussed herein, axial movement of the bundle **202** or proximal bundle **203** (typically at the handle **242**) results in movement **126**, or translation of the bundle within the sheath **106**. This action moves the distal capture portion **226** (as shown by arrows **126**). In certain variations, the device **200** is loaded into a microcatheter (not shown but discussed above) that is delivered to the site of the obstruction and crosses the obstruction.

[0173] In some variations, the sheath hub **244** includes one or more locking hubs **246**. Where actuation (either axial or rotational) of the locking hub **246** locks the main bundle **202** relative to the sheath handle **244** and sheath **106**. It follows that such locking action also locks the distal capture portion **226** relative to the proximal capture portion **266**. A variety of methods can be employed to increase a frictional interference between the locking hub **246** and the proximal bundle **203**. As a result, when a physician determines a length of an obstruction, the physician can set a spacing between the capturing portions **226** **266** by locking the proximal bundle **203** relative to the sheath hub **244**. As illustrated, the sheath hub **244** can include additional injection ports to deliver fluid or other substances through the sheath **106**.

[0174] Figs. 16A to 16E demonstrate an example of a retrieval device **200** that uses a proximal capture portion **266** that is configured to be deployed against an obstruction **2** within a vessel **6** or other lumen.

[0175] Fig. 16A illustrates a microcatheter **102** positioning a distal capture portion **226** beyond the obstruction **2**. As noted above, the distal capture portion **226** can serve as a filter by capturing debris or other particles that break free from the obstruction **2** during the procedure. Moreover, the procedures and techniques described herein can be used to assist with placing the distal capture portion **226** downstream of the obstruction **2**.

[0176] Fig. 16B illustrates the proximal capture portion **266** being deployed against the obstruction **2**. In those situations where the obstruction **2** totally or significantly occludes the vessel, deployment of the proximal capture portion **266** can re-establish

blood flow upon deployment. Although Fig. 16A illustrates the proximal capture portion **226** being deployed within the obstruction **2**, alternative variations include deployment of the proximal capture portion distally to the obstruction **2** and then translated proximally into the obstruction **2**.

[0177] Fig. 16C illustrates an optional procedure where the distal capture portion **226** can be withdrawn against the proximal capture portion **266**. The action of the distal capture portion **226** applies an axial force against the proximal capture portion **266** causing the proximal capture portion **266** to further expand against the obstruction **2**. The motion can be cycled to work the proximal capture portion **266** against the obstruction **2**. In some variations, the proximal capture portion **266** includes a translating portion **234** that facilitates entry of the distal capture portion **226** therein to assist in expanding the proximal capture portion **266** and more particularly the high density surface **290**.

[0178] At this point a physician can apply a substance (as described herein) that dissolves the obstruction **2**. In some cases, the residual obstruction **2** can be removed from the vessel **6** simply by removing the proximal capture portion **266** when the residual obstruction **2** adheres to or within the high density surface **290**. As noted herein, the distal capture portion **226** can simply function as a distal filter by trapping debris generated by the removal process. In some variations, the proximal capture portion **266** is only partially deployed when engaging the obstruction **2**. In such a case, a proximal segment of the proximal capture portion **266** can remain within the microcatheter. In addition, the microcatheter can recapture the proximal capture portion **266** and then withdraw it to the proximal side of the obstruction **2**.

[0179] Fig. 16D illustrates a condition where the residual obstruction **2** does not remain affixed to the proximal capture portion **266**. As shown, the proximal capture portion **266** is withdrawn proximally of the residual obstruction **2**. The physician can then use the proximal and distal capture portions **266** and **226** to surround and capture the obstruction **2** as described above. Fig. 16E illustrates such a condition as the distal capture portion **226** is withdrawn over the obstruction and the proximal capture portion **266** is advanced to the obstruction **2** to surround, capture, and ultimately remove the obstruction **2**. As noted above, variations of the procedure include

deploying only a section of the proximal capture portion **266** to capture the obstruction **2**. In such variations, the section of the proximal capture portion **266** that extends from the microcatheter will resemble the proximal capture portions disclosed above (e.g., Fig. 10).

[0180] Figs. 17A to 17C illustrate another variation of a working portion of an obstruction removal device **200**. In this variation, the obstruction removal device **200** includes a distal capturing portion **226** affixed to a proximal section **294** comprising one or more high density sections **296** interconnected with one or more low density sections **298**. The high density sections **296** can comprise stent-like structures such as laser cut tubes, braided, or woven filaments, wires, DFT, etc. The proximal section **294** can be coupled to a catheter, push wire, or other member **299**. The structure can be a continuous structure that is fabricated via any known manufacturing process.

[0181] Fig. 17B illustrates one use of the device of Fig. 17A. As shown, the proximal section **294** is deployed against an obstruction **2** within a vessel **6** to re-establish or increase blood flow distal to the obstruction **2**. The high density sections **296** are configured to apply a radial expansive force against the obstruction **2** and, in some variations, embed the high density section **296** within the obstruction **2**. The distal capture portion **226** serves as a distal filter by capturing debris and other material that breaks free from the obstruction **2**. As illustrated, part of the obstruction **2** will enter the low density section **298** of the proximal section **294**.

[0182] Fig. 17C illustrate the device of Fig. 17B being moved in a distal or reciprocating motion (as shown by the arrows). The reciprocating motion can shear portions of the obstruction **2** that are either embedded within the high density section **296** or are at the transition between the high density section **296** and the low density section **298**. A physician can deploy and re-deploy the device to ultimately remove the obstruction. In some variations, the obstruction adheres to the high density section **296** allowing for removal. In other variations, the obstruction **2** becomes entrapped within the distal capture portion **226** upon withdrawal of the device. It should also be noted that additional elements such as wires or filaments can be located on the inside of the body 294 to enhance the ability for the clot to stay entwined within the cavity 294.

[0183] Figs. 18A to 18H illustrate a variation of the capture portions or sections for use with the systems and methods described herein. In these variations, the capture portions are configured to deliver a substance (such as a therapeutic or obstruction dissolving substance) at a perimeter of the device so that the substance can be deployed closely to the obstruction.

[0184] Fig. 18A illustrates a simply coil stent structure **400** fabricated from a hollow structure **406** such as a super-elastic material. In one variation, the hollow structure **406** includes a number of fluid delivery ports **402** on an outer surface of the structure **400**. This placement allows for delivery of the substance directly into the obstruction **2** as the fluid flows **404** from a perimeter of the coil structure **400**. The fluid ports **402** can be drilled into the hollow structure **406** using techniques known by those skilled in the art of fabricating such medical devices, such as mechanical drilling or laser drilling. In those variations using a coil stent structure **400**, pulling back into the microcatheter or other delivery catheter 398 can deploy the stent structure **400**. Alternatively, a push wire can be used to elongate or straighten the stent structure **400** for deployment and withdrawal from the obstruction **2**.

[0185] Fig. 18B illustrates an example of a cross sectional view of the hollow structure **406** of Fig. 18A. Although the structure **406** shows a cylindrical shape, any shape can be used. Moreover, any biocompatible material can be used for the structure **406**, including but not limited to a shape memory alloy such as Nitinol.

[0186] Fig. 18C illustrates another variation of a structure **410** having fluid delivery ports **402**. In this variation a polymer layer **414** covers an inner core material **412** (e.g., Nitinol). The fluid ports **402** are located in a surface of the polymer layer **414**. Moreover, the polymer layer or the core material will have one or more fluid passages to allow for delivery of the fluid through the ports from a proximal end of the device.

[0187] Figs. 18D and 18E illustrate additional structures for use as stent or capturing structures as described herein. In Fig. 18D, the structure **416** comprises a double coil or double helix with one or more wires. Fig. 18E illustrates a braided structure **418** with one or more wires. Fluid ports can be positioned in one or more of the wires. Moreover, the stent structures described herein can be actuated using a straightening

rod for deployment and withdrawal. Alternatively, the structures can be self-expanding and deployed when released from a catheter or other sheath.

[0188] Figs. 18F and 18G illustrate an additional variation of a structure **420** incorporating fluid delivery ports **402**. However, in these variations, the fluid ports **420** are located in a fluid delivery tube **422** affixed to the structure **420**. In both variations, blood flow **B** is maintained as the fluid delivery tube **422** is affixed to a perimeter of the structure **420**. Fig. 18F illustrates a branching tube **422** having at least two branch tubes affixed to the perimeter of the structure **420**. Fig. 18G illustrates a fluid delivery tube **422** interwoven in a stent structure **420** so that fluid delivery ports **402** are situated at or near a perimeter of the structure **420**.

[0189] Fig. 18H illustrates another variation of a device **200** incorporating fluid delivery ports. This variation is similar to that shown in Fig. 15 where fluid delivery ports are fabricated in the proximal capture portion **266**. As shown, fluid flow **404** takes place at the perimeter of the capture portion **266** in direct contact or closely to any obstruction.

[0190] In addition to fluid delivery ports, any of the devices described herein can be coated with therapeutic or other substances as described herein. Alternate variations include such substances placed in reservoirs within the capture portions so that such substances need not be conveyed along a length of the system from a proximal end of the system to the capture portions.

[0191] Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. Also, any optional feature of the inventive variations may be set forth and claimed independently, or in combination with any one or more of the features described herein. Accordingly, the invention contemplates combinations of various aspects of the embodiments or combinations of the embodiments themselves, where possible. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said," and "the" include plural references unless the context clearly dictates otherwise.

[0192] It is important to note that where possible, aspects of the various described embodiments, or the embodiments themselves can be combined. Where such combinations are intended to be within the scope of this disclosure.

CLAIMS

1. A medical device for recanalizing a blood vessel having an obstruction, the medical device comprising:

a distal capturing portion having an open proximal end and a fluidly permeable distal end, the distal capturing portion having a translating surface adjacent to the open proximal end and a distal capturing surface adjacent the fluidly permeable distal end;

a proximal capturing portion having an open distal end and a fluidly permeable proximal end, the proximal capturing portion having a medial surface between the open distal end the fluidly permeable proximal end, where the medial surface comprises a stent-type structure that is configured to expand to compress the obstruction when deployed therein; and

a main bundle comprising a group of wires having a first end and a second end extending through the proximal capturing portion to the distal capturing portion, where the main bundle is moveable relative to the proximal capturing portion such that proximal movement of the main bundle decreases a distance between the open ends of the distal capturing portion and proximal capturing portion.

2. The medical device of claim 1, where the proximal capturing portion includes at a plurality of fluid delivery ports on a surface of the proximal capturing portion allowing fluid to be delivered from a perimeter of the proximal capturing portion

3. The medical device of claim 1, where the distal capturing portion is formed from the group of wires in the main bundle such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the distal capturing surface, the translating surface, and open proximal end about the main bundle.

4. The medical device of claim 3, where the translating surface and distal capturing surface are configured so that a translating surface axial strength is greater than a distal capturing surface axial strength, wherein application of a tensile force on the main bundle causes axial compression of the distal capturing surface without causing

axial compression and deformation of the translating surface sufficient to deform the translating surface as the capturing portion engages the obstruction.

5. The medical device of claim 2, further comprising at least one filament forming the proximal capturing portion, the filament including at least one fluid delivery passage extending therethrough and in fluid communication with the fluid delivery ports.

6. The medical device of claim 2, where the proximal capturing portion is fabricated from a laser cut tube, where the fluid delivery ports are located in a surface of the laser cut tube and in fluid communication with a fluid delivery passage.

7. The medical device of claim 1, where the proximal capturing portion is self expanding.

8. The medical device of claim 1, where the medial surface of the proximal capturing portion comprises mesh pattern.

9. The medical device of claim 1, where the medial surface of the proximal capturing portion comprises stent like structure.

10. The medical device of claim 1, where the distal capturing surface is configured so that when the open proximal end of the translating surface engages resistance equal to or greater than a threshold force, proximal movement of the main bundle inverts the distal capturing surface within the translating surface and reduces a size of the distal capturing surface.

11. The medical device of claim 10, where the distal capturing surface and translating surface are configured to invert upon continued proximal movement of the main bundle such that the translating surface moves distally to the distal capturing surface.

12. The medical device of claim 1, where the main bundle is joined to a proximal bundle, where the proximal bundle comprises a stiffness greater than the main bundle and where the main bundle extends for a pre-determined distance from the permeable

distal end to allow navigation of a distal portion of the medical device within the cerebral vasculature.

13. The medical device of claim 12, where the pre-determined distance is at least 20 cm.

14. The medical device of claim 1, where the distal capturing surface has an increased frictional resistance as compared to the translating surface, such that the capturing surface engages the obstruction for removal of the obstruction.

15. The medical device of claim 1, where the open proximal end further comprises a plurality of flanges extending from the translating surface.

16. The medical device of claim 15, where the flanges extend radially away from an axis of the capturing portion.

17. The medical device of claim 1, where at least a portion of the distal capturing surface comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, and a plurality of crossing wires or a combination thereof.

18. The medical device of claim 1, where the main bundle of wires includes at least a first wire and a second wire where the first and second wire each have different characteristics.

19. The medical device of claim 18, where the characteristics are selected from a group consisting of material, cross-sectional shape, and cross-sectional size.

20. The medical device of claim 1, where the main bundle of wires includes at least one shape memory alloy wire.

21. The medical device of claim 1, where the main bundle of wires includes at least one wire selected from the group consisting of a superelastic wire, a polymeric wire, or a metal alloy.

22. The medical device of claim 21, where the metal alloy comprises an alloy selected from the group consisting of stainless steel, titanium, platinum, gold, iridium, tantalum, nitinol, and combinations thereof.

23. The medical device of claim 1, further comprising at least one radiopaque material located on the capturing portion.

24. The medical device of claim 1, where the individual wires in the group of wires each comprise a bundle of smaller wires.

25. The medical device of claim 1, where the individual wire comprises a super-elastic outer shell and an inner core of a radiopaque material.

26. The medical device of claim 25, where the inner core comprises a material selected from a group consisting of platinum, iridium, gold, and tantalum.

27. The medical device of claim 1, where the distal capturing portion is jointless.

28. The medical device of claim 1, where at least one of the wires from the main bundle returns to the main bundle after forming at least a part of the distal capturing portion.

29. The medical device of claim 1, where each of the wires from the main bundle returns to the main bundle after forming a part of the capturing portion.

30. The medical device of claim 1, where the main bundle is surrounded by a coil or coiled wire.

31. A method of recanalizing a blood vessel having an obstruction, the method comprising:

inserting an expandable structure within the obstruction, where the expandable structure comprises at least one fluid delivery port adjacent to an exterior surface of the expandable structure;

expanding the expandable structure within the obstruction; and

delivering a substance through the fluid delivery port such that the substance begins to dissolve the obstruction.

32. The method of claim 31, where the expandable structure is fabricated from at least one tubular element, the tubular element comprising a fluid delivery passage extending through at least a portion of the tubular element, where the fluid delivery passage terminates in at least one of the fluid delivery ports.

33. The method of claim 31, where the expandable structure comprises a stent portion and a fluid delivery membrane located within the stent portion, where expanding the expandable structure comprises expanding the stent portion and where delivering the substance comprises delivering the substance through at least one delivery port located in the fluid delivery membrane.

34. The method of claim 33, further comprising deploying a distal capturing portion distally of the obstruction, where the distal capturing portion comprises a mesh pattern to permit blood flow therethrough, such that debris from the obstruction flowing in a distal direction in the blood vessel becomes filtered in the mesh pattern.

35. The method of claim 34, where the expandable structure comprises a proximal capturing portion having an open distal end and a fluid permeable proximal end, the method further comprising withdrawing the proximal capturing portion proximally to the obstruction and then surrounding the obstruction with the distal capturing portion and the proximal capturing portion to capture the obstruction.

36. The method of claim 35, where surrounding the obstruction occurs after sufficient time for the substance to dissolve a portion of the obstruction.

37. The method of claim 34, further comprising withdrawing the distal capturing portion against the expandable structure when the expandable structure is located in the obstruction to cause the expandable structure to increase a radial force to the obstruction.

38. The method of claim 31, where the expandable structure comprises at least two helical coils forming an expandable double helix structure, where at least one of the helical coils comprises the at least one fluid delivery port.

39. The method of claim 31, where the expandable structure comprises a braided structure comprising at least one wire element, where the at least one wire element.

40. The method of claim 31, where the expandable structure comprises an expandable structure comprising at least one super elastic element forming the expandable structure.

41. The method of claim 40, where the super elastic element comprises a super elastic tube, and where the super elastic tube comprises a plurality of holes forming the fluid delivery ports.

42. The method of claim 40, where the super elastic element comprises a super elastic wire, and where the super elastic wire comprises a polymeric layer comprising a fluid passage having a plurality of openings in the polymeric layer to form the fluid delivery ports.

43. The method of claim 31, where the expandable structure comprises a distal capturing portion having an open proximal end and a fluid permeable distal end, and a proximal stent section, where the proximal stent section comprises a plurality of high density stent sections and a plurality of low density of stent sections, where the high density stent sections comprise a high surface area of a mesh, or a woven pattern, where expanding the expandable structure comprises expanding the proximal stent section into the obstruction.

44. A method of recanalizing a blood vessel having an obstruction, the method comprising:

advancing a microcathter distal to the obstruction;

deploying a distal capturing portion distally of the obstruction;

positioning a proximal capturing portion within the obstruction, where the proximal capturing portion is sized to have a greater length than a length of the

obstruction and where proximal capturing portion expands to compress a portion of the obstruction against the vessel;

withdrawing the proximal capturing portion proximally to the obstruction;

securing the obstruction by moving the distal capturing portion and the proximal capturing portion together; and

removing the obstruction from the blood vessel.

45. The method of claim 44, where withdrawing the proximal capturing portion comprises resheathing at least a section of the proximal capturing portion within a microcatheter during withdrawal of the proximal capturing portion

46. The method of claim 45, further comprising partially deploying a segment of the proximal capturing portion from the microcatheter proximal to the obstruction such that the partially deployed segment functions as a proximal basket.

47. The method of claim 44, where the proximal capturing portion structure comprises a stent portion having a fluid permeable proximal end.

48. The method of claim 44, further comprising delivering a substance to the obstruction where the substance is configured to dissolve the obstruction.

49. The method of claim 48, where delivering the substance to the obstruction comprises delivering the substance through the microcatheter.

50. The method of claim 48, where delivering the substance to the obstruction comprises delivering the substance through a surface of the proximal capturing portion.

51. The method of claim 44, further comprising withdrawing the distal capturing portion against the proximal capturing portion while the proximal capturing portion is located in the obstruction to cause the proximal capturing portion to increase a radial force to the obstruction.

52. The method of claim 44, where positioning the proximal portion within the obstruction comprises positioning the proximal capturing portion distally to the obstruction and then withdrawing the proximal capturing portion into the obstruction.

53. A method of recanalizing a blood vessel having an obstruction, the method comprising:

advancing a catheter distal to the obstruction;

deploying a first capturing portion distally of the obstruction, where the first capturing portion comprises a permeable distal end, an open proximal end, a capture surface extending therebetween, and at least one leading wire extending through the capturing portion and through the catheter;

positioning a second capturing portion within the obstruction, the second capturing portion having an open distal end, a fluid permeable proximal end, and a medial surface extending therebetween, such that the second capturing portion compresses a portion of the obstruction against the blood vessel;

withdrawing the second capturing portion proximal to the obstruction;

capturing the obstruction between the first and second capturing portions by moving the first capturing portion and the second capturing portion together towards the obstruction by pulling on the leading wire to apply a force to the capturing portion at a location distal to the open proximal end of the first capturing portion; and

removing the obstruction from the blood vessel.

54. The method of claim 53, where withdrawing the second capturing portion comprises resheathing at least a section of the second capturing portion within a microcatheter during withdrawal of the second capturing portion

55. The method of claim 54, further comprising partially deploying a segment of the second capturing portion from the microcatheter proximal to the obstruction such that the partially deployed segment functions as a proximal basket.

56. The method of claim 53, where pulling on the leading wire to apply the force to the capturing portion comprises applying the force to the permeable distal end.

57. The method of claim 53, where pulling on the leading wire to apply the force to the capturing portion comprises applying the force to the capture surface.

58. The method of claim 53, where the proximal end of the second capturing portion is permeable and permits flow during removal of the obstruction.

59. The method of claim 53, further comprising continuing to move the first capturing portion towards the second capturing portion such that the open proximal end and the open distal end can removably engage each other.

60. The method of claim 53, further comprising compressing the second capturing portion about the obstruction to further secure the obstruction.

61. A method of removing an obstruction from a blood vessel, the method comprising:

inserting an expandable structure within the obstruction, where the expandable structure comprises a distal capturing portion having a fluid permeable distal end and a proximal stent section, where the proximal stent section comprises a plurality of high density stent sections and a plurality of low density of stent sections,; and

expanding the expandable structure within the obstruction such that one or more high density stent sections engage the obstruction.

62. The method of claim 61, further comprising withdrawing the expanded structure to break the obstruction free or shear portions of the obstruction.

63. The method of claim 61, where the expandable structure is configured as a continuous structure.

64. The method of claim 61, where the high density stent sections comprise a high surface area of a mesh, a woven pattern, and a laser cut pattern.

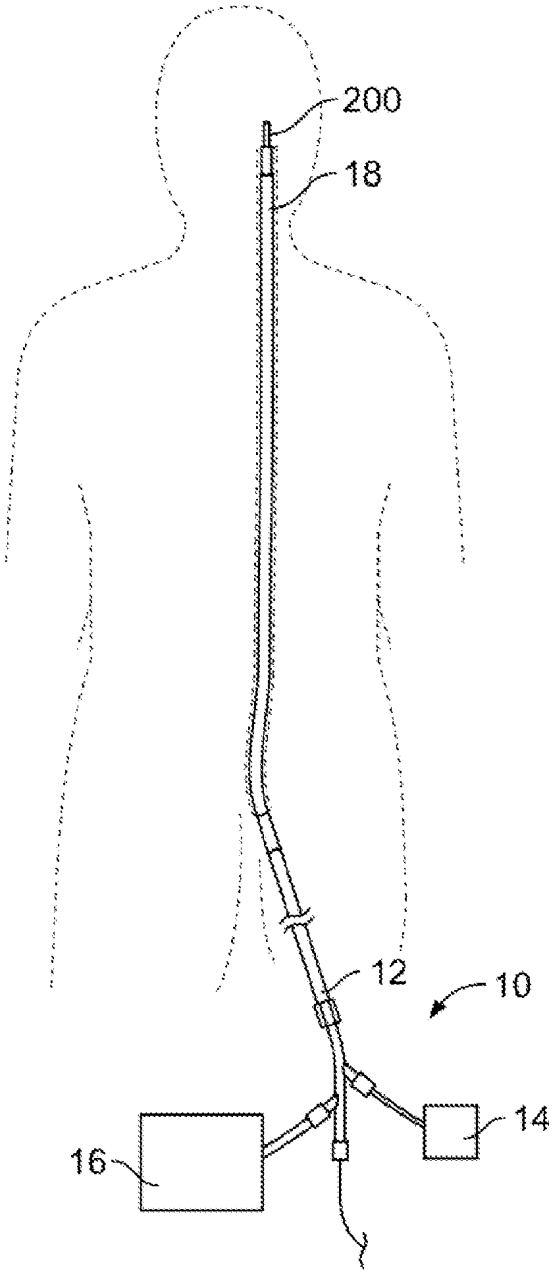


FIG. 1A

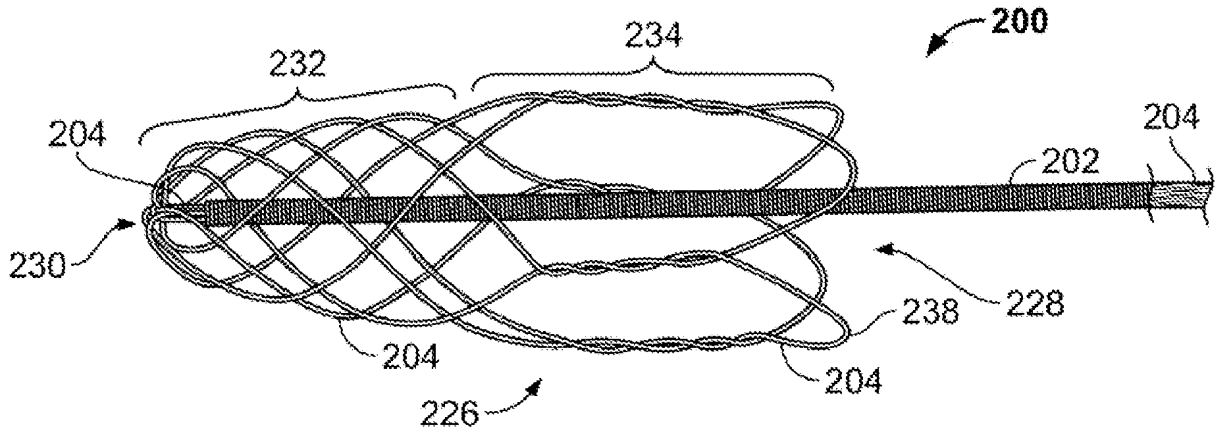

200
234
232
204
204
202
230
238
228
204
204
226

FIG. 1B

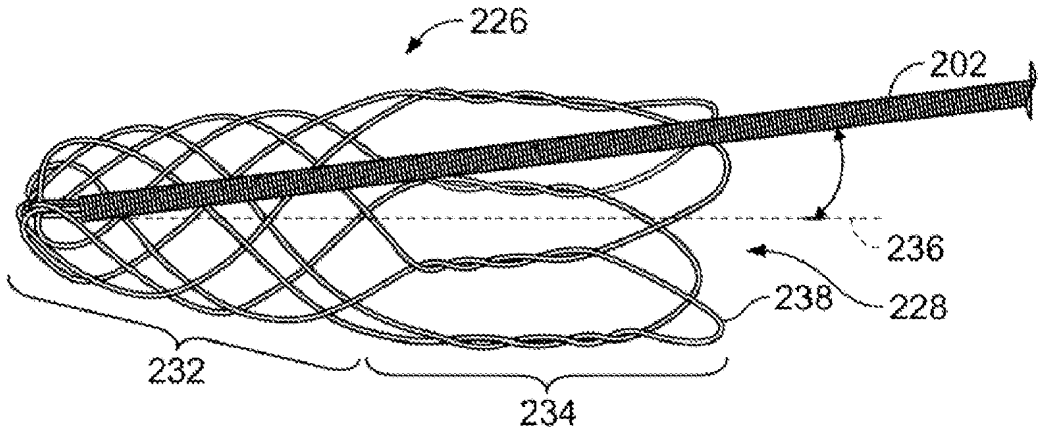

226
202
236
238
228
232
234

FIG. 1C

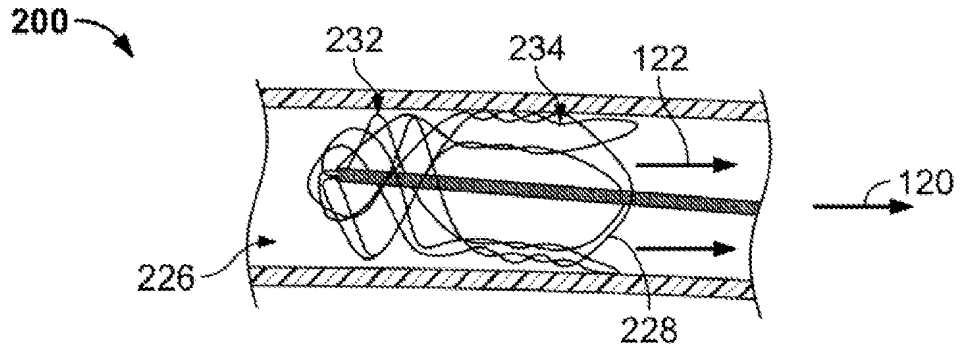


FIG. 2A

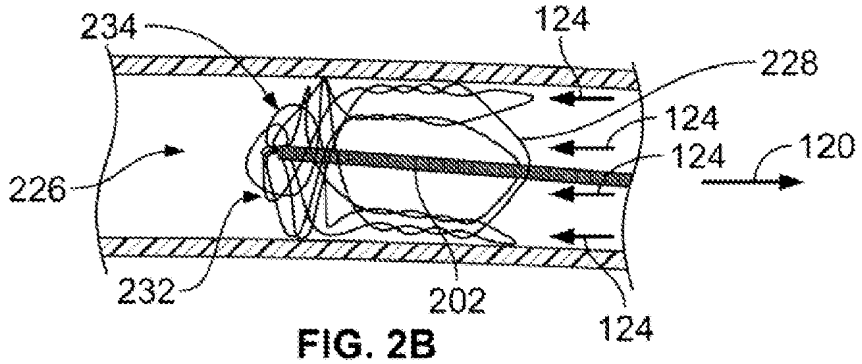


FIG. 2B

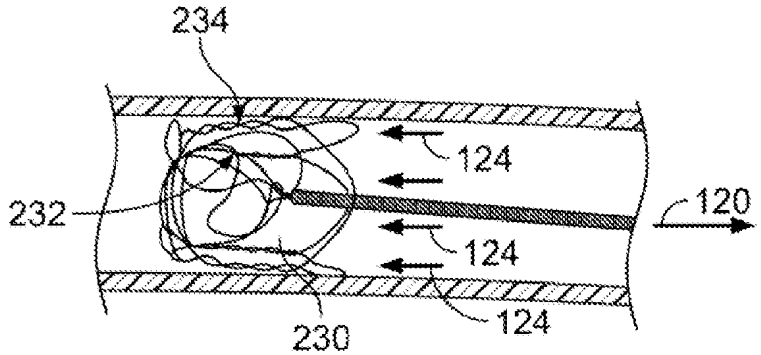


FIG. 2C

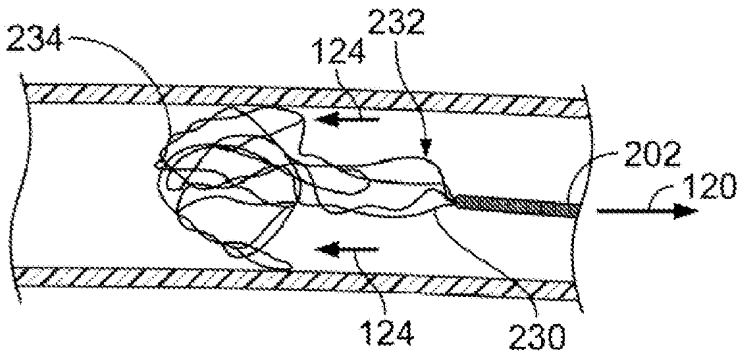


FIG. 2D

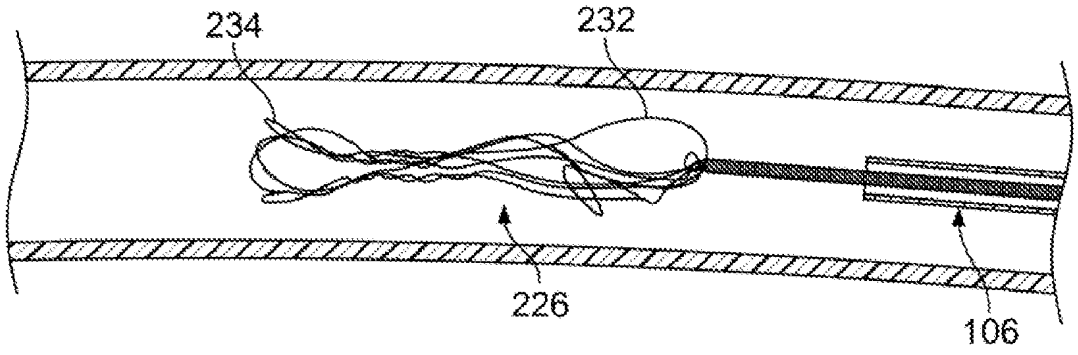


FIG. 2E

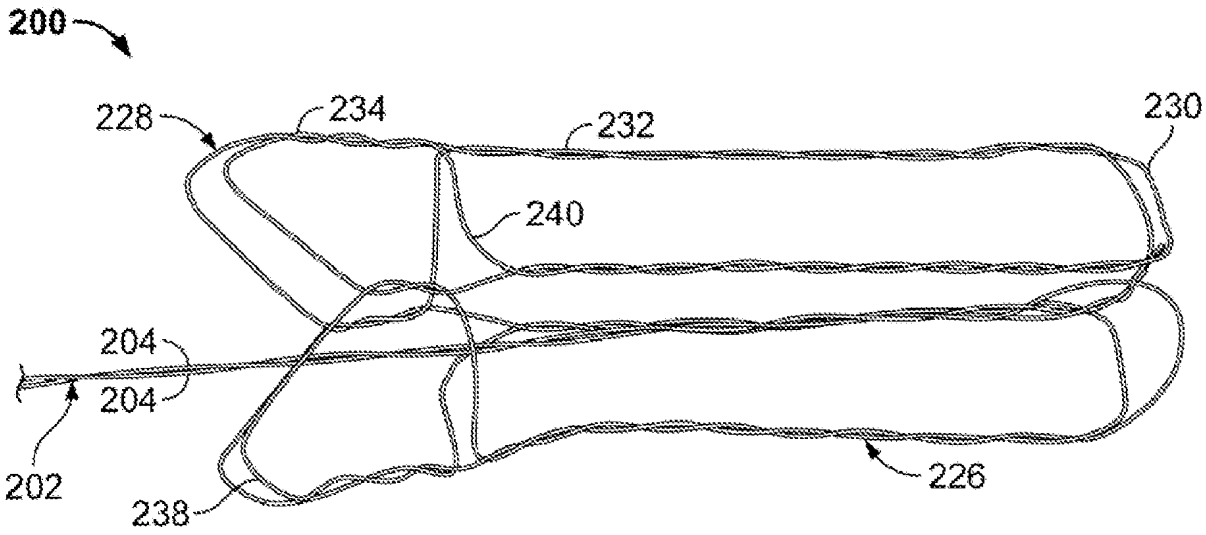

200
228
234
232
230
240
204
204
202
238
226

FIG. 3A

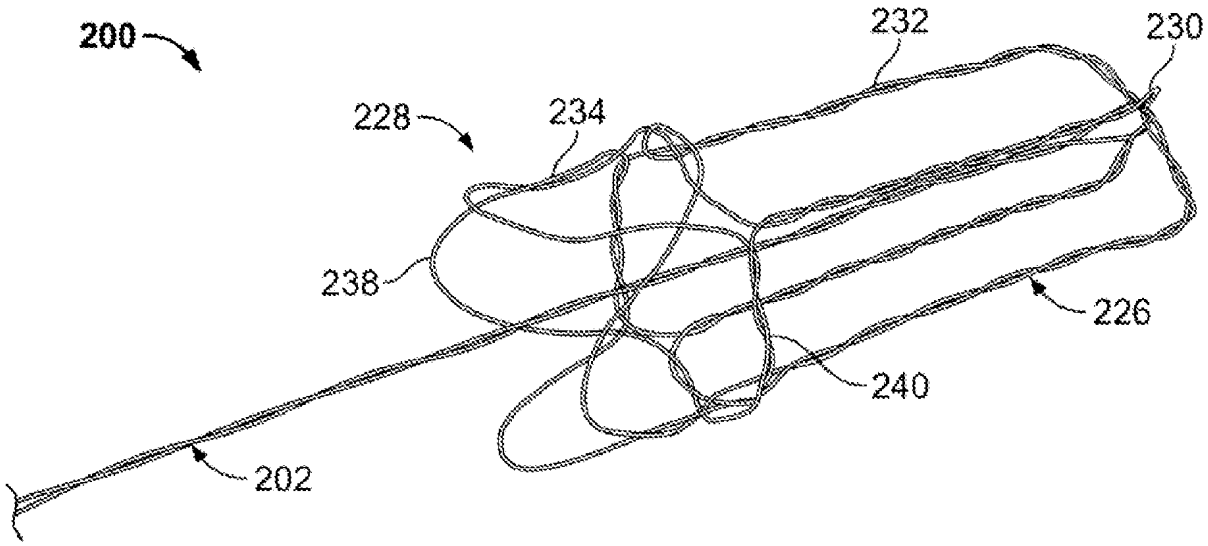

200
232
230
228
234
238
226
240
202

FIG. 3B

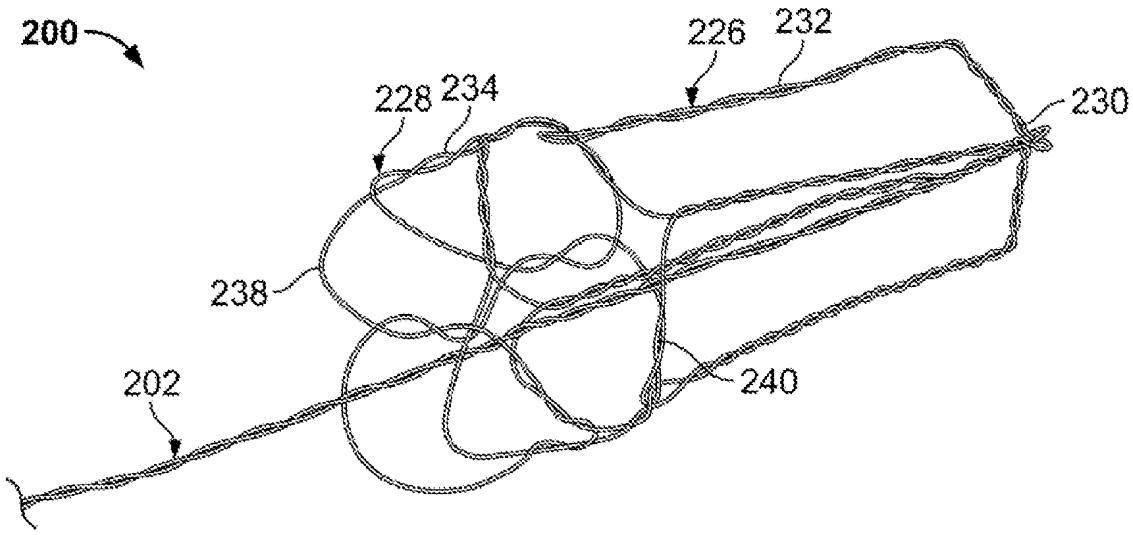


FIG. 3C

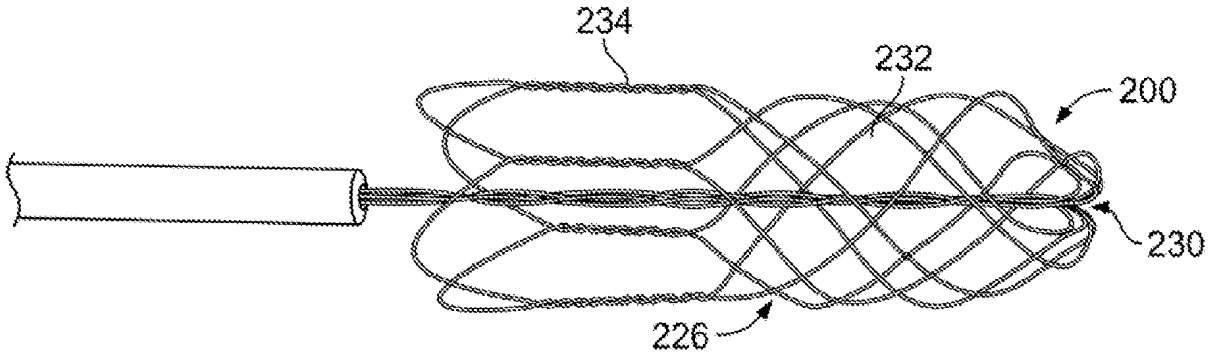


FIG. 3D

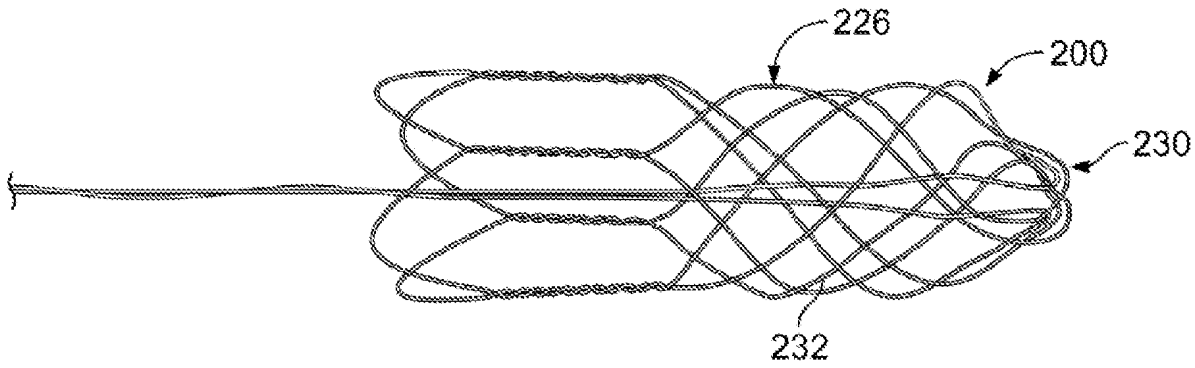


FIG. 3E

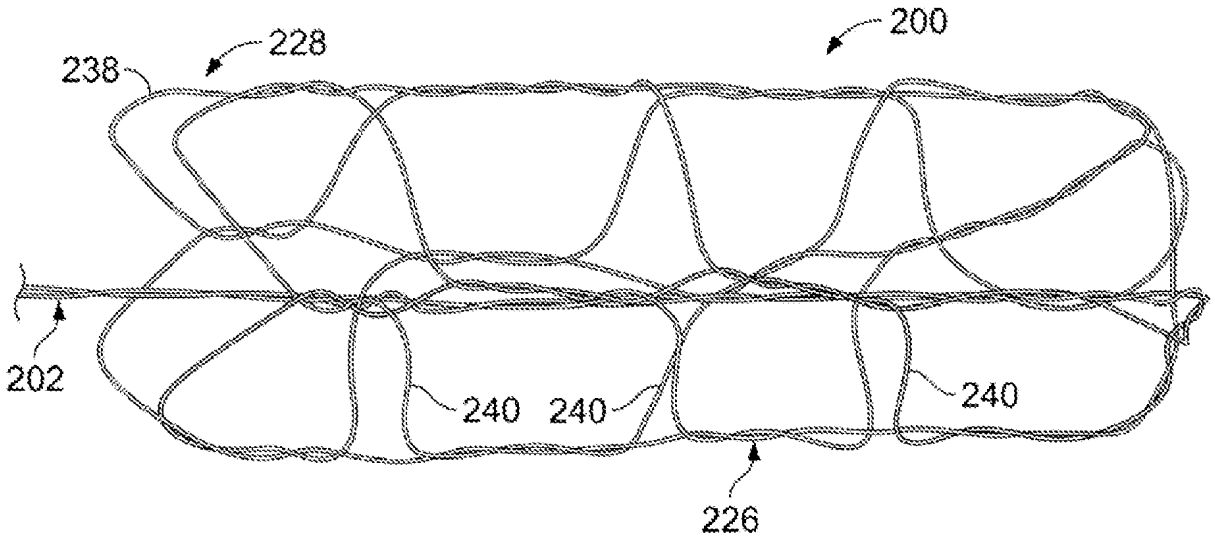


FIG. 3F

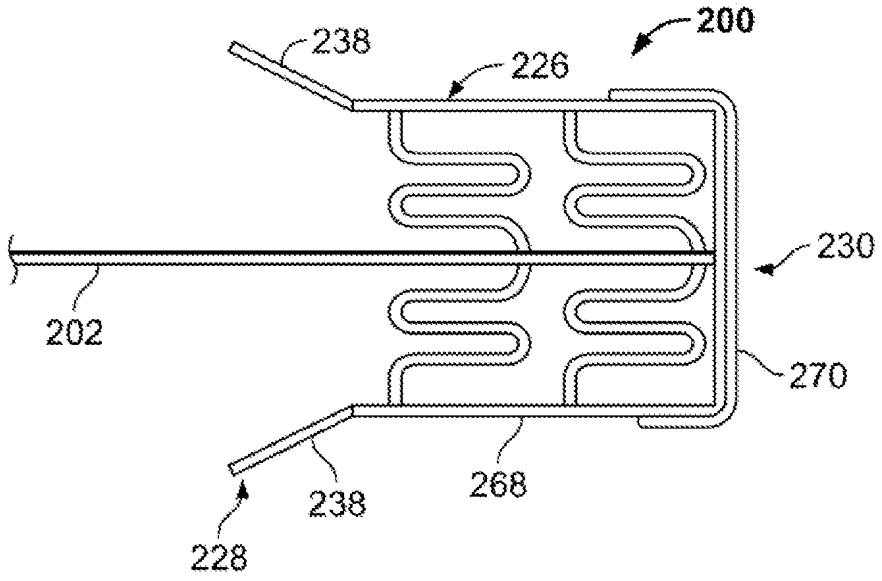


FIG. 3G

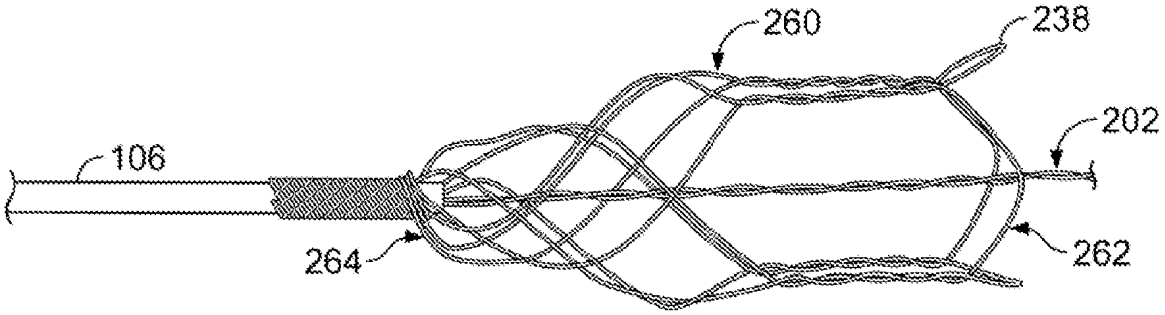


FIG. 3H

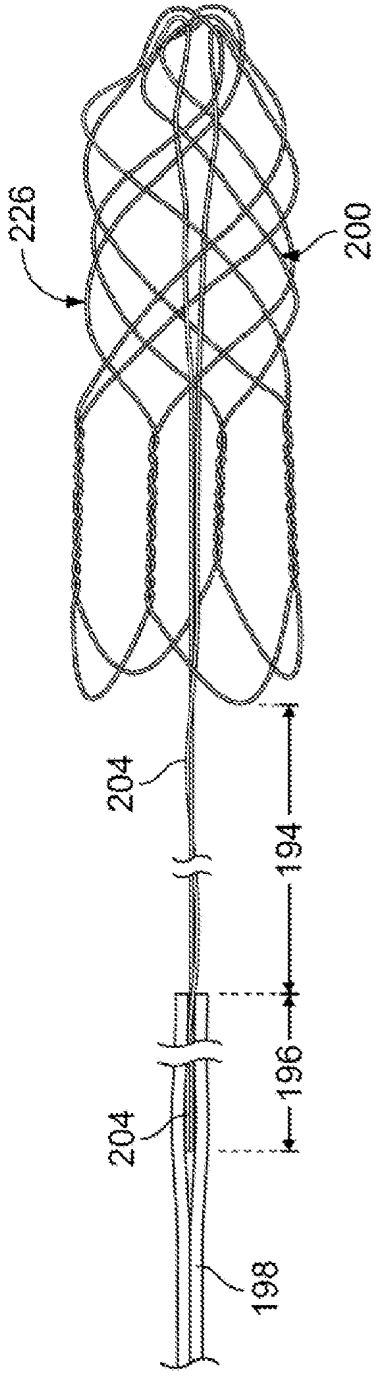


FIG. 4A

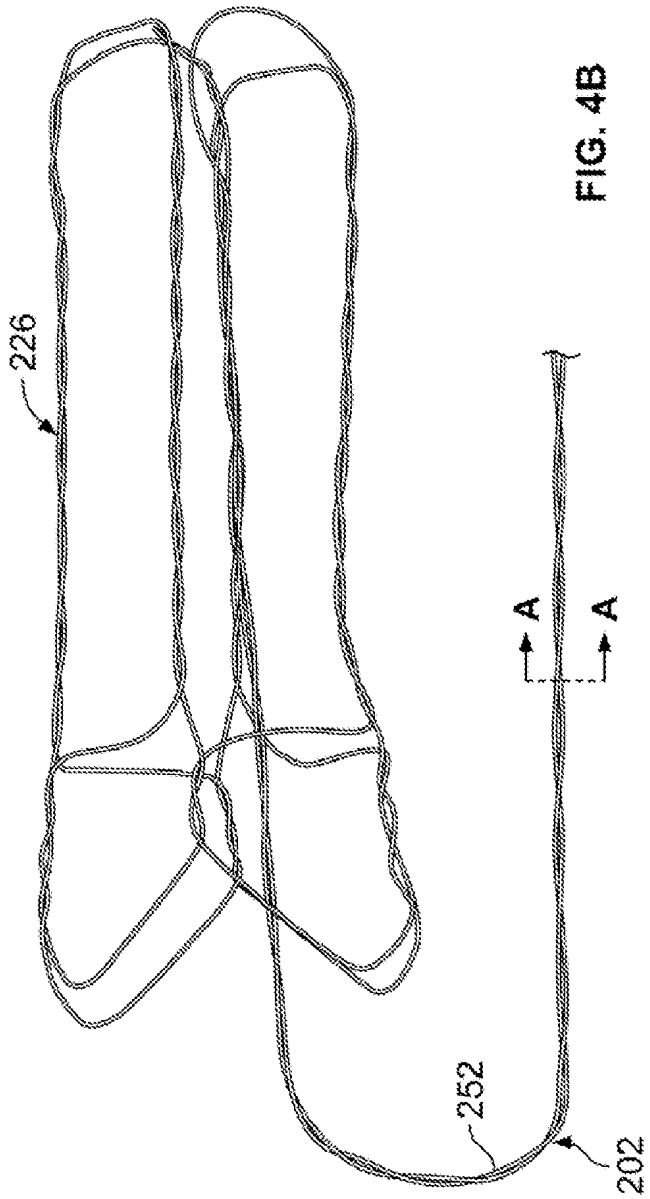


FIG. 4B

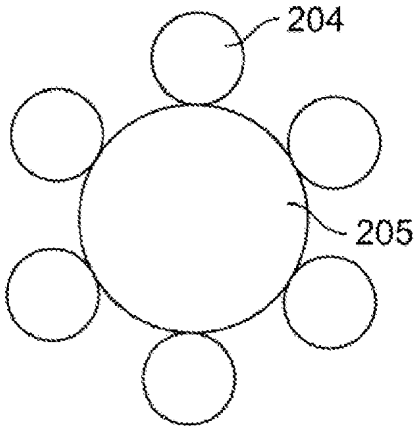


FIG. 4C

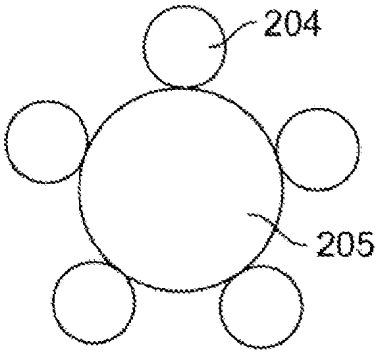


FIG. 4D

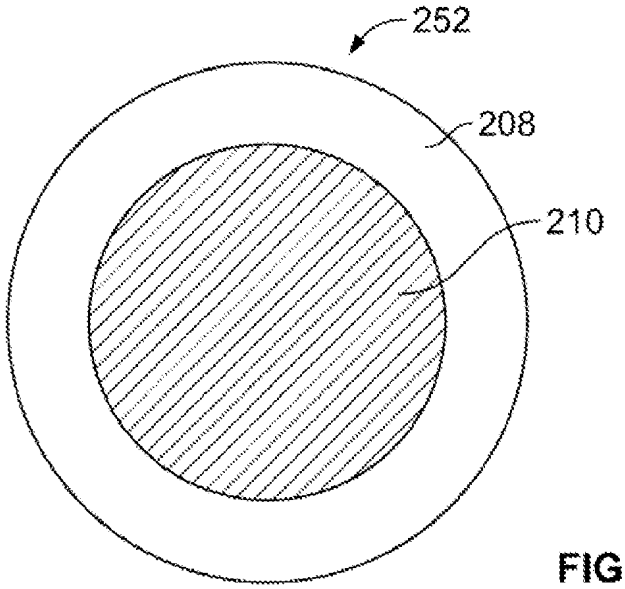


FIG. 4E

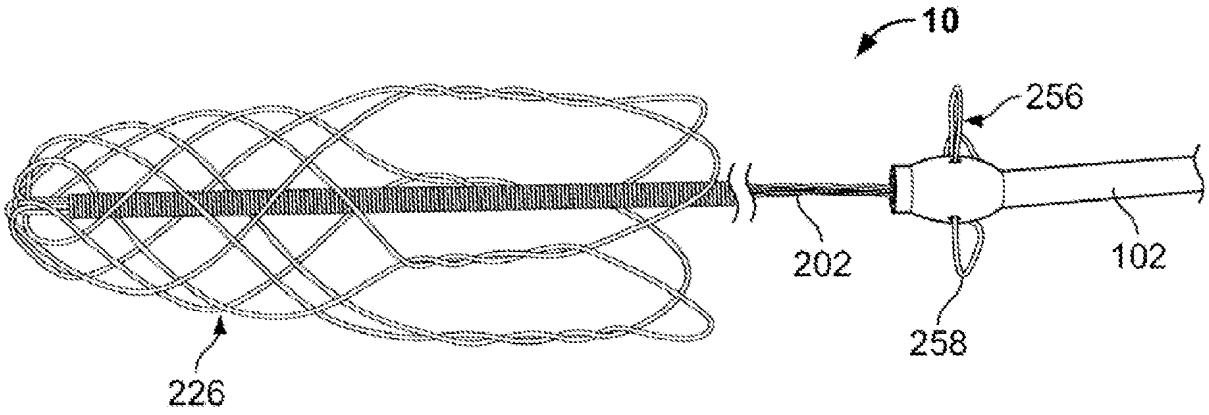


FIG. 5A

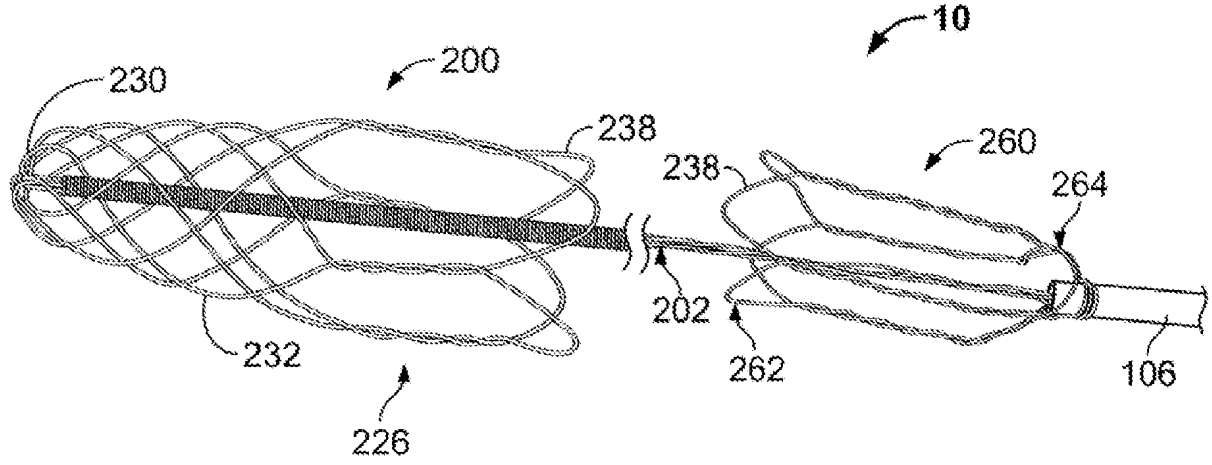


FIG. 5B

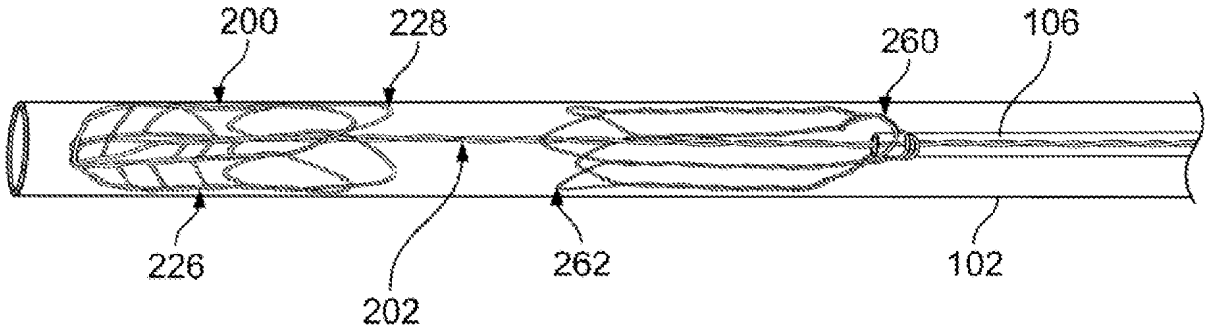


FIG. 5C

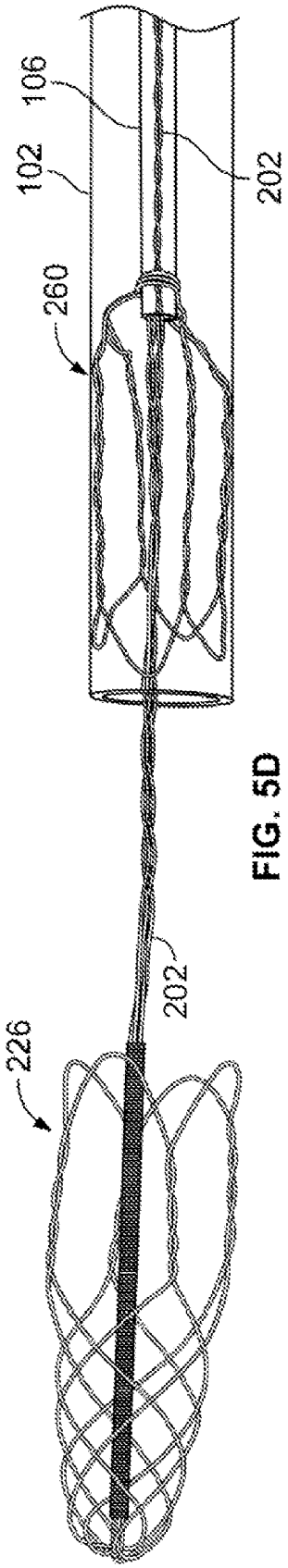


FIG. 5D

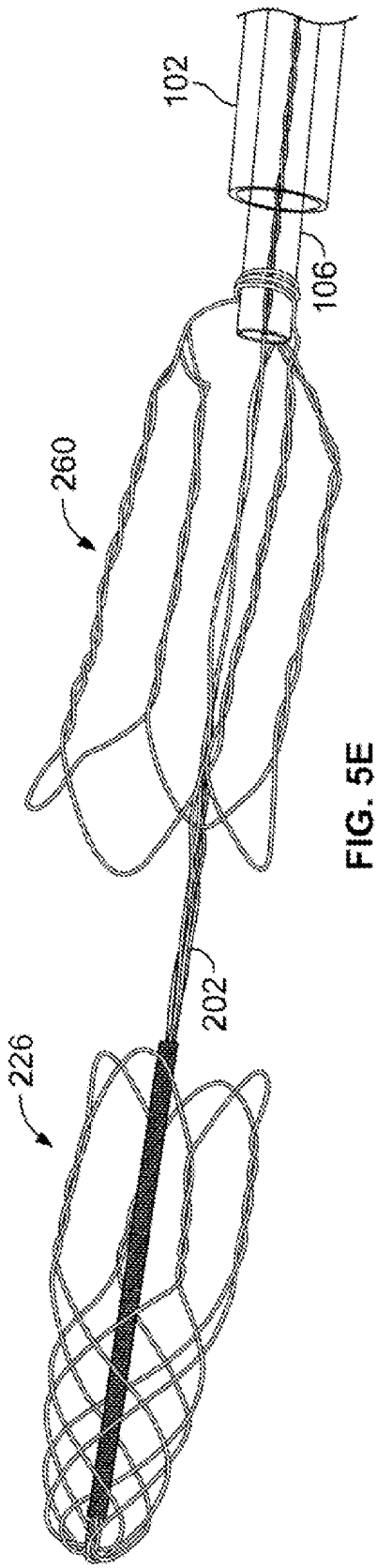


FIG. 5E

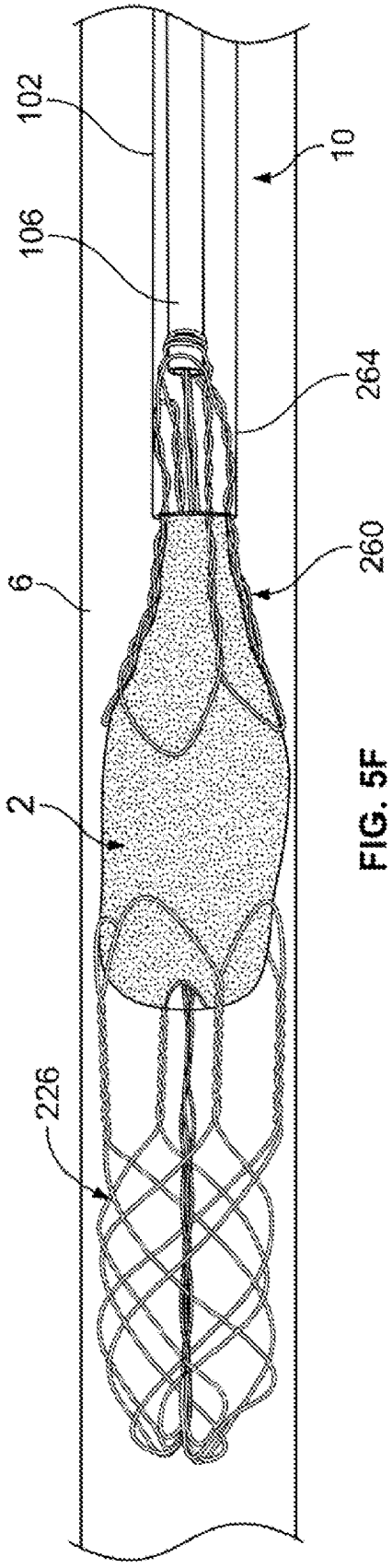


FIG. 5F

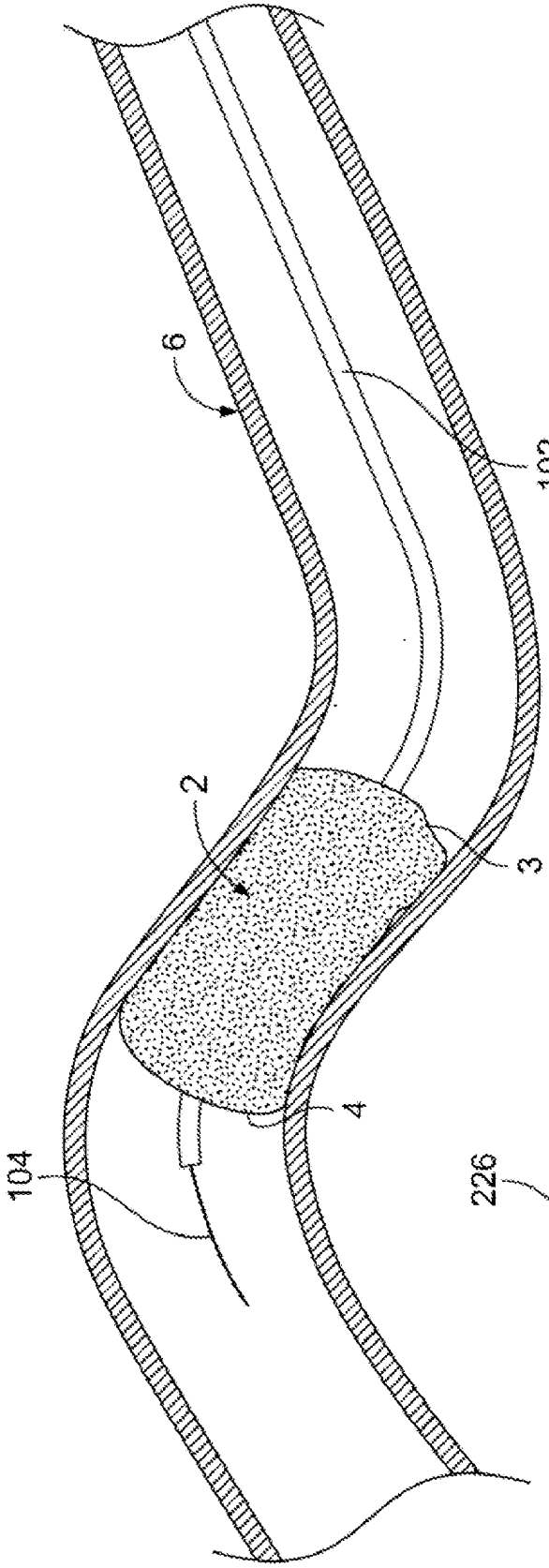


FIG. 6A

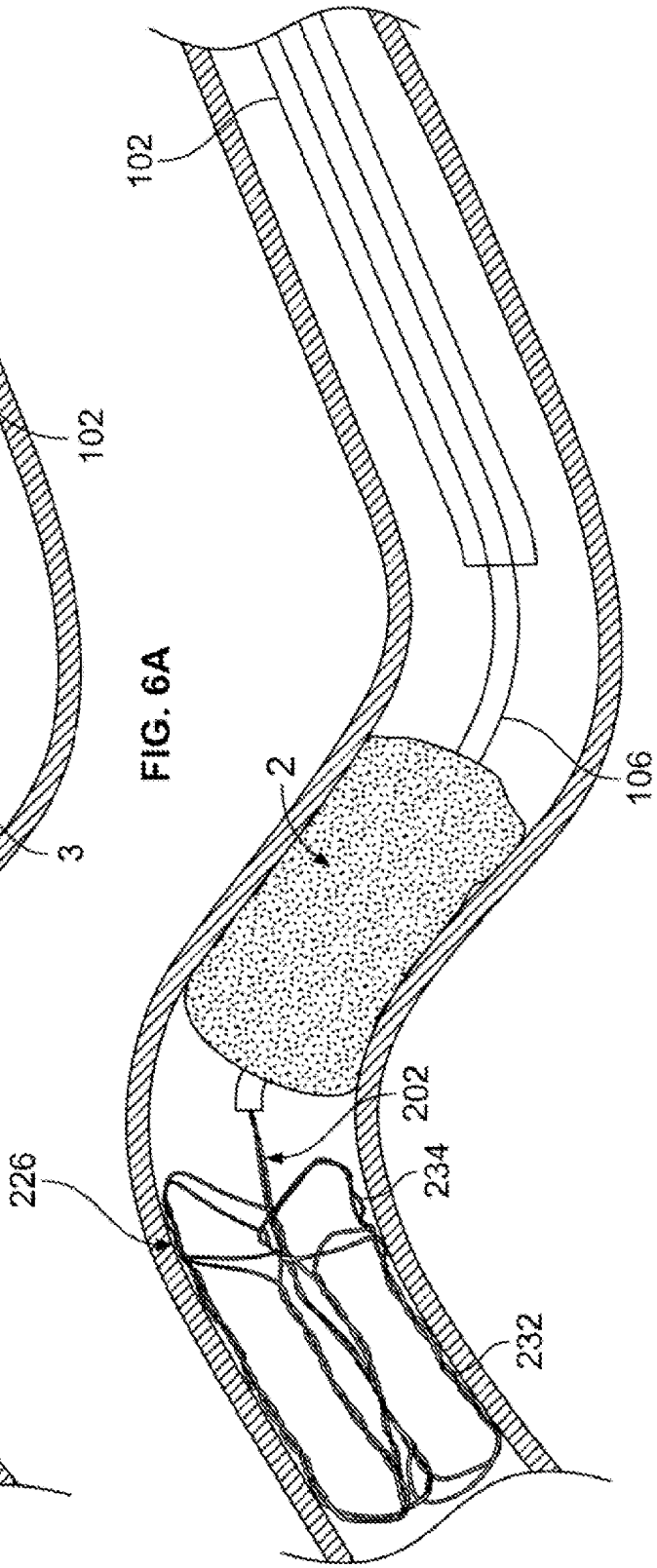


FIG. 6B

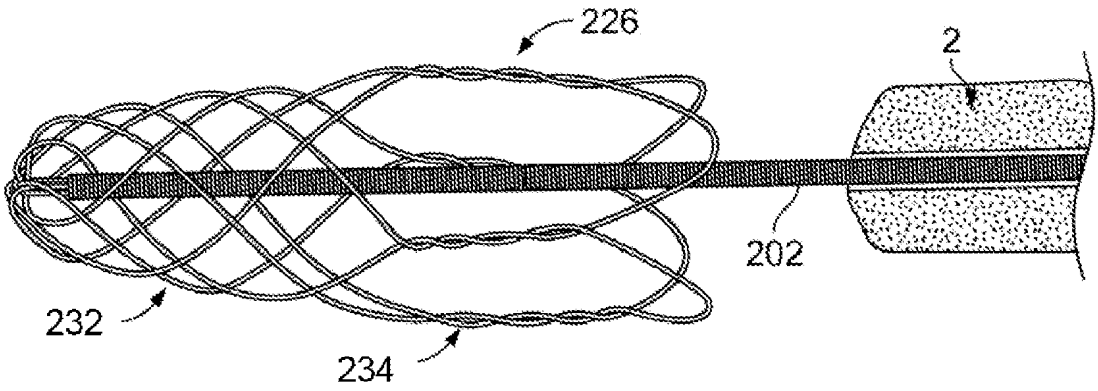


FIG. 7A

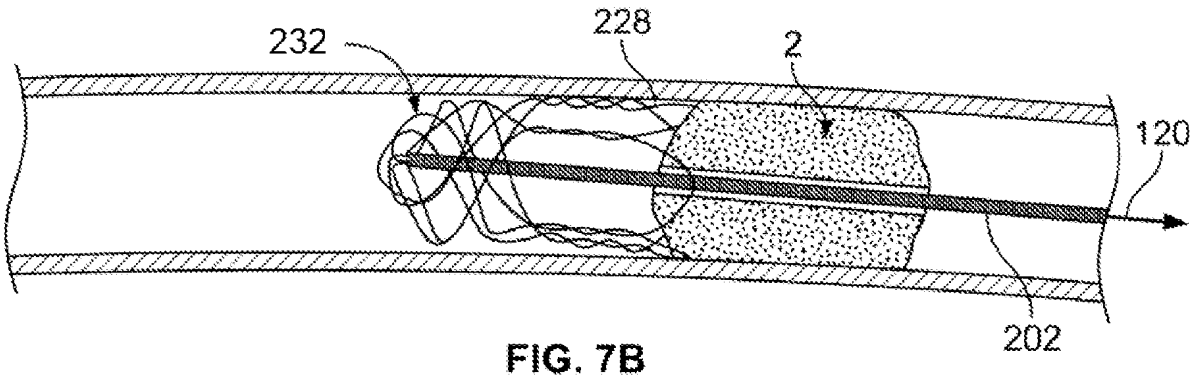


FIG. 7B

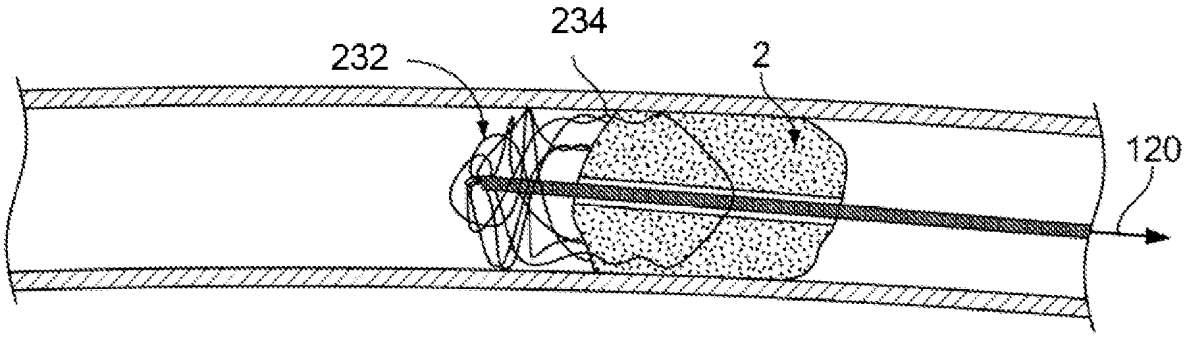


FIG. 7C

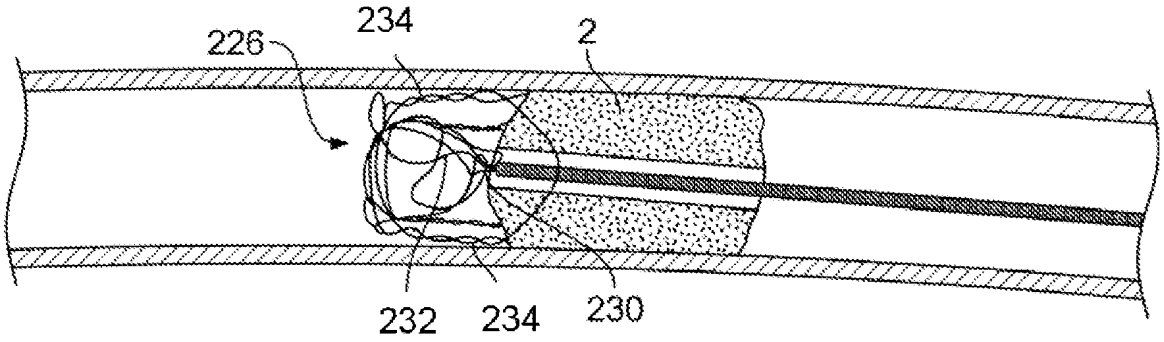


FIG. 7D

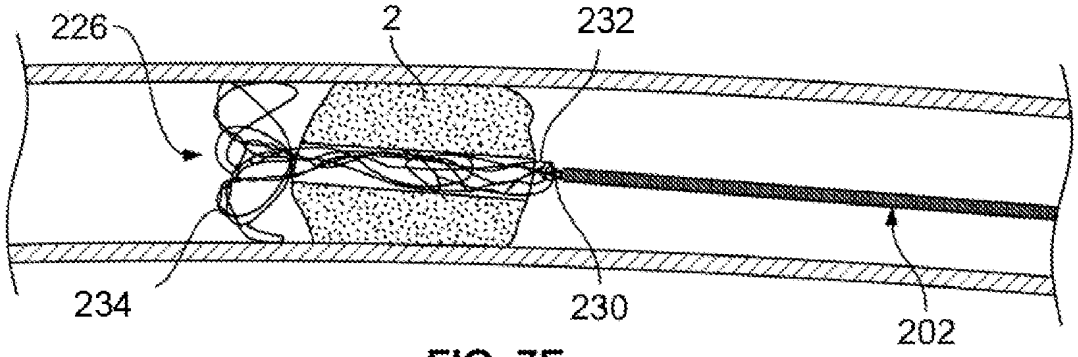


FIG. 7E

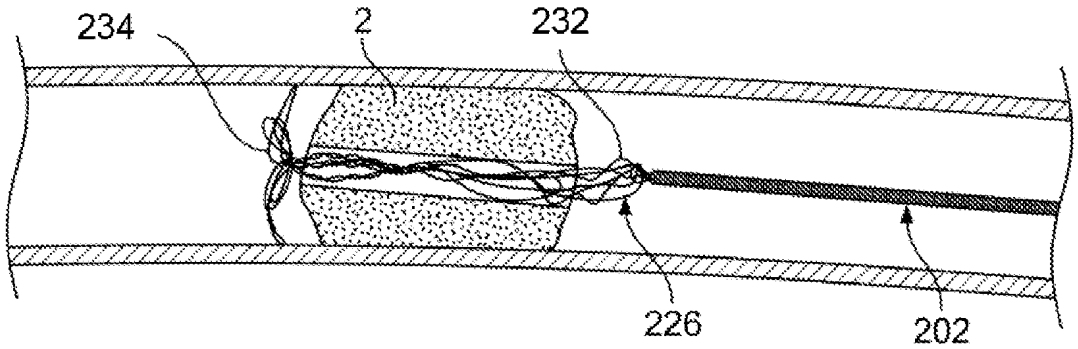


FIG. 7F

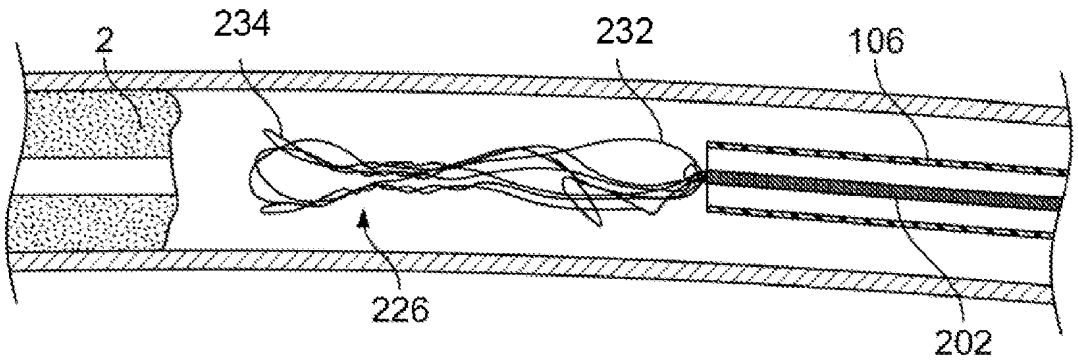


FIG. 7G

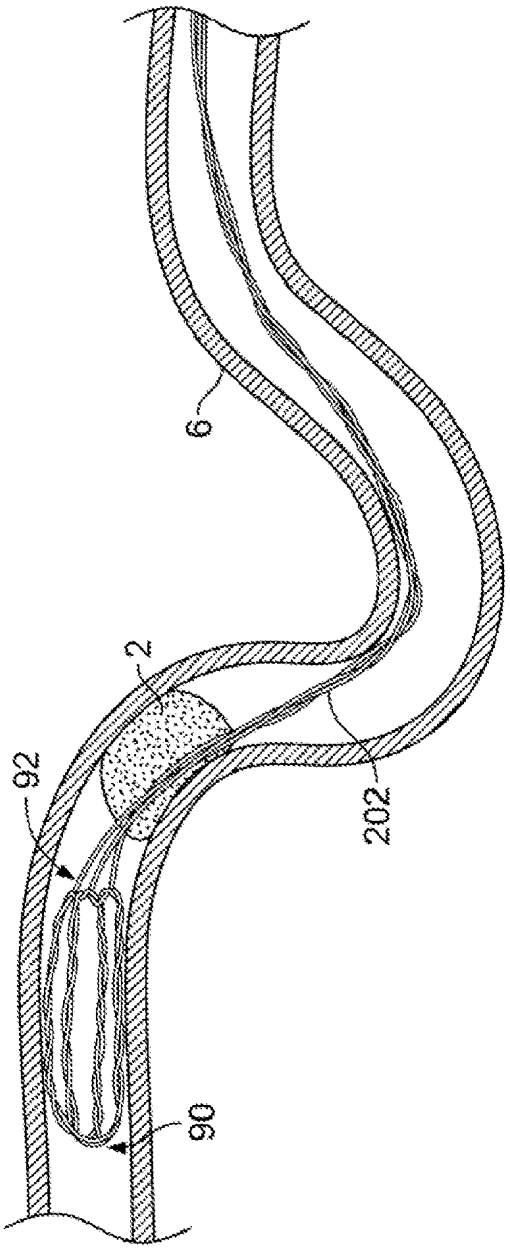


FIG. 8A

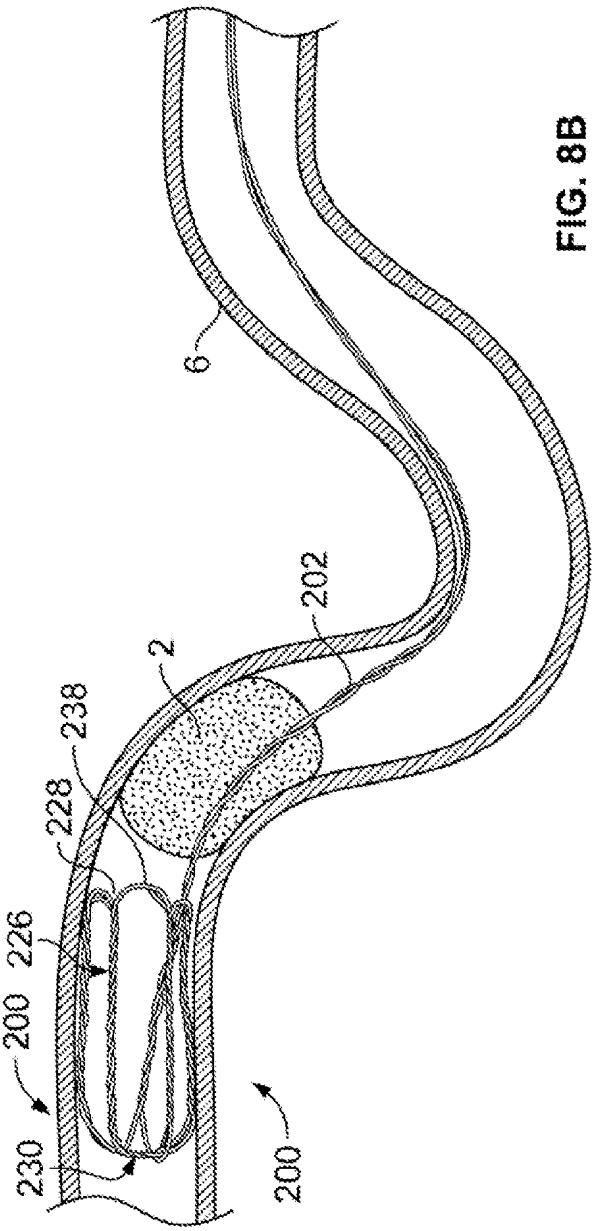


FIG. 8B

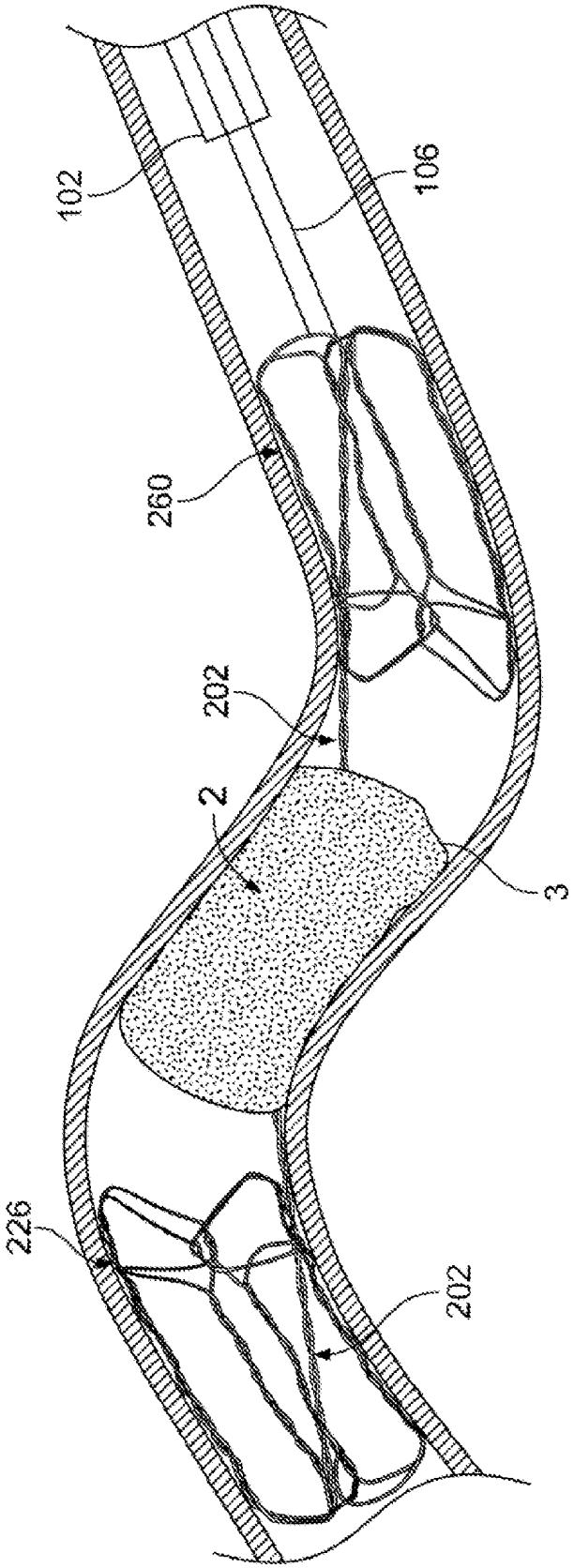


FIG. 8C

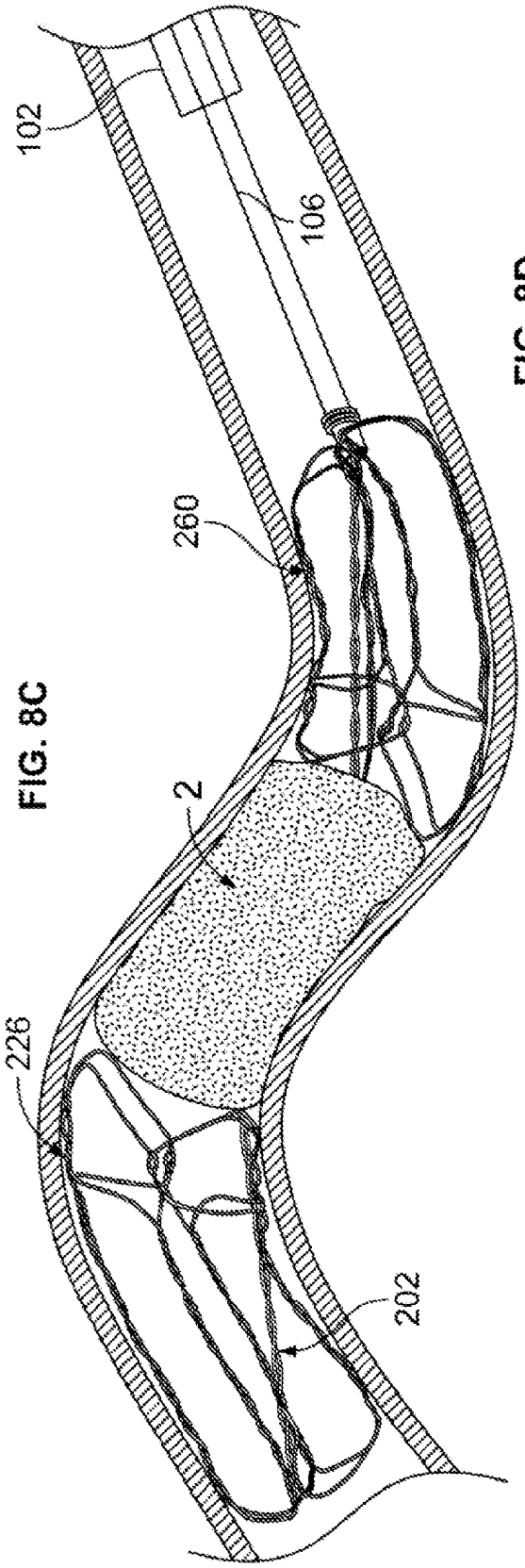


FIG. 8D

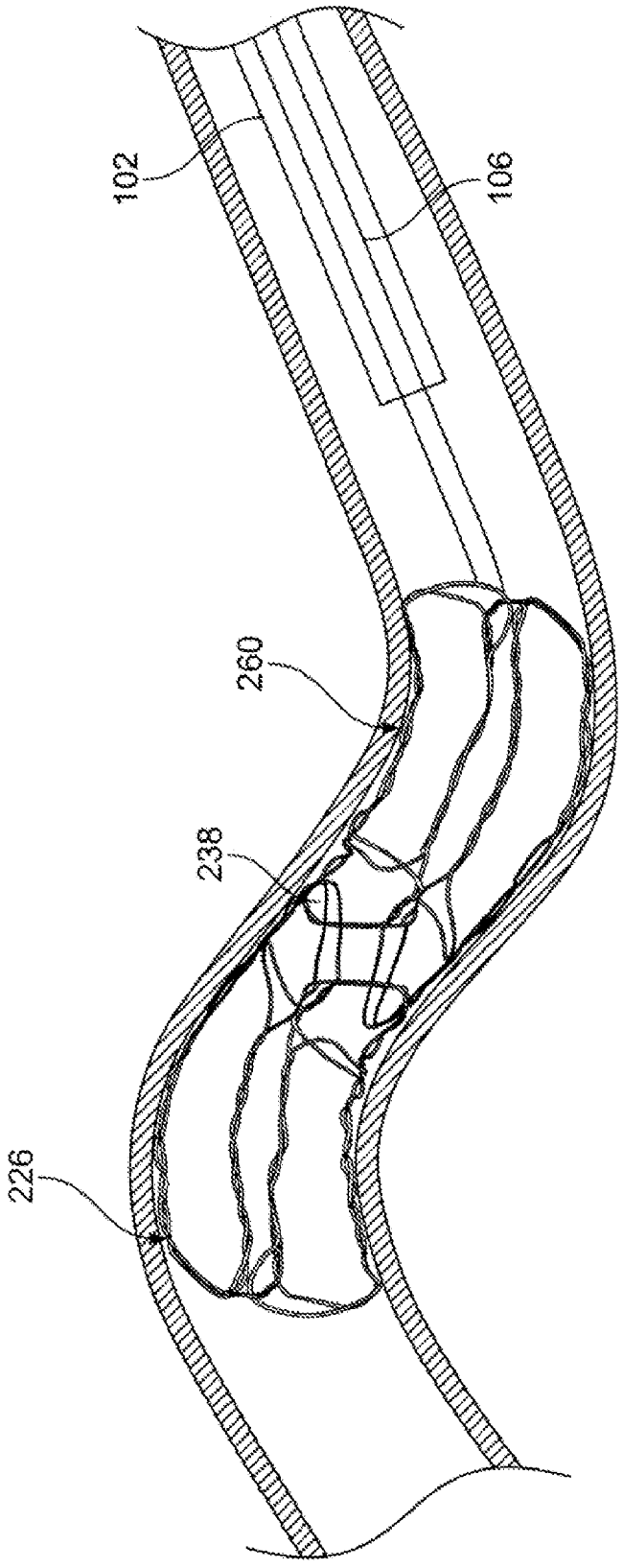


FIG. 8E

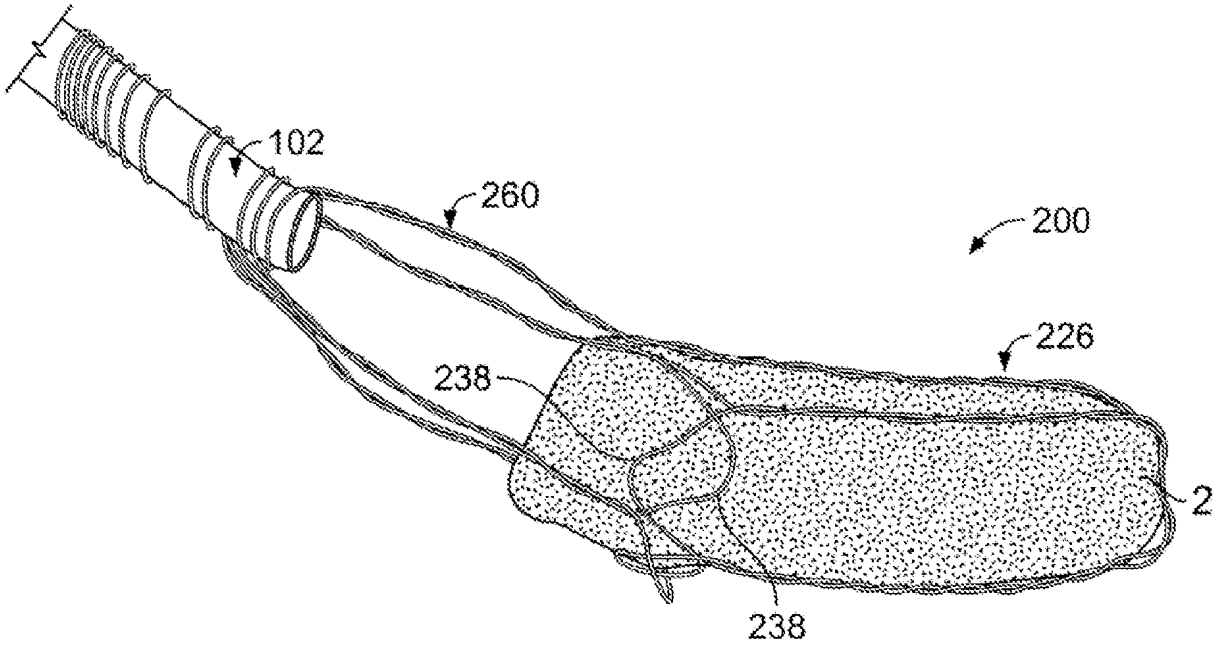


FIG. 8F

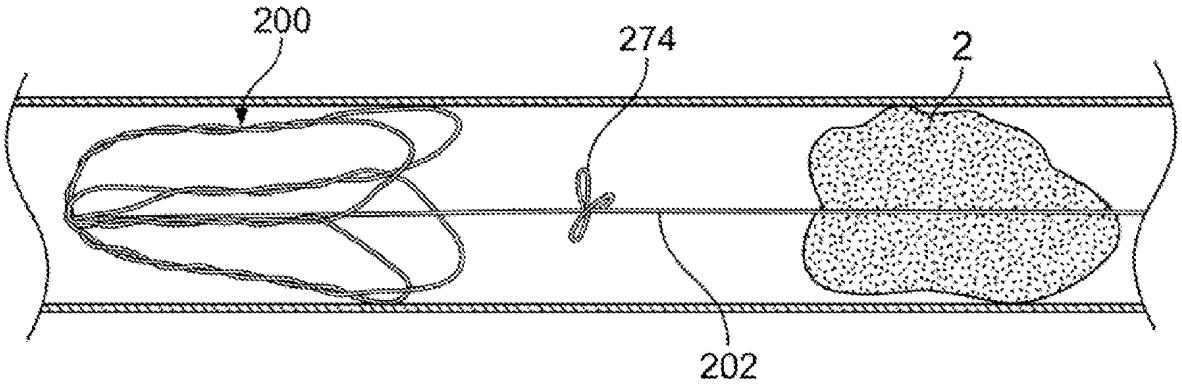


FIG. 9

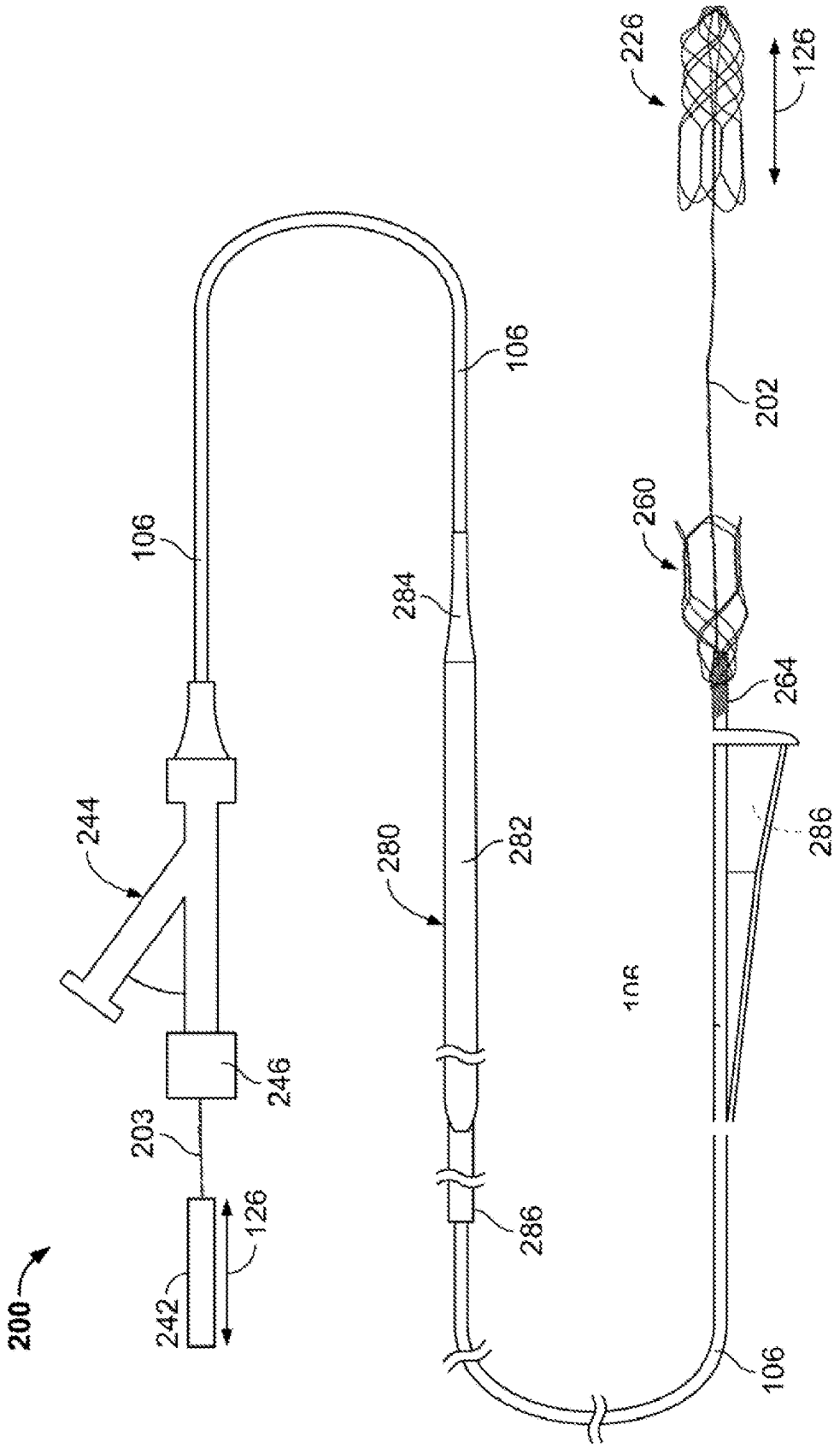

226
126
106
202
260
284
264
106
244
280
282
286
246
203
126
286
200
242
106

FIG. 10

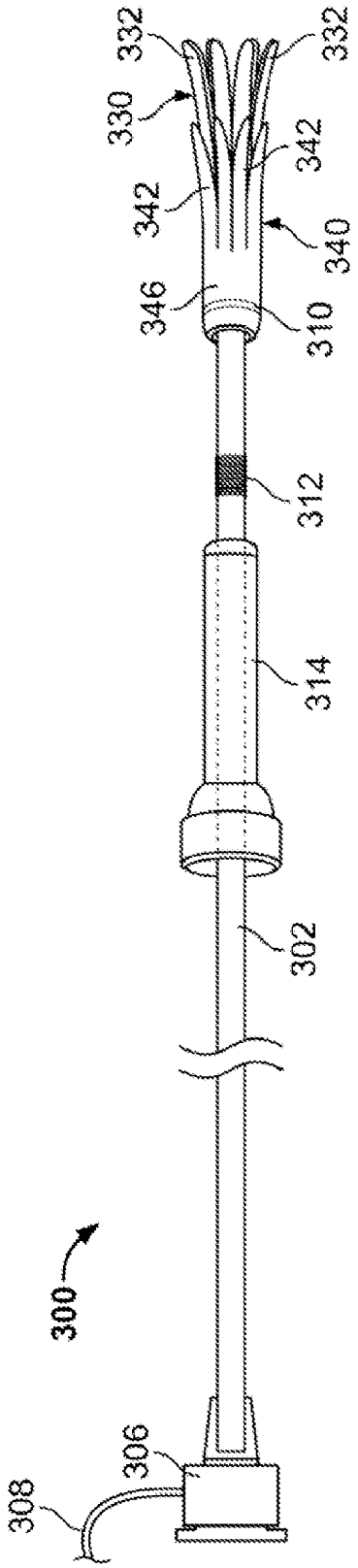


FIG. 11A

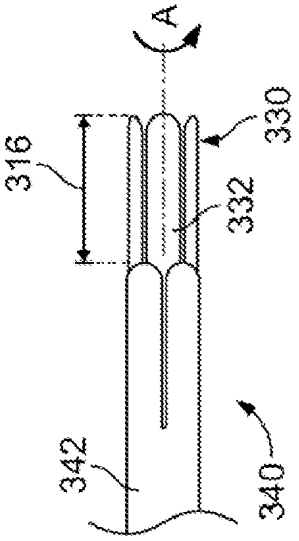


FIG. 11C

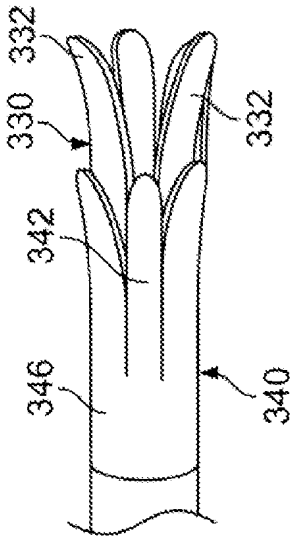


FIG. 11B

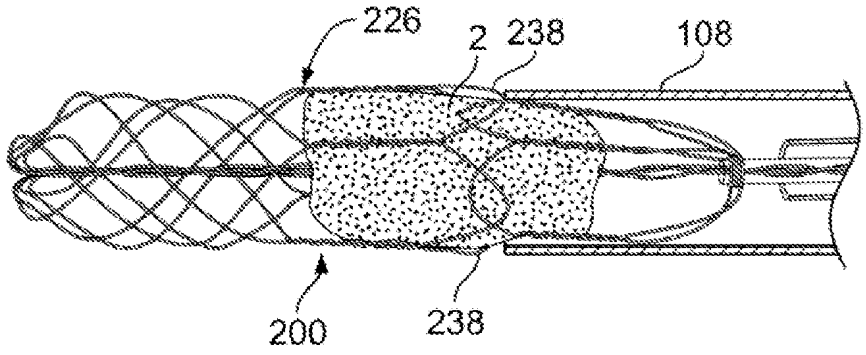


FIG. 12A

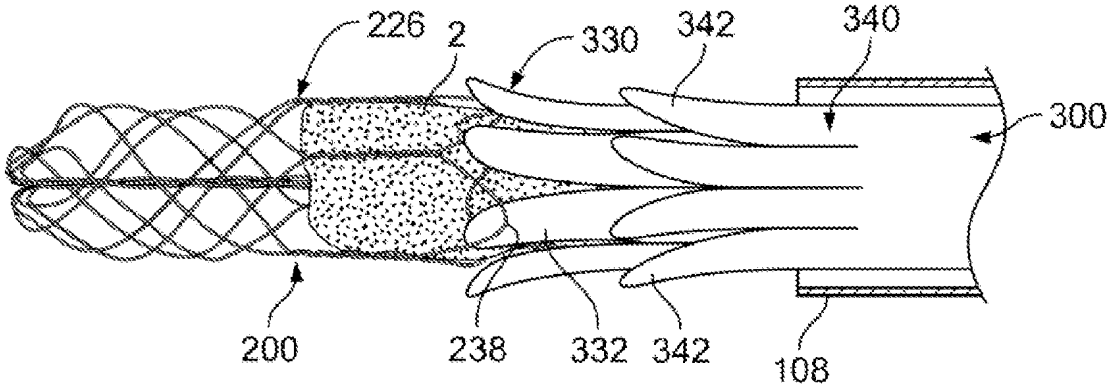


FIG. 12B

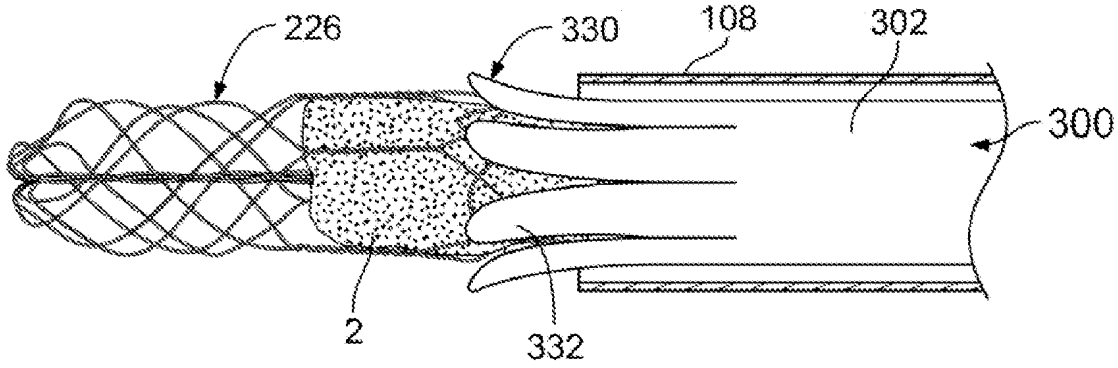


FIG. 12C

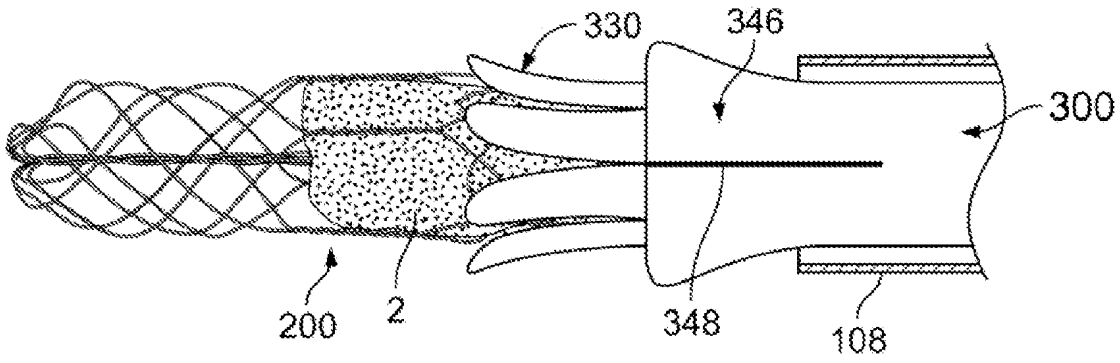


FIG. 12D

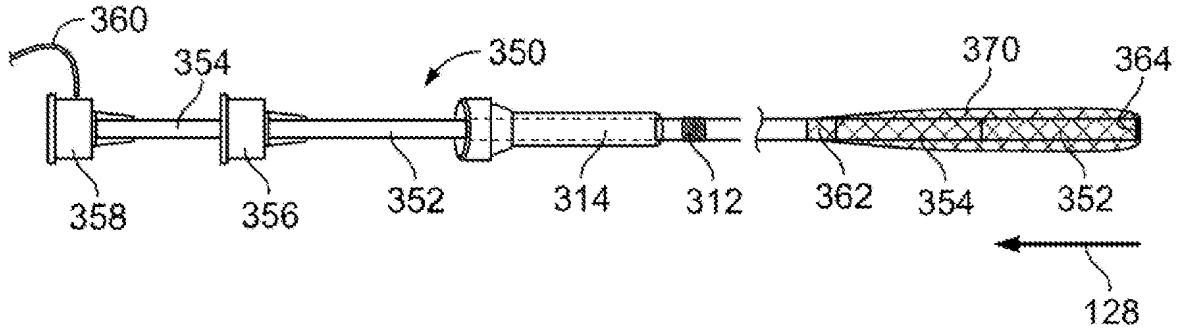


FIG. 13A

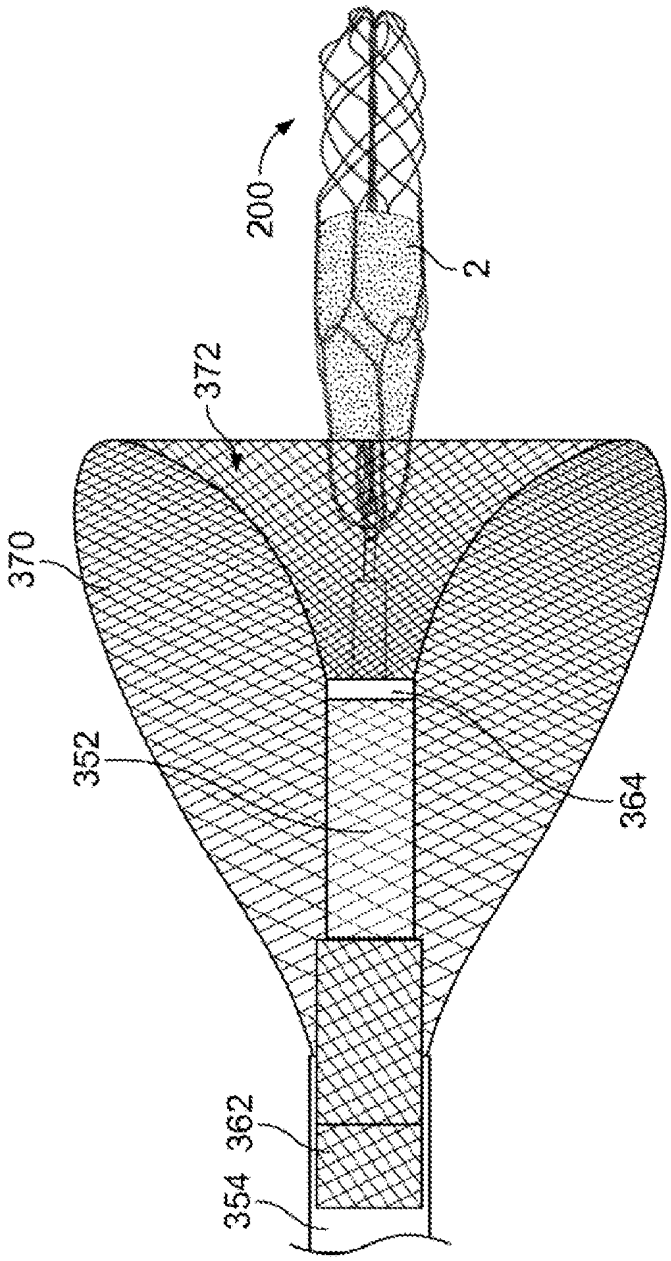


FIG. 13B

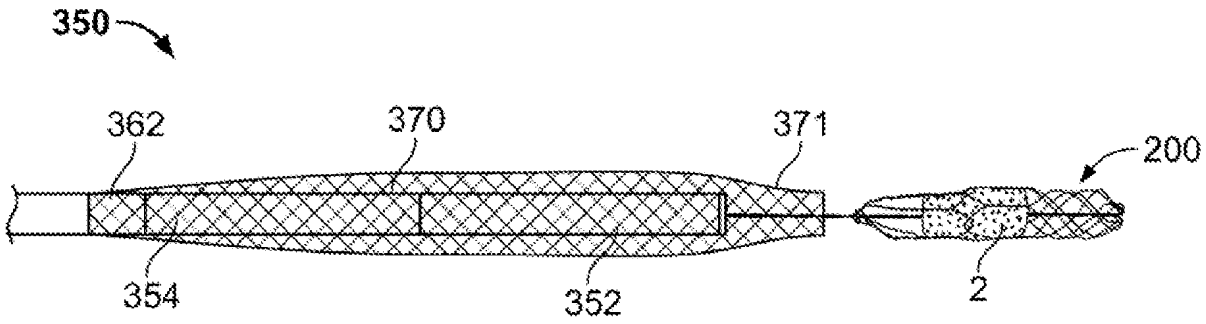


FIG. 13C

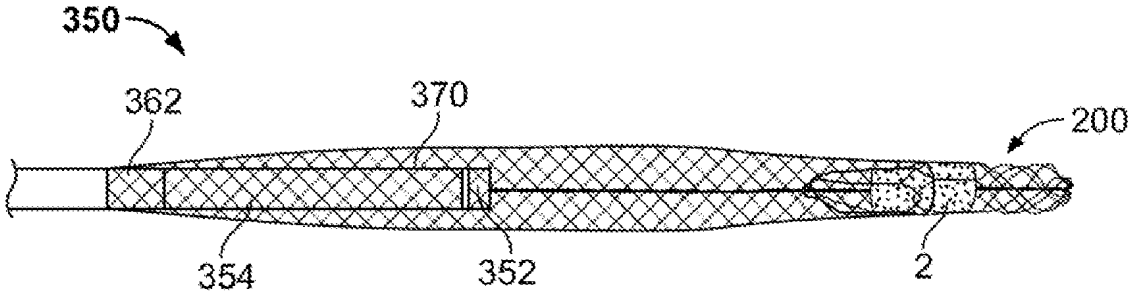


FIG. 13D

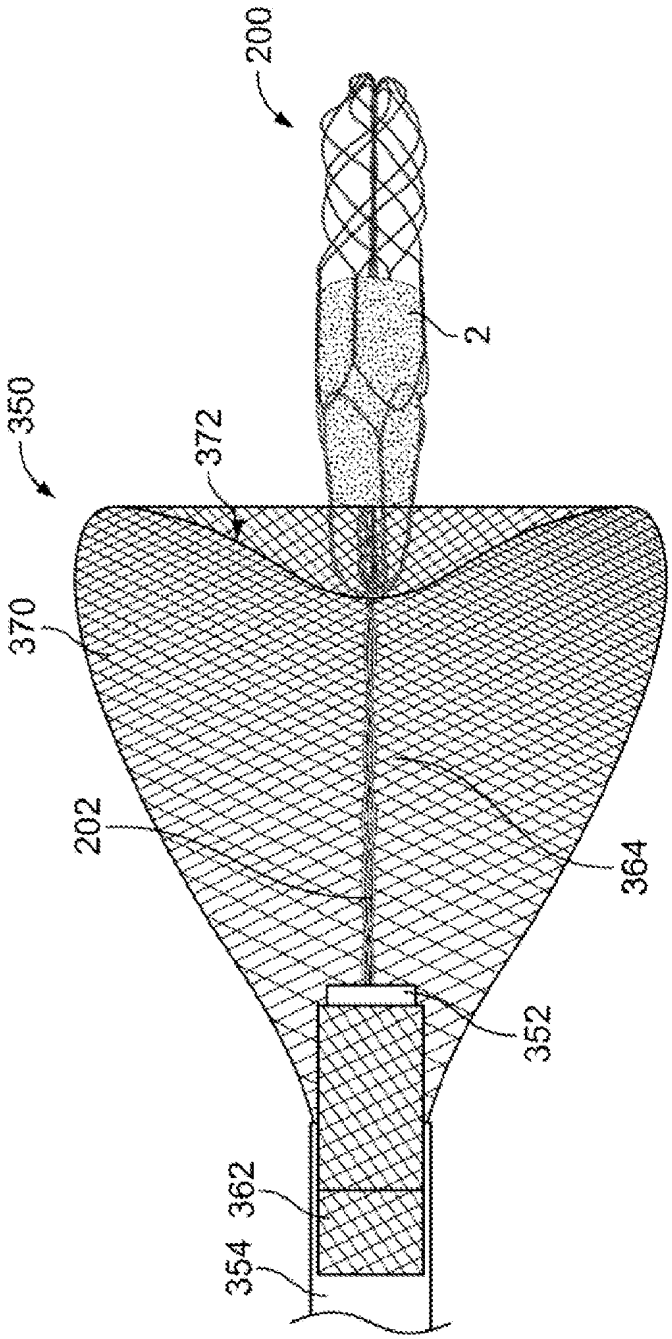


FIG. 13E

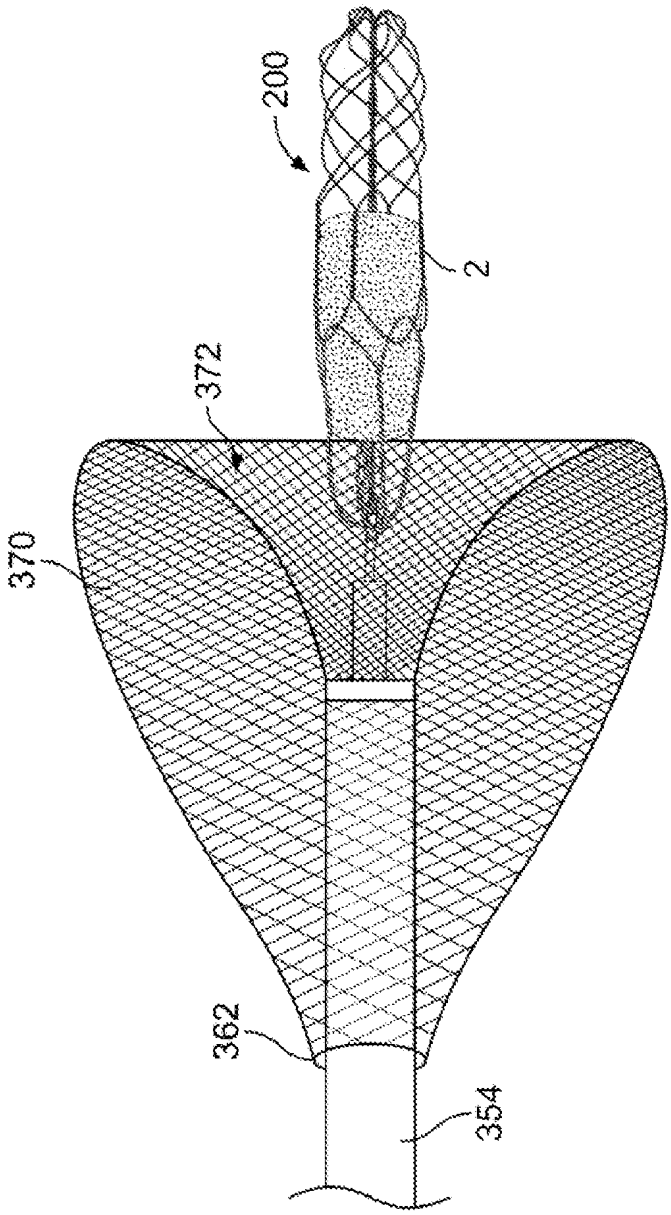


FIG. 13G

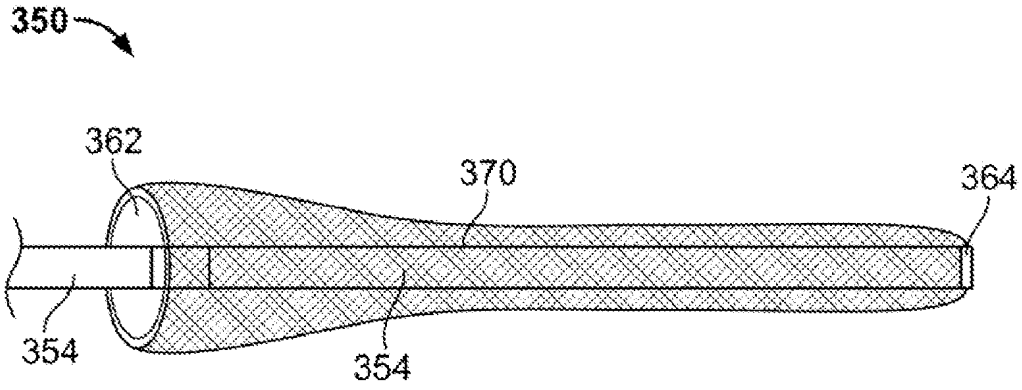


FIG. 13F

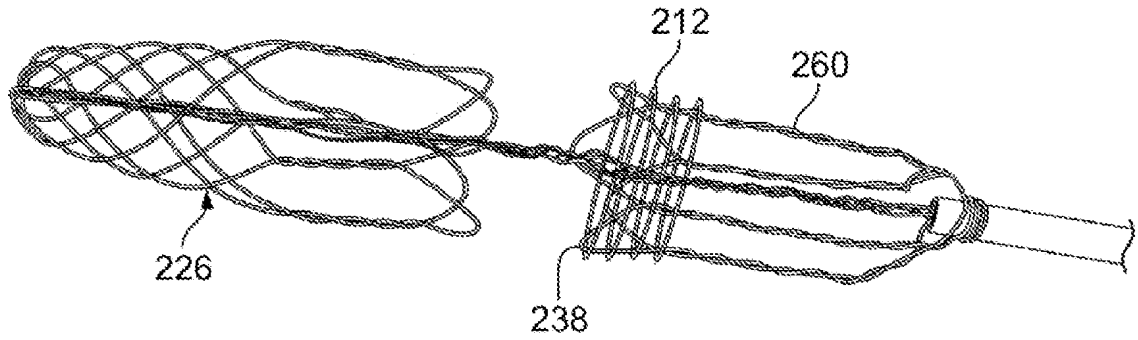


FIG. 14A

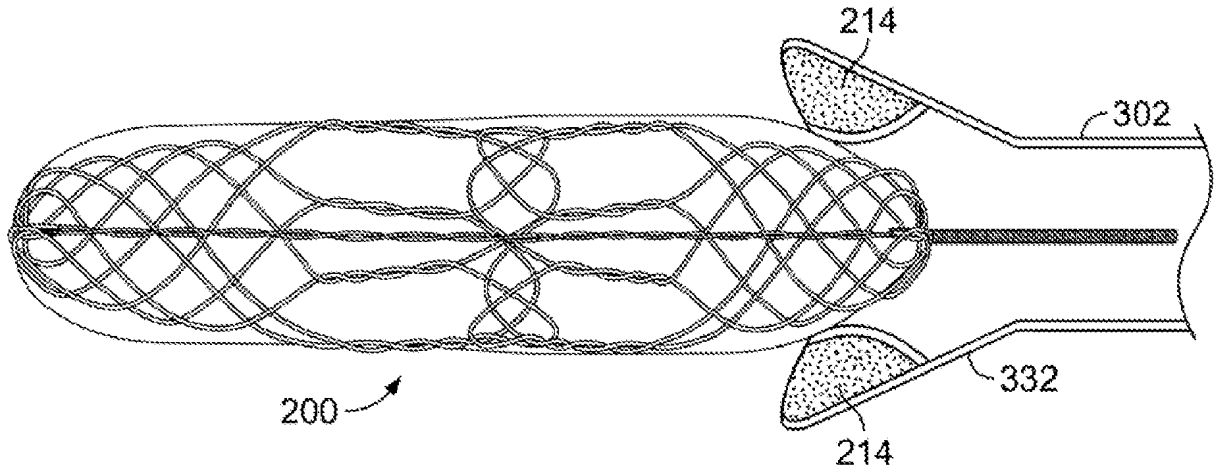


FIG. 14B

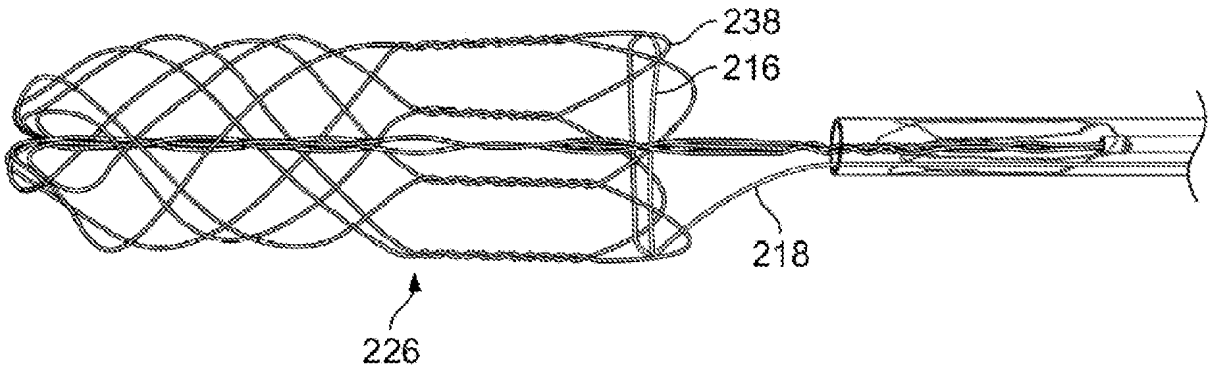


FIG. 14C

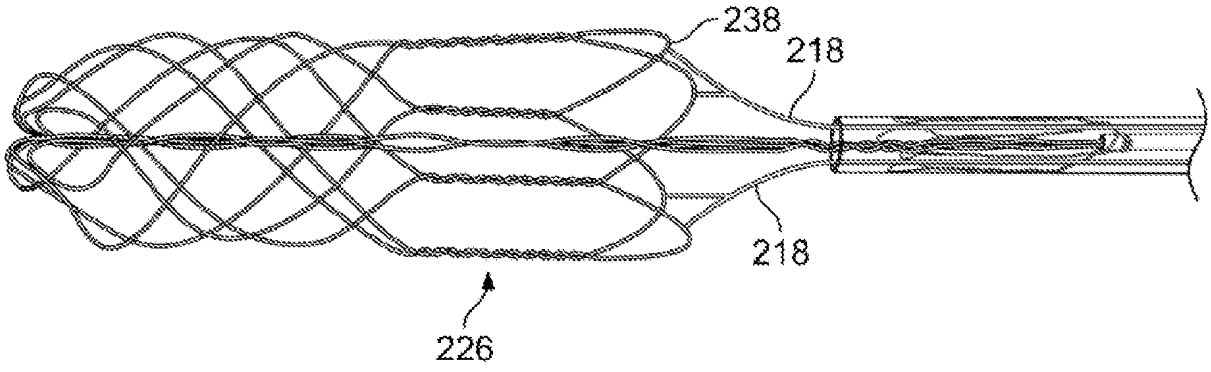


FIG. 14D

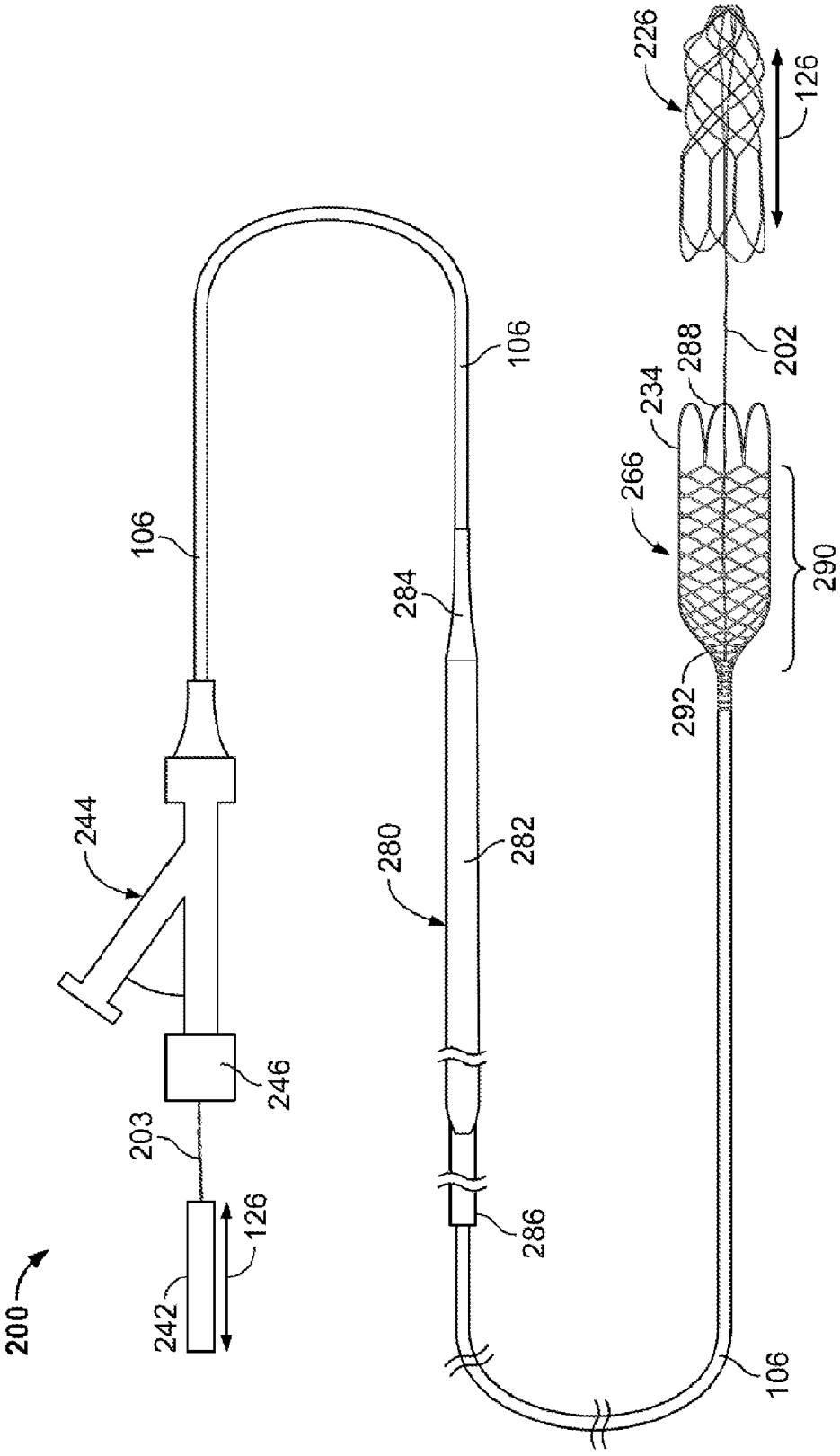

200
242
126
203
246
244
106
106
284
280
282
286
226
126
288
202
234
266
290
292
106

FIG. 15

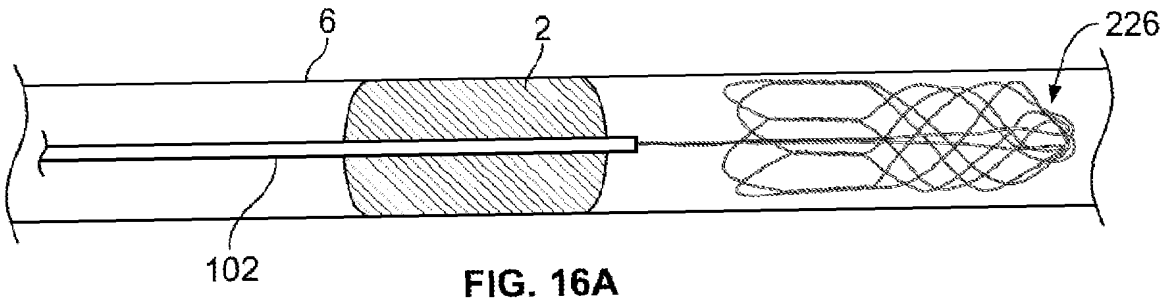


FIG. 16A

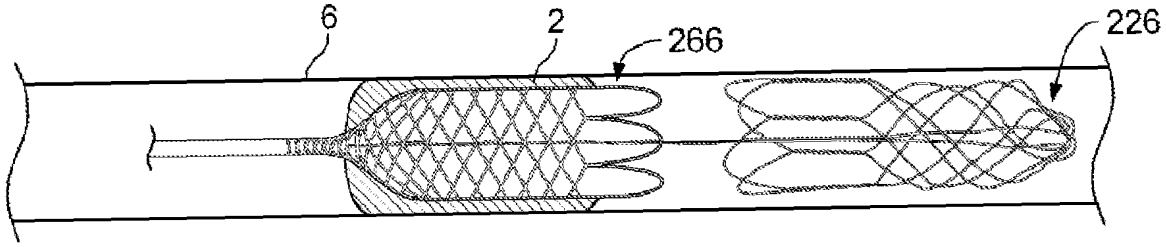


FIG. 16B

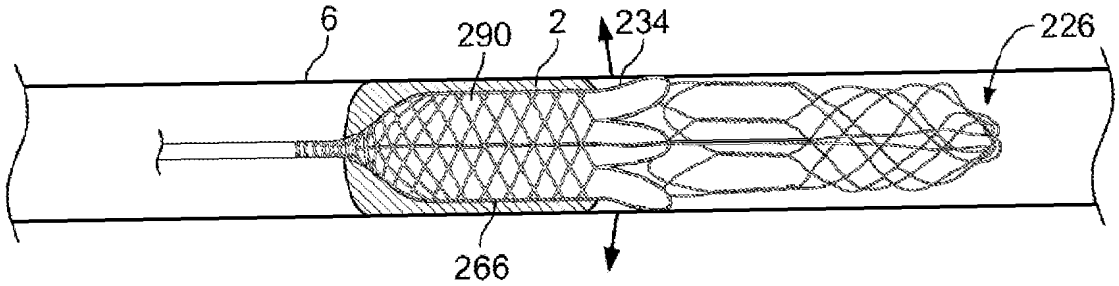


FIG. 16C

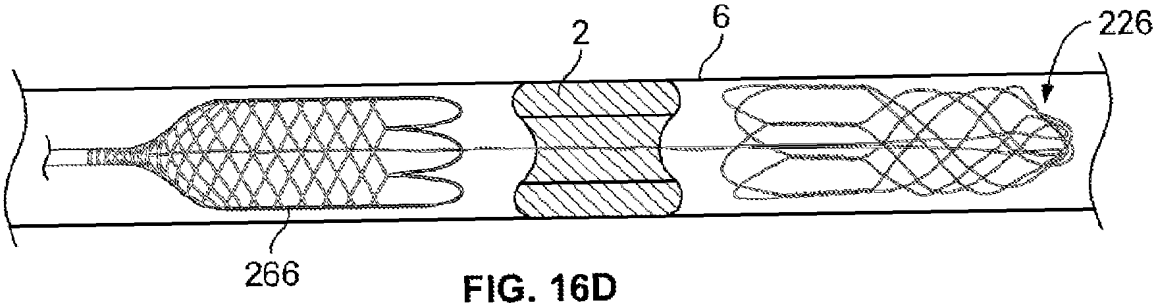


FIG. 16D

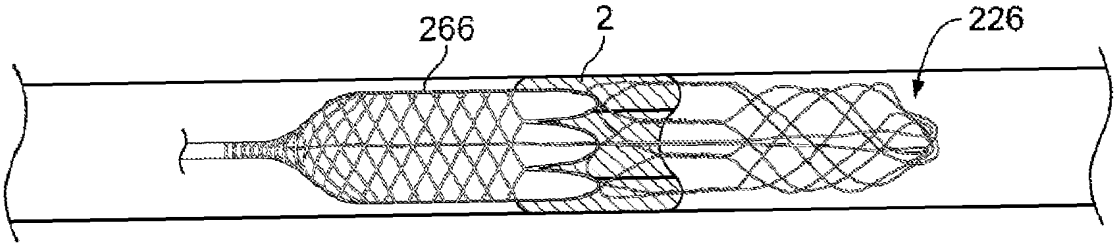


FIG. 16E

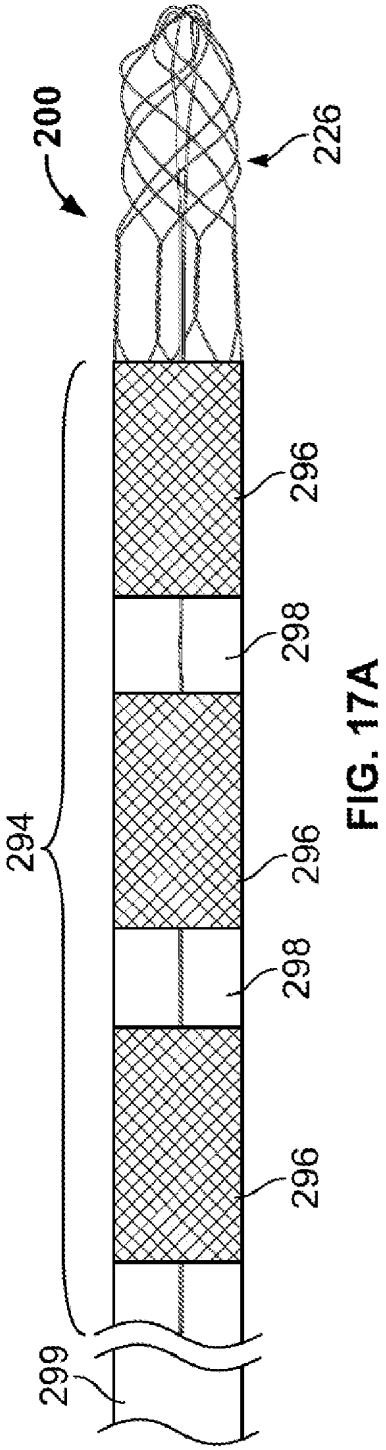


FIG. 17A

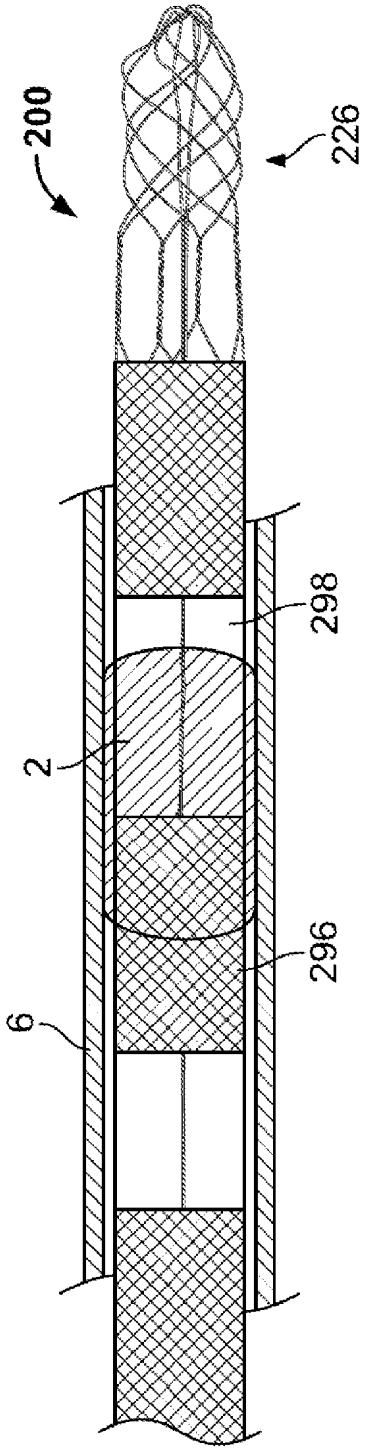


FIG. 17B

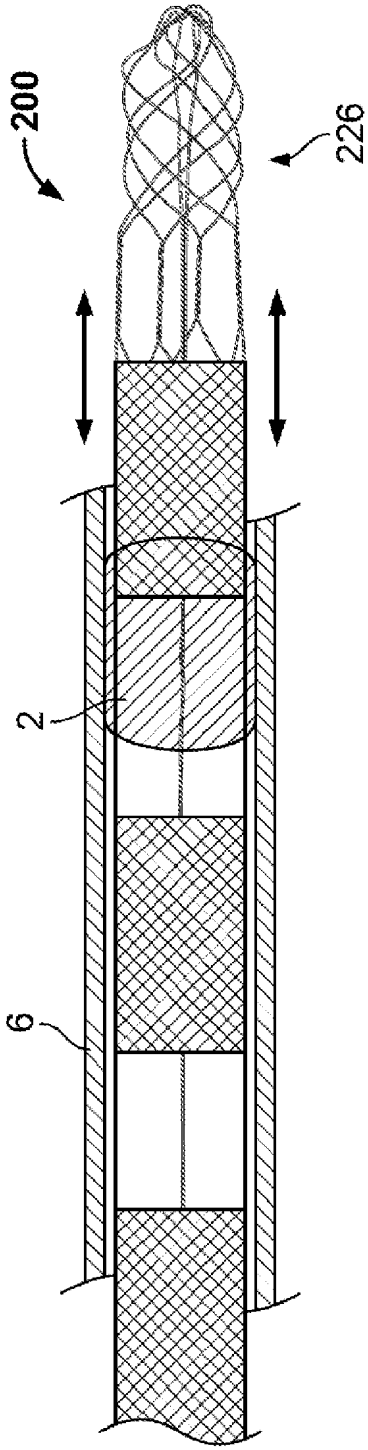


FIG. 17C

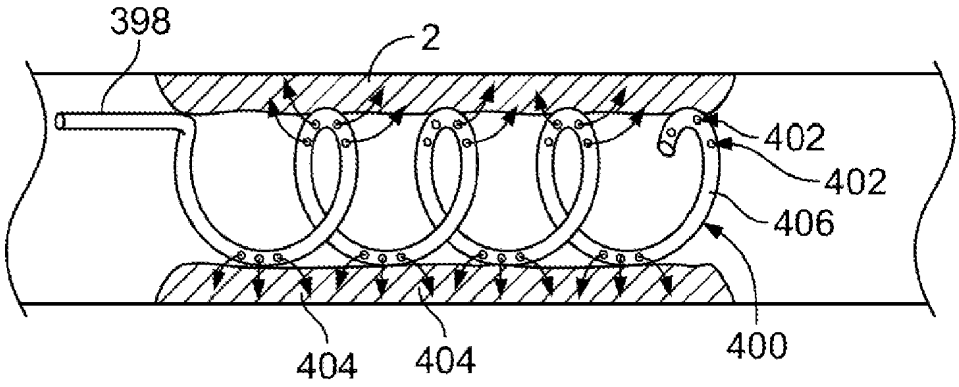


FIG. 18A

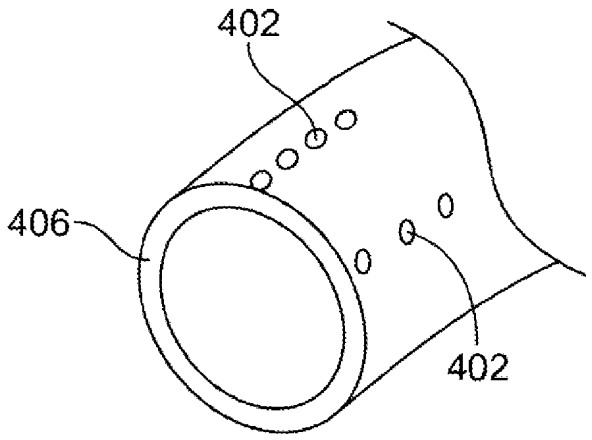


FIG. 18B

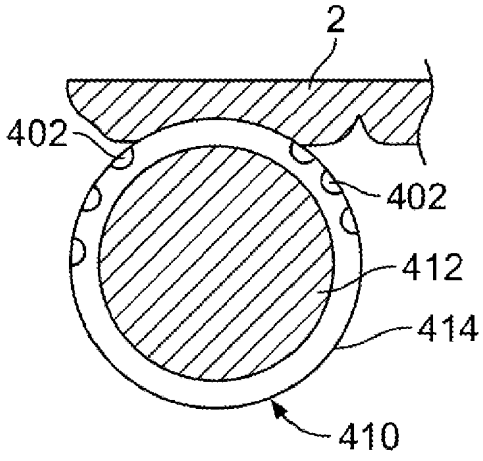


FIG. 18C

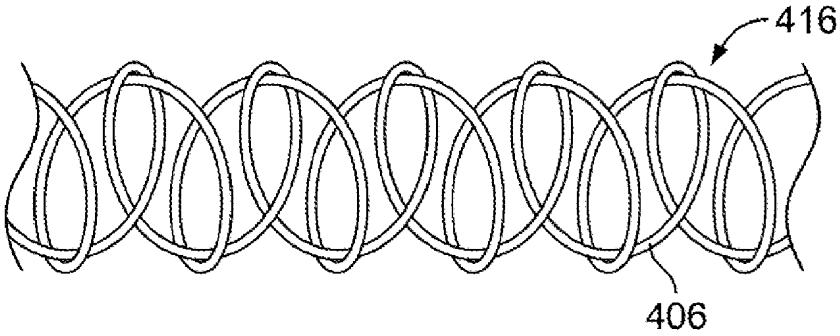


FIG. 18D

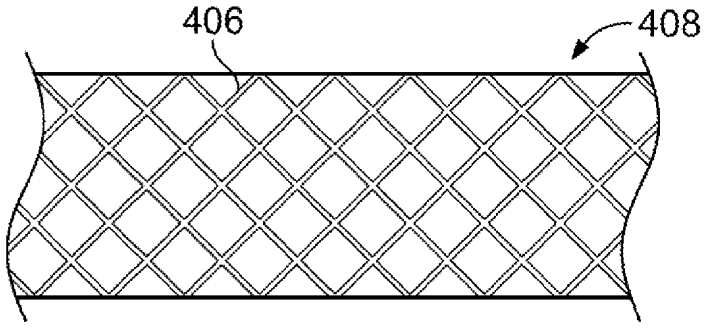


FIG. 18E

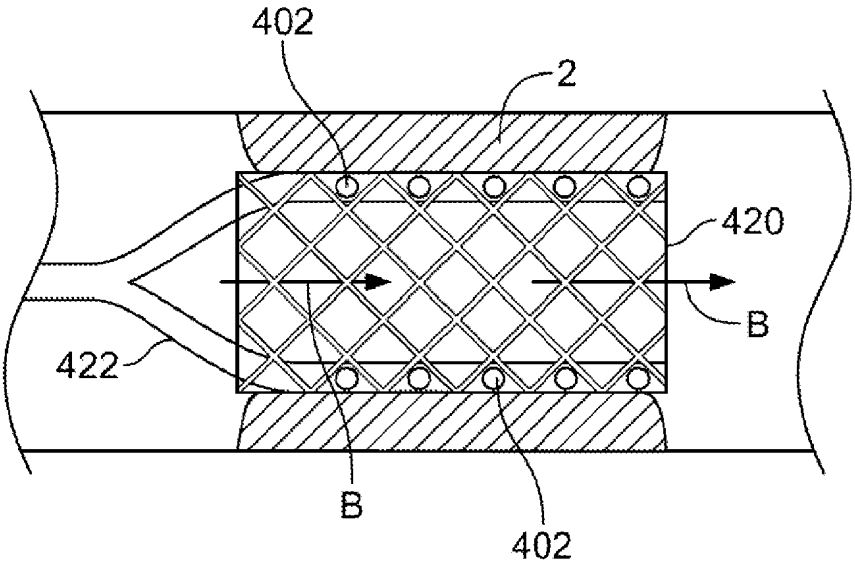


FIG. 18F

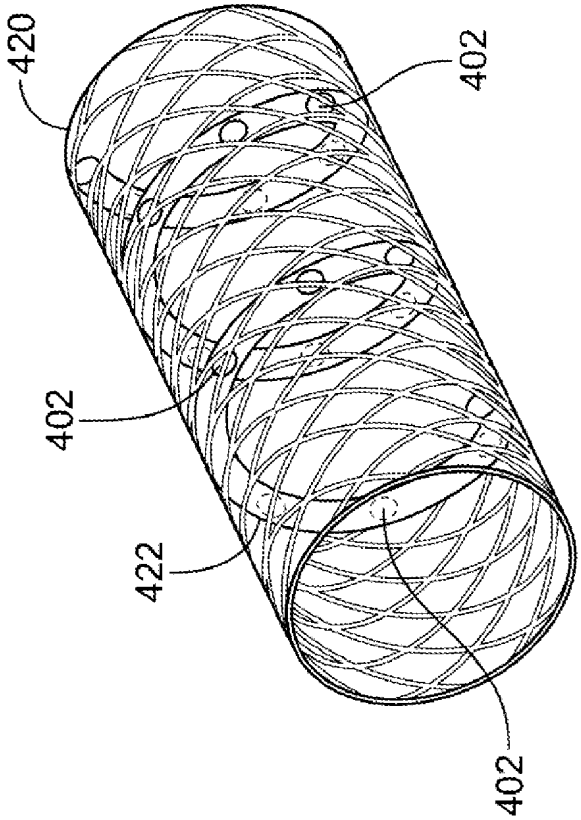


FIG. 18G

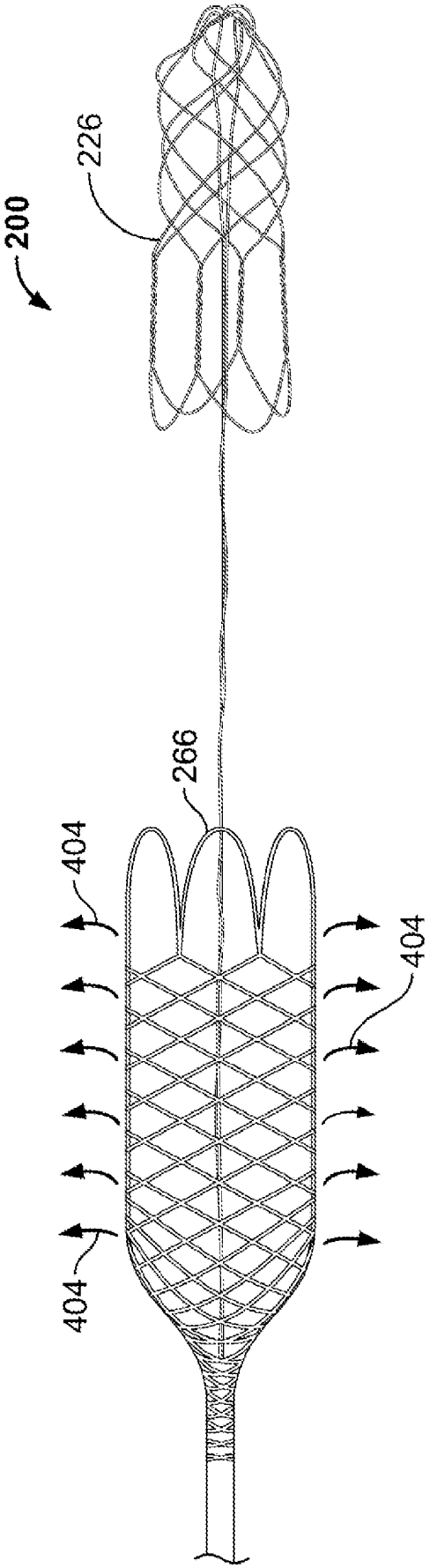


FIG. 18H

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 10/26571

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 29/00 (2010.01)
USPC - 606/200
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61M 29/00 (2010.01)
USPC: 606/200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 606/127, 159, 191, 198

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(PGPB, USPT, USOCR, EPAB, JPAB); Google Patents; Google Scholar
vessel, vein, artery, recanalization, thrombosis, embolus, basket, mesh, filter, capture, wire, catheter, stent, expandable, deploying, retracting, collapsing, sheathing, bundle, coil, permeable, fluid, delivery, force, pressure, compression, flexible, stiffness

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/0203571 A1 (MAZZOCCHI et al.) 15 September 2005 (15.09.2005) Fig. 15; para [0093], [0094], [0119], [0120], [0122], [0123], [0130], [0133], [0134], [0136], [0137], [0141], [0148], [0149], [0162], [0163], [0164]	1-30, 44-60
Y	US 2005/0283186 A1 (BERRADA et al.) 22 December 2005 (22.12.2005) para [0015], [0063], [0065], [0075], [0094], [0104], [0119], [0121], [0128], [0130], [0135], [0154]	1-30, 44-60
Y	US 6,264,664 B1 (AVELLANET) 24 July 2001 (24.07.2001) Figs. 2, 3a; col 1, ln 34-36; col 4, ln 54-64 ;col 5, ln 26-32, 46-51, 62-67; col 6, ln 1-10, 25-30	1-30
Y	US 2003/0023265 A1 (FORBER) 30 January 2003 (30.01.2003) para [0008], [0014], [0052], [0064], [0075], [0102]	3, 4, 9, 12, 13, 24, 47, 58
Y	US 7,235,061 B1 (TSUGITA) 26 June 2007 (26.06.2007) col 7, ln 62-64; col 8, ln 4-11	2, 5, 6
Y	US 2005/0085847 A1 (GALDONIK et al.) 21 April 2005 (21.04.2005) para [0087], [0122], [0131], [0132], [0133], [0143], [0154], [0166], [0203]	15, 16

☐ 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
11 July 2010 (11.07.2010)	09 JUL 2010
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) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 10/26571

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:
Group I: Claims 1-30, 44-60; directed to methods and devices for removing an obstruction from a blood vessel utilizing first and second capturing portions. Group II: Claims 31-43; directed to methods for removing an obstruction from a blood vessel utilizing a fluid delivery port. Group III: Claims 61-64; directed to methods for removing an obstruction from a blood vessel utilizing a stent with a plurality of varying density stent sections. 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: The special technical feature of Group I is first and second capturing portions, which is not present in Group II or III. The special technical feature of Group II is a fluid delivery port, which is not present in Group I or III. The special technical feature of Group III is a a plurality of high density stent sections and a plurality of low density of stent sections, which is not present in Group I or II. The sole element of commonality between groups I-III is that of inserting an expandable structure within the obstruction and expanding the expandable structure within the obstruction, which is known in the prior art (ref. US 6,623,450 B1 to Freudenthal et al., col 3, ln 47 to col 4, ln 50; Fig. 1-3). The sole element of commonality between groups I and III is that of the expandable structure comprising a distal capturing portion having a fluid permeable distal end and a proximal stent section, which is known in the prior art (ref. US 6,623,450 B1 to Freudenthal et al., col 3, ln 47 to col 4, ln 50; Fig. 1-3). Accordingly, unity of invention is lacking under PCT Rule 13.1.

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.:
1-30, 44-60

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 2009)